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Presidential Documents

Title 3—

The President

Executive Order 13974 of January 13, 2021

Amending Executive Order 13959—Addressing the Threat From Securities Investments That Finance Communist Chinese Military Companies

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), and section 301 of title 3, United States Code,

I, DONALD J. TRUMP, President of the United States of America, in order to take additional steps with respect to the national emergency declared in Executive Order 13959 of November 12, 2020 (Addressing the Threat from Securities Investments that Finance Communist Chinese Military Companies), to address the threat posed by the People's Republic of China's military-industrial complex, hereby order as follows:

Section 1. Section 1(b) and (c) of Executive Order 13959 are amended to read as follows:

''(b) Notwithstanding subsection (a)(i) of this section, any transaction entered into on or before 11:59 p.m. eastern standard time on November 11, 2021, solely to divest, in whole or in part, from securities that any United States person held as of 9:30 a.m. eastern standard time on January 11, 2021, in a Communist Chinese military company as defined in section 4(a)(i) of this order, is permitted. Effective at 11:59 p.m. eastern standard time on November 11, 2021, possession of any such securities by a United States person is prohibited.

(c) Notwithstanding subsection (a)(ii) of this section, for a person determined to be a Communist Chinese military company pursuant to section 4(a)(ii) or (iii) of this order, any transaction entered into on or before 365 days from the date of such determination, solely to divest, in whole or in part, from securities that any United States person held in such person, as of the date 60 days from the date of such determination, is permitted. Effective at 11:59 p.m. eastern standard time on the date 365 days after the date of such determination, possession of any such securities by a United States person is prohibited.''

Sec. 2. Subsections (a)(ii) and (iii) of section 4 of Executive Order 13959 are amended to read as follows:

''(ii) any person that the Secretary of Defense, in consultation with the Secretary of the Treasury, publicly lists as a Communist Chinese military company meeting the criteria in section 1237(b)(4)(B) of Public Law 105–261, as amended by section 1233 of Public Law 106–398 and section 1222 of Public Law 108–375, and that operates directly or indirectly in the United States or any of its possessions, until such time as the Secretary of Defense removes such person from such list. This definition shall apply regardless of whether the Secretary of Defense must provide the report described in section 1237(b)(2) of Public Law 105–261, as amended by section 1233 of Public Law 106–398 and section 1222 of Public Law 108–375; or

(iii) any person that the Secretary of the Treasury publicly lists as meeting the criteria described in section (a)(ii) of this section, or publicly lists as a subsidiary of a person already determined to be a Communist Chinese

military company, until the Secretary of the Treasury determines that such person no longer meets that criteria and removes such person from such list.''

Sec. 3. Section 4(e) of Executive Order 13959 is amended to read as follows:

''(e) the term ''transaction'' means the purchase for value, or sale, of any publicly traded security; and''.

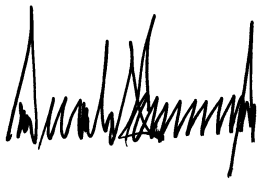
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 13, 2021.

[FR Doc. 2021–01228
Filed 1–15–21; 8:45 am]
Billing code 3295–F1–P

Rules and Regulations

Federal Register
Vol. 86, No. 11
Tuesday, January 19, 2021

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 9

[Docket ID: FSA–2020–0006]

RIN 0503–AA65

Coronavirus Food Assistance Program; Additional Assistance

AGENCY: Office of the Secretary, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The Coronavirus Food Assistance Program (CFAP) provides assistance to agricultural producers impacted by the effects of the COVID–19 outbreak. The Secretary of Agriculture implemented CFAP through two rounds of payments (CFAP 1 and CFAP 2). This rule amends the CFAP 1 provisions to provide additional assistance for swine producers who previously applied for assistance during the CFAP 1 application period. This rule also amends the CFAP 2 provisions to provide assistance for certain swine and poultry contract producers, clarify eligible sales-based commodities, add additional commodities that are eligible for payment, change the payment calculation for sales-based commodities, and change the yield used to calculate payment for price-trigger crops for certain applicants. The change to the payment calculation for sales-based commodities is being made to implement a change required by the recently enacted Consolidated Appropriations Act, 2021. Other changes to CFAP in this rule are discretionary changes being made in response to ongoing evaluation of CFAP and the need to provide additional assistance.

DATES: Effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Graham; telephone: (202) 720–6825; email: *Kimberly.Graham@usda.gov*. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

USDA established CFAP to assist producers of agricultural commodities marketed in 2020 who face continuing market disruptions, reduced farm-level prices, and increased production and marketing costs due to COVID–19 under authority provided by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; Pub. L. 116–136) and sections 5(b), (d), and (e) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714c(b), (d), and (e)). USDA implemented CFAP through two rounds of payments (CFAP 1 and CFAP 2). CFAP 1 was implemented through a final rule published in the **Federal Register** on May 21, 2020 (85 FR 30825–30835), with corrections published in the **Federal Register** on June 12, 2020 (85 FR 35799–35800), July 10, 2020 (85 FR 41328–41330), August 14, 2020 (85 FR 49593–49594), and September 21, 2020 (85 FR 59174–59175), and documents published in the **Federal Register** on May 22, 2020 (85 FR 31062–31065), June 12, 2020 (85 FR 35812), July 10, 2020 (85 FR 41321–41323), and August 14, 2020 (85 FR 49589–49593). USDA implemented CFAP 2 through a final rule published in the **Federal Register** on September 22, 2020 (85 FR 59380–59388).

The Consolidated Appropriations Act, 2021 (Pub. L. 116–260), signed on December 27, 2020, provided additional funding and made several changes to CFAP. This rule implements a provision of the Consolidated Appropriations Act, 2021, to amend the payment calculation for sales commodities as described below.[1] Other changes to CFAP in this rule are discretionary changes being made in response to ongoing evaluation of CFAP and the need to provide additional assistance.

CFAP is administered by USDA's Farm Service Agency (FSA). FSA accepted CFAP 1 applications from May 26, 2020, through September 11, 2020,[2] and CFAP 2 applications from September 21, 2020, through December 11, 2020. This rule amends the provisions for CFAP 1 and CFAP 2 as described below.

CFAP 1

For eligible producers of hogs and pigs, CFAP 1 provided financial assistance in an amount equal to the sum of the following two calculations:

- Unpriced livestock sold between January 15, 2020, to April 15, 2020, multiplied by the applicable Coronavirus Aid, Relief, and Economic Stability Act (CARES Act) payment rate in 7 CFR 9.102; and
- Livestock inventory owned between April 16, 2020, to May 14, 2020, multiplied by the applicable Commodity Credit Corporation (CCC) payment rate in § 9.102.

This rule provides additional CFAP 1 payments for hog and pig inventory owned between April 16, 2020, and May 14, 2020, based on a rate of $17 per head (which results in a total CFAP 1 payment rate of $34 per head for that inventory including the prior $17 per head payment for CFAP 1). For the swine (hog and pig) sector, the inventory payment rates were determined to be insufficient to alleviate ongoing market price losses in the sector.

This additional assistance is also intended to help swine producers who face continuing market disruptions from changes in U.S. meat consumption due to the pandemic. These disruptions are reflected in futures prices. Generic lean hog futures prices at the end of November 2020 were 5.4 percent lower than on January 2, 2020. In contrast, futures prices for commodities such as soybeans and corn have been increasing in the second half of 2020 to levels above those in early January of 2020.

FSA is not reopening the CFAP 1 application period. Only producers who previously applied for CFAP 1 are eligible to receive this additional assistance. Eligible producers do not need to submit a new CFAP 1 application form or take any action to receive the additional payment. Producers are subject to a payment limitation of $250,000 for all CFAP 1

[1] Other changes to CFAP included in the Consolidated Appropriations Act, 2021, not made in this final rule will be addressed in a subsequent rulemaking.

[2] Certain producers in Louisiana, Oregon, and Texas had through October 9 to apply due to natural disasters.

payments,[3] including this additional assistance, as provided in § 9.7(e).

CFAP 2

In this final rule, USDA is also including certain producers that raise swine and poultry (including broilers, pullets, layers, chicken eggs, and turkeys) under a production contract that sustained revenue losses due to market disruptions and reduced harvesting facility output resulting from the COVID–19 outbreak. A swine or poultry contract producer is one who produces swine or poultry owned by someone else under a production contract. Not all production contracts operate the same way, so not all contract producers will be eligible. Only those producers who grow or produce an eligible commodity under contract for or on behalf of another person or entity and are not entitled to a share from sales proceeds of the commodity are eligible. For example, a farmer who raises chickens pursuant to a production contract where such chickens are owned by a company that produces chicken products could be an eligible contract grower if such farmer does not receive payment for chickens that die before reaching maturity or when young animals are not supplied to the farmer by the company, or whose income is reduced when fewer young animals than normal are provided by the company.

USDA did not include swine and poultry contract producers in CFAP 1 because the impacts to these producers from COVID–19 was not known at the time the rule was published in the **Federal Register** on May 21, 2020. The impacts from COVID–19 on contract producers such as delayed delivery of young poultry and hogs to contract producers, decreased housing densities, additional costs for keeping animals longer than typical durations, and damage caused by animals too large for housing, were known when USDA published the rule implementing CFAP 2 in the **Federal Register** on September 22, 2020. However, those producers could not be included since CFAP 2 payments were issued using funds authorized under CCC Charter Act (15 U.S.C. 714c(b), (d), and (e)) to assist with the transition to a more orderly marketing system, and swine and poultry contract producers do not ordinarily market the animals they raise. CARES funding, as authorized, remains available until expended to support agricultural producers impacted by COVID–19, including producers of specialty crops, producers that supply local food systems (including farmers markets, restaurants, and schools), and livestock producers. This remaining CARES Act funding will assist contract producers facing reduced revenue due to the impacts noted above.

Certain contract producers have been eligible for assistance under the Livestock Indemnity Program (LIP); Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP); and the Livestock Forage Disaster Program (LFP) since these permanent supplemental disaster programs were authorized in the 2008 Farm Bill (Pub. L. 110–234; 7 U.S.C. 9081, see also 7 CFR parts 760 and 1416). These programs provide financial assistance to contract producers who are impacted by adverse weather events such as hurricane, flood, blizzard, disease, drought, or extreme cold or heat. Including certain swine and poultry contract producers in CFAP 2 parallels their inclusion in these permanent supplemental disaster programs that provide financial assistance to contract producers due to weather events that are not expected. The impacts of a global pandemic are beyond normal production conditions and have had a negative financial impact on swine and poultry producers including those raising animals under a production contract.

USDA is including this subset of contract producers because the COVID–19 global pandemic not only disrupted protein markets as consumer consumption abruptly shifted from food service to home preparation, but also reduced harvesting facility output because of COVID–19 outbreaks among the workforce and when facilities reduced processing capacity to ensure worker health. Swine and poultry contract producers provided data and other information to USDA to illustrate the impact of these coronavirus disruptions on their operations. The impacts of slowdowns and shutdowns at processing facilities in late spring and early summer are still being felt in the poultry and swine industry. In some instances, companies managed and continue to manage the lack of harvest capacity by reducing or eliminating new production, which means that contract producers had fewer animals to produce under contract per cycle or did not have young animals delivered by the company for some periods. In other situations, companies required some contract producers to keep animals longer than they typically keep them before shipping them to the harvesting facility, which actions increased costs such as producer labor, and for additional wear and tear and water use associated with larger animals. In addition, swine and poultry contract producers cannot use their specialized growing facilities for other purposes to generate revenue as the sector works through the supply chain bottlenecks.

Contract producers are eligible for payments if they produced swine or poultry (including broilers, pullets, layers, chicken eggs, turkeys) under a contract in both the 2019 and 2020 calendar years, suffered a loss in eligible revenue for the period from January 1, 2020, through December 27, 2020, as compared to the period from January 1, 2019, through December 27, 2019, and meet all other requirements for CFAP eligibility. Eligible revenue is the revenue received by a contract producer for contract production of the eligible commodity, as reported on Internal Revenue Service Form 1099. Payments to eligible contract producers will be calculated by subtracting the contract producer's eligible revenue for the period from January 1, 2020, through December 27, 2020, from their eligible revenue for the period from January 1, 2019, through December 27, 2019, and multiplying the result by 80 percent. This calculation is subject to the availability of funds and will be factored, if needed. Contract producers must submit a complete CFAP 2 application between January 19, 2021, and February 26, 2021. Contract producers are subject to a payment limitation of $250,000 for all CFAP 2 payments,[4] including any CFAP 2 payments received for other commodities not grown under a contract, as provided in § 9.7(e).

USDA has determined that producers of pullets, water buffalo, yak, and turfgrass sod face continuing market disruptions, low farm-level prices, and significant marketing costs associated with the COVID–19 outbreak, similar to producers of commodities that were previously determined to be eligible for CFAP 2 assistance. As a result, USDA is amending the definitions of ''Other livestock'' and ''Sales-based commodities'' in § 9.201 to include those commodities. USDA will reopen signup specifically for pullets, turfgrass sod, and contract growers on January 19, 2021. through February 26, 2021. The change to accept applications for water buffalo and yak was previously implemented by USDA; therefore, the

[3] Corporations, limited liability companies, limited partnerships, trusts, and estates may qualify for an increased CFAP 1 payment limitation. See 7 CFR 9.7(e).

[4] Corporations, limited liability companies, limited partnerships, trusts, and estates may qualify for an increased CFAP 2 payment limitation. See 7 CFR 9.7(e).

deadline is not extended for those livestock types. USDA is also amending the definition of ''Other livestock'' to clarify that reptiles and bees are ineligible.

This rule also amends the definition of ''Other livestock'' in § 9.201 to clarify that by-products of live animals included as ''Other livestock'' are eligible for CFAP 2. As provided in § 9.203(i)(1), the payment calculation for sales-based commodities is based on sales of raw commodities; the portion of sales derived from adding value to the commodity, such as processing and packaging, is not included when calculating a payment. For example, sales of alpaca fleece would be included for payment calculation; however, if the alpaca fleece is further processed into alpaca yarn prior to sale, the portion of the sale price derived from that processing is not included. Eligible by-products of other livestock do not include eggs that are sold to be hatched for breeding stock. This change was previously implemented by USDA; therefore, the deadline is not extended for by-products of ''Other livestock.''

USDA is amending the payment calculation for sales-based commodities to include the amount of crop insurance indemnities received and payments made under the Noninsured Crop Disaster Assistance Program (NAP) and the Wildfires and Hurricanes Indemnity Program Plus (WHIP+) payments for crop year 2019 in addition to the amount of the producer's 2019 sales, as required by the Consolidated Appropriations Act, 2021. CFAP 2 uses a producer's 2019 sales as an approximation of the amount of what the producer would expect to market in 2020. This change is intended to more accurately represent what a producer would expect to have marketed in 2020 by taking into account commodities that would have been marketed in 2019 if not for losses covered by crop insurance, NAP or WHIP+. For producers who began farming in 2020 and had no sales in 2019, CFAP 2 payments will continue to be based on the farmer's actual 2020 sales, without inclusion of crop insurance indemnities or NAP or WHIP+ payments, since payments are based on the actual crop that incurred marketing costs and was impacted by market disruptions and low farm-level prices. Producers of eligible sales-based commodities who applied for CFAP 2 before the December 11, 2020, application deadline and received crop insurance indemnities or NAP or WHIP+ payments for the 2019 crop year may amend their CFAP 2 applications from January 19, 2021, through February 26, 2021, to include those amounts. This rule is not extending the CFAP 2 deadline for producers of sales-based commodities who did not previously apply for CFAP 2, except for producers of pullets and turfgrass sod as described above.

USDA is also amending the calculation for price-trigger commodities. As published on September 22, 2020, payments are calculated using the 2019 Agriculture Risk Coverage-County Option (ARC–CO) benchmark yield multiplied by 85 percent when FSA is unable to obtain a 2020 actual production history (APH) approved yield. This rule amends the calculation to use 100 percent of the ARC–CO benchmark yield when the applicant:

- Has coverage for the crop under an Area Risk Protection Insurance Plan, Margin Protection Plan, Stacked Income Protection Plan, Supplemental Coverage Option, or Whole-Farm Revenue Protection Plan under the Federal Crop Insurance Act (7 U.S.C. 1501–1524);
- Is a landlord of the applicable acreage and their share of the crop is insured by the tenant under a policy or plan of insurance under the Federal Crop Insurance Act;
- Is a tenant of the applicable acreage and their share of the crop is insured by the landlord under a policy or plan of insurance under the Federal Crop Insurance Act; or
- Is a joint venture and the crop is insured by one of the members under a policy or plan of insurance under the Federal Crop Insurance Act.

In these situations, FSA does not have 2020 APH approved yield for the CFAP 2 applicant because the insurance plan does not require calculation of an APH approved yield or because the record of the APH approved yield would not be associated with the CFAP 2 applicant. However, the crop was insured in these situations and using 100 percent of the ARC–CO benchmark yield is intended to treat producers with crop insurance coverage but without an available 2020 APH approved yield in a more favorable way to other producers who had crop insurance. All applicants affected by this change were previously eligible under the original rule; therefore, this rule is not extending the CFAP 2 deadline for those producers who did not previously apply for CFAP 2. Applicants affected by this change must contact FSA to have their payment recalculated using 100 percent of the ARC–CO benchmark yield.

This document also makes minor corrections to the definitions of ''fruits'' and ''tree nuts'' in § 9.201 and to the calculation in § 9.202(c). In § 9.1, it adds the applicable date that livestock must have been physically located in the United States for CFAP 2, which was inadvertently omitted from the previous final rule. These corrections do not affect administration of CFAP 2.

The changes in this document are consistent with our original intent in creating and administering CFAP 2 and are not expected to increase expected costs beyond the original approved amount.

Notice and Comment and Effective Date

The Administrative Procedure Act (APA, 5 U.S.C. 553(a)(2)) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified actions, including matters relating to benefits. This rule governs CFAP for payments to certain commodity producers and therefore falls within the benefits exemption.

The Office of Management and Budget (OMB) designated this rule as major under the Congressional Review Act (CRA), as defined by 5 U.S.C. 804(2). Section 808 of the CRA allows an agency to make a major regulation effective immediately if the agency finds there is good cause to do so. The beneficiaries of this rule have been significantly impacted by the COVID–19 outbreak, which has resulted in significant declines in demand and market disruptions. USDA finds that notice and public procedure are contrary to the public interest. Therefore, even though this rule is a major rule for purposes of the Congressional Review Act, USDA is not required to delay the effective date for 60 days from the date of publication to allow for Congressional review. Accordingly, this rule is effective upon publication in the **Federal Register**.

Executive Orders 12866, 13563, and 13777

Executive Order 12866, ''Regulatory Planning and Review,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The requirements in Executive Orders 12866 and 13573 for the analysis of costs and benefits apply to rules that are determined to be significant. Executive

Order 13777, ''Enforcing the Regulatory Reform Agenda,'' established a federal policy to alleviate unnecessary regulatory burdens on the American people.

The Office of Management and Budget (OMB) designated this rule as economically significant under Executive Order 12866 and therefore, OMB has reviewed this rule.

In general response to the requirements of Executive Order 13777, USDA created a Regulatory Reform Task Forces, and USDA agencies were directed to remove barriers, reduce burdens, and provide better customer service both as part of the regulatory reform of existing regulations and as an on-going approach. USDA reviewed this regulation and made changes to provide better customer service. The costs and benefits of this rule are summarized below. The full cost benefit analysis is available on *regulations.gov.*

Cost Benefit Analysis Summary

CFAP 1 and CFAP 2 assist producers of agricultural commodities marketed in 2020 who face continuing market disruptions, reduced farm-level prices, and increased production and marketing costs due to COVID–19. These additional costs are associated with declines in demand, surplus production, or disruptions to shipping patterns and marketing channels.

As mentioned above, in implementing the CFAP 1 and CFAP 2, FSA received feedback from local office staff and the agricultural industry. As a result, additional CFAP assistance and other changes are being made to provide assistance to additional growers that suffered COVID-related revenue losses, to ensure that calculations most accurately reflect sales, to provide equitable producer treatment, and to clarify certain provisions appearing in CFAP 2.

These changes (referred to as ''CFAP Additional Assistance''), along with the associated gross and net estimated outlays, are shown in Table 1 (at the end of this section). Payments for item 1 (the ''top up'' for swine producers) and item 2 (payments to contract livestock producers) will draw on CARES funding. Payments for items 3, 4, and 5 in Table 1 (all payments referenced as CFAP 2 payments or modified CFAP 2 payments) draw on CCC funding that remains given CFAP 1 and CFAP 2 payments. These payments are authorized by the CCC Charter Act (section 5 (b), (d) and (e)).

Estimated gross outlays for CFAP Additional Assistance are estimated at $3.10 billion (see Table 1). After taking into account payment limitations, net outlays are estimated at $2.28 billion. Payments to contract swine, chicken, egg, and turkey producers account for 87 percent of the total.

FSA, which implemented CFAP 1 and 2, will start accepting CFAP Additional Assistance applications for contract producers and turfgrass sod and pullet producers on January 19, 2021. Producers who did not apply by the CFAP 1 deadline (September 11, 2020) are not eligible for the swine top-up payment.

Net payments represent benefits to producers, which is the government cost of the program. Outlays shown in Table 1 are estimated at expected maximum levels. Some producers must take additional actions under this rule if they are interested in receiving benefits. These producers realize administrative costs associated with participation, which are estimated at $4.15 million.

TABLE 1—SUMMARY OF CFAP ADDITIONAL ASSISTANCE REGULATORY CHANGES AND ESTIMATED COSTS

Item	Gross estimated outlays (in billion $)	Net estimated outlays (in billion $)
Item 1—Provide a ''top up'' inventory payment to swine producers eligible for CFAP 1	$0.81	$0.15.
Item 2—Assist contract producers of swine, chickens, eggs, and turkeys	$1.98	$1.98.
Item 3—Include turfgrass sod, pullets, and by-products of live animals as ''sales-based commodities'' for CFAP 2 eligibility.	$0.21	$0.10.
Item 4—Include 2019 crop insurance indemnities and 2019 NAP WHIP+ payments to the producer's 2019 sales to compute CFAP 2 payments.	$0.08	$0.03.
Item 5—Change the calculation for price-trigger commodities with respect to ARC–CO	$0.02	$0.02.
Item 6—Clarify that reptiles and bees are ineligible for CFAP 2	No change in outlays	No change in outlays.
Item 7—Make minor corrections to the definitions of ''fruits'' and ''tree nuts'' in §§ 9.201 and 9.202(c).	No change in outlays	No change in outlays.
Total	$3.10	$2.28.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare a regulatory analysis of any rule whenever an agency is required by APA or any other law to publish a proposed rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule is not subject to the Regulatory Flexibility Act because as noted above, this rule is exempt from notice and comment rulemaking requirements of the APA and no other law requires that a proposed rule be published for this rulemaking initiative.

Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and because USDA will be making the payments to producers the USDA regulations for compliance with NEPA (7 CFR part 1b).

Although OMB has designated this rule as ''economically significant'' under Executive Order 12866, ''. . . economic or social effects are not intended by themselves to require preparation of an environmental impact statement'' when not interrelated to natural or physical environmental effects (see 40 CFR 1502.16(b)). CFAP was designed to avoid skewing planting decisions. Producers continue to make their planting and production decisions with the market signals in mind, rather than any expectation of what a new USDA program might look like. The discretionary aspects of CFAP (for example, determining AGI and payment limitations) were designed to be consistent with established USDA and the CCC programs and are not expected to have any impact on the human

environment, as CFAP payments will only be made after the commodity has been produced. Accordingly, the following Categorical Exclusion in 7 CFR part 1b applies: § 1b.3(a)(2), which applies to activities that deal solely with the funding of programs, such as program budget proposals, disbursements, and the transfer or reprogramming of funds. As such, the implementation of and participation in CFAP do not constitute major Federal actions that would significantly affect the quality of the human environment. Therefore, an environmental assessment or environmental impact statement for this regulatory action, will not be prepared; this rule serves as documentation of the programmatic environmental compliance decision for this Federal action.

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with State and local officials that would be directly affected by proposed Federal financial assistance. The objectives of the Executive order are to foster an intergovernmental partnership and a strengthened federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance and direct Federal development. For reasons specified in the final rule related notice regarding 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), the programs and activities in this rule are excluded from the scope of Executive Order 12372.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial actions may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR parts 11 and 780 are to be exhausted.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, ''Federalism.'' The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, except as required by law. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

USDA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that required Tribal consultation under Executive Order 13175 at this time. If a Tribe requests consultation, the USDA Office of Tribal Relations (OTR) will ensure meaningful consultation is provided where changes, additions, and modifications are not expressly mandated by law. Outside of Tribal consultation, USDA is working with Tribes to provide information about CFAP additional assistance and other issues.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions of State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA, for State, local and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Federal Assistance Programs

The titles and numbers of the Federal Domestic Assistance Programs found in the Catalog of Federal Domestic Assistance to which this rule applies are:

10.130—Coronavirus Food Assistance Program 1

10.132—Coronavirus Food Assistance Program 2

Paperwork Reduction Act

FSA is requesting emergency approval on the additional information collection required for this rule for CFAP to provide assistance for contract producers of chickens, eggs, turkeys, and swine and to provide additional assistance for other commodities as clarified in this rule. The additional assistance for swine producers who previously applied for assistance under 0560–0297 does not require any new information collection. All of the information collection uses forms currently approved under 0560–0297.

E-Government Act Compliance

USDA is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 9

Agricultural commodities, Agriculture, Disaster assistance, Indemnity payments.

For the reasons discussed above, this final rule amends 7 CFR part 9 as follows:

PART 9—CORONAVIRUS FOOD ASSISTANCE PROGRAM

■ 1. Revise the authority citation for part 9 to read as follows:

Authority: 15 U.S.C. 714b and 714c; Division B, Title I, Pub. L. 116–136, 134 Stat. 505; and Division N, Title VII, Subtitle B, Chapter 1, Pub. L. 116–260.

Subpart A—General Provisions

■ 2. In § 9.1, revise paragraphs (a)(1) and (2) to read as follows:

§ 9.1 Applicability and administration.

(a) * * *

(1) For assistance under subpart B of this part:

(i) On January 15, 2020, and remaining in the United States until sold, for livestock sold between January 15, 2020, and April 15, 2020; or

(ii) On the applicable date selected for livestock in inventory between April 16, 2020, and May 14, 2020; and

(2) For assistance under subpart C of this part, on the applicable date selected

for livestock in inventory between April 16, 2020, and August 31, 2020.

* * * * *

■ 3. Amend § 9.4 as follows:

■ a. In paragraph (a)(1), remove ''of this part; and'' and add a semicolon in its place;

■ b. Revise paragraph (a)(2);

■ c. Add paragraph (a)(3); and

■ d. In paragraph (d), remove the reference to ''§ 9.202(a) or (b)'' and add ''§ 9.203(a) or (b)'' in its place.

The revision and addition read as follows:

§ 9.4 Time and method of application.

(a) * * *

(2) December 11, 2020, for payments issued under § 9.203, except for applications for pullets, turfgrass sod, and contract producers; and

(3) February 26, 2021, for payments issued under § 9.203 for applications for pullets, turfgrass sod, and contract producers.

* * * * *

Subpart C—CFAP 1

■ 4. Amend § 9.102 as follows:

■ a. In paragraph (d) introductory text, remove the word ''two'' and add the word ''three'' in its place;

■ b. In paragraph (d)(1), remove the word ''and'';

■ c. In paragraph (d)(2), remove the period and add ''; and'' in its place;

■ d. Add paragraph (d)(3).

The addition reads as follows:

§ 9.102 Calculation of payments.

* * * * *

(d) * * *

(3) Hog and pig inventory owned between April 16, 2020, to May 14, 2020, multiplied by a payment rate of $17 per head.

* * * * *

Subpart C—CFAP 2

■ 5. Amend § 9.201 as follows:

■ a. Add the definitions of ''Contract producer'', ''Crop insurance'', and ''Eligible revenue'' in alphabetical order;

■ b. Revise the definition of ''Fruits'';

■ c. Add the definitions of ''Layer'' and ''NAP'' in alphabetical order;

■ d. Revise the definition of ''Other livestock'';

■ e. In the definition of ''Producer'', remove the second sentence;

■ f. Add the definition of ''Pullet'' in alphabetical order;

■ g. In the definition of ''Sales-based commodities'', remove the words ''and wool'' and add the words ''wool, and turfgrass sod'' in their place;

■ h. Revise the definition of ''Tree nuts''; and

■ i. Add the definition of ''WHIP+'' in alphabetical order.

The additions and revisions read as follows.

§ 9.201 Definitions.

* * * * *

Contract producer means a producer who grows or produces an eligible commodity under contract for or on behalf of another person or entity. The contract producer does not have ownership in the commodity and is not entitled to a share from sales proceeds of the commodity.

Crop insurance means an insurance policy reinsured by Federal Crop Insurance Corporation under the provisions of the Federal Crop Insurance Act, as amended. It does not include private plans of insurance.

* * * * *

Eligible revenue means the revenue received by a contract producer for contract production of broilers, pullets, layers, chicken eggs, turkeys, hogs, or pigs, as reported on Internal Revenue Service Form 1099.

* * * * *

Fruits means any of the following fruits: Abiu, acerola (Barbados cherry), achachairu, antidesma, apples, apricots, aronia (chokeberry), atemoya (custard apple), avocados, bananas, blueberries, breadfruit, cacao, caimito, calabaza melon, canary melon, canary seed, caneberries, canistel, cantaloupes, carambola (star fruit), casaba melon, cherimoya (sugar apple), cherries, Chinese bitter melon, citron, citron melon, coconuts, cranberries, crenshaw melon, dates, donaqua (winter melon), durian, elderberries, figs, genip, gooseberries, grapefruit, grapes, ground cherry, guamabana (soursop), guava, guavaberry, honeyberries, honeydew, huckleberries, Israel melons, jack fruit, jujube, juneberries, kiwiberry, kiwifruit, Korean golden melon, kumquats, langsat, lemons, limequats, limes, longan, loquats, lychee, mangos, mangosteen, mayhaw berries, mesple, mulberries, nectarines, noni, olives, oranges, papaya, passion fruits, pawpaw, peaches, pears, persimmons, pineapple, pitaya (dragon fruit), plantain, plumcots, plums, pomegranates, prunes, pummelo, quinces, raisins, rambutan, sapodilla, sapote, schizandra berries, sprite melon, star gooseberry, strawberries, tangelos, tangerines, tangors, wampee, watermelon, wax jamboo fruit, and wolfberry (goji).

* * * * *

Layer means a chicken producing table or commercial type shell eggs.

NAP means the Noninsured Crop Disaster Assistance Program under section 196 of the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. 7333) and part 1437 of this title.

* * * * *

Other livestock means any of the following livestock: Animals commercially raised for food, fur, fiber, or feathers, including alpacas, bison, buffalo, beefalo, deer, ducks, elk, emus, geese, goats, guinea pigs, llamas, mink, ostrich, pheasants, pullets, quail, rabbits, reindeer, turkey, water buffalo, and yak. It includes by-products of those live animals (such as fleece). It excludes all equine, reptiles, bees, breeding stock (including eggs to be hatched for breeding stock), companion or comfort animals, pets, and animals raised for hunting or game purposes.

* * * * *

Pullet means a young female chicken that has not laid an egg.

* * * * *

Tree nuts means any of the following tree nuts: Almonds, carob, cashew, chestnuts, coffee, hazel nuts, jojoba, macadamia nuts, pecans, pine nuts, pistachios, and walnuts.

* * * * *

WHIP+ means the Wildfires and Hurricanes Indemnity Program Plus (WHIP+) under part 760, subpart O, of this title.

§ 9.202 [Redesignated as § 9.203]

■ 6. Redesignate § 9.202 as § 9.203.

■ 7. Add new § 9.202 to read as follows:

§ 9.202 Eligibility.

(a) Producers, excluding contract producers, are eligible for payment under § 9.203(a) through (i) if they meet all other requirements for eligibility under this part.

(b) Contract producers are not eligible for payment under § 9.203(a) through (i). Contract producers are eligible for payment under § 9.203(l) if they:

(1) Produced broilers, pullets, layers, chicken eggs, turkeys, hogs, or pigs under a contract in both the 2019 and 2020 calendar years and received revenue under such a contract during the period from January 1, 2020, through December 27, 2020;

(2) Had a loss in eligible revenue for the period from January 1, 2020, through December 27, 2020, as compared to the period from January 1, 2019, through December 27, 2019; and

(3) Meet all other requirements for eligibility under this part.

(c) Contract producers must provide a copy of their contract pursuant to which they raised an eligible commodity as specified in paragraph (b)(1) of this section and provide documentation to

support the information provided on their application if requested by FSA.

■ 8. Amend newly redesignated § 9.203 as follows:

■ a. Revise paragraph (a)(3);

■ b. Add paragraph (a)(4);

■ c. In paragraph (c), remove the words ''producer multiplied'' and add the words ''producer, multiplied'' in their place;

■ d. Revise paragraph (i)(1);

■ e. In paragraph (i)(2), remove the words ''sales as'' and add the words ''sales, without crop insurance indemnities and NAP and WHIP+ payments, as'' in their place;

■ f. In the heading of the first column of Table 2 to paragraph (j), add ''(including crop insurance indemnities and NAP and WHIP+ payments)'' immediately after ''2019 Sales range''; and

■ g. Add paragraph (l).

The additions and revision read as follows:

§ 9.203 Calculation of payments.

(a) * * *

(3) Under paragraph (a) of this section, eligible acres include the producer's share of the determined acres, or reported acres if determined acres are not present, of the crop planted for the 2020 crop year, excluding prevented planted and experimental acres. For producers who insured acres of the crop under a policy or plan of insurance under the Federal Crop Insurance Act (7 U.S.C. 1501–1524), the yield will be the average of the producer's 2020 actual production history (APH) approved yield from all of the producer's insured acres nationwide. For producers for whom FSA is unable to obtain a 2020 APH approved yield, the yield will be:

(i) The 2019 Agriculture Risk Coverage-County Option (ARC–CO) benchmark yield if the applicant:

(A) Has coverage for the crop under an Area Risk Protection Insurance Plan, Margin Protection Plan, Stacked Income Protection Plan, Supplemental Coverage Option, or Whole-Farm Revenue Protection Plan under the Federal Crop Insurance Act;

(B) Is a landlord of the applicable acreage and their share is insured by the tenant under a policy or plan of insurance under the Federal Crop Insurance Act;

(C) Is a tenant of the applicable acreage and their share is insured by the landlord under a policy or plan of insurance under the Federal Crop Insurance Act; or

(D) Is a joint venture and the crop is insured by one of the members under a policy or plan of insurance under the Federal Crop Insurance Act; or

(ii) The 2019 Agriculture Risk Coverage-County Option (ARC–CO) benchmark yield multiplied by 85 percent for all other applicants.

(4) ARC–CO yields in paragraph (a)(3) of this section for producers growing a crop in multiple counties will be weighted based on the producer's crop acreage physically located in each county.

* * * * *

(i)(1) Payments for sales commodities will be equal to the sum of the results for the following calculation for each 2019 sales range in Table 2 of paragraph (j) of this section: The sum of the amount of the producer's eligible sales for the sales commodities in calendar year 2019 and the producer's crop insurance indemnities and NAP and WHIP+ payments for the sales commodities for the 2019 crop year within the specified range, multiplied by the payment rate for that range in Table 2 of paragraph (j) of this section. Eligible sales only includes sales of raw commodities grown by the producer; the portion of sales derived from adding value to the commodity, such as processing and packaging, and from sales of products purchased for resale is not included in the payment calculation unless determined eligible by the Secretary.

* * * * *

(l) For eligible contract producers of broilers, pullets, layers, chicken eggs, turkeys, hogs, or pigs, if eligible revenue for the period from January 1, 2020, through December 27, 2020, decreased compared to eligible revenue for the period from January 1, 2019, through December 27, 2019, then payments will be equal to:

(1) Eligible revenue received from January 1, 2019, through December 27, 2019, minus eligible revenue received from January 1, 2020, through December 27, 2020; multiplied by

(2) 80 percent.

(3) This calculation is subject to the availability of funds and will be factored, if needed.

William Northey,

Under Secretary, U.S. Department of Agriculture.

[FR Doc. 2021–01077 Filed 1–15–21; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2020–BT–STD–0001]

RIN 1904–AE86

Energy Conservation Program: Establishment of New Product Classes for Residential Clothes Washers and Consumer Clothes Dryers; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; correction.

SUMMARY: On December 16, 2020, the U.S. Department of Energy (''DOE'') published a final rule establishing separate product classes for top-loading consumer clothes washers and consumer clothes dryers that offer cycle times for a normal cycle of less than 30 minutes, and for front-loading residential clothes washers that offer cycle times for a normal cycle of less than 45 minutes. This correction responds to specific comments submitted by the Pacific Gas and Electric Company (''PG&E''), San Diego Gas and Electric (''SDG&E''), and Southern California Edison (''SCE'') in response to DOE's notice of proposed rulemaking (''NOPR''), which were inadvertently omitted from the final rule. DOE has considered the comments and determined that in most instances, these comments raise issues substantially similar to those raised by other commenters that DOE previously considered and addressed in the final rule. To the extent these comments raise issues not explicitly addressed in the preamble of the final rule, DOE determined that the comments submitted by PG&E, SDG&E, and SCE do not alter any of the conclusions reached in support of the final rule and would not have resulted in an outcome different than as set forth in the final rule.

DATES: Effective January 15, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Kathryn McIntosh, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586–2002. Email: *Kathryn.McIntosh@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE published a final rule in the **Federal Register** on December 16, 2020 (the ''December 2020 final rule''), establishing separate product classes for top-loading consumer clothes washers and consumer clothes dryers that offer cycle times for a normal cycle of less

than 30 minutes, and for front-loading residential clothes washers that offer cycle times for a normal cycle of less than 45 minutes. 85 FR 81359. This document responds to comments unintentionally omitted from the final rule.

Correction

DOE received a submission from the Pacific Gas and Electric Company (''PG&E''), San Diego Gas and Electric (''SDG&E''), and Southern California Edison (''SCE'') (collectively referred to as the ''CA IOUs'') in response to the notice of proposed rulemaking to establish separate product classes for consumer clothes washers and consumer clothes dryers, 85 FR 49297 (Aug. 13, 2020). Through an unintentional oversight, DOE did not make specific reference to the CA IOUs comments submitted in response to the notice of proposed rulemaking in the final rule. DOE considered the comments and determined that many of the substantive issues the CA IOUs comment brought to DOE's attention were also raised by the other commenters and addressed by DOE in the final rule.

Like other commenters, CA IOUs opposed the rulemaking and expressed various arguments regarding DOE's determination that cycle time was a performance related feature under the Energy Policy and Conservation Act (''EPCA''), 42 U.S.C. 6295(q), that justified the creation of the new product classes. Like other commenters, the CA IOUs also argued that, if finalized, the product classes would result in illegal backsliding of the applicable energy conservation standards under 42 U.S.C. 6295(o)(1). (No. 0036, pp. 6–8) Commenters, including the CA IOUs, stated that the notice of proposed rulemaking (''NOPR''), 85 FR 68724 (Oct. 30, 2020), failed to provide evidence that the current energy and water conservation standards were precluding the shorter normal cycle products from being made available. (No. 0036, p. 1) Like other commenters, CA IOUs also noted that DOE's data implied that multiple clothes washers on the market already met the proposed requirements for the new product classes while also meeting the current energy and water conservation standards. (No. 0036, at p. 3; see also NEEA, No. 0044, pp. 2–5) Commenters, including the CA IOUs, also challenged DOE's determination regarding the environmental impact of the new product classes and urged DOE to conduct and publicly release the analysis to confirm that the proposed product classes should be granted an A5 Categorical Exclusion under the National Environmental Policy Act (''NEPA'') of 1969. (No. 0036, p. 11) Like other commenters, CA IOUs also opposed establishing the new product classes without accompanying test procedures and standards, explaining that the new product classes introduce potential market uncertainties and distortions. They continue that because cycle time is not a factor recorded in the current test procedure for either product and the NOPR lacked reference to reporting requirements, DOE should delay finalizing the rule until greater clarity is provided. (No. 0036, p. 5)

DOE responded to these concerns in the December 2020 final rule, concluding that cycle time was a performance related feature and that the establishment of the new product classes would not result in a violation of EPCA's anti-backsliding provision, *see* 85 FR 81359, 81362–81368, 81368–81370. DOE maintains that the concerns raised by commenters regarding the overall applicability of EPCA's anti-backsliding provision to clothes washers is too broad and ignores the limitations that EPCA itself places on the scope of the anti-backsliding provision, 42 U.S.C. 6295(o)(1). 85 FR 81369–81370.

DOE responded to those comments discussing the necessity of the new product classes in the final rule. 85 FR 81359, 81365–81366. DOE concluded that even if products with comparable cycle times were already on the market, products under the new product classes would be distinguishable because they are specifically characterized as offering short normal cycles and would be subject to manufacturer testing.

Additionally, DOE stated in the December 2020 final rule that the rulemaking, once finalized, would only establish new product classes, and would not cause adverse environmental impacts, therefore, leaving the rulemaking within the scope of the A5 Categorical Exclusion. 85 FR 81359, 81370.

DOE explained in the final rule that the product class provision under EPCA, 42 U.S.C. 6295(q)(1)(B), does not require the Department to simultaneously establish energy conservation standards in the same rulemaking as the determination of a new product class. The establishment of a new product class is functionally equivalent to the finalization of a coverage determination where a covered product would then exist without an applicable standard until the Department completes a test procedure rulemaking for that product. 42 U.S.C. 6292(b); 85 FR 81359, 81367.

Here, DOE is not acting inconsistently with past practices by establishing the new product classes without accompanying test procedures or standards. Commenters can look to the Department's 2009 beverage vending machines energy conservations standard rulemaking and the 2007 distribution transformer energy conservation standards rulemaking as examples of prior instances where DOE established a new product class without simultaneously prescribing an associated conservation standard. 81 FR 44914, 44920 (Aug. 31, 2009); 72 FR 58190, 58197 (Oct. 12, 2007). See 85 FR 81359, 81367–81368. DOE intends, as these commenters requested, to conduct the necessary rulemakings to consider and evaluate the energy and water consumption limits for the new product classes and determine the applicable standards that provide the maximum energy efficiency that is technologically feasible and economically justified, and will result in a significant conservation of energy, 42 U.S.C. 6295(o)(2)(A). DOE will conduct these rulemakings following EPCA's requirements and the procedures set out in the Process Rule,[1] which will provide the clarity these commenters requested regarding the implementation of this rulemaking. 85 FR 81359, 81368, 81372.

In addition to these shared concerns, the CA IOUs also raised unique comments that DOE addresses in the following paragraphs.

The CA IOUs, in challenging the validity of the short cycle thresholds, noted that DOE tested the 14 consumer clothes dryers for which data was presented according to the Appendix D2 test procedure, which is the optional test procedure for those products. The CA IOUs argued that Appendix D1, which is available for product certification, allows for shorter cycle times while maintaining compliance with the energy efficiency standard according to data produced through DOE-sponsored research at the Oak Ridge National Laboratory. To support their assertion of the unreasonableness of cycle thresholds proposed, CA IOUs continued that this research demonstrated that five products tested under Appendix D1 already offered a cycle time of less than 30 minutes (high temperature setting) while meeting the

[1] Procedures for Use in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment (''Process Rule''), 85 FR 8626 (Feb. 14, 2020); Appendix A to Subpart C of Part 430—Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment.

current standard, in addition to the one product that also had a cycle time of 30 minutes (high temperature setting) and met the standard when tested under Appendix D2. The CA IOUs also conducted independent testing, using Appendix D1, that showed there were multiple clothes dryers on the market offering a 30 minute or less cycle time (high temperature setting) that also met the current energy conservation standard. (No. 0036, pp. 3–4) These commenters concluded that based on this data, short cycle time was not a feature justifying a different a standard and the proposed product classes were not warranted for clothes washers and clothes dryers. (No. 0036, p. 5)

DOE testing presented in the NOPR was conducted according to the Appendix D2 methodology because, unlike Appendix D1, it produces a cycle time that is representative of an average use cycle (even though cycle time is not currently recorded in either test procedure). The methodology in Appendix D1 will not allow for the measurement of a cycle time that is representative of average use, because the cycle is interrupted before completion. While cycle time measured using Appendix D1 would be shorter than the cycle time measured under Appendix D2, DOE maintains that this is not an accurate representation of how consumers would use these products.

As DOE explained in the December 2020 final rule, even if clothes washers and clothes dryers with short normal cycle times for were available, the product class provision, 42 U.S.C. 6295(q), would still be appropriately applied in this rulemaking. While there are some products on the market that may complete a cycle within the time thresholds, DOE is establishing these short cycle product classes to facilitate the development of products design to complete a normal cycle within the threshold times and be subject to testing by the manufacturer. DOE notes that the impact of this rulemaking is to establish product classes based on short normal wash or dry cycles, therefore incentivizing manufacturers to develop such products that can meet consumer needs. 85 FR 81359, 81367.

The CA IOUs reliance on the Oak Ridge study, and the CA IOUs own data, are also out of place in the context of this rulemaking because these data were generated using the test method set forth in Appendix D1. As DOE explained in the NOPR, Appendix D1 does not provide data that can be used to determine a ''cycle time'' as experienced by the consumer. This is because Appendix D1 requires manually stopping operation at a specified moisture content, normalizing, and applying a field use factor, therefore, the length of time that a clothes dryer is operated during an Appendix D1 test does not necessarily correspond to the length of time that a consumer would operate the clothes dryers (in contrast to the calculated energy use, which is representative of the energy use experienced by the consumer). 85 FR 49297, 49303. This means that while testing under Appendix D1 may identify products on the market that could dry clothes in 30 minutes, it is not an accurate representation of how consumers would use these products because the cycle is manually stopped at the target remaining moisture content. DOE established these short cycle product classes so that consumers would have access to products that accomplish normal washing or drying within the specified cycle time, not just in control room settings.

The CA IOUs also present their review of 111 products in the Consumer Reports database that showed ''no clear relationship between normal cycle time and consumer satisfaction'' and requested DOE provide evidence of consumer demand. (No. 0036, p. 7) Comments submitted by the Competitive Enterprise Institute (''CEI'') and the 60 Plus Association demonstrated that consumers want and desire these faster products. CEI shared feedback it received from consumers that expressed a need for faster appliances and identified growing consumer dissatisfaction with the current length of cycles. 85 FR 81359, 81366 referencing No. 0031, pp. 2–3. The 60 Plus Association submitted comments, arguing on behalf of its senior citizen members, that the rulemaking offers a significant benefit to individuals looking to make the most of their time. This commenter noted that the time saved by utilizing future, short normal cycle products would make a noticeable difference in the lives of its underrepresented members. 85 FR 81363, referencing No. 0043, p. 1.

The CA IOUs also worried that some manufacturers may easily modify their current products to meet the requirements of the new product classes at the expense of the consumer. (No. 0036, p. 5) While DOE acknowledges these concerns, DOE has no information to support the contention, and does not anticipate that manufacturers would reengineer products already on the market in response to this rulemaking. Further, it remains the consumer's choice ultimately to decide which product on the market that they will choose to purchase. The creation of the new product classes does not set a mandate that consumers must purchase products from these product classes.

DOE thanks the CA IOUs for their comments and directs them to the responses provided in the December 2020 final rule for the shared issues they raised. After considering the unique comments provided by the CA IOUs, DOE affirms the conclusions reached in the December 2020 final rule.

Signing Authority

This document of the Department of Energy was signed on January 11, 2021, by Daniel R. Simmons, Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 12, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–00842 Filed 1–15–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2019–BT–STD–0008]

RIN 1904–AD29

Energy Conservation Program: Energy Conservation Standards for Small Electric Motors

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final determination.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including small electric motors (''SEMs''). EPCA also requires the U.S. Department of Energy (''DOE'') to periodically determine whether more-stringent standards would be technologically feasible and

economically justified, and would result in significant conservation of energy. In this final determination, DOE has determined that more stringent SEMs standards would not be cost effective, and thus has determined that standards for SEMs should not be amended.

DATES: The effective date of this final determination is January 19, 2021.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at: *https://www.regulations.gov/docket?D=EERE-2019-BT-STD-0008.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For further information on how to review the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Synopsis of the Final Determination

Title III, Part C [1] of the Energy Policy and Conservation Act, as amended (''EPCA''),[2] established the Energy Conservation Program for Certain Industrial Equipment, (42 U.S.C. 6311–6317), which includes small electric motors (''SEMs''), the subject of this final determination.

Pursuant to the EPCA requirement that not later than 6 years after issuance of any final rule establishing or amending an energy conservation standard for covered equipment, DOE must publish either a notice of determination that standards for the equipment do not need to be amended, or a notice of proposed rulemaking (''NOPR'') including new proposed energy conservation standards. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m))

DOE analyzed the SEMs currently subject to the standards found at title 10 of the Code of Federal Regulations (''CFR'') part 431. See 10 CFR 431.446. Of these motors, DOE first analyzed the technological feasibility of more efficient SEMs. For currently available SEMs with efficiencies exceeding the levels of the current energy conservation standards, DOE determined that more stringent standards would be technologically feasible. For these SEMs, DOE evaluated whether more stringent standards would also be cost effective by conducting preliminary life-cycle cost (''LCC'') and payback period (''PBP'') analyses.

Based on these analyses, as summarized in section V of this document, DOE has determined that more stringent energy conservation standards would not be cost effective. Therefore, DOE has determined that the current standards for SEMs do not need to be amended.

II. Introduction

The following section briefly discusses the statutory authority underlying this final determination, as well as some of the relevant historical background related to the establishment of standards for SEMs.

A. Authority and Background

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part C of EPCA includes the small electric motors that are the subject of this final determination. (42 U.S.C. 6311(13)(G)) As discussed in the following paragraphs, EPCA directed DOE to establish test procedures and prescribe energy conservation standards for SEMs. (42 U.S.C. 6317(b))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and

[1] For editorial reasons, upon codification in the U.S. Code, Part C was re-designated Part A–1.

[2] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

reports from manufacturers (42 U.S.C. 6316).

EPCA directed DOE to establish a test procedure for those SEMs for which DOE determined that energy conservation standards would (1) be technologically feasible and economically justified and (2) result in significant energy savings. (42 U.S.C. 6317(b)(1)) Manufacturers of covered equipment must use the Federal test procedures as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). The DOE test procedures for SEMs appear at 10 CFR part 431, subpart X.

EPCA further directed DOE to prescribe energy conservation standards for those SEMs for which test procedures were established. (42 U.S.C. 6317(b)(2)) Additionally, EPCA prescribed that any such standards shall not apply to any SEM which is a component of a covered product under 42 U.S.C. 6292(a) or covered equipment under 42 U.S.C. 6311 of EPCA. (42 U.S.C. 6317(b)(3)) Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (See 42 U.S.C. 6316(a) and (b); 42 U.S.C. 6297(a)–(c)).

EPCA requires that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE evaluate the energy conservation standards for each type of covered equipment, including those at issue here, and publish either a notice of determination that the standards do not need to be amended, or a NOPR that includes new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)). EPCA further provides that, not later than 3 years after the issuance of a final determination not to amend standards, DOE must make a new determination not to amend the standards or issue a NOPR including new proposed energy conservation standards. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(3)(B)) DOE must make the analysis on which a determination is based publicly available and provide an opportunity for written comment. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(2))

In making a determination that the standards do not need to be amended, DOE must evaluate under the criteria of 42 U.S.C. 6295(n)(2) whether amended standards (1) will result in significant conservation of energy, (2) are technologically feasible, and (3) are cost effective as described under 42 U.S.C. 6295(o)(2)(B)(i)(II). (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A) and 42 U.S.C. 6295(n)(2)) Under 42 U.S.C. 6295(o)(2)(B)(i)(II), an evaluation of cost effectiveness requires DOE to consider savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products which are likely to result from the imposition of the standard.

DOE is publishing this document in accordance with its authority under EPCA, and in satisfaction of its statutory requirement under EPCA.

1. Current Standards

The current energy conservation standards for SEMs are located in title 10 CFR 431.446, and are presented in Table II–1 and Table II–2.

TABLE II–1—FEDERAL ENERGY CONSERVATION STANDARDS FOR POLYPHASE SMALL ELECTRIC MOTORS

Motor horsepower/ standard kilowatt equivalent	Average full load efficiency		
	Open motors (number of poles)		
	6	4	2
0.25/0.18	67.5	69.5	65.6
0.33/0.25	71.4	73.4	69.5
0.5/0.37	75.3	78.2	73.4
0.75/0.55	81.7	81.1	76.8
1/0.75	82.5	83.5	77.0
1.5/1.1	83.8	86.5	84.0
2/1.5	N/A	86.5	85.5
3/2.2	N/A	86.9	85.5

TABLE II–2—FEDERAL ENERGY CONSERVATION STANDARDS FOR CAPACITOR-START INDUCTION-RUN AND CAPACITOR-START CAPACITOR-RUN SMALL ELECTRIC MOTORS

Motor horsepower/ standard kilowatt equivalent	Average full load efficiency		
	Open motors (number of poles)		
	6	4	2
0.25/0.18	62.2	68.5	66.6
0.33/0.25	66.6	72.4	70.5
0.5/0.37	76.2	76.2	72.4
0.75/0.55	80.2	81.8	76.2
1/0.75	81.1	82.6	80.4
1.5/1.1	N/A	83.8	81.5
2/1.5	N/A	84.5	82.9
3/2.2	N/A	N/A	84.1

2. History of Standards Rulemakings for Small Electric Motors

In 2006, DOE determined that energy conservation standards for certain single-phase, capacitor-start, induction-run, SEMs are technologically feasible and economically justified, and would result in significant energy savings. 71 FR 38799 (July 10, 2006). Later, in 2010, DOE issued a final rule (the ''March 2010 Final Rule'') establishing energy conservation standards for SEMs manufactured starting on March 9, 2015.[3] 75 FR 10874 (March 9, 2010).

In April 2019, DOE published a request for information (''April 2019 ECS RFI'') to solicit input and data from interested parties to aid in the development of the technical analyses for the determination of whether new and/or amended standards for SEMs are warranted. 84 FR 14027 (April 9, 2019). The comment period was re-opened in response to a request from an interested party, see NEMA, No. 4 at p. 1, until June 7, 2019. See 84 FR 25203 (May 31, 2019).

In April 2020, DOE published a notice of proposed determination (''April 2020 NOPD'') with the tentative determination that energy conservation standards for SEMs do not need to be amended. 85 FR 24146 (April 30, 2020). The comment period for this notice closed on June 29, 2020. On September 18, 2020, DOE published a notification of webinar public meeting and a limited reopening of the comment period (''September 2020 Notice''), which extended the comment period to October 20, 2020. 85 FR 58299. On October 6, 2020, DOE held a webinar to present the results from the April 2020 NOPD.

DOE received nine relevant comments from interested parties in response to the April 2020 NOPD and the September 2020 Notice. These comments are listed in Table II–3.[4] NEMA and CA IOUs each had two separate comment submissions: One in response to the April 2020 NOPD and another as a follow up to the September 2020 Notice.

TABLE II–3—APRIL 2020 NOPD AND SEPTEMBER 2020 NOTICE WRITTEN COMMENTS

Commenter/organization(s)	Reference in this NOPD	Organization type
Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') and Association of Home Appliance Manufacturers (''AHAM'').	AHRI and AHAM	Trade Associations.
Appliance Standards Awareness Project (''ASAP''), Alliance to Save Energy, American Council for an Energy-Efficient Economy, the California Energy Commission, and Northwest Energy Efficiency Alliance.	ASAP, et al	Advocacy Groups and State Governmental Agency.
California Investor-Owned Utilities (''CA IOUs'')—Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison.	CA IOUs	Utilities.
General Electric Appliances (''GEA'')	GEA	Manufacturer.
Lennox International Inc	Lennox	Manufacturer.
National Electrical Manufacturers Association (''NEMA'')	NEMA	Trade Association.

DOE also notes that NEMA submitted a comment related to certification, compliance and enforcement issues, but this comment fell outside the scope of this rulemaking and is not addressed in this document. Additionally, DOE received a comment from an individual commenter (Tyler Crosby) who noted the potential impact of small electric motors standards to increase the number electric bicycle users—an outcome that the commenter supported. While DOE appreciates this feedback, it also falls outside of the specific issues raised in the NOPD. The remaining relevant comments and DOE's responses are provided in the appropriate sections of this document.

III. General Discussion

A. Scope of Coverage and Equipment Classes

This document covers equipment meeting the definition of ''small electric motor,'' as codified in 10 CFR 431.442 and consistent with the statutory definition set by Congress for this term. ''Small electric motor'' means a ''NEMA general purpose alternating current single-speed induction motor, built in a two-digit frame number series in accordance with NEMA Standards Publication MG1–1987, including IEC metric equivalent motors.'' 10 CFR 431.442.[5] The scope of coverage for these motors is discussed in further detail in section IV.A.1 of this document.

When evaluating and establishing energy conservation standards, DOE divides covered equipment into equipment classes by the type of energy used, or by capacity or other performance-related features that justify a different standard. (42 U.S.C. 6316(a); 42 U.S.C. 6295(q)) In determining whether capacity or another performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE deems appropriate. (*Id.*) The equipment classes for this final determination are discussed further in section IV.A.2 of this document.

B. Test Procedure

As noted, EPCA directed DOE to establish a test procedure for those SEMs for which DOE determined that energy conservation standards would (1) be technologically feasible and economically justified and (2) result in significant energy savings. (42 U.S.C. 6317(b)(1))

In April 2019, DOE proposed amending its test procedure for SEMs (''April 2019 NOPR''). 84 FR 17004 (April 23, 2019). In the April 2019 NOPR, DOE proposed to harmonize its procedure with industry practice by incorporating a new industry standard that manufacturers would be permitted to use in addition to the three industry standards currently incorporated by reference as options for use when testing SEM efficiency. 84 FR 17004, 17012–17014. The proposed industry standards from the Institute of Electrical

[3] In a technical correction, DOE revised the compliance date for energy conservation standards to March 9, 2015, for each small electric motor manufactured (alone or as a component of another piece of non-covered equipment), or March 9, 2017, in the case of a small electric motor which requires listing or certification by a nationally recognized safety testing laboratory. 75 FR 17036 (April 5, 2010).

[4] DOE received two comments unrelated to the issues raised by the Notice of Proposed Determination (See Crosby, No. 30 and Crosby, No. 31).

[5] The term ''IEC'' refers to the International Electrotechnical Commission.

and Electronics Engineers (''IEEE''), Canadian Standards Association (''CSA''), and the International Electrotechnical Commission (''IEC'') are listed in Table III–1. In addition, DOE proposed to adopt industry provisions related to the test conditions used to ensure the comparability of test results for SEMs. 84 FR 17004, 17014–17018.

TABLE III–1—APRIL 2019 NOPR PROPOSED INDUSTRY STANDARDS FOR SMALL ELECTRIC MOTORS

Equipment description	Industry test procedure
Single-phase small electric motors	IEEE 114–2010. CSA C747–09. IEC 60034–2–1:2014 Method 2–1–1A.
Polyphase small electric motors less than or equal to 1 horsepower	IEEE 112–2017 Test Method A. CSA C747–09. IEC 60034–2–1:2014 Method 2–1–1A.
Polyphase small electric motors greater than 1 horsepower	IEEE 112–2017 Test Method B. CSA C390–10. IEC 60034–2–1:2014 Method 2–1–1B.

C. Technological Feasibility

1. General

In evaluating potential amendments to energy conservation standards, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the product or equipment at issue. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available equipment or in working prototypes to be technologically feasible. See 10 CFR part 430, subpart C, appendix A, sections 6(c)(3)(i) and 7(b)(1); 10 CFR 431.4.

After DOE has determined that particular options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on equipment utility or availability; (3) adverse impacts on health or safety; and (4) unique-pathway proprietary technologies. 10 CFR part 430, subpart C, appendix A, sections 6(c)(3)(ii)–(v) and 7(b)(2)–(5); 10 CFR 431.4.

Section IV.B of this final determination discusses the results of the screening analysis for SEMs, particularly the designs DOE considered, those it screened out, and those that are the basis for the final determination. In this final determination, based on its review of the market and comments received in response to the April 2020 NOPD and September 2020 Notice, DOE has determined that no significant technical advancements in induction motor technology within the scope of SEMs have been made since publication of the March 2010 Final Rule.

2. Maximum Technologically Feasible Levels

When DOE evaluates the potential for new or amended standards, DOE must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such equipment. (42 U.S.C. 6316(a); 42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max tech'') improvements in energy efficiency for SEMs using the design parameters for the most efficient equipment available on the market or in working prototypes. The max-tech levels that DOE has determined are described in section IV.C of this final determination.

D. Significance of Energy Savings

In determining whether to amend the current energy conservation standards for SEMs, DOE must assess whether amended standards will result in significant conservation of energy. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A). See also 42 U.S.C. 6295(n)(2).) While the term ''significant'' is not defined in EPCA, DOE has established a significance threshold for energy savings. See 10 CFR part 430, subpart C, appendix A, section 6(b); 10 CFR 431.4. In evaluating the significance of energy savings, DOE conducts a two-step approach that considers both an absolute site energy savings threshold and a threshold that is percent reduction in the covered equipment energy use. *Id.* DOE first evaluates the projected energy savings from a potential maximum technologically feasible (''max-tech'') standard over a 30-year period against a 0.3 quads of site energy threshold. 10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, section 6(b)(2). If the 0.3 quad-threshold is not met, DOE then compares the max-tech savings to the total energy usage of the covered equipment to calculate a percentage reduction in energy usage. 10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, section 6(b)(3). If this comparison does not yield a reduction in site energy use of at least 10 percent over a 30-year period, the analysis ends and DOE proposes that no significant energy savings would likely result from setting new or amended standards. 10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, section 6(b)(3). The two-step approach allows DOE to ascertain whether a potential standard satisfies EPCA's significant energy savings requirements in EPCA to ensure that DOE avoids setting a standard that ''will not result in significant conservation of energy.''

EPCA defines ''energy efficiency'' as the ratio of the useful output of services from an article of industrial equipment to the energy use of such article, measured according to the Federal test procedures. (42 U.S.C. 6311(3)) EPCA defines ''energy use'' as the quantity of energy directly consumed by an article of industrial equipment at the point of use, as measured by the Federal test procedures. (42 U.S.C. 6311(4))

As discussed in section V.B of this document, DOE has determined that amended standards would not satisfy the cost-effectiveness criterion as required by EPCA when determining whether to amend its standards for a given covered product or equipment. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A) and 42 U.S.C. 6295(n)(2)(C)) See also sections IV.F and V.B (discussing in greater detail DOE's analysis of the available data in reaching this determination). Consequently, DOE did not separately determine whether

the potential energy savings would be significant for the purpose of 42 U.S.C. 6295(n)(2).

E. Cost Effectiveness

In making a determination of whether amended energy conservation standards are needed, EPCA requires DOE to consider the cost effectiveness of amended standards in the context of the savings in operating costs throughout the estimated average life of the covered equipment class compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered equipment that are likely to result from a standard. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A); 42 U.S.C. 6295(n)(2))

In determining cost effectiveness, DOE conducted LCC and PBP analyses that estimate the costs and benefits to users from standards. The LCC is the sum of the initial price of equipment (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the equipment. The LCC analysis requires a variety of inputs, such as equipment prices, equipment energy consumption, energy prices, maintenance and repair costs, equipment lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as equipment lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of more-efficient equipment through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more-stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analyses, DOE assumes that consumers would purchase the covered equipment in the first year of compliance with any amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F of this final determination.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE performed for this final determination regarding SEMs. Separate subsections address each component of DOE's analyses and responses to related comments. DOE used a spreadsheet tool that calculates the LCC savings and PBP of potential energy conservation standards. This spreadsheet tool is available on the website: *https://www.regulations.gov/docket?EERE-2019-BT-STD-0008.*

Lennox supported DOE's proposed determination not to amend energy conservation standards for SEMs. (Lennox, No. 21 at p. 1) NEMA concurred with DOE that it is not cost effective to increase the stringency of SEM energy conservation standards. (NEMA, No. 22 at p. 5; NEMA, No. 32 at p. 2–3) CA IOUs also concurred with DOE that there is limited opportunity for additional energy efficiency in the current scope of regulation for SEMs. (CA IOUs, No. 24 at p. 2; CA IOUs, No. 33 at p. 2) As discussed previously, based on the analyses summarized in section V of this document, DOE has determined that more stringent energy conservation standards would not be cost effective. Therefore, DOE has determined that the current standards for SEMs do not need to be amended under the relevant criteria in 42 U.S.C. 6295(m)(1)(A) and 42 U.S.C. 6295(n)(2). See also 42 U.S.C. 6316(a) (applying 42 U.S.C. 6295(m) and 42 U.S.C. 6295(n) to small electric motors).

A. Market and Technology Assessment

DOE has conducted a market and technology assessment in support of the final determination for SEMs. DOE develops information in the market and technology assessment that provides an overall picture of the market for the equipment concerned, including the purpose of the equipment, the industry structure, manufacturers, market characteristics, and technologies used in the equipment. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this final determination include (1) a determination of the scope and equipment classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of SEMs. The key findings of DOE's market assessment are summarized in the following sections. See chapter 3 of the final determination technical support document (''TSD'') for further discussion of the market and technology assessment.

1. Scope of Coverage

By statute, a ''small electric motor'' is ''a NEMA general purpose alternating-current single-speed induction motor, built in a two-digit frame number series in accordance with NEMA Standards Publication MG 1–1987.'' (42 U.S.C. 6311(13)(G)) DOE later clarified by regulation that this definition also includes IEC metric equivalent motors—*i.e.,* those motors that otherwise satisfy the statutory definition of ''small electric motor'' but that happen to be built in accordance with metric units. See 10 CFR 431.442. Equipment meeting this definition are within DOE's scope of coverage but not all may be subject to DOE's current standards.

DOE's standards regulate the energy efficiency of those SEMs that fall within three topologies (*i.e.,* arrangements of component parts): Capacitor-start induction-run (''CSIR''), capacitor-start capacitor-run (''CSCR''), and polyphase motors. See 10 CFR 431.446. EPCA prescribes that standards for SEMs do not apply to any SEM which is a component of a covered product or covered equipment under EPCA. (42 U.S.C. 6317(b)(3)) DOE's current energy conservation standards only apply to SEMs manufactured alone or as a component of another piece of non-covered equipment. 10 CFR 431.446(a).

Subpart X of part 431 includes energy conservation standards and test procedures for the SEMs listed in Table IV–1. In the April 2020 NOPD, DOE did not propose any changes to the scope of SEMs subject to energy conservation standards (*i.e.,* ''scope of applicability'').

TABLE IV–1—SMALL ELECTRIC MOTORS CURRENTLY SUBJECT TO ENERGY CONSERVATION STANDARDS

[Manufactured alone or as a component of another piece of non-covered equipment]

Motor topology	Pole configuration	Motor output power
Single-phase:		
CSIR	2, 4, 6	0.25–3 hp. (0.18–2.2 kW).*

TABLE IV–1—SMALL ELECTRIC MOTORS CURRENTLY SUBJECT TO ENERGY CONSERVATION STANDARDS—Continued

[Manufactured alone or as a component of another piece of non-covered equipment]

Motor topology	Pole configuration	Motor output power
CSCR	2, 4, 6	0.25–3 hp. (0.18–2.2 kW).
Polyphase	2, 4, 6	0.25–3 hp. (0.18–2.2 kW).

Certain motor categories are not currently subject to standards. These include:
- Polyphase, 6-pole, 2 and 3 hp motors;
- CSCR and CSIR, 6-pole, 1.5, 2, and 3 hp motors;
- CSCR and CSIR, 4-pole, 3 hp motors.

* The values in parentheses are the equivalent metric ratings.

In response to the April 2020 NOPD and September 2020 Notice, DOE received a number of comments relevant to the scope of applicability of energy conservation standards for SEMs. Lennox, AHRI and AHAM supported maintaining the existing standards scope for SEMs. (Lennox, No. 21 at p. 2; AHRI and AHAM, No. 25 at p. 2) In addition, NEMA stated that motor efficiency has reached its peak of practicality, and that system efficiency in applications must be the focus. NEMA commented in support of DOE's efforts investigating or already establishing Extended Product Rulemakings (*e.g.,* pumps) which set a system efficiency, rather than continue to focus on components (*i.e,.* the motor). (NEMA, No. 32 at p. 2)

The Efficiency Advocates asserted that given DOE's mandate to carry out the energy conservation purposes of the Energy Policy and Conservation Act, DOE must consider expanding the scope of its motor standards, either in this docket or the electric motors docket. (Efficiency Advocates, No. 23 at p. 2) Similarly, the CA IOUs commented that there is limited opportunity for additional energy efficiency gains in the current scope of regulation for SEMs and added that the industry technical standards on which the current SEM definition is based—NEMA MG1–1987—is no longer representative of the market. (CA IOUs, No. 24 at p. 2; No. 33 at p. 2)

In the view of the CA IOUs, DOE should expand the scope of the SEM rulemaking to consider advances in motor technology and incorporate brushless direct current (DC) and synchronous permanent magnet AC (''PMAC'') motors, irrespective of the limits already defined by Congress. See 42 U.S.C. 6311(13)(G) (defining the term ''small electric motor'') and 10 CFR 431.442 (incorporating motors meeting the statutory definition that are built in metric units). The CA IOUs provided an analysis and market data and technical information as to the energy savings potential, cost, and technical feasibility of brushless DC motors such as electronically commutated motors (''ECMs'') and PMAC motors compared to other available motor technologies such as permanent-split capacitor (''PSC'') motors. The CA IOUs further commented that motor consumers and regulators in other markets are already considering advanced motor technologies as substitutes for SEMs within the current scope of DOE's energy conservation standards. (CA IOUs, No. 24 at p. 2–7; No. 33 at p. 2–8)

In addition, the CA IOUs recommended that DOE consider expanding the definition of SEMs beyond the ''general purpose motor'' definition included in NEMA MG1–1987 (and as specified in the statute) to include additional motors used in general purpose applications such as split-phase, shaded pole, and PSC motors. In cases where the application requirements rely on part-load operation, the CA IOUs recommended that these motors be compared in a technology-neutral manner against other motor designs optimized for part load operation (*i.e.,* brushless DC, synchronous PMAC/Q-Sync). (CA IOUs, No. 24 at p. 7; No. 33 at p. 8–9)

Regarding the potential coverage of ECMs, NEMA commented that ECMs were not squirrel cage induction motors but instead are permanent magnet synchronous motors with electronic controls/drives integral to the machine and were not included in the scope of SEMs (NEMA, No. 32 at p. 2).[6] In addition, NEMA commented that ECMs tend to be more expensive than single-speed SEMs, and typically installed as components in appliances that DOE already regulates. In these instances, strict energy efficiency requirements on those appliances and the use of better motor controls outweigh the increased expense of using ECMs. NEMA added that making ECMs more efficient would not make regulated appliances more efficient because of component efficiency tradeoffs in satisfying efficiency requirements and protections from double-regulation. (NEMA, No. 32 at p. 2–3) NEMA commented that bringing ECMs into scope could have significant impacts on Original Equipment Manufacturers (''OEMs''). NEMA added that ECMs are not drop-in fit replacements for SEMs and that DOE has not sufficiently examined the downstream impacts of adding such motors in scope on OEMs. (NEMA, No. 32 at p. 2) Regarding PMAC/Q-sync designs, NEMA noted that such PMAC/Q-sync motors did not meet NEMA MG–1–1987 torque requirements and were not effective substitutes for SEMs, as indicated by their small market share. (NEMA, No. 32 at p. 3)

As previously stated in section III.A, this document pertains only to equipment meeting the definition of small electric motor, as codified in 10 CFR 431.442, which includes general purpose single speed induction motors. *See* 42 U.S.C. 6311(13)(G) and 10 CFR 431.442. Single-speed induction motors, as delineated and described in MG1–1987, fall into five categories: Split-phase, shaded-pole, capacitor-start (both CSIR and CSCR), PSC, and polyphase. Of these five motor categories, DOE determined in the March 2010 Final Rule that only CSIR, CSCR, and polyphase motors were able to meet the relevant performance requirements in NEMA MG1–1987 and fell within the general purpose alternating current motor category, as indicated by the listings found in manufacturers' catalogs. 75 FR 10874, 10882–10883. Therefore, for this determination, DOE only considered the regulated SEMs currently subject to energy conservation standards.[7]

[6] DOE notes that the definition of a SEM only includes single speed induction motors.

[7] DOE also notes that were it to determine that expansion of the scope is warranted and permissible, it would first need to establish test methods for any such motors. See 10 CFR 431.4; 10 CFR part 430 subpart C appendix A section 8(d). Nothing DOE has reviewed—or that commenters have submitted—suggests that the existing test procedures for SEM are appropriate for motors that fall outside of the already prescribed small electric motor scope set by Congress and the definition of

Continued

AHAM and AHRI referenced the statutory exemption regarding the application of energy conservation standards for SEMs that are components of covered products (42 U.S.C. 6317(b)(3)) and requested that DOE interpret the exemption to apply to all SEMs destined for or used in covered products or equipment. (AHAM and AHRI, No. 25 at p. 4) Lennox commented that it opposes regulating components used in products and equipment already regulated by DOE, instead it supports a finished-product approach to energy efficiency regulation. (Lennox, No. 21 at p. 2) GEA commented that any regulation of individual components in products whose energy consumption is regulated on a product level will provide little to no energy savings for consumers, will disrupt the complex balance of component selection and design, and will likely increase cost for consumers for no benefit to consumers. (GEA, No. 26 at p. 2) NEMA commented that because SEMs are always used as a component in larger product systems that consume electricity, there already exist dozens of appliance- and device-level regulations that address energy consumption of those end-use products. NEMA suggested examining and measuring energy savings at the end-use device makes the most sense, as system dynamics can vary for designs within each product class and from class to class. (NEMA, No. 22 at p. 2)

As noted, EPCA directs DOE to establish test procedures and energy conservation standards for SEMs, see 42 U.S.C. 6317(b), both of which DOE has already done. EPCA further provides that standards shall not apply to any SEM which is a component of a covered product or covered equipment. (42 U.S.C. 6317(b)(3)) DOE has evaluated the scope of the SEM standards in this final determination in accordance with EPCA.

2. Equipment Classes

When evaluating and establishing energy conservation standards, DOE divides covered equipment into equipment classes by the type of energy used, or by capacity or other performance-related features that justify a different standard. (42 U.S.C. 6316(a); 42 U.S.C. 6295(q)) In determining whether capacity or another performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE deems appropriate. (*Id.*) For the April 2020 NOPD, DOE assessed the 62 equipment classes currently established based on phase count (*i.e.,* single-phase versus polyphase), topology of single-phase motors, number of poles, and horsepower. This section reviews the motor characteristics used to delineate equipment classes for SEMs.

The first characteristic used to establish equipment classes is phase count. Polyphase and single-phase equipment classes are used to differentiate motors based on the fundamental differences in how the two types of motors operate. 10 CFR 431.446(a). For a rotor to move, the stator (*i.e.,* the stationary part of the motor) must produce a rotating magnetic field. To operate on single-phase alternating current (''AC'') power, the single-phase motor uses an auxiliary winding (or start winding) with current and voltage out of phase with the original (main) winding to produce a net rotating magnetic field. To operate on three-phase power, the polyphase motor uses windings arranged such that when supplied by three-phase alternating current, a rotating magnetic field is produced. In short, three-phase power in a polyphase motor naturally produces rotation, whereas a single-phase motor requires the auxiliary winding to ''engineer'' the conditions for rotation. Due to these differences, polyphase motors are inherently more efficient but require use of a three-phase power source. Based on the differences in efficiency and consumer utility, DOE separated equipment classes based on phase count in the March 2010 Final Rule. 75 FR 10874, 10886. DOE relied on the same approach for the proposed determination. See 85 FR 24146, 24153.

In addition to differentiating equipment classes by phase count, equipment classes are differentiated by the topology of single-phase motors. 10 CFR 431.446(a). DOE identified two topologies of single-phase motors meeting the statutory definition of SEMs: CSIR and CSCR. CSIR and CSCR motors both utilize a capacitor (''start-capacitor'') and two windings (''start-winding'' and ''run-winding''). The difference between the two motors occurs when reaching operating speed; while CSIR motors run on the run-winding alone with no capacitor, CSCR motors run using an additional ''run-capacitor'' and both windings. While this additional capacitor can boost CSCR motor efficiency to levels higher than those exhibited by CSIR motor designs, it usually constitutes dimensional changes due to the need to mount the run-capacitor externally on the motor housing. This additional spatial requirement could potentially limit the use of CSCR motors in space-constrained applications, and would cause motor topology to directly impact consumer utility. Given that motor topology can affect motor performance and consumer utility, DOE differentiated single-phase equipment classes by topology in the March 2010 Final Rule. 75 FR 10886. DOE proposed to use the same approach in the April 2020 NOPD. See 85 FR 24146, 24153.

The current energy conservation standards also differentiate classes based on the number of poles in a motor. 10 CFR 431.446(a). The number of poles in an induction motor determines the synchronous speed (*i.e.,* revolutions per minute). There is an inverse relationship between the number of poles and speed: As a motor design increases from two to eight poles, the synchronous speed drops from 3,600 to 900 revolutions per minute. The desired synchronous speed varies by end use application, making the number of poles in a motor a factor directly impacting consumer utility. By examining the efficiency ratings for 1–200 horsepower polyphase electric motors (10 CFR 431.25),[8] motors meeting the NEMA Premium Motor standard, and manufacturer catalogs, DOE observed that full-load efficiency percentages tend to decrease with the number of poles. Therefore, DOE determined that the number of poles has a direct impact on the motor's performance and consumer utility, and consequently, the number of poles is a further means of differentiating among equipment classes. 75 FR 10886. DOE relied on the same approach for the proposed determination. See 85 FR 24146, 24153.

Finally, DOE employs motor horsepower as an equipment class setting factor under the current energy conservation standards. 10 CFR 431.446(a). Average full load efficiency generally correlates with motor horsepower (*e.g.,* a 3-horsepower motor is usually more efficient than a ¼-horsepower motor). DOE found that motor efficiency varies with motor horsepower by evaluating manufacturers' catalog data, the efficiency ratings of the established SEM energy conservation standards (10 CFR 431.446), and the efficiency

small electric motor. Comments related to the scope of applicability of the DOE test procedure for small electric motors were discussed as part of DOE's test procedure NOPR. 84 FR 17004, 17009 (April 23, 2019).

[8] While there is no overlap between the scope of applicability for electric motor standards at 10 CFR 431.25 and small electric motors standards at 10 CFR 431.446, the pole-efficiency relationships observed in the electric motor standards from 1 to 3 horsepower can be considered when determining appropriate pole-efficiency relationships for small electric motors in this horsepower range.

requirements of the NEMA Premium Motor program. Additionally, motor horsepower dictates the maximum load that a motor can drive, which means that a motor's rated horsepower can influence and limit the end use applications where that motor can be used. Horsepower is a critical performance attribute of a small electric motor, and since horsepower has a direct relationship with average full load efficiency and consumer utility, DOE used this element as a criterion for distinguishing among equipment classes in the March 2010 Final Rule. 75 FR 10886. DOE relied on the same approach for the proposed determination. See 85 FR 24146, 24153.

DOE did not receive any comments on the current structure of the equipment classes as assessed in the April 2020 NOPD. Accordingly, in this final determination DOE continues to assess the SEM equipment classes as currently established. Table IV–2 summarizes the structure of the equipment classes identified for this final determination and as designated by the current standards at 10 CFR 431.446.

TABLE IV–2—SUMMARY OF SMALL ELECTRIC MOTOR EQUIPMENT CLASSES

Motor topology	Pole configuration	Motor output power *hp*
Single-phase:		
CSIR	2, 4, 6	0.25–3
CSCR	2, 4, 6	0.25–3
Polyphase	2, 4, 6	0.25–3

See chapter 3 of the final determination TSD for further discussion of the equipment classes.

3. Technology Options for Efficiency Improvement

The purpose of the technology assessment is to develop a list of technology options that could improve the efficiency of SEMs. For the motors covered in this determination, energy efficiency losses are grouped into four main categories: I^2R losses,[9] core losses, friction and windage losses, and stray load losses. The technology options considered in this section are categorized by these four categories of losses.

The SEMs evaluated in this determination are all AC induction motors. Induction motors have two core components: A stator and a rotor. The components work together to convert electrical energy into rotational mechanical energy. This is done by creating a rotating magnetic field in the stator, which induces a current flow in the rotor. This current flow creates an opposing magnetic field in the rotor, which creates rotational forces. Because of the orientation of these fields, the rotor field follows the stator field. The rotor is connected to a shaft that also rotates and provides the mechanical energy output.

Table IV–3 summarizes the technology options identified in the April 2020 NOPD.

TABLE IV–3—SUMMARY OF TECHNOLOGY OPTIONS FOR IMPROVING EFFICIENCY

Type of loss to reduce	Technology option applied
I^2R Losses	Use a copper die-cast rotor cage.
	Reduce skew on conductor cage.
	Increase cross-sectional area of rotor conductor bars.
	Increase end ring size.
	Changing gauges of copper wire in stator.
	Manipulate stator slot size.
	Decrease radial air gap.
	Change run-capacitor rating.
Core Losses	Improve grades of electrical steel.
	Use thinner steel laminations.
	Anneal steel laminations.
	Add stack height (*i.e.,* add electrical steel laminations).
	Use high-efficiency lamination materials.
	Use plastic bonded iron powder.
Friction and Windage Losses	Use better bearings and lubricant.
	Install a more efficient cooling system.

85 FR 24146, 24155.

DOE did not receive comments on the technology options identified in the April 2020 NOPD. Accordingly, DOE continued to consider the technology options identified in the April 2020 NOPD in developing this final determination. Chapter 3 of the TSD provides details on the DOE's market and technology assessment for SEMs.

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable [10] for further consideration of new or amended energy conservation standards:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that

[9] I^2R losses refer to conductor losses. In AC circuits, these losses are computed as the square of the current (''I'') multiplied by the conductor resistance (''R'').

[10] DOE refers to the technology options that pass the screening criteria as ''design options.''

technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have a significant adverse impact on the utility of the product to significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-Pathway Proprietary Technologies.* If a design option utilizes proprietary technology that represents a unique pathway to achieving a given efficiency level, that technology will not be considered further due to the potential for monopolistic concerns.

10 CFR part 430, subpart C, appendix A, 6(c)(3) and 7(b); 10 CFR 431.4.

In summary, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the above five criteria, it will be excluded from further consideration in the engineering analysis.

Table IV–3 provides a summary of all the technology options DOE considered for improving SEM efficiency. For a description of how each of these technology options improves SEM efficiency, see final determination TSD chapter 3. For the April 2020 NOPD, DOE initially screened out three of the identified technology options: Reducing the air gap below .0125 inches, amorphous metal laminations, and plastic bonded iron powder (''PBIP'').

Reducing the air gap between the rotor and stator can improve motor efficiency. For SEMs, the air gap is commonly set at 15 thousandths of an inch. A reduction in air gaps is technologically feasible and DOE is unaware of any adverse impacts on health or safety associated with reducing the radial air gap below 12.5 thousandths of an inch. However, this technology option fails the screening criterion of being practicable to manufacture, install, and service. Such a tight air gap may cause problems in manufacturing and service, with the rotor potentially coming into contact with the stator. This technology option also fails the screening criterion of avoiding adverse impacts on consumer utility and reliability, because the motor may experience higher failure rates in service when the manufactured air gaps are less than 12.5 thousandths of an inch.

Using amorphous metals in the rotor laminations is another potential technology option to improve the efficiency of SEMs. Amorphous metal is extremely thin, has high electrical resistivity, and has little or no magnetic domain definition. Because of amorphous steel's high resistance, it exhibits a reduction in hysteresis and eddy current losses, which in turn reduces overall losses in SEMs. However, amorphous steel is a very brittle material which makes it difficult to punch into motor laminations.[11]

Although amorphous metals have the potential to improve efficiency, DOE does not consider this technology option technologically feasible, because it has not been incorporated into a working prototype of a small electric motor. Furthermore, DOE is uncertain whether amorphous metals are practicable to manufacture, install, and service, because a prototype amorphous metal-based SEM has not been made and little information is available on the feasibility of adapting this technology for manufacturing SEMs to reach any conclusions regarding the practicability of using this option. DOE is not aware of any adverse impacts on consumer utility, reliability, health, or safety associated with amorphous metal laminations.

Using PBIP to manufacture SEMs could cut production costs while increasing production output. Although other researchers may be working on this technology option, DOE notes that a research team at Lund University in Sweden published a paper in 2007 about using PBIP in manufacturing, which is the most recent applicable paper on the subject. This technology option is based on an iron powder alloy that is suspended in plastic, and is used in certain motor applications such as fans, pumps, and household appliances.[12] The compound is then shaped into motor components using a centrifugal mold, reducing the number of manufacturing steps. Researchers claim that this technology option could cut losses by as much as 50 percent. The Lund University study, which is the most recent research paper to address the use of PBIP in the production context, indicated that its study team already produced inductors, transformers, and induction heating coils using PBIP, but had not yet produced a small electric motor. In addition, it appears that PBIP technology is aimed at torus, claw-pole, and transversal flux motors, none of which are with in the regulatory definition of SEMs at 10 CFR 431.442. DOE has found no evidence of any significant research or technical advancement in PBIP methodologies that could be applied to SEMs since publication of the March 2010 Final Rule or the April 2020 NOPD.

Although PBIP has the potential to improve efficiency while reducing manufacturing costs, DOE does not consider this technology option technologically feasible because it has not been incorporated into a working prototype of a small electric motor. Also, DOE is uncertain whether the material has the structural integrity to form into the necessary shape of a SEM steel frame. Specifically, properties of PBIP can differ depending on the processing. If the metal particles are too closely compacted and begin to touch, the material will gain electrical conductivity, counteracting one of its most important features of preventing electric current from developing, which is critical because this essentially eliminates losses in the core due to eddy currents. If the metal particles are not compacted closely enough, its structural integrity could be compromised because the resulting material will be very porous.

Furthermore, DOE is uncertain whether PBIP is practicable to manufacture, install, and service, because a prototype PBIP SEM has not yet been made and little information is available on the feasibility of adapting this option for manufacturing SEMs. DOE continues to be unaware of any adverse impacts on product utility, product availability, health, or safety that may arise from the use of PBIP in SEMs.

In the April 2020 NOPD, DOE tentatively determined that the remaining technology options listed in Table IV–2 are technologically feasible. The evaluated technologies all have been used (or are being used) in commercially available products or working prototypes. These technologies all incorporate materials and components that are commercially available in today's supply markets for the SEMs that are the subject of this document.

DOE did not receive comments on the screening analysis in the April 2020 NOPD. Accordingly, DOE considered the same screening analysis from the

[11] 1 S.R. Ning, J. Gao, and Y.G. Wang. Review on Applications of Low Loss Amorphous Metals in Motors. 2010. ShanDong University. Weihai, China.

[12] Horrdin, H., and E. Olsson. Technology Shifts in Power Electronics and Electric Motors for Hybrid Electric Vehicles: A Study of Silicon Carbide and Iron Powder Materials. 2007. Chalmers University of Technology. Göteborg, Sweden.

April 2020 NOPD in this final determination and is screening out the following technology options: Reducing the air gap below .0125 inches, amorphous metal laminations, and plastic bonded iron powder (''PBIP''). DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.,* practicable to manufacture, install, and service and do not result in adverse impacts on consumer utility, product availability, health, or safety, and do not represent unique pathway proprietary technologies). Chapter 4 of the TSD provides details on the DOE's screening analysis for SEMs.

C. Engineering Analysis

The engineering analysis establishes the relationship between the efficiency and cost of an SEM. There are two elements to consider in the engineering analysis; the selection of efficiency levels to analyze (*i.e.,* the ''efficiency analysis'') and the determination of product cost at each efficiency level (*i.e.,* the ''cost analysis''). In determining the performance of higher-efficiency equipment, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each equipment class, DOE estimates the baseline cost, as well as the incremental cost for the equipment at efficiency levels above the baseline. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses). The following sections provide further details on the engineering analysis methodology.

1. Summary of Significant Data Sources

DOE utilized two principal data sources for the engineering analysis: (1) The database of SEM manufacturer suggested retail price (''MSRP'') and performance data based on the current market (as evaluated in the April 2020 NOPD), and (2) motor modeling data, test data, and performance specifications from the March 2010 Final Rule. DOE determined that relying on the data from the March 2010 Final Rule was reasonable because a review of the catalog data suggested that there were no significant technological advancements in the motor industry that could lead to more efficient or lower cost motor designs relative to the motors modeled for the March 2010 Final Rule. In response to the April 2020 NOPD, NEMA also commented that the motor designs and associated efficiency levels adopted from the March 2010 Final Rule analysis are appropriate. (NEMA, No. 22 at p. 3) Accordingly, in preparing this determination, DOE continued to evaluate the motor designs that were modeled for the March 2010 Final Rule analysis.

DOE collected MSRP and performance data from product literature and catalogs distributed by four major motor manufacturers: ABB (which includes the manufacturer formerly known as Baldor Electric Company), Nidec Motor Corporation (which includes the US Motors brand), Regal-Beloit Corporation (which includes the Marathon and Leeson brands), and WEG Electric Motors Corporation.[13] Based on market information from the Low-Voltage Motors World Market Report,[14] DOE estimates that the four major motor manufacturers noted comprise the majority of the U.S. SEM market and are consistent with the motor brands considered in the March 2010 Final Rule. (Throughout this document this data will be referred to as the ''manufacturer catalog data.'')

2. Representative Equipment Classes

Due to the large number of equipment classes, DOE did not directly analyze all 62 equipment classes of SEMs considered under this final determination. Instead, DOE selected representative classes based on two factors: (1) The quantity of motor models available within an equipment class and (2) the ability to scale to other equipment classes.

DOE notes that the minimum energy conservation standards adopted in the March 2010 Final Rule correspond to the efficiency level that represented the maximum technologically feasible efficiency for CSIR motors. As discussed previously, DOE was unable to identify any additional design options that passed the screening criteria that would indicate that a motor design meeting a higher efficiency level is technologically feasible and commercially viable. In addition, DOE was unable to identify any CSIR motors in the manufacturer catalog data that exhibited efficiency levels exceeding the current energy conservation standards for CSIR motors. From this information, DOE proposed in the April 2020 NOPD that more stringent energy conservation standards for CSIR motors do not appear to be technologically feasible. Consequently, DOE did not include a representative CSIR equipment class as part of the engineering analysis.

The minimum energy conservation standards adopted in the March 2010 Final Rule corresponded to efficiency levels below the maximum technologically feasible levels for the CSCR and polyphase topologies, and therefore DOE elected to analyze one representative equipment class for each of these motor topologies. Equipment classes in both the polyphase and CSCR topologies were directly analyzed due to the fundamental differences in their starting and running electrical characteristics. These differences in operation have a direct impact on performance and indicate that polyphase motors are typically more efficient than single-phase motors. In addition, the efficiency relationships across horsepower and pole configuration are different between single-phase and polyphase motors.

DOE did not vary the pole configuration of the representative classes it analyzed because analyzing the same pole configuration provided the strongest relationship upon which to base its scaling. See section IV.C.5 of this document for details on DOE's scaling methodology. Keeping as many design characteristics constant as possible enabled DOE to more accurately identify how design changes affect efficiency across horsepower ratings. For each motor topology, DOE directly analyzed the most common pole-configuration. For both motor topologies analyzed, 4-pole motors constitute the largest fraction of motor models on the market.

When DOE selected its representative equipment classes, DOE chose the horsepower ratings that constitute a high volume of motor models and approximate the middle of the range of covered horsepower ratings so that DOE could develop a reasonable scaling methodology. DOE notes that the representative equipment classes for polyphase and CSCR motors that were selected for the engineering analysis align with the representative classes that were directly analyzed in the March

[13] ABB (Baldor-Reliance): Online Manufacturer Catalog, accessed January 3, 2019. Available at *https://www.baldor.com/catalog#category=2;* Nidec: Online Manufacturer Catalog, accessed December 26, 2018. Available at *ecatalog.motorboss.com/Catalog/Motors/ALL*; Regal (Marathon and Leeson): Online Manufacturer Catalog, accessed December 27, 2018. Available at *https://www.regalbeloit.com/Products/Faceted-Search?category=Motors&brand=Leeson,Marathon%20Motors*; WEG: Online Manufacturer Catalog, accessed December 24, 2018. Available at *http://catalog.wegelectric.com/.*

[14] Based on the Low-Voltage Motors, World Market Report (IHS Markit Report September 2017, Edition 2017–2018) Table 5.15: Market Share Estimates for Low-voltage Motors: Americas; Suppliers 'share of the Market in 2015 and 2016.

2010 Final Rule. 75 FR 10874, 10888. The proposed representative equipment classes from the April 2020 NOPD are outlined in Table IV–4.

TABLE IV–4—REPRESENTATIVE EQUIPMENT CLASSES

Motor topology	Pole configuration	Motor output power *hp*
Polyphase	4	1.00
Single-phase CSCR	4	0.75

NEMA commented that the selected representative equipment classes are appropriate because there have not been any significant changes to design practices which might warrant modification. (NEMA, No. 22 at p. 2) DOE did not receive any other comments regarding the representative equipment classes. Accordingly, DOE continued to analyze the same representative equipment classes from the April 2020 NOPD in preparing this final determination.

3. Efficiency Analysis

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) Relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). Using the efficiency-level approach, the efficiency levels established for the analysis are determined based on the market distribution of existing products (in other words, based on the range of efficiencies and efficiency level ''clusters'' that already exist on the market). Using the design option approach, the efficiency levels established for the analysis are determined through detailed engineering calculations and/or computer simulations of the efficiency improvements from implementing specific design options that have been identified in the technology assessment. DOE may also rely on a combination of these two approaches. For example, the efficiency-level approach (based on actual products on the market) may be extended using the design option approach to interpolate to define ''gap fill'' levels (to bridge large gaps between other identified efficiency levels) and/or to extrapolate to the ''max-tech'' level (particularly in cases where the ''max tech'' level exceeds the maximum efficiency level currently available on the market).

In the March 2010 Final Rule DOE and in the April 2020 NOPD, DOE relied on the design option approach. DOE maintained the design option approach for this final determination. In this design option approach, DOE considers efficiency levels corresponding to motor designs that meet or exceed the efficiency requirements of the current energy conservation standards at 10 CFR 431.446. DOE has determined that there are no additional technology options that pass the screening criteria that would enable the consideration of any additional efficiency levels representing higher efficiency levels than the maximum technologically feasible level analyzed in the March 2010 Final Rule.

For each equipment class, DOE generally selects a baseline model as a reference point, and measures changes resulting from potential energy conservation standards against the baseline. The baseline model in each equipment class represents the characteristics of a product/equipment typical of that class (*e.g.,* capacity, physical size). Generally, a baseline model is one that just meets current energy conservation standards, or, if no standards are in place, the baseline is typically the most common or least efficient unit on the market.

DOE considered the current minimum energy conservation standards to establish the baseline efficiency levels for each representative equipment class. As discussed previously, DOE selected representative equipment classes that align with the classes analyzed in the March 2010 Final Rule. See March 2010 Final Rule TSD, sec. 5.2.1. DOE identified specific motor designs from the March 2010 Final Rule engineering analysis that exhibit full-load efficiency ratings that are representative of the minimum energy conservation standards for SEMs. DOE used these motor designs to form the baseline against which to compare improved efficiency design options in DOE's analysis. Each increase in efficiency over the baseline level that DOE analyzed was assigned an efficiency level (''EL'') number.

For the March 2010 Final Rule engineering analysis, DOE purchased and tested motors with the lowest catalog efficiency rating available in the market for each representative equipment class. DOE's technical expert tore down each motor to obtain dimensions, a BOM, and other pertinent design information. DOE worked with a subcontractor to reproduce these motor designs using modeling software and then applied design options to a modeled motor that would increase that motor's efficiency to develop a series of motor designs spanning a range of efficiency levels. For the current evaluation, DOE continued to base its analysis on the modeled motor designs. In light of its catalog review, DOE discerned no significant technological advancements in the motor industry that could lead to more efficient or lower cost motor designs relative to the motors modeled for the March 2010 Final Rule. In addition, DOE did not receive any contrasting comments suggesting any significant technological advancements for small electric motors within current scope.

In developing the modeled motor designs and associated costs, DOE also considered both space-constrained and non-space-constrained scenarios. DOE prepared designs of increased efficiency covering both scenarios for each representative equipment class. The design levels prepared for the space-constrained scenario included baseline and intermediate levels, a level for a design using a copper rotor, and a max-tech level with a design using a copper rotor and exotic core steel. The high-efficiency space-constrained designs incorporate copper rotors and exotic core steel in order to meet comparable levels of efficiency to the high-efficiency non-space-constrained designs while meeting the parameters for minimally increased stack length. The design levels created for the non-space-constrained scenario corresponded to the same efficiency levels created for the space-constrained scenario. Further information on the development of modeled motor designs is available in section 5.3 of the March 2010 Final Rule TSD.

NEMA commented that improving efficiency in SEMs may not always result in overall equipment-level efficiency improvements. It noted that any modification to energy conservation standards or scope of regulated SEMs would require a revised analysis of the downstream impact of SEM design changes on OEM devices and appliances. NEMA asserted that changes in motor size, weight, rotational speed, slip,[15] and other factors due to more stringent energy conservation standards have not been sufficiently evaluated. It added that because of the potential increase in the speed of the motor due to increases in efficiency, more stringent energy conservation standards could have significant downstream impacts in OEM devices which use these motors and would not always guarantee higher efficiency or better performance by that end-use device. (NEMA, No. 22 at pp. 1–2, 5; No. 32 at p. 2)

DOE continued to use the designs analyzed for the March 2010 Final Rule in preparing this final determination. The designs analyzed in the engineering analysis did not show a significant (less than 2 percent) and consistent increase in speed with increasing efficiency (some more efficient designs had slightly lower speeds) across all ELs (See Final Determination TSD Chapter 5). In addition, as discussed previously, to account for motor size and weight limitations, DOE also analyzed both space-constrained and non-space-constrained scenarios. However, in this final determination, DOE is not considering amending the current energy conservation standards for this equipment.

Given that DOE was unable to identify any additional design options for improving efficiency that passed the screening criteria and were not already considered in the March 2010 Final Rule engineering analysis, DOE analyzed the same motor designs that were developed for the March 2010 Final Rule except for CSIR motors (which, as indicated earlier, did not appear to have any technologically-feasible options available to improve their efficiency). For each representative equipment class, DOE established an efficiency level for each motor design that exhibited improved efficiency over the baseline design. As discussed previously, DOE considered the current minimum energy conservation standards as the baseline efficiency levels for each representative equipment class. These April 2020 NOPD efficiency levels are summarized in Table IV–5.

TABLE IV–5—SUMMARY OF EFFICIENCY LEVELS

Representative equipment class	EL	Efficiency (%)
Single-phase CSCR, 4-pole, 0.75-hp	0	81.8
	1	82.8
	2	84.0
	3	84.6
	4	86.7
	5	87.9
Polyphase, 4-pole, 1-hp	0	83.5
	1	85.2
	2	86.3
	3	87.8

As mentioned previously, NEMA commented that the motor designs and associated efficiency levels adopted into this analysis from the March 2010 Final Rule analysis are appropriate. (NEMA, No. 22 at p. 3) Accordingly, similar to the April 2020 NOPD, DOE adopted the motor modeling approach used in support of the March 2010 Final Rule to analyze and establish efficiency levels and incremental motor MSPs. DOE did not identify any additional design options in the market for improving efficiency that were not already considered in the March 2010 Final Rule.

4. Cost Analysis

The cost analysis portion of the Engineering Analysis is conducted using one or a combination of cost approaches. The selection of cost approach depends on a suite of factors, including the availability and reliability of public information, characteristics of the regulated product and the availability and timeliness of purchasing the equipment on the market. The cost approaches are summarized as follows:

- *Physical teardowns:* Under this approach, DOE physically dismantles a commercially available product, component-by-component, to develop a detailed bill of materials for the product.
- *Catalog teardowns:* In lieu of physically deconstructing a product, DOE identifies each component using parts diagrams (available from manufacturer websites or appliance repair websites, for example) to develop the bill of materials (''BOM'') for the product.
- *Price surveys:* If neither a physical nor catalog teardown is feasible (for example, for tightly integrated products such as fluorescent lamps, which are infeasible to disassemble and for which parts diagrams are unavailable) or cost-prohibitive and otherwise impractical (*e.g.* large commercial boilers), DOE conducts price surveys using publicly available pricing data published on major online retailer websites and/or by soliciting prices from distributors and other commercial channels.

In the present case, a standard BOM was constructed for each motor design that includes direct material costs and labor time estimates along with costs. DOE notes that the costs established for direct material costs and labor time were initially determined in terms of $2009 for the March 2010 Final Rule. For the April 2020 NOPD, DOE updated these material and labor costs to be representative of the market in 2018. DOE adjusted historical material prices to $2018 using the historical Bureau of Labor Statistics Producer Price Indices (''PPI'')[16] for each commodity's industry. In addition, DOE updated labor costs and markups based on the most recent and complete version (*i.e.*

[15] ''Motor slip'' is the difference between the speed of the rotor (operating speed) and the speed of the rotating magnetic field of the stator (synchronous speed). When net rotor resistance of a motor design is reduced, efficiency of the motor increases but slip decreases, resulting in higher operating speeds.

[16] *www.bls.gov/ppi/.*

2012) of the Economic Census of Industry by the U.S. Census Bureau.[17]

DOE did not receive comments on the cost analysis presented in the April 2020 NOPD. Accordingly, using the same methodology presented in the April 2020 NOPD, in this final determination DOE updated the material and labor costs to be representative of the market in 2019$.

5. Scaling Relationships

In analyzing the equipment classes, DOE developed a systematic approach to scaling efficiency across horsepower ratings and pole configurations, while retaining reasonable levels of accuracy, in a manner similar to the March 2010 Final Rule. DOE's current energy conservation standards for SEMs found at 10 CFR 431.446 list minimum required efficiencies over a range of horsepower and pole configurations, providing a basis for scaling efficiency across horsepower and pole configurations for polyphase and single-phase motors. The efficiency relationships in the established standards are based on a combination of NEMA recommended efficiency standards, NEMA premium designations, catalog data, and test data for individual manufacturer motor product lines.

In the April 2020 NOPD, DOE proposed to apply the same scaling methodologies used to support the March 2010 Final Rule to the engineering analysis. This includes scaling to two additional representative units needed in the energy use and life-cycle cost analyses to separately analyze consumers of integral (*i.e.,* with horsepower greater than or equal to 1 hp) single-phase CSCR SEMs and fractional (*i.e.,* with horsepower less than 1 hp) polyphase SEMs. This scaling approach has been presented previously to stakeholders and has been updated based on stakeholder input. Additionally, the approach has the added advantage of reducing the analytical complexity associated with conducting a detailed engineering analysis of the cost-efficiency relationship on all 62 equipment classes. 75 FR 10874, 10894–10895.

NEMA commented that the previously developed scaling methodologies remain effective and appropriate. (NEMA, No. 22 at p. 3) DOE did not receive any other comments on the scaling analysis methodology proposed in the April 2020 NOPD. DOE continues to apply the scaling analysis methodology from the April 2020 NOPD in this final determination. Chapter 5 of the TSD provides details on the DOE's engineering analysis for SEMs.

D. Markups Analysis

To account for manufacturers' non-production costs and profit margin, DOE applies a non-production cost multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. DOE developed an average manufacturer markup by examining the annual Securities and Exchange Commission 10–K reports filed by publicly-traded manufacturers primarily engaged in appliance manufacturing and whose combined product range includes SEM.

The markups analysis develops appropriate markups (*e.g.,* retailer markups, distributor markups, contractor markups) in the distribution chain to convert the MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the equipment to cover business costs and profit margin. For SEMs, the main parties in the distribution chain are manufacturers, distributors, contractors or installers, OEMs of equipment incorporating SEMs, and consumers.

DOE relied on estimates provided by NEMA during the March 2010 Final Rule to establish the proportion of shipments through each distribution channel.[18] In response to the April 2020 NOPD, DOE did not receive any comments or data to support alternative distribution channels for SEMs. In this final determination, DOE relied on the same distributions of shipments by distribution channels as in the April 2020 NOPD. Further, DOE did not receive any comments on the approach used to develop markups. DOE continued to rely on the same methodology for developing markups and updated relevant data sources to the most recent information available in preparation of this final determination. DOE used data from the U.S. Census Bureau and US Economic Census [19] and the Sales Tax Clearinghouse [20] to develop distribution channel markups and sales tax estimates.

DOE used the same approach as in the April 2020 NOPD and developed baseline and incremental markups for each actor in the distribution chain. Baseline markups are applied to the price of equipment with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[21] DOE relied on economic data from the U.S. Census Bureau to estimate average baseline and incremental markups.

Further, in the space-constrained scenario, DOE developed a modified OEM markup to account for the costs faced by those OEMs of equipment incorporating SEMs needing to redesign their products in order to incorporate SEMs of different, including larger, sizes. Nationally, businesses spend about 2.7 percent of U.S. gross domestic product on research and development (''R&D'').[22] DOE estimates that R&D by equipment OEMs, including the design of new products, approximately represents at most 2.7 percent of company revenue. DOE followed the same approach used in the March 2010

[17] U.S. Census Bureau, 2012 Economic Census of Industry Series Reports for Industry, U.S. Department of Commerce, 2012; NAICS code 3353121 ''Fractional Horsepower Motors'' Production workers hours and wages. Although some summary statistics of the 2017 Economic Census for Manufacturing is currently available, the detailed statistics for the U.S. is estimated to be released in the time frame of November 2020-September 2021. *https://www.census.gov/programs-surveys/economic-census/about/release-schedules.html.*

[18] For more details see chapter 7 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

[19] U.S. Census Bureau. 2017 Annual Wholesale Trade Report. 2017. Washington, DC (Last accessed June 19, 2019.) *https://www.census.gov/wholesale/index.html;* U.S. Census Bureau. 2017 Annual Retail Trade Survey, 2017. (Last accessed June 19, 2019.) *https://www.census.gov/programs-surveys/arts/data/tables.2017.html.;* 2017 Economic Census: Manufacturing: Summary Statistics for the U.S., States, and Selected Geographies: 2017. 2020. U.S. Census Bureau. (Last accessed October 21, 2020.) *https://www.census.gov/data/tables/2017/econ/economic-census/naics-sector-31-33.html.*

[20] Sales Tax Clearinghouse Inc. State Sales Tax Rates Along with Combined Average City and County Rates. October 21, 2020. (Last accessed October 21, 2020.) *http://thestc.com/STrates.stm.*

[21] Because the projected price of standards-compliant products (and equipment) is typically higher than the price of baseline products (and equipment), using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive it is unlikely that imposing more stringent standards would lead to a sustainable increase in profitability in the long run.

[22] National Science Board. January 15, 2020. Science and Engineering Indicators 2020. Research and Development: U.S Trends and International Comparisons. Figure 4–3, Ratio of U.S. R&D to gross domestic product, by roles of federal, business, and other nonfederal funding for R&D: 1953–2017. 2020. National Science Board: Arlington, VA: National Science Foundation (NSB–2020–3).

Final Rule and accounted for the additional costs to redesign products and incorporate differently-shaped motors by adding 2.7 percent to the OEM markups.[23]

Table IV–6 summarizes the overall baseline and incremental markups for each distribution channel considered for SEMs. These markups were updated since the April 2020 NOPD to reflect updates to relevant data sources to the most recent information available.

TABLE IV–6—SMALL ELECTRIC MOTORS DISTRIBUTION CHANNEL MARKUPS

Distribution channel (from manufacturer) / Main party	Direct to OEMs (65%)		Via wholesalers to OEMs (30%)		Via wholesalers to end-users (5%)	
	Baseline	Incremental	Baseline	Incremental	Baseline	Incremental
Motor Wholesaler	.....	.....	1.35	1.20	1.35	1.20
Original Equipment Manufacturer (OEM) *	1.45/1.48	1.20/1.23	1.45/1.48	1.20/1.23	.....	.....
Equipment Wholesaler	1.41	1.20	1.41	1.20	.....	.....
Retailer	.....	.....	.....	.....	1.53	1.27
Contractor	1.1	1.1	1.1	1.1	1.1	1.1
Sales Tax	1.0727		1.0727		1.0727	
Overall	2.42/2.47	1.69/1.73	3.26/3.33	2.04/2.08	2.44	1.80

* Non-space-constrained scenario/space-constrained scenario.

Chapter 6 of the TSD provides details on the DOE's markup analysis for SEMs.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of SEMs at different efficiency levels and to assess the energy savings potential of increased efficiency. The analysis estimates the range of energy use of SEMs in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

The analysis focuses on the two representative units identified in the engineering analysis (see section IV.C) for which engineering analysis results were obtained at levels at and above the baseline. Two additional representative units were included to separately analyze consumers of integral (*i.e.,* with horsepower greater than or equal to 1 hp) single-phase CSCR SEMs and fractional (*i.e.,* with horsepower less than 1 hp) polyphase SEMs (see Table IV–7).[24] For each representative unit, DOE determined the annual energy consumption value by multiplying the motor input power by the annual operating hours for a representative sample of motor consumers.

TABLE IV–7—REPRESENTATIVE UNITS ANALYZED IN THE ENERGY USE AND LIFE-CYCLE COST ANALYSES

Representative unit	Equipment class group	Pole configuration	Rated horsepower
1	Single-phase, CSCR	4-pole	0.75
2	Polyphase	4-pole	1
3	Single-phase, CSCR	4-pole	1
4	Polyphase	4-pole	0.5

In response to the April 2020 NOPD, NEMA commented that the inputs used to characterize the energy use of SEMs were appropriate. (NEMA, No. 22 at p. 3) Additionally, NEMA commented that improving SEM efficiency may not always result in overall equipment-level efficiency improvements. NEMA commented that any modification to energy conservation standards or scope of regulated SEMs would require a revised analysis of the downstream impact of SEM design changes on OEM devices and appliances, before proceeding to modify energy savings methodology and estimates. (NEMA, No. 22 at p. 5)

As discussed previously, to account for motor size and weight limitations (including in OEM devices and appliances), DOE analyzed both space-constrained and non-space-constrained scenarios. DOE did not modify the scope or amend the current energy conservation standards for this equipment. Chapter 7 of the TSD provides details on the DOE's energy use analysis for SEMs.

1. Consumer Sample

DOE used the same approach as in the April 2020 NOPD and created consumer samples for each representative unit, including three individual sectors: Residential, commercial, and industrial. DOE used the samples to determine SEM annual energy consumption as well as for conducting the LCC and PBP analyses. Each consumer in the sample was assigned a sector and an application. DOE used data from the March 2010 Final Rule to establish distributions of SEMs by sector. Five

[23] Fore more details see chapter 7 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

[24] Similar to the approach used in the engineering analysis when selecting representative units, DOE reviewed model counts from the manufacturer online catalog data to identify these additional units. DOE reviewed counts of CSCR, 4-poles small electric motors and polyphase, 4-poles, small electric motors models. For CSCR motors, the 1 horsepower value had the most counts and DOE selected a unit at 1 horsepower. For polyphase motors, the 0.33, 0.5, and 0.75 horsepower values had the most counts (and similar counts) and DOE selected a unit at 0.5 horsepower (*i.e.* the mid-range of these horsepower values).

main motor applications were selected as representative applications (compressors, fans, pumps, material handling, and others). In order to characterize the distributions of SEMs across applications in the industrial sector, DOE used data from hundreds of field assessments aggregated in two databases: (1) A database of motor nameplate and field data and;[25] (2) a database of motor nameplate and field data compiled by the Industrial Assessment Center at Oregon University (''field assessment data'').[26] For the commercial and residential sectors, DOE used data from a previous DOE publication to estimate distribution of SEMs by application.[27] DOE also assumed that 20 percent of consumers had space-constraints and 80 percent were non-space-constrained based on data from the March 2010 Final Rule. In response to the April 2020 NOPD, NEMA commented that the inputs used to characterize the distributions of consumers across sectors and applications were appropriate. (NEMA, No. 22 at p. 3) DOE used the same consumer sample as in the April 2020 NOPD for this final determination.

See Chapter 7 of the TSD for more details on the resulting distribution of consumers by sector and applications.

2. Motor Input Power

DOE used the same approach as in the April 2020 NOPD and calculated the motor input power as the sum of the motor rated horsepower multiplied by the motor operating load (*i.e.,* the motor output power) and of the losses at the operating load (*i.e.,* part-load losses). DOE determined the part-load losses using outputs from the engineering analysis (full-load efficiency at each efficiency level) and published part-load efficiency information from manufacturer catalogs to model motor part-load losses as a function of the motor's operating load. DOE estimated the operating load using operating load data specific to motors in the 0.25–3 hp range, which was based on additional field assessments data collected since the publication of the March 2010 Final Rule.[28]

In response to the April 2020 NOPD, NEMA commented that an upcoming publication from DOE's Advanced Manufacturing Office ''Motor System Market Assessment'' may provide additional information regarding load. (NEMA, No. 22 at p. 4) DOE is aware of this upcoming report but notes that it is not yet available. Accordingly, DOE used the same load distributions as in the April 2020 NOPD for this final determination.

See chapter 7 of the TSD for the resulting distribution of load for each application.

3. Annual Operating Hours

DOE used the same approach as in the April 2020 NOPD and DOE developed distributions of operating hours by application and sector. For the industrial sector, DOE used data specific to motors in the 0.25–3 hp range from the field assessment data to establish distributions of annual operating hours by application.[29] For the commercial and residential sectors, DOE used operating hours data from the March 2010 Final Rule.[30] In response to the April 2020 NOPD, NEMA commented in support of the annual operating hours values used in the NOPD. NEMA commented that if DOE were to consider standards for a different scope, these assumptions would no longer be adequate. (NEMA, No. 22 at p. 4) As discussed previously, DOE is not modifying the scope of the energy conservation standards for SEMs. Accordingly, DOE used the same operating hour distributions as in the April 2020 NOPD for this final determination. Table IV–8 shows the estimated average annual energy use at each efficiency level analyzed.

The annual energy use values are calculated as an intermediate result in the LCC and PBP analysis. As further discussed section IV.F, the computer model DOE uses to calculate the LCC and PBP relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. Although the energy use calculation performed in preparation of this final rule relied on the same probability distributions as used in the April 2020 NOPD, each Monte Carlo simulation run randomly samples input values from the probability distributions and consumer samples, which resulted in updated annual energy use results.

TABLE IV–8—SMALL ELECTRIC MOTORS ANNUAL ENERGY USE RESULTS

Rep. Unit	Description	Kilowatt-hours per year					
		EL 0	EL 1	EL 2	EL 3	EL 4	EL 5
1	Single-phase, CSCR, 4-pole, 0.75 hp	1,653.6	1,628.2	1,598.5	1,583.8	1,536.0	1,509.0
2	Polyphase, 4-pole, 1 hp	2,092.8	2,047.7	2,020.8	1,983.8	.....	.....
3	Single-phase, CSCR, 4-pole, 1 hp	2,191.9	2,159.1	2,122.7	2,103.9	2,043.2	2,008.0
4	Polyphase, 4-pole, 0.5 hp	1,152.6	1,117.9	1,096.7	1,068.1	.....	.....

See Chapter 7 of the TSD for more details on the distributions of annual operating hours by application and sector.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for SEMs. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase price. DOE used

[25] Database of motor nameplate and field measurement data compiled by the Washington State University Extension Energy Program (WSU) and Applied Proactive Technologies (APT) under contract with the New York State Energy Research and Development Authority (NYSERDA).

[26] Strategic Energy Group (January 2008), Northwest Industrial Motor Database Summary. Regional Technical Forum. Available at *http://rtf.nwcouncil.org/subcommittees/osumotor/Default.htm.*

[27] W. Goetzler, T. Sutherland, C. Reis. ''Energy Savings Potential and Opportunities for High-Efficiency Electric Motors in Residential and Commercial Equipment'' U.S. Department of Energy, December 4, 2013. Available at *https://energy.gov/sites/prod/files/2014/02/f8/Motor%20Energy%20Savings%20Potential%20Report%202013-12-4.pdf.*

[28] This horsepower range was selected as it corresponds to the motor horsepower of small electric motors that are currently subject to standards (see section IV.A.1).

[29] Database of motor nameplate and field measurement data compiled by the Washington State University Extension Energy Program (WSU) and Applied Proactive Technologies (APT) under contract with the New York State Energy Research and Development Authority (NYSERDA).

[30] For more details see chapter 6 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

the following two metrics to measure consumer impacts:

• The LCC is the total consumer expense of equipment over the life of that equipment, consisting of total installed cost (MSP, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the equipment.

• The simple PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of more-efficient equipment through lower operating costs. DOE calculates the simple PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of SEMs in the absence of new or amended energy conservation standards. In contrast, the simple PBP for a given efficiency level is measured relative to the baseline equipment. The analysis focuses on the four representative units identified in Table IV–7.

For each considered efficiency level in each equipment class, DOE calculated the LCC and PBP for a nationally representative set of consumers. As stated previously, DOE developed a sample based on distributions of consumers across sectors and applications, as well as across efficiency levels. For each sample consumer, DOE determined the unit energy consumption and appropriate energy price. By developing a representative sample of consumers, the analysis captured the variability in energy consumption and energy prices associated with the use of SEMs.

Inputs to the calculation of total installed cost include the cost of the equipment—which includes MSPs, retailer markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, equipment lifetimes, and discount rates. DOE created distributions of values for equipment lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC and PBP relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and consumer samples. The model calculated the LCC and PBP for equipment at each efficiency level for 10,000 consumers per representative unit per simulation run. The analytical results include a distribution of 10,000 data points showing the range of LCC savings for a given efficiency level relative to the no-new-standards case efficiency distribution. In performing an iteration of the Monte Carlo simulation for a given consumer, equipment efficiency is chosen based on its probability. If the chosen equipment efficiency is greater than or equal to the efficiency of the standard level under consideration, the LCC and PBP calculation reveals that a consumer is not impacted by the standard level. By accounting for consumers who already purchase more-efficient equipment, DOE avoids overstating the potential benefits from increasing equipment efficiency.

DOE calculated the LCC and PBP for all consumers as if each were to purchase a new motor in the expected year of compliance with amended standards. For purposes of its analysis, DOE estimated that any amended standards would apply to SEMs manufactured 5 years after the date on which the amended standard is published. DOE estimated publication of a final rule in the first half of 2023. Therefore, for purposes of its analysis, DOE used 2028 as the first full year of compliance.

Table IV–9 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. DOE updated relevant data sources to the most recent information available in preparation of this final determination. The subsections that follow provide further discussion.

TABLE IV–9—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSIS *

Inputs	Source/method
Equipment Cost	Derived by multiplying MSPs by distribution channel markups and sales tax, as appropriate.
Installation Costs	Assumed no change with efficiency level other than shipping costs.
Annual Energy Use	Motor input power multiplied by annual operating hours per year. Variability: Based on plant surveys and previous DOE study.
Energy Prices	Electricity: Used average and marginal prices methodology from (Coughlin and Beraki) and updated data from Edison Electric Institute Typical Bill and Average Rates Reports Winter 2019, Summer 2019.
Energy Price Trends	Based on *AEO 2020* price projections.
Repair and Maintenance Costs	Assumed no change with efficiency level.
Equipment Lifetime	Estimated using information from March 2010 Final Rule and from DOE's Advanced Manufacturing Office.
Discount Rates	Residential: Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances. Commercial: Calculated as the weighted average cost of capital for entities purchasing small electric motors. Primary data source was Damodaran Online.
Compliance Date	2028.

* References for the data sources mentioned in this table are provided in the sections following the table.

1. Equipment Cost

To calculate consumer equipment costs, DOE multiplied the MSPs developed in the engineering analysis by the distribution channel markups described in section IV.D (along with sales taxes). DOE used different markups for baseline motors and higher-efficiency motors, because DOE applies an incremental markup to the increase in MSP associated with higher-efficiency equipment. Further, in this final determination, DOE assumed the prices of SEMs would remain constant over time (no decrease in price).

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the equipment. In response to the April 2020 NOPD, DOE did not receive any information on SEM consumer installation costs and has relied on the same approach to estimate installations costs for this final determination. Based on information from the March 2010 Final Rule and installation cost data from RS Means Electrical Cost Data 2020,[31] DOE estimated that installation costs do not increase with equipment efficiency except in terms of shipping costs depending on the weight of the more efficient motor.[32] To arrive at total installed costs, DOE included shipping costs as part of the installation costs. These were based on weight data from the engineering analysis, which accounted for updated manufacturer catalog data collected by DOE.

See Chapter 8 of the TSD for more information on the installation costs for SEMs.

3. Annual Energy Consumption

For each sampled consumer, DOE determined the energy consumption for SEMs in each standards case analyzed using the approach described in section IV.E of this final determination.

4. Energy Prices

In response to the April 2020 NOPD, DOE did not receive any comments on electricity prices and relied on the same approach to develop national annual marginal and average prices and estimate energy prices in future years. DOE updated data sources to the most recent information available. For electricity prices, DOE used average and marginal electricity prices. As in the April 2020 NOPD, DOE estimated these prices using the methodology provided in two Lawrence Berkeley National Laboratory reports (Coughlin and Beraki).[33] In addition, in preparation for this final determination, DOE used updated data published from the Edison Electric Institute Typical Bills and Average Rates reports for summer and winter 2019 to reflect the latest electricity price information available. To estimate energy prices in future years, DOE multiplied the energy prices by a projection of annual change in average price consistent with the projections in the Energy Information Administration's (EIA's) Annual Energy Outlook 2020 (*AEO 2020*),[34] which has an end year of 2050. To estimate price trends after 2050, DOE used the average annual rate of change in prices from 2028 to 2050.

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing SEM components that have failed; maintenance costs are associated with maintaining the operation of the equipment. SEMs are usually not repaired. Most small motors are mass produced and are not constructed or designed to be repaired because the manufacturing process uses spot welding welds and rivets to fasten or secure the frame and assembled components, not nuts and bolts—meaning that the SEM cannot be readily disassembled and reassembled. In addition, during the rulemaking for the March 2010 Final Rule, DOE found no evidence that repair or maintenance costs, if any, would increase with higher motor energy efficiency.[35] DOE reviewed more recent motor repair cost data for SEMs and found no evidence that maintenance and repair costs increase with efficiency for SEMs in scope.[36] In response to the April 2020 NOPD, NEMA supported DOE's finding that SEMs are generally not repaired. (NEMA, No. 22 at p. 4)

Accordingly, similar to what was done in the April 2020 NOPD, DOE did not account for any repair costs in the LCC calculation.

See Chapter 8 of the TSD for more information on the repair and maintenance costs for SEMs.

6. Motor Lifetime

To characterize lifetimes in a manner to reflect that this factor depends on an SEM's application, DOE used two Weibull distributions.[37] One characterizes the motor lifetime in total operating hours (*i.e.,* mechanical lifetime), while the other characterizes the lifetime in years of use in the application (*e.g.,* a pump).

In response to the April 2020 NOPD, NEMA commented in support of the lifetime distributions developed by DOE. (NEMA, No. 22 at pp. 4–5) Consistent with the approach used in the April 2020 NOPD, DOE used mechanical lifetime data from the March 2010 Final Rule analysis and from a 2012 report from DOE's Advanced Manufacturing Office[38] to derive an estimated average mechanical lifetime of 30,000 hours for CSCR motors and 40,000 hours for polyphase motors. The Weibull parameters from the March 2010 Final Rule were used to derive these lifetime distributions.[39] In the course of the LCC analysis, DOE's current analysis further combines these two distributions with OEM application lifetimes to estimate the distribution of SEM lifetimes. DOE determined the mechanical lifetime of each motor in years by dividing its mechanical lifetime in hours by its annual hours of operation. DOE then compared this mechanical lifetime (in years) with the sampled application lifetime (also in years), and assumed that the motor would be retired at the younger of these two ages. In the March 2010 Final Rule, this approach resulted in projected average lifetimes of 7 years for single-phase CSCR motors and 9 years for polyphase motors. Because of updates made to the annual operating hours (see section IV.E.3) and calculation rounding, the updated analysis for this final determination yielded average lifetimes of 7.0 years for single-phase CSCR motors and 8.7 years for polyphase motors.

See Chapter 8 of the TSD for more information on the lifetime of SEMs.

7. Discount Rates

In calculating LCC, DOE applies discount rates appropriate to commercial, industrial, and residential consumers to estimate the present value

[31] RS Means. *Electrical Cost Data, 43rd Annual Edition,* 2020. Rockland, MA. p. 315.

[32] For more details see chapter 8 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

[33] *See* Coughlin, K. and B. Beraki. Residential Electricity Prices: A Review of Data Sources and Estimation Methods. 2018. Lawrence Berkeley National Lab. (LBNL), Berkeley, CA (United States). Report No. LBNL–2001169. (Last accessed May 21, 2019.) *https://ees.lbl.gov/publications/residential-electricity-prices-review. See also* Coughlin, K. and B. Beraki. Non-residential Electricity Prices: A Review of Data Sources and Estimation Methods. 2019. Lawrence Berkeley National Lab. (LBNL), Berkeley, CA (United States). Report No. LBNL–2001203. (Last accessed May 21, 2019.) *https://ees.lbl.gov/publications/non-residential-electricity-prices.*

[34] U.S. Energy Information Administration, Office of Energy Analysis, U.S. Department of Energy. *U.S. Energy Information Administration. Annual Energy Outlook 2020 with projections to 2050. 2020.* Washington DC. 20585 (Last accessed August 11, 2020). *https://www.eia.gov/outlooks/AEO/pdf/AEO2020.pdf.*

[35] For more details see chapter 8 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

[36] Vaughen's (2013), Vaughen's Motor & Pump Repair Price Guide, 2013 Edition. Available at *www.vaughens.com.*

[37] The Weibull distribution is one of the most commonly used distributions in reliability. It is commonly used to model time to fail, time to repair and material strength.

[38] U.S. Department of Energy. Advanced Manufacturing Office. *Motors Systems Tip Sheet #3. Energy Tips: Motor Systems. Extending the Operating Life of Your Motor.* 2012. *https://www.energy.gov/sites/prod/files/2014/04/f15/extend_motor_operlife_motor_systemts3.pdf.*

[39] For more details see chapter 8 of the 2010 small electric motors final rule TSD, at *https://www.regulations.gov/document?D=EERE-2007-BT-STD-0007-0036.*

of future operating costs. DOE estimated a distribution of discount rates for SEMs based on the cost of capital of publicly traded firms in the sectors that purchase SEMs.

As part of its analysis, DOE also applies weighted average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates.[40] DOE notes that the LCC does not analyze the equipment purchase decision, so the implicit discount rate is not relevant in this model. The LCC estimates net present value over the lifetime of the equipment, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long time horizon modeled in the LCC, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's Survey of Consumer Finances[41] (''SCF'') for 1995, 1998, 2001, 2004, 2007, 2010, 2013, and 2016. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect.

For commercial and industrial consumers, DOE used the cost of capital to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so the cost of capital is the weighted-average cost to the firm of equity and debt financing. This corporate finance approach is referred to as the weighted-average cost of capital. DOE used currently available economic data in developing discount rates. In response to the April 2020 NOPD, DOE did not receive any comments on discount rates. DOE used the same approach for developing discount rates as in the April 2020 NOPD for this final determination. DOE updated data sources to the most recent information available. See chapter 8 of the TSD for details on the development of end-user discount rates.

8. Efficiency Distribution in the No-New-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of equipment efficiencies in the ''no-new-standards'' case (*i.e.,* the case without amended or new energy conservation standards) in the compliance year. In its analysis for the March 2010 Final Rule, DOE developed no-new standards case efficiency distributions based on the distributions of then currently available models for which SEM efficiency is included in catalog listings. In preparation for the April 2020 NOPD, DOE collected updated catalog data and analyzed the distribution of SEMs in the manufacturer catalog data for CSCR and polyphase SEMs.[42] DOE projected that these efficiency distributions would remain constant throughout 2028. In response to the April 2020 NOPD, DOE did not receive any comments related to efficiency distributions and efficiency trends. Accordingly, DOE retained the same efficiency distributions used in the April 2020 NOPD in preparing this final determination. See chapter 8 of the TSD for the estimated efficiency distributions.

9. Payback Period Analysis

The PBP is the amount of time it takes the consumer to recover the additional installed cost of more-efficient equipment, compared to baseline equipment, through energy cost savings. PBPs are expressed in years. PBPs that exceed the life of the equipment mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the simple PBP calculation for each efficiency level are the change in total installed cost of the equipment and the change in the first-year annual operating expenditures relative to the baseline. The simple PBP calculation uses the same inputs as the LCC analysis, except that discount rates are not needed.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for SEMs examined by DOE. It addresses the ELs examined by DOE and the projected impacts of each of these levels. Additional details regarding DOE's analyses are contained in the NOPD TSD supporting this document.

A. Energy Savings

For each standards case considered, DOE estimated the per unit lifetime energy savings for SEMs purchased in the expected compliance year of any potential standards. The per unit energy savings were used in the calculation of the LCC and PBP values. DOE did not separately evaluate the significance of the potential energy conservation under the considered amended standards because it has determined that the potential standards would not be cost-effective as defined in EPCA.[43] (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A); 42 U.S.C. 6295(n)(2))

B. Cost Effectiveness

In general, higher-efficiency equipment affects consumers in two ways: (1) Purchase price increases and (2) annual operating cost decreases. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* equipment price plus installation costs),

[40] The implicit discount rate is inferred from a consumer purchase decision between two otherwise identical goods with different first cost and operating cost. It is the interest rate that equates the increment of first cost to the difference in net present value of lifetime operating cost, incorporating the influence of several factors: Transaction costs; risk premiums and response to uncertainty; time preferences; interest rates at which a consumer is able to borrow or lend.

[41] Board of Governors of the Federal Reserve System. *Survey of Consumer Finances.* 1995, 1998, 2001, 2004, 2007, 2010, 2013, and 2016. Available at: *http://www.federalreserve.gov/econresdata/scf/scfindex.htm.*

[42] DOE relied on 140 models of CSCR small electric motors and 229 models of polyphase small electric motors identified in the manufacturer catalog data. More details on the distributions of currently available models for which motor catalog list efficiency is available in Chapter 8 of the TSD.

[43] The March 2010 Final Rule estimated the national energy savings achieved by the current energy conservation standards to be 2.2 quads of primary energy savings (*i.e.,* 0.29 quad at TSL 4b for polyphase SEMs and 1.91 quad at TSL 7 for single phase SEMs). The March 2010 Final Rule also estimated that the TSL resulting in the maximum national energy savings would provide a total of 2.7 quads of primary energy savings (*i.e.,* 0.37 quad at TSL 7 for polyphase SEMs and 2.33 quad at TSL 8 for single phase SEMs). 75 FR 10874, 10916 (March 9, 2010) Although DOE did not separately evaluate the significance of the potential energy conservation under the considered amended standards, this previous analysis indicates an upper limit of 0.5 quad of primary energy savings (2.7 − 2.2 = 0.5) which corresponds to 0.2 quad site national energy savings and is below the 0.3 quad threshold for determining whether energy savings would be significant.

and operating costs (*i.e.,* annual energy and water use, energy and water prices, energy and water price trends, repair costs, and maintenance costs). The LCC calculation also uses equipment lifetime and a discount rate. Chapter 8 of the final determination TSD provides detailed information on the LCC and PBP analyses.

Table V–1 through Table V–7 show the LCC and PBP results for the ELs considered for each equipment class. These results were updated since the April 2020 NOPD to reflect updates of relevant data sources to the most recent information available. Results for each representative unit are presented by two tables: In the first of each pair of tables, the simple payback is measured relative to the baseline equipment. In the second table, the impacts are measured relative to the efficiency distribution in the no-new-standards case in the expected compliance year for the potential standards considered. Because some consumers purchase equipment with higher efficiency in the no-new-standards case, the average savings are greater than the difference between the average LCC of the baseline equipment and the average LCC at each EL. The savings refer only to consumers who are affected by a standard at a given EL. Those who already purchase SEMs with an efficiency at or above a given EL are not affected. Consumers for whom the LCC-increases at a given EL experience a net cost.

TABLE V–1—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR REPRESENTATIVE UNIT 1: SINGLE-PHASE, CSCR, 4-POLE, 0.75 hp

Efficiency level	Average costs 2019$				Simple payback *years* total installed cost	Average lifetime years first year's operating cost
	Total installed cost	First *year's* operating cost	Lifetime operating cost	LCC		
0	488.1	156.8	631.5	1,119.5	.....	6.97
1	504.4	154.4	621.8	1,126.2	6.8	6.97
2	525.7	151.6	610.6	1,136.3	7.3	6.97
3	567.1	150.3	605.0	1,172.0	12.0	6.97
4	594.7	145.8	586.8	1,181.5	9.6	6.97
5	1,411.4	143.2	576.6	1,988.0	67.9	6.97

Note: The results for each EL represent the average value if all purchasers in the sample use equipment with that efficiency level. The PBP is measured relative to the baseline equipment.

TABLE V–2—LCC SAVINGS RELATIVE TO THE NO-NEW STANDARDS CASE EFFICIENCY DISTRIBUTION FOR REPRESENTATIVE UNIT 1: SINGLE-PHASE, CSCR, 4-POLE, 0.75 hp

Efficiency level	Life-cycle cost savings	
	Percent of customers that experience	Average savings *
	Net cost (percent)	2019$
1	81.4	−6.4
2	83.3	−16.2
3	91.7	−51.4
4	88.8	−59.9
5	100.0	−855.0

* The savings represent the average LCC for affected consumers.

TABLE V–3—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR REPRESENTATIVE UNIT 2: POLYPHASE, 4-POLE, 1 hp

Efficiency level	Average costs 2019$				Simple payback *years* total installed cost	Average lifetime *years* first year's operating cost
	Total installed cost	First *year's* operating cost	Lifetime operating cost	LCC		
0	451.0	193.1	969.5	1,420.5	.....	8.73
1	520.7	189.0	948.8	1,469.5	16.9	8.73
2	580.0	186.5	936.4	1,516.3	19.5	8.73
3	1,395.5	183.1	919.3	2,314.8	94.5	8.73

Note: The results for each EL represent the average value if all purchasers in the sample use equipment with that efficiency level. The PBP is measured relative to the baseline equipment.

TABLE V–4—LCC SAVINGS RELATIVE TO THE NO-NEW STANDARDS CASE EFFICIENCY DISTRIBUTION FOR REPRESENTATIVE UNIT 2: POLYPHASE, 4-POLE, 1 hp

Efficiency level	Life-cycle cost savings	
	Percent of customers that experience	Average savings *
	Net cost (percent)	*2019$*
1	89.5	−48.1
2	99.1	−92.3
3	100.0	−878.7

* The savings represent the average LCC for affected consumers.

TABLE V–5—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR REPRESENTATIVE UNIT 3: SINGLE-PHASE, CSCR, 4-POLE, 1 hp

Efficiency level	Average costs 2019$				Simple payback *years* total installed cost	Average lifetime *years* first year's operating cost
	Total installed cost	First *year's* operating cost	Lifetime operating cost	LCC		
0	554.8	208.4	831.5	1,386.4	.....	6.95
1	573.5	205.3	819.2	1,392.6	6.0	6.95
2	597.8	201.9	805.4	1,403.2	6.6	6.95
3	643.6	200.1	798.3	1,441.9	10.7	6.95
4	675.1	194.4	775.4	1,450.5	8.6	6.95
5	1,581.3	191.0	762.1	2,343.4	59.2	6.95

Note: The results for each EL represent the average value if all purchasers in the sample use equipment with that efficiency level. The PBP is measured relative to the baseline equipment.

TABLE V–6—LCC SAVINGS RELATIVE TO THE NO-NEW STANDARDS CASE EFFICIENCY DISTRIBUTION FOR REPRESENTATIVE UNIT 3: SINGLE-PHASE, CSCR, 4-POLE, 1 hp

Efficiency level	Life-cycle cost savings	
	Percent of customers that experience	Average savings *
	Net cost (percent)	2019$
1	76.9	−6.0
2	79.7	−16.2
3	88.5	−54.3
4	85.6	−61.8
5	100.0	−942.1

* The savings represent the average LCC for affected consumers.

TABLE V–7—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR REPRESENTATIVE UNIT 4: POLYPHASE, 4-POLE, 0.5 hp

Efficiency level	Average costs 2019$				Simple payback *years* total installed cost	Average lifetime *years* first year's operating cost
	Total installed cost	First *year's* operating cost	Lifetime operating cost	LCC		
0	375.7	106.6	535.2	910.9	.....	8.70
1	433.1	103.5	519.2	952.2	18.0	8.70
2	482.6	101.5	509.3	991.9	20.8	8.70
3	1,148.6	98.9	496.1	1,644.7	99.6	8.70

Note: The results for each EL represent the average value if all purchasers in the sample use equipment with that efficiency level. The PBP is measured relative to the baseline equipment.

TABLE V–8—LCC SAVINGS RELATIVE TO THE NO-NEW STANDARDS CASE EFFICIENCY DISTRIBUTION FOR REPRESENTATIVE UNIT 4: POLYPHASE, 4-POLE, 0.5 hp

Efficiency level	Life-cycle cost savings	
	Percent of customers that experience	Average savings *
	Net cost (percent)	2019$
1	91.7	−40.5
2	99.6	−77.9
3	100.0	−721.4

* The savings represent the average LCC for affected consumers.

C. Final Determination

For this final determination, DOE analyzed whether amended standards for SEMs would be technological feasible and cost effective. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A) and 42 U.S.C. 6295(n)(2)) EPCA mandates that DOE consider whether amended energy conservation standards for SEMs would be technologically feasible. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A) and 42 U.S.C. 6295(n)(2)(B)) DOE has determined that there are technology options that would improve the efficiency of SEMs. These technology options are being used in commercially available SEMs and therefore are technologically feasible. (See section IV.B for further information.) Hence, DOE has determined that amended energy conservation standards for SEMs are technologically feasible.

EPCA requires DOE to consider whether energy conservation standards for SEMs would be cost effective through an evaluation of the savings in operating costs throughout the estimated average life of the covered product/equipment compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products/equipment which are/is likely to result from the imposition of an amended standard. (42 U.S.C. 63136(a); 42 U.S.C. 6295(m)(1)(A), 42 U.S.C. 6295(n)(2)(C), and 42 U.S.C. 6295(o)(2)(B)(i)(II)) As presented in the prior section, the average customer purchasing a representative SEM would experience an increase in LCC at each evaluated standards case as compared to the no new standards case. The simple PBP for the average of a representative SEM customer at each EL is projected to be generally longer than the mean lifetime of the equipment. Based on the above considerations, DOE has determined that more stringent amended energy conservation standards for SEMs cannot satisfy the relevant statutory requirements because such standards would not be cost effective as required under EPCA. (See 42 U.S.C. 6295(n)(2); 42 U.S.C. 6295(o)(2)(B)(II); 42 U.S.C. 6316(a))

Having determined that amended energy conservation standards for SEMs would not be cost-effective, DOE did not separately evaluate the significance of the amount of energy conservation under the considered amended standards because it has determined that the potential standards would not be cost-effective (and by extension, would not be economically justified) as required under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(m)(1)(A); 42 U.S.C. 6295(n)(2); 42 U.S.C. 6295(o)(2)(B))

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866

This final determination has been determined to be not significant for purposes of Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (Oct. 4, 1993). As a result, the Office of Management and Budget (''OMB'') did not review this final determination.

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' E.O. 13771 stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. E.O. 13771 stated it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

Additionally, on February 24, 2017, the President issued E.O. 13777, ''Enforcing the Regulatory Reform Agenda.'' See 82 FR 12285 (March 1, 2017). E.O. 13777 required the head of each agency to designate an agency official as its Regulatory Reform Officer (''RRO''). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

(1) Eliminate jobs, or inhibit job creation;

(2) Are outdated, unnecessary, or ineffective;

(3) Impose costs that exceed benefits;

(4) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(5) Are inconsistent with the requirements of the Information Quality Act, or the guidance issued pursuant to that Act, particularly those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

(6) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE concludes that this final determination is consistent with the directives set forth in these executive orders. As discussed in this document, DOE is not amending the current energy conservation standards for SEMs and will not have any cost impact on manufacturers of SEMs. Therefore, this determination is an E.O. 13771 Other Action.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility

analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*http://energy.gov/gc/office-general-counsel*).

DOE reviewed this final determination pursuant to the Regulatory Flexibility Act and the procedures and policies discussed above. DOE has concluded that, based on the data and available information it has been able to review, amended energy conservation standards for SEMs would not be cost-effective. Therefore, DOE is not amending the current energy conservation standards for SEMs. On the basis of the foregoing, DOE certifies that this final determination will not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared an FRFA for this final determination. DOE has transmitted its certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act

Manufacturers of SEMs must certify to DOE that their equipment comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their equipment according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including SEMs. 76 FR 12422 (March 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number. This final determination, which concludes that amended energy conservation standards for SEMs would not be cost effective (and by extension, not economically justified) as required under the relevant statute, imposes no new information or recordkeeping requirements. Accordingly, clearance from the OMB is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq.*)

E. Review Under the National Environmental Policy Act of 1969

DOE analyzed this final determination in accordance with the National Environmental Policy Act (''NEPA'') and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for actions which are interpretations or rulings with respect to existing regulations. 10 CFR part 1021, subpart D, Appendix A4. DOE has determined that this action qualifies for categorical exclusion A4 because it is an interpretation or ruling in regards to an existing regulation and otherwise meets the requirements for application of a categorical exclusion. See 10 CFR 1021.410.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. As this final determination does not amend the standards for SEMs, there is no impact on the policymaking discretion of the States. Therefore, no action is required by Executive Order 13132.

G. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final determination meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The

UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.* This final determination does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of $100 million or more in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector. As a result, the analytical requirements of UMRA do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final determination will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

Pursuant to Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), DOE has determined that this final determination will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *https://www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this final determination under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (''OIRA'') at OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

Because this final determination does not amend the current standards for SEMs, it is not a significant energy action, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

M. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The ''Energy Conservation Standards Rulemaking Peer Review Report'' dated February 2007 has been disseminated and is available at: *http://www.energy.gov/eere/buildings/peer-review.*

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final determination.

Signing Authority

This document of the Department of Energy was signed on January 5, 2021, by Daniel R Simmons, Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 6, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–00336 Filed 1–15–21; 8:45 am]

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DEPARTMENT OF COMMERCE

15 CFR Part 7

[Docket No. 210113–0009]

RIN 0605–AA51

Securing the Information and Communications Technology and Services Supply Chain

AGENCY: U.S. Department of Commerce.

ACTION: Interim final rule; request for comments.

SUMMARY: The Department of Commerce is promulgating regulations to implement provisions of Executive Order 13873, ''Executive Order on Securing the Information and Communications Technology and Services Supply Chain'' (May 15, 2019). These regulations create the processes and procedures that the Secretary of Commerce will use to identify, assess, and address certain transactions, including classes of transactions, between U.S. persons and foreign persons that involve information and communications technology or services designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary; and pose an undue or unacceptable risk. While this interim final rule will become effective on March 22, 2021, the Department of Commerce continues to welcome public input and is thus seeking additional public comment. Once any additional comments have been evaluated, the Department is committed to issuing a final rule.

DATES: Effective March 22, 2021.

Comments to the interim final rule must be received on or before March 22, 2021.

ADDRESSES: All comments must be submitted by one of the following methods:

- *By the Federal eRulemaking Portal: http://www.regulations.gov* at docket number [DOC–2019–0005].
- *By email directly to: ICTsupplychain@doc.gov.* Include ''RIN 0605–AA51'' in the subject line.
- *Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. For those seeking to submit confidential business information (CBI), please clearly mark such submissions as CBI and submit by email, mail, or hand delivery as instructed above. Each CBI submission must also contain a summary of the CBI, clearly marked as public, in sufficient detail to permit a reasonable understanding of the substance of the information for public consumption. Such summary information will be posted on *regulations.gov.*
- Supporting documents:
  - The Regulatory Impact Analysis is available at *http://www.regulations.gov* at docket number [DOC–2019–0005];
  - The Center for Strategic & International Studies, ''Significant Cyber Incidents 2020'' is available at *https://www.csis.org/programs/technology-policy-program/significant-cyber-incidents;*
  - The National Security Strategy of the United States is available at *https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf;*
  - ODNI's 2016–2019 Worldwide Threat Assessments of the U.S. Intelligence Community are available at *https://www.dni.gov/files/documents/Newsroom/Testimonies/SSCI%20Unclassified%20SFR%20-%20Final.pdf* (2017), *https://www.dni.gov/files/documents/Newsroom/Testimonies/2018-ATA---Unclassified-SSCI.pdf* (2018), *https://www.dni.gov/files/ODNI/documents/2019-ATA-SFR---SSCI.pdf* (2019); and
  - The 2018 National Cyber Strategy of the United States of America is available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Cyber-Strategy.pdf.*

FOR FURTHER INFORMATION CONTACT: Henry Young, U.S. Department of Commerce, telephone: (202) 482–0224. For media inquiries: Meghan Burris, Director, Office of Public Affairs, U.S. Department of Commerce, telephone: (202) 482–4883.

SUPPLEMENTARY INFORMATION:

I. Background

The information and communications technology and services (ICTS) supply chain is critical to nearly every aspect of U.S. national security. U.S. business and governments at all levels rely heavily on ICTS, which: Underpin our economy; support critical infrastructure and emergency services; and facilitate the Nation's ability to store, process, and transmit vast amounts of data, including sensitive information, that is used for personal, commercial, government, and national security purposes. The ICTS supply chain must be secure to protect our national security, including the economic strength that is an essential element of our national security. Ensuring the resilience of, and trust in, our ICTS supply chain is an issue that touches upon national security, including economic security, and public health and safety.

The purchase, incorporation, and use by U.S. persons of ICTS—such as network management or data storage—produced by any person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary—can create multiple opportunities for those foreign adversaries to exploit potential vulnerabilities in the ICTS. That, in turn, could cause direct and indirect harm to both the immediate targets of the adverse action and to the United States as a whole. While attacks can originate from remote foreign sources, incorporating certain software, equipment, and products into U.S. domestic ICTS networks, as well as the use of certain cloud, network management, or other services, greatly increases the risk that potential vulnerabilities may be introduced, or that vulnerabilities may be present without being detected. These potential vulnerabilities, if exploited, could undermine the confidentiality, integrity, and availability of U.S. person data including personally identifiable information or other sensitive personal data.

Some foreign adversaries are known to exploit the sale of software and hardware to introduce vulnerabilities that can allow them to steal critical intellectual property, research results (*e.g.,* health data), or government or financial information from users of the software or hardware. Such vulnerabilities can be introduced in the network, cloud service, or individual product data; allow traffic monitoring or surveillance; and may be resistant to detection by private purchasers or telecommunications carriers. Once detected, such vulnerabilities may be extremely costly or impossible to remediate.

Vulnerabilities to data integrity can be created by including a foreign adversary's hardware and software into U.S. networks and systems. This incorporated hardware and software poses opportunities to add or remove important information, modify files or data streams, slow down, or otherwise modify the normal transmission or availability of data across U.S. networks. Such capabilities could be exercised in areas as diverse as financial market communications, satellite communications or control, or sensitive consumer information.

A foreign adversary could also exploit vulnerabilities provided by the incorporation of hardware and software into U.S. environments by fully or

partially closing down critical networks or functions at key times. These types of attacks are known as denial of service attacks. Such attacks could cause widespread problems, such as if they occur during periods of crisis, or they could be used selectively by targeting individual corporations or important infrastructure elements or functions. They could also be masked to make the source of the disruption difficult to attribute and, therefore, difficult to trace and stop.

These risks are not necessarily confined to infrastructure environments. They could, for example, be present in the use of cloud services, as well as in the widespread use of some consumer devices, networked surveillance cameras, drones, or interconnection via the internet of computing devices embedded in everyday objects, enabling them to send and receive data. For example, applications (''apps''), which may be downloaded from app stores or web browsers by a user to a mobile device, may automatically capture vast swaths of sensitive personal data from its users, including internet and other network activity information such as location data and browsing and search histories. This data exfiltration—supported by U.S. web data hosting and storage servers—threatens to allow foreign adversaries to exploit Americans' personal and proprietary information by allowing a foreign adversary to track the locations of Americans, build dossiers of sensitive personal data for blackmail, and conduct corporate espionage from inside the borders of the United States.

Multiple reported cybersecurity incidents in the United States and among major allies in 2020 illustrate the potential risk in permitting unrestricted access to U.S. ICTS supply chains, such as:

—In July 2020, two Chinese hackers working with the Chinese Ministry of State Security were indicted by the U.S. Department of Justice for conducting a global computer intrusion campaign targeting U.S. intellectual property and confidential business information, including COVID–19 vaccine research;

—German officials announced that a Russian hacking group associated with the Federal Security Bureau had compromised the networks of energy, water, and power companies in Germany by exploiting ICTS supply chains; and

—Japan's Defense Ministry announced it was investigating a large-scale cyber attack against Mitsubishi Electric that could have compromised details of new state-of-the-art missile designs.

See, e.g., Center for Strategic & International Studies, ''Significant Cyber Incidents 2020,'' available at *https://www.csis.org/programs/technology-policy-program/significant-cyber-incidents.*

Consequently, the President has determined that the unrestricted acquisition or use of ICTS that are designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary constitutes an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States.

Executive Order 13873 of May 15, 2019, ''Securing the Information and Communications Technology and Services Supply Chain'' (84 FR 22689) (Executive Order), was issued pursuant to the President's authority under the Constitution and the laws of the United States, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), and section 301 of Title 3, United States Code. IEEPA and the Executive Order grant the Secretary of Commerce (Secretary) the authority to prohibit any acquisition, importation, transfer, installation, dealing in, or use of any ICTS (an ''ICTS Transaction'') by any person, or with respect to any property, subject to United States jurisdiction, when such ICTS Transaction involves any property in which a foreign country or national has any interest, and the Secretary, in consultation with other agency heads (the Secretary of the Treasury, the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Homeland Security, the United States Trade Representative, the Director of National Intelligence, the Administrator of General Services, the Chairman of the Federal Communications Commission, and the heads of any other executive departments and agencies as the Secretary determines is appropriate) determines that the ICTS Transaction: (1) Involves ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary; and (2) poses an undue or unacceptable risk. Executive Order, Section 1(a). The Executive Order further provides the Secretary with the authority to prohibit such an ICTS Transaction or ''design or negotiate measures to mitigate concerns'' about an ICTS Transaction's impact on national security. Executive Order, Section 1(b).

On November 27, 2019, the Department of Commerce (Department) published a proposed rule to implement the terms of the Executive Order. (84 FR 65316). The proposed rule set forth processes for (1) how the Secretary would evaluate and assess transactions involving ICTS to determine whether they pose an undue risk of sabotage to or subversion of the ICTS supply chain, or an unacceptable risk to the national security of the United States or the security and safety of U.S. persons; (2) how the Secretary would notify parties to transactions under review of the Secretary's decision regarding the ICTS Transaction, including whether the Secretary would prohibit or mitigate the transaction; and (3) how parties to transactions reviewed by the Secretary could comment on the Secretary's preliminary decisions. The proposed rule also provided that the Secretary could act without complying with the proposed procedures where required by national security. Finally, the Secretary would establish penalties for violations of mitigation agreements, the regulations, or the Executive Order.

In addition to seeking general public comment, the Department requested comments from the public on five specific questions: (1) Whether the Secretary should consider categorical exclusions or whether there are classes of persons whose use of ICTS cannot violate the Executive Order; (2) whether there are categories of uses or of risks that are always capable of being reliably and adequately mitigated; (3) how the Secretary should monitor and enforce any mitigation agreements applied to a transaction; (4) how the terms, ''transaction,'' ''dealing in,'' and ''use of'' should be clarified in the rule; and (5) whether the Department should add record-keeping requirements for information related to transactions.

In response to requests for additional time in which to comment on the proposed rule, the Department extended the initial comment period from December 27, 2019, until January 10, 2020. (84 FR 70445). As reflected herein, the Department has carefully considered and addressed the public's comments in promulgating this rule.

Nonetheless, because several commenters requested that the Department provide for an additional round of public comment, and in an effort to continue the Department's work to protect the national security while reducing the regulatory impact on the public, the Department is taking further public comment on the rule. However, mindful of the urgent need of the United States to address national security concerns related to ICTS Transactions,

this interim final rule will be effective March 22, 2021. The Department is committed to issuing a subsequent final rule in which the Department will consider and respond to additional comments received. In addition, the Department will implement and publish procedures for a licensing process by May 19, 2021.

II. Response to Comments

During the public comment period on the proposed rule, the Department received a number of written submissions reflecting a wide range of views. All comments received by the end of the comment period are available on the public rulemaking docket at *https://www.regulations.gov.* Additionally, the Department participated in a number of meetings with foreign governments and industry groups to discuss the proposed rule prior to the comment period ending. Summaries of those meetings are available at *https://www.regulations.gov.* Below, the Department addresses the comments as they pertain to each relevant provision of the regulation.

§ 7.2 Definitions

§ 7.2—Definition of ''appropriate agency heads''

Numerous comments addressed the extent to which the Department interacts with other agencies and department heads throughout the process for reviewing ICTS Transactions. Some commenters advocated for the rule to require interagency review of all parts of the investigations and final determinations, while other commenters noted that interagency review should only happen during certain parts of the review process. Other commenters requested that the Secretary notify the heads of relevant agencies when a review is initiated.

Requirements regarding interagency review are already contained within the Executive Order and, thus, are not subject to change.

Nevertheless, for clarification, the Department has replaced the term ''identified secretaries'' with ''appropriate agency heads,'' to address the fact that some of the individuals referenced are not Cabinet Secretaries, but rather are heads of agencies. For clarity, the term ''appropriate agency heads'' refers to the Secretary of the Treasury, the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Homeland Security, the United States Trade Representative, the Director of National Intelligence, the Administrator of General Services, the Chairman of the Federal Communications Commission, and the heads of any other executive departments and agencies the Secretary of Commerce determines is appropriate. The Executive Order makes clear the Secretary of Commerce will confer with other agencies and departments as needed.

§ 7.2—Definition of ''Department''

Although it was not defined in the proposed rule, the Department has added a definition of the term ''Department'' to clarify that it refers to the United States Department of Commerce, rather than any other Cabinet-level agency.

§ 7.2—Definition of ''foreign adversary''

The rule grants the Secretary the authority to block or mitigate certain ICTS Transactions involving a foreign adversary. Commenters suggested limiting the definition of a ''foreign adversary'' to entities already identified in legislation. Some commenters recommended changing the concept of ''foreign adversary'' to focus on entities or persons instead of nation-states. Other commenters suggested that the Department create a list of adversaries and a list of exempt countries and distinguish between government and non-governmental entities. Commenters also recommended narrowing the scope of the term ''foreign adversary'' to situations where a foreign adversary has controlling interest in the company executing the covered transaction.

The rule makes no changes to the definition of ''foreign adversary,'' which is consistent with the Executive Order's definition. However, as discussed further below, the rule now includes a provision titled ''Determination of foreign adversaries'' in section 7.4. This provision sets out the list of foreign governments and foreign non-government persons that the Secretary has determined, solely for the purposes of the Executive Order, this rule, and any subsequent rules, are ''foreign adversaries.'' It also explains some of the factors that the Secretary considered, and will consider, when making any future determinations of whether a country is a ''foreign adversary.'' Pursuant to the Secretary's discretion, the list of foreign adversaries will be revised as determined to be necessary. Because the determination of foreign adversaries is subject solely to the Secretary's discretion, such revisions will be effective immediately upon publication in the **Federal Register** without prior notice or opportunity for public comment.

The list of ''foreign adversaries'' consists of the following foreign governments and non-government persons: The People's Republic of China, including the Hong Kong Special Administrative Region (China); the Republic of Cuba (Cuba); the Islamic Republic of Iran (Iran); the Democratic People's Republic of Korea (North Korea); the Russian Federation (Russia); and Venezuelan politician Nicolás Maduro (Maduro Regime). The provision clarifies that the Secretary's determination is based on multiple sources, including the National Security Strategy of the United States, the Office of the Director of National Intelligence's 2016–2019 Worldwide Threat Assessments of the U.S. Intelligence Community, and the 2018 National Cyber Strategy of the United States of America, as well as other reports and assessments from the U.S. Intelligence Community, the U.S. Departments of Justice, State and Homeland Security, and other relevant sources. Additionally, the provision notes that the Secretary will periodically review this list in consultation with appropriate agency heads and may add to, subtract from, supplement, or otherwise amend the list.

It is important to note that the list at section 7.4 identifies ''foreign adversaries'' solely for the purposes of the Executive Order, this rule, and any subsequent rules. It does not reflect a determination by the United States about the nature of such foreign governments or foreign non-government persons for any other purpose.

§ 7.2—Definition of ''ICTS Transaction''

The proposed rule defined the term ''transaction'' using terms from the Executive Order, to mean, ''any acquisition, importation, transfer, installation, dealing in, or use of any information and communications technology or service.'' It also noted that the term ''transaction'' ''includes a class of transactions.''

Some commenters requested the Department refine the definition of ''transaction'' in various ways. For example, some commenters suggested adopting language from the Securities Exchange Act of 1934 to define some of the terms in the definition, such as ''dealing in.'' Others urged the Department to further clarify the definition ''transaction'' to define the terms ''acquisition,'' or ''use'' in the definition.

The Department acknowledges that the terms ''transaction,'' ''acquisition,'' and ''use'' are broad, and retain their commonly-accepted meanings in the rule. The concerns raised by the

commenters are addressed by defining the term ''ICTS Transaction'' to include (1) ''ongoing activities, such as managed services, data transmission, software updates, repairs, or the platforming or data hosting of applications for consumer download;'' and (2) ''any other transaction, the structure of which is designed or intended to evade or circumvent the application of the Executive Order.'' The purpose of these additions is to clarify that the Secretary may review ICTS Transactions, including the provision of services, that occur on or after January 19, 2021, by any person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary. Providing services, such as software updates, to U.S. persons may provide a foreign adversary an opportunity to engage in the types of activities that may threaten U.S. national security, as described above. Further, the definition of ICTS Transaction clarifies that attempting to structure a transaction in order to circumvent Secretarial review is nonetheless an ICTS Transaction subject to this rule.

§ 7.2—Definition of ''party or parties to a transaction''

Several commenters expressed an interest in the Department further clarifying what entities are covered by the rule. Further, in revising the proposed rule for finalization, the Department used the term ''party to a transaction'' in several instances and believes it would be beneficial to define that term. Accordingly, the rule adds a definition of ''party or parties to a transaction,'' to mean a person engaged in an ICTS Transaction, including the person acquiring the ICTS and the person from whom the ICTS is acquired. The term ''person'' is also defined by the rule and is unchanged from the proposed rule.

''Party or parties to a transaction'' include entities designed or intended to evade or circumvent application of the Executive Order. For purposes of this rule, this definition does not include common carriers that transport goods for a fee on behalf of the general public, except to the extent that a common carrier knows, or should have known (as the term ''knowledge'' is defined in 15 CFR 772.1), it was providing transportation services of ICTS to one or more of the parties to a transaction that has been prohibited in a final written determination made by the Department or permitted subject to mitigation measures.

This addition narrows the scope of the rule by adding clarity regarding which persons are responsible for a reviewable transaction. This also affects which parties will be notified by the Department regarding any potential review of a transaction.

§ 7.2—Definition of ''Person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary''

In addition to defining ''party or parties to a transaction,'' the Department sought to add clarity to the rule by defining the phrase ''person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary,'' as many commenters expressed concern that leaving such terms undefined might create confusion about the breadth of the rule's reach. The Department defines ''person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary'' to mean ''any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part by a foreign adversary; any person, wherever located, who is a citizen or resident of a nation-state controlled by a foreign adversary; any corporation, partnership, association, or other organization organized under the laws of a nation-state controlled by a foreign adversary; and any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary.''

§ 7.2—Sensitive Personal Data

Many commenters requested additional clarity about the specific ICTS that is subject to this rule. While it is impossible to identify all of the ICTS that may present undue or unnecessary risks, the Department has defined the term, ''sensitive personal data,'' to identify, along with the information identified in section 7.3 of the rule, some of types of information or communications that might be involved in an ICTS Transaction reviewed under this rule where a party or parties to a transaction use, possess, or retain, or are expected to use, possess, or retain sensitive personal data.

The term ''sensitive personal data'' includes: (1) Personally Identifiable Information (*i.e.,* data that can identify individuals) that is maintained or collected by a U.S. business operating in specific areas, and that is maintained or collected on over one million people over a 12 month period; and (2) results of individual genetic testing.

The categories of identifiable data of concern to the Department are: Financial data that could be used to indicate an individual's financial distress or hardship; the set of data included in consumer reports; the set of data used for health and certain financial insurance applications; data relating to the physical, mental, or psychological health condition of an individual; non-public electronic communication information, such as personal emails; geolocation data used in certain technologies; biometric data; data stored and processed for generating Federal, State, Tribal, Territorial, or other government identification cards; data concerning U.S. Government personnel security clearance status; and data from security clearance or employment applications.

As indicated in section 7.3, Scope, the Department believes that ICTS Transactions involving sensitive personal data could create risks for the U.S. national security and also believes it is important to specifically identify these categories of data to provide the regulated community with additional specificity and certainty as to the scope of the rule's application.

§ 7.2—Definition of ''Undue or unacceptable risk''

Commenters recommended various alternative uses for and limits on this term. For example, some suggested that the Department identify certain industries or types of transactions that do not pose a risk to national security, and that the Department should exempt certain types of transactions from the rule.

Most of the suggestions could unnecessarily limit the United States' ability to determine its national security interests and, thus, could limit the ability to protect the Nation. However, the Department agrees the term requires definition, and in this rule adopts the definition of ''undue or unacceptable risks'' as those risks identified in Section 1(a)(ii) of the Executive Order. Section 1(a)(ii) of the Executive Order includes the following risks . . . an undue risk of sabotage to or subversion of the design, integrity, manufacturing, production, distribution, installation, operation, or maintenance of information and communications technology or services in the United States; . . . an undue risk of catastrophic effects on the security or resiliency of United States critical infrastructure or the digital economy of the United States; or . . . an unacceptable risk to the national

security of the United States or the security and safety of United States persons.

§ 7.3 Scope of Covered ICTS Transactions

Many commenters suggested ways the Department could narrow the scope of the rule to provide more guidance for the types of transactions the Department may review. For example, commenters noted the potential impact of the proposed rule on certain types of transactions, such as transportation services of ICTS, and argued the rule would harm commenters' industries. They also argued that the proposed rule was overly broad and that narrowing the scope would bring greater economic certainty to ICTS Transactions and the technology industry as a whole.

Other commenters sought to have the Department identify categorical exemptions for select industries, such as ICTS Transactions involving medical devices or services for air traffic control, while yet others sought to exempt transactions involving companies with their business headquarters in allied nations, such as Japan. Commenters also suggested that, provided appropriate cybersecurity mitigation techniques exist, transactions involving otherwise banned equipment should be exempted from this rule.

The Department concludes that categorical exemptions of specific industries or geographic locations are unwarranted at this time, although the Secretary may consider this possibility in the future. Wholesale exemptions of industries and geographic locations would not serve the rule's intended purpose of securing the ICTS supply chain because such exemptions would contradict the Department's evaluation method for ICTS Transactions. Such exemptions would indicate to foreign adversaries whole classes of ICTS Transactions outside the scope of evaluation under this rule. This would allow foreign adversaries to pinpoint certain types of ICTS Transactions that would more easily escape Departmental oversight and, therefore, threaten U.S. national security. By retaining broad authority across industries, the Department will be better able to mitigate identified risks.

While the rule does not contain categorical exemptions of specific industries or geographic locations, the rule now specifies that ICTS Transactions that involve certain technologies, hardware, or software will be considered to be covered ICTS Transactions. Additionally, the rule does make clear that, as further discussed below, the acquisition of ICTS items by a United States person as a party to a transaction authorized under a U.S. government-industrial security program, is not an ICTS Transaction. Additionally, the Department acknowledges that ICTS Transactions solely involving personal ICTS hardware devices, such as handsets, do not warrant particular scrutiny.

§ 7.3—Technology Sectors

Many commenters requested that the Department identify those technologies or products that the Department considers create the greatest risks to the national security of the United States. The Department understands the desire for additional certainty and broke down the scope of technologies included under the scope of this rule into six main types of ICTS Transactions involving: (1) ICTS that will be used by a party to a transaction in a sector designated as critical infrastructure by Presidential Policy Directive 21—Critical Infrastructure Security and Resilience, including any subsectors or subsequently designated sectors; (2) software, hardware, or any other product or service integral to wireless local area networks, mobile networks, satellite payloads, satellite operations and control, cable access points, wireline access points, core networking systems, or long- and short-haul systems; (3) software, hardware, or any other product or service integral to data hosting or computing services that uses, processes, or retains, or is expected to use, process, or retain, sensitive personal data on greater than one million U.S. persons at any point over the twelve months preceding an ICTS Transaction; (4) certain ICTS products which greater than one million units have been sold to U.S. persons at any point over the twelve months prior to an ICTS Transaction; (5) software designed primarily for connecting with and communicating via the internet that is in use by greater than one million U.S. persons at any point over the twelve months preceding an ICTS Transaction; (6) ICTS integral to artificial intelligence and machine learning, quantum key distribution, quantum computing, drones, autonomous systems, or advanced robotics.

§ 7.3—Licensing Process for Potential Transactions

Many commenters requested that the Department establish a process for entities to seek pre-approval of their ICTS Transactions, similar to the process by which entities may inform the Committee on Foreign Investment in the United States (CFIUS) of investments in U.S. businesses, and obtain ''safe harbor'' for those transactions. Commenters argued that such a process would help ease business uncertainty in specific cases.

To afford parties greater certainty, within 60 days of the publication date of this rule, the Department intends to publish procedures to allow a party or parties to a proposed, pending, or ongoing ICTS Transaction to seek a license, pursuant to Section 2(b) of the Executive Order, in a manner consistent with the national security of the United States. Within 120 days of the publication date of this rule, the Department intends to implement this licensing process. The published procedures will establish criteria by which persons may seek a license to enter into a proposed or pending ICTS Transaction or engage in an ongoing ICTS Transaction. Persons who may seek a license will include any parties to a proposed, pending, or ongoing ICTS Transaction as that term is defined in this rule. License application reviews will be conducted on a fixed timeline, not to exceed 120 days from accepting a license application, to enable qualifying parties to conclude permissible transactions without undue delay. If the Department does not issue a license decision within 120 days from accepting a license application, the application will be deemed granted. In no event, however, would the Department issue a license decision on an ICTS Transaction that would reveal sensitive information to foreign adversaries or others who may seek to undermine U.S. national security. Qualifying parties may voluntarily apply for a license, and a party's decision not to seek a license will not create a negative inference or unfavorable presumption with respect to a transaction.

§ 7.3—Presidential Policy Directive 21—Critical Infrastructure Security and Resilience

Regarding the Department's assessment of undue and unacceptable risk, commenters suggested that the Department create risk criticality categories for transactions, such as low, medium, and high, along with different assessment approaches. Other commenters advocated using risk scores or categories to determine the frequency and rigor of monitoring.

The Department agrees that the scope of the rule could be narrowed to indicate more specifically the types of ICTS Transactions that may be reviewed. Accordingly, the Department clarifies that ICTS Transactions include those that involve, among other aspects, a sector designated as critical

infrastructure by Presidential Policy Directive 21—Critical Infrastructure Security and Resilience, including any subsectors or subsequently designated sectors. As explained below, the Department has also clarified that transactions involving certain sensitive personal data, regardless of whether they involve a critical infrastructure sector, will be considered ICTS Transactions for the purposes of the rule.

§ 7.3—Exclusions

Many commenters sought clarity about the relationship of this rule to the rules relating to CFIUS's review of transactions. In response, the Department is clarifying that this rule does not apply to an ICTS Transaction that CFIUS is actively reviewing, or has reviewed, as a covered transaction or covered real estate transaction or as part of such a transaction under section 721 of the Defense Production Act of 1950, as amended, and its implementing regulations. Note, however, that a transaction involving ICTS that is separate from, and subsequent to, a transaction for which CFIUS has concluded action under section 721 may be subject to review under this rule, if and to the extent that such transactions are separate from the transaction reviewed by CFIUS. Parties should therefore be aware that CFIUS review related to a particular ICTS, by itself, does not present a safe harbor for future transactions involving the same ICTS that may present undue or unnecessary risks as determined by the Department.

§ 7.3—Exclusions of ICTS Transactions

Commenters requested categorical exclusions across many sectors, industries, functions, and nations. The Secretary recognizes the need to be judicious and deliberate in deciding what types of ICTS Transactions pose an undue or unacceptable risk. To that end, the rule excludes from the scope of the rule those transactions that involve the acquisition of ICTS items by a United States person as a party to a transaction authorized under a U.S. Government-industrial security program, because they are subject to continuous security oversight by, and contractual obligations to, other Federal agencies.

§ 7.3—Retroactivity of Rule's Applicability

Some commenters argued that the rule should not apply to transactions that took place prior to May 15, 2019, when the Executive Order was issued. Other commenters advocated for the complete elimination of the proposed rule's retroactivity provisions, and proposed the Department only evaluate potential transactions prospectively. Other commenters proposed grandfathering some ICTS equipment for a predetermined duration, potentially up to 10 years. In reviewing these comments and the proposed rule, the Department determined that the temporal limits of the rule's application could be clarified.

In response to these comments, the Department has clarified, in section 7.3(a)(3), that the rule applies to an ICTS Transactions that is initiated, pending, or completed on or after January 19, 2021. Further, any act or service with respect to an ICTS Transaction, such as execution of any provision of a managed services contract or installation of software updates, is an ICTS Transaction on the date that the service or update is provided. Thus, if a person that is owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary engages in an ICTS Transaction with a person subject to the jurisdiction of the United States on or after January 19, 2021, even if the service was provided pursuant to a contract initially entered into prior to January 19, 2021, that transaction is an ICTS Transaction that may be reviewed under this rule. The service is a new transaction separate from the underlying contract that will be subject to review by the Secretary.

§ 7.4 Determination of Foreign Adversaries

As noted above, many commenters requested the Department identify those countries that it considers to be ''foreign adversaries.'' Naming these countries, the commenters argued, would facilitate global trade by allowing U.S. businesses to assess the risks of certain types of ICTS Transactions from certain countries. It would also allow companies to adjust their supply chains to avoid the risks in such transactions, including the risk of an ICTS Transaction being reviewed, and possibly prohibited or modified, under this rule. Several commenters also noted that defining ''foreign adversaries'' would help determine, and possibly reduce, the adverse economic impact the rule may have on businesses through better business planning.

In response to these comments, the Department reconsidered its prior determination not to identify specific ''foreign adversaries.'' The Department has determined that it is beneficial for the clarity of the rule, as well as for persons with ICTS Transactions that may be subject to the rule, to identify certain foreign governments and foreign non-government persons that are considered, solely for the purposes of the Executive Order, this rule, and any subsequent rules, to be ''foreign adversaries.'' The list of foreign governments and foreign non-government persons this rule identifies as being ''foreign adversaries'' are: The People's Republic of China, including the Hong Kong Special Administrative Region (China); the Republic of Cuba (Cuba); the Islamic Republic of Iran (Iran); the Democratic People's Republic of Korea (North Korea); the Russian Federation (Russia); and Venezuelan politician Nicolás Maduro (Maduro Regime). The Secretary identified these foreign adversaries because they have engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons, including taking actions and enacting policies that are inimical to the interests of the United States.

The determination to identify these ''foreign adversaries'' is based on multiple sources, including threat assessments and reports from the U.S. Intelligence Community, the U.S. Departments of Justice, State, and Homeland Security, and other relevant sources. Additionally, the Secretary will periodically review this list in consultation with appropriate agency heads and may add to, subtract from, supplement, or otherwise amend the list. Accordingly, this list may be revised at any time in the future. Any such changes will be announced in the **Federal Register**.

It is important to note that the list is solely for the purposes of the Executive Order, this rule, and any subsequent rules and does not reflect a determination by the United States about the nature of such foreign governments and foreign non-government persons for any purposes other than that ICTS Transactions with persons (as defined in this rule) owned by, controlled by, or subject to the jurisdiction or direction of an identified foreign adversary may pose an undue or unacceptable risk. Further, the rule states that any amendment to this list will apply to any ICTS Transaction that is initiated, pending, or completed on or after the date that the list is amended.

§ 7.5 Effect on Other Laws

Many commenters suggested that this rule should not apply if overlapping and existing U.S. authorities are in force, referencing in particular existing national security regulatory regimes. Specifically, commenters pointed to CFIUS; authorities under various National Defense Authorization Acts;

the Export Administration Regulations; the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (*i.e.,* Team Telecom); and other programs under the authority of the Federal Communications Commission, the Department of Homeland Security, and the Office of the Director of National Intelligence. Other commenters recommended exempting equipment provided by companies involved in mitigation agreements with the Federal Government.

This rule does not alter or affect any of these existing authorities; it is intended to complement, not supplant, these existing regimes. However, the Department understands the need for regulatory and business certainty, and in the interest of not duplicating efforts by other parts of the U.S. Federal government, the rule states that it does not apply to ICTS Transactions that CFIUS is actively reviewing, or has reviewed, as a covered transaction or covered real estate transaction or as part of such a transaction under section 721 of the Defense Production Act of 1950, as amended, and its implementing regulations. However, this exclusion in no way precludes a review of a subsequent ICTS Transaction if distinct from the previously CFIUS-reviewed transaction or new information is discovered.

Other provisions of the rule provide additional means of ensuring that any action taken by the Secretary neither conflicts with nor frustrates the purposes of other existing laws, regulations or processes. Thus, there are two separate points during the review process at which the Secretary is expressly required to consult with appropriate agency heads: before making an initial determination that the transactions is an ICTS Transaction that poses an undue or unacceptable risk (section 7.104) and before making a final determination (section 7.108). In requiring that the Secretary consult with other agency heads, the rule provides for a coordination mechanism with other agencies and Departments that have potentially overlapping jurisdiction. For example, before making an initial determination concerning a transaction, the review of which might potentially overlap with a review under CFIUS, the Secretary is required to consult with, among others, the Secretary of the Treasury, who serves as the Chairperson of CFIUS, thereby helping to ensure coordination and avoid redundancy.

In addition, section 7.100(a) of the rule provides that the Secretary may consider all relevant information provided by any U.S. Government national security body or other Federal Government agency, department or regulatory body in determining what action may be necessary to ameliorate a threat posed by an ICTS Transaction.

Subpart B—Review of ICTS Transactions

Commenters largely recommended the final rule clarify the review process, requesting the specific criteria by which the Department will use to review transactions. As a whole, Subpart B adds a more detailed review process, as requested by commenters.

§ 7.100 General

§ 7.100(a)—Consideration of Relevant Information

Many commenters sought clarity as to the type of information on which the Secretary could base a determination to commence an evaluation of a transaction. In response to these comments, section 7.100(a) identifies sources or information, factors, and other variables related to a transaction that the Secretary may consider when reviewing a transaction. This list is non-exclusive and does not prevent the Secretary from reviewing any available information; the list is intended to provide parties to transactions with greater clarity about the types of materials on which the Secretary may rely when deciding whether to review (and during that review of) a transaction.

The rule states that the Secretary may consider information provided by any U.S. Government national security body or other Federal agencies. In addition, the rule clarifies that the Secretary, when making determinations about specific transactions, may also consider information that includes: (1) Relevant public information; (2) confidential business or proprietary information; (3) classified national security information; (4) information from State, local, tribal, or foreign governments; (5) information from parties to a transaction, including records related to such transaction that any party keeps or uses, or would be expected to keep or use, in their ordinary course of business for such a transaction; (6) information obtained through the authority granted under sections 2(a) and (c) of the Executive Order and IEEPA; and (7) information provided by any other U.S. Government agency, department, or other regulatory body.

The rule further revises section 7.100(a) to specify that information may be obtained through any administrative investigative or enforcement action undertaken pursuant to the authority granted under sections 2(a) and (c) of the Executive Order and IEEPA. The purpose of this clarification is to set out precisely the authorities that grant the Secretary the power to access and collect documents related to investigations and determinations of potentially prohibited transactions.

§ 7.100(c)—Determining Foreign Adversary Involvement

In order to provide industry with more clarity regarding the determination of whether an ICTS Transaction involves ICTS designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, the Department added guidance about what information it will consider when making these decisions. These factors include: (1) Whether the party or its component suppliers have headquarters, research, development, manufacturing, test, distribution, or service facilities or other operations in a foreign country, including one controlled by a foreign adversary; (2) personal and professional ties between the party—including its officers, directors or similar officials, employees, consultants, or contractors—and any foreign adversary; (3) laws and regulations of the foreign adversary in which the party is headquartered or conducts operations, including research and development, manufacturing, packaging, and distribution; and (4) any other criteria that the Secretary deems appropriate.

§ 7.100(d)—Factors for Determining an Undue or Unacceptable Risk

Commenters also requested additional information from the Department about how it will determine whether an ICTS Transaction poses an undue or unacceptable risk. Along with listing factors to help determine the relationship between a foreign party to an ICTS Transaction and a foreign adversary, the Department has provided guidance on some of the information that the Secretary, in consultation with the appropriate agency heads, will consider when determining the impact of an ICTS Transaction on U.S. national security.

Specifically, when determining whether an ICTS Transaction poses an undue or unacceptable risk, the Secretary and the appropriate agency heads will consider factors such as: (1) Threat assessments and reports prepared by the Director of National Intelligence pursuant to section 5(a) of the Executive Order; (2) removal or exclusion orders issued by the Secretary

of Homeland Security, the Secretary of Defense, or the Director of National Intelligence (or their designee) pursuant to recommendations of the Federal Acquisition Security Council, under 41 U.S.C. 1323; (3) relevant provisions of the Defense Federal Acquisition Regulation and the Federal Acquisition Regulation, and their respective supplements; (4) entities, hardware, software, and services that present vulnerabilities in the United States as determined by the Secretary of Homeland Security pursuant to section 5(b) of the Executive Order, Department of Homeland Security Cybersecurity and Infrastructure Security Agency, ''Information and Communications Technology Supply Chain Risk Management Task Force: Interim Report,'' September 18, 2019; (5) actual and potential threats to execution of a ''National Critical Function'' identified by the Department of Homeland Security Cybersecurity and Infrastructure Security Agency; (6) the nature, degree, and likelihood of consequence to the United States public and private sectors that could occur if ICTS vulnerabilities were to be exploited; and (7) any other source or information that the Secretary deems appropriate.

§ 7.100(d)—Risk Management

The Department specifically requested comments on transactions that could present an undue or unacceptable risk, but where that risk could be reliably and adequately mitigated or prevented. Commenters suggested creating national security risk categories for transactions and providing assurance that the Secretary would impose the least intrusive measures to mitigate transactions in each category. Other commenters advocated creating risk categories or bands with different assessment approaches. The Department did not adopt these suggestions. ICTS Transaction reviews are made on a case-by-case basis. Therefore, categorically labeling transactions with pre-determined mitigation requirements would effectively counteract that individualized approach and may result in ICTS Transactions proceeding that otherwise should have been reviewed, and possibly prohibited or mitigated.

In determining whether an ICTS Transaction poses an undue or unacceptable risk, the rule clarifies the risk factors the Secretary, in consultation with the appropriate agency heads, may consider. Specifically, the Secretary may consider: (1) Threat assessments and reports prepared by the Director of National Intelligence pursuant to section 5(a) of the Executive Order; (2) removal or exclusion orders issued by the Secretary of Homeland Security, the Secretary of Defense, or the Director of National Intelligence (or their designee) pursuant to recommendations of the Federal Acquisition Security Council, under 41 U.S.C. 1323; (3) relevant provisions of the Defense Federal Acquisition Regulation and the Federal Acquisition Regulation, and their respective supplements; (4) entities, hardware, software, and services that present vulnerabilities in the United States as determined by the Secretary of Homeland Security pursuant to section 5(b) of the Executive Order, Department of Homeland Security Cybersecurity and Infrastructure Security Agency, ''Information and Communications Technology Supply Chain Risk Management Task Force: Interim Report,'' September 18, 2019; (5) actual and potential threats to execution of a ''National Critical Function'' identified by the Department of Homeland Security Cybersecurity and Infrastructure Security Agency; (6) the nature, degree, and likelihood of consequence to the United States public and private sectors that could occur if ICTS vulnerabilities were to be exploited; and (7) any other source or information that the Secretary deems appropriate.

§ 7.101 Information To Be Furnished on Demand

The proposed rule contemplated that individuals might be requested to furnish the Secretary with information related to a transaction under review. Section 7.101 in this rule clarifies that, under the Secretary's authority pursuant to IEEPA, persons may be required to furnish under oath complete information relative to any ICTS Transaction under review. The Secretary may require that such reports include the production of any books, contracts, letters, papers, or other hard copy or electronic documents relating to any such act, transaction, or property, in the custody or control of the persons required to make such reports. Reports may be required either before, during, or after an ICTS Transaction under review. Additionally, under the authorities provided by IEEPA, the Secretary may, through any person or agency, conduct investigations, hold hearings, administer oaths, examine witnesses, receive evidence, take depositions, and require by subpoena the attendance and testimony of witnesses and the production of any books, contracts, letters, papers, and other hard copy or electronic documents relating to any matter under investigation.

§ 7.102 Confidentiality of Information

The proposed rule requested comments and recommendations from stakeholders on additional recordkeeping requirements for information related to transactions. Most commenters focused on the confidentiality and the public availability of any information received. Commenters strongly advocated that the Department protect confidential or proprietary business information when making or publishing reports. Some commenters advocated for more open publication of these reports, and how each threat was mitigated or eliminated.

To address these concerns and provide additional certainty for entities required to produce documents related to transactions, the rule clarifies the Department's responsibility to preserve the confidentiality of information requested by the Department. Specifically, the rule provides that information or documentary materials that are not otherwise publicly or commercially available, submitted or filed with the Secretary under this part, will not be released publicly except to the extent required by law. However, the Secretary may disclose information or documentary materials, not otherwise publicly or commercially available: (1) Pursuant to any administrative or judicial proceeding; (2) pursuant to an act of Congress; (3) pursuant to a request from any duly authorized committee or subcommittee of Congress; (4) pursuant to a request to any domestic governmental entity, or to any foreign governmental entity of a United States ally or partner, information or documentary materials, not otherwise publicly or commercially available and important to the national security analysis or actions of the Secretary, but only to the extent necessary for national security purposes, and subject to appropriate confidentiality and classification requirements; (5) where the parties or a party to a transaction have consented the information or documentary materials not otherwise publicly or commercially available may be disclosed to third parties; and (6) any other purpose authorized by law. These provisions largely incorporate the record release requirements of the Freedom of Information Act, 5 U.S.C. 552. While the Department will, as always, seek to protect business and other confidential information provided by parties, parties providing such information in response to this rule must clearly mark those documents as business or other confidential.

§ 7.103 Initial Review of ICTS Transactions

Many commenters addressed the manner in which an ICTS Transaction could be identified to the Secretary as a transaction that should be reviewed. In particular, many commenters sought clarity on the proposed provision that the Secretary could commence evaluations of transactions based on information received from private parties ''that the Secretary determines to be credible.'' The commenters requested clear guidance on what types of information, or parties, the Secretary would deem credible. Additionally, several commenters noted that such a provision might incentivize parties to engage in anti-competitive behavior that would not necessarily lead to identifying transactions posing risks to national security. In light of these comments and concerns, the rule clarifies that the Secretary may consider any referral for review of a transaction (referral): (1) Upon receipt of any information identified in section 7.100(a); (2) upon written request of an appropriate agency head; or (3) at the Secretary's discretion. Following receipt of a referral, the Secretary will assess whether the referral falls within the scope of § 7.3(a) and involves ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction of direction of a foreign adversary, and determine whether to: (1) Accept the referral and commence an initial review of the transaction; (2) request additional information, as identified in § 7.100(a), including information from the referring entity regarding the referral; or (3) reject the referral.

Several commenters requested the rule establish clearer procedures for how the Secretary will review ICTS Transactions. Commenters also advocated for differing determination timeframes, deadlines, or milestones based on device nature, threat severity, equipment replacement risks, and other potential harms.

In response to these and other comments, the Department provides that, unless the Secretary determines in writing that additional time is necessary, the Secretary shall issue the final determination within 180 days of accepting a referral and commencing the initial review of the ICTS Transaction. Regarding the procedures for the Secretary's review of ICTS Transactions, the Executive Order provides a careful process for the Secretary's decision-making. The rule further sets out the factors that the Secretary will consider to assist the decision-making process. Specifically, the rule provides that the Secretary shall assess whether the ICTS Transaction: Falls within the scope of § 7.3(a) of the rule; involves ICTS designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary; and poses an undue or unacceptable risk. The Secretary will evaluate each transaction, on a case-by-case basis, based upon the particular facts and circumstances, including the identity of the parties involved.

The rule also further articulates what the Secretary will consider when determining whether an ICTS Transactions poses an undue or unacceptable risk. The Department has identified ten criteria for such determinations. Along with other factors, when determining if an ICTS Transaction poses an undue or unacceptable risk, the Secretary will consider the nature of the information and communications technology or services at issue in the ICTS Transaction, including technical capabilities, applications, and market share considerations; the nature and degree of the direction or jurisdiction exercised by the foreign adversary over the design, development, manufacture, or supply at issue in the ICTS Transaction; and the statements and actions of the foreign adversary at issue in the ICTS Transaction. Other considerations include whether the ICTS Transaction poses a discrete or persistent threat and the nature of the vulnerability implicated by the ICTS Transaction.

§ 7.104 First Interagency Consultation

The Department has clarified that the Secretary will consult with the appropriate agency heads after finding that an ICTS Transaction may fall within the scope of the Executive Order.

§ 7.105 Initial Determination

This rule clarifies that if, after review of an ICTS Transaction and consultation with the appropriate agency heads, the Secretary determines that such ICTS Transaction meets the criteria in section 7.103(c) of the rule, the Secretary shall then issue an initial written determination explaining the finding and whether the Secretary has determined to prohibit or propose mitigation measures to the ICTS Transaction at issue. The initial determination will contain no confidential information, even if such was relied upon to make the initial determination. Notice of this initial determination shall be served upon the parties to the ICTS Transaction known to the Secretary at the time of service. Service may be made by registered U.S. mail, facsimile, electronic transmission, or third-party commercial carrier, to an addressee's last known address or by personal delivery. Service of documents will be considered effective upon the date of postmark, facsimile transmission, delivery to third party commercial carrier, electronic transmission or upon personal delivery. Notice of the initial determination to the parties may also be accomplished by publication in the **Federal Register** where the Secretary determines that the initial determination concerns or could impact entities beyond the parties to the ICTS Transaction, where one or more of the parties to the ICTS Transaction are unknown to the Secretary, or in any other circumstance at the Secretary's discretion.

§ 7.106 Retention of Records

The proposed rule requested public comments on whether to require parties to undertake additional recordkeeping for information related to transactions. Some commenters argued that the Department should not impose additional recordkeeping requirements. Additionally, some commenters suggested that the recordkeeping requirement begin upon receipt of a transaction notice, rather than being an ongoing duty for any potentially prohibited ICTS Transaction.

After reviewing these comments, and consistent with IEEPA, the rule provides that, after receiving notification that an ICTS Transaction is under review or that an initial determination concerning an ICTS Transaction has been made, a notified person must immediately take steps to retain any and all records related to such transaction.

§ 7.107 Procedures Governing Response and Mitigation

Commenters requested that the final rule explain how the Secretary's determinations may be ''appealed'' and how mitigation agreements will be reached and enforced. Commenters also sought more robust procedures for waivers, appeals, and mitigation. The proposed rule had provided that, within 30 days of a preliminary determination by the Secretary that a transaction was an ICTS Transaction that would pose an undue or unacceptable risk to the U.S. national security, parties to that transaction could submit a response to the decision. The proposed rule also allowed the Secretary to require a transaction be mitigated to reduce the risks the Secretary identified in the preliminary determination.

In response to these comments, the Department has added provisions to enhance and clarify when and how parties to an ICTS Transaction that is the subject of an initial determination may engage with the Secretary about the initial determination. The rule establishes a clear process for responding to an initial determination concerning an ICTS Transaction and provides further guidance on how any identified risks may be mitigated so that an identified ICTS Transaction may proceed. Similar to the proposed rule, within 30 days of being notified of an initial determination, pursuant to section 7.105 of the rule, parties to that transaction may respond to the initial determination or assert that the circumstances leading to the initial determination no longer apply. A party may submit arguments or evidence in support of their response and may also propose remedial steps that the party believes would negate the basis for the Secretary's initial determination. The rule also allows parties to an ICTS Transaction that is subject to an initial determination to request a meeting with the Department, which may be granted at the Secretary's discretion. Additionally, the rule clarifies that if the parties to an ICTS Transaction do not submit a response to the Secretary's initial determination within 30 days following service of the initial determination, that initial determination will become final.

Other commenters recommended the adoption of an appeals process for parties notified of a final determination. The Department has adopted a process for reconsidering an initial determination by the Secretary. However, an administrative appeals process would hinder the Secretary's ability to move swiftly to prevent an undue or unacceptable risk.

Some commenters also requested that the Department establish a maximum life span for imposed mitigations, arguing that such a rule would reduce the inhibiting effects that mitigations would have on ICTS innovation. The Department disagrees with commenters, finding that such a clause would prevent the Department from evaluating the mitigations put in place on ICTS Transactions. Failing to reevaluate would effectively limit mitigation requirements and potentially reopen national security vulnerabilities.

§ 7.108 Second Interagency Consultation

The proposed rule set out the review process that must be followed before the Secretary issues a final determination that constitutes a final agency action. The process involved response periods, as well as possible extensions, given to any party affected by a preliminary determination. Commenters addressed communications regarding initial and final determinations within the context of this process. Some commenters suggested that the Secretary should collaborate with private industry when making determinations, similar to the process within the Department of Homeland Security's Supply Chain Risk Management Task Force. Similar comments were received advocating for the establishment of a mechanism for industry to seek guidance on specific work programs or participants involved.

The Department has declined to add specific provisions relating to collaborating with industry on ICTS Transaction determinations. However, in consideration of these comments there is now a provision explaining what factors and sources the Secretary will take into consideration during the second consultation. Specifically, the Secretary will take into account the views of the appropriate agency heads, through the interagency consultation processes. In providing their views, the appropriate agency heads may consider the perspective of relevant public-private working groups and advisory committees with which they convene or engage. For instance, DHS's views could incorporate input from the Supply Chain Risk Management Task Force. The Department also points out that it maintains a number of advisory committees that provide regular opportunities for industry and the regulated community to provide feedback to the Department on issues impacting their operations. Under the Secure and Trusted Communications Networks Act of 2020, the National Telecommunications and Information Administration is also charged with establishing a program to share supply chain risk information with telecommunication providers and manufacturers.

Commenters also requested that the Department explain whether and how the Secretary's determinations may be appealed or reviewed by another authority. This rule adds a provision that, should any appropriate agency head oppose the Secretary's proposed final determination, the Secretary shall notify the President of the Secretary's proposed final determination and such opposition. After receiving direction from the President regarding the Secretary's proposed final determination and any appropriate agency head's opposition thereto, the Secretary shall issue a final determination pursuant to § 7.109.

Additionally, the Department will implement, within 120 days of publishing this rule, procedures for how parties to a proposed, pending, or ongoing ICTS Transaction may seek a license, pursuant to Section 2(b) of the Executive Order, in a manner consistent with the national security of the United States.

As noted above, after reviewing an ICTS Transaction that the Secretary believes may pose an undue or unacceptable risk, the Secretary will engage in a first interagency consultation with the appropriate agency heads to discuss the ICTS Transaction and the Secretary's concerns. Following that consultation, the Secretary will make an initial determination and, if that decision includes a determination to prohibit an ICTS Transaction, will notify the parties to the transaction of the Secretary's initial determination. After the parties are afforded an opportunity to respond to the initial determination and propose mitigation measures, the Secretary will engage in a second interagency consultation with the appropriate agency heads, to discuss the transaction, the initial determination, and any response. This process will help ensure that all information regarding ICTS Transactions and the views of the appropriate agency head are considered when the Secretary makes a final determination.

§ 7.109 Final Determination

As noted above, the Department appreciates the comments requesting additional clarity on the process by which the Secretary will make decisions about ICTS Transactions. The rule now provides a specific step for issuing final determinations on ICTS Transactions. The outcome of a final determination remains unchanged from the proposed rule and will provide that an ICTS Transaction is either: (1) Prohibited; (2) not prohibited; or (3) permitted pursuant to the adoption of agreed-upon mitigation measures. Moreover, the rule clarifies that the written final determinations will include directions on the timing and manner of cessation of a prohibited ICTS Transaction, as applicable, along with the penalties, as authorized by IEEPA, for violations of applicable mitigation terms or other direction or prohibition issued under this rule. The final determination will provide a specific description of the prohibited ICTS Transaction and shall be limited in force to the circumstances described therein. Moreover, if the Secretary determines that an ICTS Transaction is prohibited, the final determination shall direct the least

restrictive means that the Secretary, in the Secretary's discretion, determines to be necessary to attenuate or alleviate the undue or unacceptable risk posed by the ICTS Transaction.

§ 7.109(c)—Notification of Final Determination

Commenters also provided a number of suggestions on how to further ensure the Secretary is held accountable for his or her actions under the authority of this rule. Recommendations include limiting the Secretary's ability to assign a designee with final decision-making authority and deleting the emergency action provision set forth in section 7.100(f) of the proposed rule. These suggestions are intended to ensure that Congress can hold the executive branch accountable for enforcement actions.

In response to these comments, the final rule enhances transparency by requiring final written determinations to be published in the **Federal Register**, where they are readily accessible to both the Congress and the public. Moreover, the rule now clarifies that the publication shall omit any confidential business information.

§ 7.200 Penalties

Commenters requested the final rule clarify the type and scope of penalties for noncompliance with the Secretary's prohibition or mitigation of a transaction. We agree with commenters that the type and scope of the penalties for noncompliance were unclear, and the section has been revised accordingly. The rule now clarifies that any person who commits a violation of any final determination, direction, or mitigation agreement may be liable to the United States for civil or criminal penalties under IEEPA.

Other Comments

The Department received other comments with which the Department disagrees. The Department responds to those comments below.

First, one commenter requested that the Department expand the meaning of the term ''electronic means'' within the definition of ICTS. While the Department cannot modify the definition of ICTS contained in the Executive Order, the Department clarifies that ''electronic means'' includes electromagnetic, magnetic, and photonic means. This change is not intended to widen the scope of the rule, but merely to clarify the means by which ICTS must function in order for the rule to apply.

Second, some commenters requested that the Department provide technical assistance for parties forced to alter ICTS infrastructure. However, the Department is unable to offer technical assistance at this time. Accordingly, the Department declines to implement any provision for technical assistance in the rule, and the parties to the transaction will bear the responsibility and cost of complying with any prohibition or mitigation measure.

Third, one commenter argued that the rule imposes an unfunded mandate on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (UMRA), contrary to the determination made by the Department in the proposed rule. The commenter further argued that UMRA requires that before the rule becomes final, the Department must include in the rule a written statement assessing the costs and benefits of the rule, and estimates of future compliance costs, as required by UMRA. The Department continues to believe that the rule does not constitute a ''Federal private sector mandate'' as defined by UMRA, in that the rule does not impose ''an enforceable duty'' upon the private sector. *See* 2 U.S.C. 658(7). Rather, the rule sets out the processes and procedures that the Secretary of Commerce will use to identify, assess, and address certain transactions, including classes of transactions. However, as the commenter notes, when a rule does constitute a ''Federal private sector mandate,'' UMRA requires the agency prepare a written statement containing information about the costs and benefits of the mandate, including, where feasible, future compliance costs, 2 U.S.C. 1532, as well as that the agency identify and consider regulatory alternatives and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, 2 U.S.C. 1535. Thus, even in the event that the rule were considered to constitute a federal private sector mandate, the Department has met these requirements in full through the preparation of the accompanying Regulatory Impact Analysis.

Changes From the Proposed Rule

Upon consideration of the public comments received, the Department makes several changes, as discussed in detail above, from the proposed rule in order to increase clarity and certainty for the public. First, the rule provides detail on the procedures the Secretary will follow when reviewing ICTS Transactions, including identifying the criteria and information the Secretary will consider. For example, the rule provides clarity as to when the Secretary will consult with the appropriate agency heads as part of the review and determination process. Second, the rule details the requirements for responding to initial determinations. Third, the rule clarifies that parties may respond to an initial determination or seek to negotiate a mitigation agreement with the Secretary. Fourth, the rule now provides that unless the Secretary determines in writing that additional time is necessary, the Secretary shall issue a final determination within 180 days of accepting a referral and commencing the initial review of an ICTS Transaction, eliminating the uncertainty of an open-ended review process. Fifth, the rule ensures transparency by specifically requiring the Secretary to publish the results of final determinations, absent any confidential business information, in the **Federal Register**. Sixth, the rule now specifies that an ICTS Transactions between parties outside of a sector designated as critical infrastructure must involve a clearly specified technology or service in order to be considered a covered ICTS Transactions.

Additionally, in response to commenters seeking clarity regarding the scope of the rule, including numerous requests for the identification of ''foreign adversaries,'' the Department defines certain terms. The added definitions help to clarify the scope of the rule by providing guidance on which entities may be subject to the rule, what constitutes an ICTS Transaction, and whether an ICTS Transaction involves a foreign adversary. This additional clarity will assist entities with making appropriate decisions regarding ICTS Transactions that may present risks to the national security, therefore helping to protect the United States' ICTS supply chain.

Classification

A. Executive Order 12866 (Regulatory Policies and Procedures)

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this rule is economically significant.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule is not subject to the requirements of Executive Order 13771 because the benefit-cost analysis demonstrates that the regulation is anticipated to improve national security as its primary direct benefit.

ICTS has become integral to the daily operations and functionality of U.S. critical infrastructure, as well as much,

if not most, of U.S. industry. Moreover, ICTS accounts for a large part of the U.S. economy. Accordingly, if vulnerabilities in the ICTS supply chain—composed of hardware, software, and managed services from third-party vendors, suppliers, service providers, and contractors—are exploited, the consequences can affect all users of that technology or service, potentially causing serious harm to critical infrastructure, U.S. Government operations, and disrupting the United States and the global economy. These harms are already occurring. As noted in Executive Order 13873, ''foreign adversaries are increasingly creating and exploiting vulnerabilities in information and communications technology and services, which store and communicate vast amounts of sensitive information, facilitate the digital economy, and support critical infrastructure and vital emergency services.''

U.S. entities purchasing and incorporating ICTS equipment and using ICTS services, such as network management or data storage, provided by foreign adversaries can create multiple opportunities for foreign adversaries to exploit potential vulnerabilities in the ICTS. That, in turn, could cause direct and indirect harm to both the immediate targets of the adverse action and to the United States as a whole. Incorporation of a foreign adversary's software, equipment, and products into domestic ICTS networks, as well as the use of use of foreign cloud, network management, or other services, greatly increases the risk that potential vulnerabilities may be introduced, or that they may be present without being detected. These potential vulnerabilities are often categorized under the general concepts of threats to privacy, data integrity, and denial of service.

Some foreign actors are known to exploit the sale or lease of software and hardware to introduce vulnerabilities that can allow them to steal critical intellectual property, research results (*e.g.,* health data), or government or financial information from users of the software or hardware. Such vulnerabilities can be introduced at the network, cloud service or individual product data, allow traffic monitoring or surveillance, and may be resistant to detection by private purchasers or telecommunications carriers. Once detected, the existence of such vulnerabilities may be extremely costly or impossible to remediate.

Vulnerabilities to data integrity can be created by including an adversary's hardware and software into U.S. networks and systems. This incorporated hardware and software could then pose opportunities to add or remove important information, modify files or data streams, slow down, or otherwise modify the normal transmission or availability of data across U.S. networks. Such capabilities could be exercised in areas as diverse as financial market communications, satellite communications or control, or other sensitive consumer information. Privileged access to market movement and trends, or other manipulation, could disrupt and harm the operation of major exchanges.

A foreign adversary could also effectively deny access to critical services by exploiting vulnerabilities provided by the incorporation of hardware and software into U.S. environments, fully or partially shutting down critical networks or functions at key times. These types of attacks are known as denial of service attacks. Such attacks could cause widespread problems, such as if they occur during periods of crisis, or they could be used selectively by targeting individual corporations, infrastructure elements, or other important infrastructure functions. They could also be masked to make the source of the disruption difficult to attribute, and therefore be difficult to trace and terminate.

Such risks can be substantially increased by incorporating the software and equipment from unreliable adversaries into the U.S. telecommunications infrastructure. However, these risks are not necessarily confined to infrastructure environments. They could, for example, be present in the use of cloud services, as well as in the widespread use of some consumer devices, networked surveillance cameras, drones, or interconnection via the internet of computing devices embedded in everyday objects, enabling them to send and receive data.

The number of attacks by foreign adversaries on the ICTS supply chain are known to be increasing. The associated costs are borne by the U.S. Government as well as private industry. Given the ubiquity of ICTS in the modern economy and especially in critical infrastructure, the benefits of preventing significant disruptions or harms to the ICTS supply chain that could cause incalculable costs to U.S. firms, consumers, and the U.S. Government, would be very high.

This rule provides a process through which serious disruptions to the United States telecommunications infrastructure can be avoided or ameliorated. The rule provides the means of bringing to bear the information and analytical resources of the U.S. government to address ICTS supply chain issues before they arise, and which may be beyond the means of individual telecommunications carriers or other U.S. ICTS purchasers or users to address on their own. As noted above, the costs associated with the potential attacks, loss of service, or disruption to the ICTS supply chain are not known at this time, and are in actuality unknowable due to the generally clandestine nature of the attacks and the fact that they may or may not occur. However, by deterring, preventing, or mitigating these attacks, this rule will provide the United States with substantial, though unknowable, economic benefits as well as benefits to the national security of the United States.

C. Regulatory Flexibility Analysis

The Department has examined the economic implications of this final rule on small entities as required by the Regulatory Flexibility Act (RFA). The RFA requires an agency to describe the impact of a rule on small entities by providing a regulatory flexibility analysis. The Department published an initial regulatory flexibility analysis in the proposed rule issued on November 27, 2019 (84 FR 65316) and has posted a final regulatory flexibility analysis (FRFA) as part of the RIA (*see* **ADDRESSES**). This final rule is likely to have a significant economic impact on a substantial number of small entities. A summary of the FRFA follows.

A Statement of the Significant Issues Raised by Public Comments or by the Chief Counsel for Advocacy of the Small Business Administration in Response to the IRFA, a Statement of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Proposed Rule as a Result of Such Comments

Many commenters discussed the possibility that this rule could present significant economic costs. For example, one commenter stated that ''Commerce's proposed rules would result in an extremely broad and unprecedented increase in regulatory jurisdiction over private ICT transactions. The notice of proposed rulemaking thus marks a watershed regulatory moment for companies in or adjacent to the ICT market—which is to say, virtually every company in United States—given the government's newfound stance that it can determine key terms of what ICT companies can buy, sell, or use. As a result, this proceeding and the rules that result from it inescapably will impose additional costs on ICT companies, such as the increased practical need—even

absent a legal requirement—to document supply chain risk management analysis in the event a transaction is investigated, along with related due diligence to consider the as-yet uncertain possibilities for government intervention.'' In the RIA, the Department estimated costs associated with developing and implementing a plan to conduct due diligence on potentially covered transactions, including estimating the number of small entities that could be affected by the rule and the economic impact on those small entities.

Statement of the Objectives of, and Legal Basis for, the Final Rule

A description of this final rule, why it is being implemented, the legal basis, and the purpose of this final rule are contained in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of this preamble, as well as in the preamble to the Notice of Proposed Rulemaking issued on November 27, 2019 (84 FR 65316), and are not repeated here.

A Description and, Where Feasible, Estimate of the Number of Small Entities to Which the Final Rule Applies

Small Business Administration (SBA) size standards for businesses are based on annual receipts and average employment. For the purpose of this analysis we define a small business as one employing fewer than 500 persons. This definition allows us to use 2017 Census data on firm employment by NAICS industry to estimate the number of affected small entities.

In the RIA, the Department identified 4,533,000 firms that imported significant amounts of goods and services potentially subject to review under the Rule. This formed our upper bound estimate for the total number of affected entities. By replicating this methodology with firm employment data, the Department finds that 4,516,000 of these firms, about 99.6 percent, have less than 500 employees. Assuming the lower bound estimate of 268,000 affected entities is also made up of 99.6 percent small businesses, the Department estimates that between 266,995 and 4,516,000 small businesses will be potentially affected by this rule.

Federal Rules That May Duplicate, Overlap or Conflict With the Final Rule

The Department did not identify any Federal rule that duplicates, overlaps, or conflicts with this final rule.

Description and Estimate of Economic Effects on Entities, by Entity Size and Industry

In the Costs section of the RIA, the Department estimates that costs to all affected entities will range between approximately $235 million and $20.2 billion, or about $2,800 to $6,300 per entity. The Department estimated the costs to small entities using the same methodology. All small entity calculations and assumptions can be found in Tables 10 through 14. These tables are analogous to Tables 5 through 9 in the RIA. While most of the assumptions below are identical to those found in the previous estimates, there are 3 important adjustments to assumptions in the small entity cost estimates:

1. Entities potentially impacted by the rule reduced by 0.4 percent to account for our finding that 99.6 percent of all affected entities have less than 500 employees.
2. Small entities are less likely to have the resources to develop and implement a compliance plan. This analysis thus reduces estimates of the share of small firms likely to engage in these activities accordingly.
3. Small entities engage in fewer transactions than large entities. This analysis reduces the estimates of the number of transactions subject to the rule per small firm accordingly.

As a result of these adjustments, the Department estimates that costs to affected small entities will range between approximately $109 million and $10.9 billion, or about $1,800 and $3,900 per small entity.

Potential Economic Impact of the Rule on Small Entities

Small businesses, as opposed to larger firms, may not have the same ability to deal with the burdens, both direct and indirect, associated with the rule. Faced with the various costs associated with compliance, firms will have to absorb those costs and/or pass them along to their consumers in the form of higher prices. Either action will reduce the profits of firms. Due to their lack of market power, and their lower profit margins, small firms may find it difficult to pursue either or both of those responses while remaining viable.

A similar situation will hold with respect to the indirect impacts of the rule. Small firms downstream of impacted industries are likely to face increases in the prices of ICT products they use as inputs and either absorb the increase in cost and/or raise their prices. Given this situation, it is possible that the rule will have a more substantial adverse impact on small firms relative to larger firms.

However, the changes made from the proposed rule benefit small businesses by limiting the scope of transactions subject to the rule. Small entities have fewer suppliers and engage in fewer transactions than large entities. As a result, by identifying specific foreign adversaries and providing guidance on which entities may be subject to the rule as well as additional criteria on what constitutes an ICTS Transaction, small entities will more readily be able to determine whether their transactions are subject to review under the rule—and may in some cases, find that none of their transaction are likely to be within the scope of the rule. Additionally, by specifically requiring the Secretary to publish the results of final determinations in the **Federal Register**, small businesses will be able to assess whether their transactions are substantially similar to those that have been prohibited. Finally, the rule reduces the potential burdens on small entities by emphasizing that (1) the Secretary will choose the least burdensome restriction that still allows for protection of the national security when deciding whether to prohibit or mitigate an ICTS Transaction, and (2) the Secretary shall issue a final determination within 180 of commencing an initial review.

A Description of, and an Explanation of the Basis for, Assumptions Used

SBA size standards for businesses are based on annual receipts and average employment. For the purpose of this analysis, the Department defines a small business as one employing fewer than 500 persons. This definition allows the Department to use 2017 Census data on firm employment by NAICS industry to estimate the number of affected small entities. The Department does not have access to sufficiently detailed data on firm employment and receipts to make use of the full set of SBA size standard thresholds.

The Department notes, however, that 84% of SBA employee thresholds are above 500, and 91% of SBA receipt thresholds are above $6 million. Census data show that average receipts for firms employing less than 500 employees are $2.2 million. Thus, using our threshold of 500 employees we estimate that 99.6% of affected entities are small businesses which is likely a slight underestimate.

Description of Any Significant Alternatives to the Final Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Economic Impact of the Rule on Small Entities

This rule will allow the Secretary to review ICTS Transactions to determine whether they present an undue or unacceptable risk, a function which is currently not performed by any other private or public entity. As noted above, private industry often lacks the incentive, information, or resources to review their ICTS purchases for malicious suppliers or other potentially bad actors in the ICTS supply chain. The U.S. Government is uniquely situated to determine threats and protect the national security, including economic security.

The Department considered two regulatory alternatives to reduce the burden on small entities: (1) Excluding small entities with 5 or fewer employees, and (2) excluding certain industries and sectors. However, the Department determined that neither of these two alternatives would achieve the goal of protecting the national security, nor would they eliminate the rule's significant economic impact on a substantial number of small entities.

First, the Department considered providing an exemption for small entities that have 5 or fewer employees. (''smallest entities''). According to Census Bureau's most recent dataset of number of firms by employee count, about 61% of all firms have less than 5 employees.

Second, the Department examined the feasibility of eliminating the application of the rule to certain small entities involved in specific industries or sectors by excluding: (a) ICTS Transactions that involve only the acquisition of commercial items as defined by Federal Acquisition Regulation Part 2.101; (b) ICTS Transactions that are used solely for the purpose of cybersecurity mitigation or legitimate cybersecurity research; and (c) ICTS Transactions under which a United States person is subject to a security control agreement, special security agreement, or proxy agreement approved by a cognizant security agency to offset foreign ownership, control, or influence pursuant to the National Industrial Security Program regulations (32 CFR part 2004).

Ultimately, the Department decided against adopting either of these regulatory alternatives. Exempting certain industries or sectors or eliminating the application of the rule to smallest entities could inadvertently allow potentially problematic transactions that are substantially similar to those conducted by non-exempt entities to avoid review, undermining the rule's national security objectives. For example, a company that is headquartered in a foreign adversary country, regardless of its size or main industry sector, may be involved in legitimate cybersecurity research and development initiatives performed under the National Cooperative Research and Production Act, 15 U.S.C. 4301–06, and the foreign company may study foreign equipment to gain insights on new innovations or potential network security risks. However, that same company may also be conducting operations during other ICTS Transactions that could harm U.S. national security interests. By promulgating the chosen alternative for the rule, the Department sought to remove both the possibility for confusion as well as the ability for malicious actors to argue that some legitimate cybersecurity research performed by a company would exempt all cybersecurity research by a company, legitimate or otherwise. Thus, the rule applies to types of ICTS Transactions most affecting U.S. national security as opposed to exempting entire industries, sectors, or regulated smallest entities from review.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB) approval and displays a currently valid OMB Control Number. This rulemaking does not contain a collection of information requirement subject to review and approval by OMB under the PRA.

E. Unfunded Mandates Reform Act of 1995

This rule would not produce a Federal mandate (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995) for State, local, and tribal governments or the private sector.

F. Executive Order 13132 (Federalism)

This rule does not contain policies having federalism implications requiring preparations of a Federalism Summary Impact Statement.

G. Executive Order 12630 (Governmental Actions and Interference With Constitutionally Protected Property Rights)

This rule does not contain policies that have unconstitutional takings implications.

H. Executive Order 13175 (Consultation and Coordination With Indian Tribes)

The Department has analyzed this proposed rule under Executive Order 13175 and has determined that the action would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal law.

I. National Environmental Policy Act

The Department has reviewed this rulemaking action for the purposes of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*). It has determined that this final rule would not have a significant impact on the quality of the human environment.

List of Subjects in 15 CFR Part 7

Administrative practice and procedure, Business and industry, Communications, Computer technology, Critical infrastructure, Executive orders, Foreign persons, Investigations, National security, Penalties, Technology, Telecommunications.

This document of the Department of Commerce was signed on January 13, by Wilbur Ross, Secretary of Commerce. That document with the original signature and date is maintained by the Department of Commerce. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned Department of Commerce Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Commerce. This administrative process in no way alters

the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2021.

Asha Mathew,

Federal Register Liaison Officer, U.S. Department of Commerce.

■ For the reasons set out in the preamble, 15 CFR part 7 is added to read as follows:

PART 7—SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN

Subpart A—General

7.1 Purpose.
7.2 Definitions.
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7.4 Determination of foreign adversaries.
7.5 Effect on other laws.
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7.100 General.
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Subpart C—Enforcement

7.200 Penalties.

Authority: 50 U.S.C. 1701 *et seq.;* 50 U.S.C. 1601 *et seq.;* E.O. 13873, 84 FR 22689.

Subpart A—General

§ 7.1 Purpose.

These regulations set forth the procedures by which the Secretary may: (a) Determine whether any acquisition, importation, transfer, installation, dealing in, or use of any information and communications technology or service (ICTS Transaction) that has been designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries poses certain undue or unacceptable risks as identified in the Executive Order; (b) issue a determination to prohibit an ICTS Transaction; (c) direct the timing and manner of the cessation of the ICTS Transaction; and (d) consider factors that may mitigate the risks posed by the ICTS Transaction. The Secretary will evaluate ICTS Transactions under this rule, which include classes of transactions, on a case-by-case basis. The Secretary, in consultation with appropriate agency heads specified in Executive Order 13873 and other relevant governmental bodies, as appropriate, shall make an initial determination as to whether to prohibit a given ICTS Transaction or propose mitigation measures, by which the ICTS Transaction may be permitted. Parties may submit information in response to the initial determination, including a response to the initial determination and any supporting materials and/or proposed measures to remediate or mitigate the risks identified in the initial determination as posed by the ICTS Transaction at issue. Upon consideration of the parties' submissions, the Secretary will issue a final determination prohibiting the transaction, not prohibiting the transaction, or permitting the transaction subject to the adoption of measures determined by the Secretary to sufficiently mitigate the risks associated with the ICTS Transaction. The Secretary shall also engage in coordination and information sharing, as appropriate, with international partners on the application of these regulations.

§ 7.2 Definitions.

Appropriate agency heads means the Secretary of the Treasury, the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Homeland Security, the United States Trade Representative, the Director of National Intelligence, the Administrator of General Services, the Chairman of the Federal Communications Commission, and the heads of any other executive departments and agencies the Secretary determines is appropriate.

Commercial item has the same meaning given to it in Federal Acquisition Regulation (48 CFR part 2.101).

Department means the United States Department of Commerce.

Entity means a partnership, association, trust, joint venture, corporation, group, subgroup, or other non-U.S. governmental organization.

Executive Order means Executive Order 13873, May 15, 2019, ''Securing the Information and Communications Technology and Services Supply Chain''.

Foreign adversary means any foreign government or foreign non-government person determined by the Secretary to have engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons.

ICTS Transaction means any acquisition, importation, transfer, installation, dealing in, or use of any information and communications technology or service, including ongoing activities, such as managed services, data transmission, software updates, repairs, or the platforming or data hosting of applications for consumer download. An ICTS Transaction includes any other transaction, the structure of which is designed or intended to evade or circumvent the application of the Executive Order. The term ICTS Transaction includes a class of ICTS Transactions.

IEEPA means the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.*).

Information and communications technology or services or ICTS means any hardware, software, or other product or service, including cloud-computing services, primarily intended to fulfill or enable the function of information or data processing, storage, retrieval, or communication by electronic means (including electromagnetic, magnetic, and photonic), including through transmission, storage, or display.

Party or parties to a transaction means a person engaged in an ICTS Transaction, including the person acquiring the ICTS and the person from whom the ICTS is acquired. Party or parties to a transaction include entities designed, or otherwise used with the intention, to evade or circumvent application of the Executive Order. For purposes of this rule, this definition does not include common carriers, except to the extent that a common carrier knew or should have known (as the term ''knowledge'' is defined in 15 CFR 772.1) that it was providing transportation services of ICTS to one or more of the parties to a transaction that has been prohibited in a final written determination made by the Secretary or, if permitted subject to mitigation measures, in violation of such mitigation measures.

Person means an individual or entity.

Person owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary means any person, wherever located, who acts as an agent, representative, or employee, or any person who acts in any other capacity at the order, request, or under the direction or control, of a foreign adversary or of a person whose activities are directly or indirectly supervised, directed, controlled, financed, or subsidized in whole or in majority part

by a foreign adversary; any person, wherever located, who is a citizen or resident of a nation-state controlled by a foreign adversary; any corporation, partnership, association, or other organization organized under the laws of a nation-state controlled by a foreign adversary; and any corporation, partnership, association, or other organization, wherever organized or doing business, that is owned or controlled by a foreign adversary.

Secretary means the Secretary of Commerce or the Secretary's designee.

Sensitive personal data means:

(1) Personally-identifiable information, including:

(i) Financial data that could be used to analyze or determine an individual's financial distress or hardship;

(ii) The set of data in a consumer report, as defined under 15 U.S.C. 1681a, unless such data is obtained from a consumer reporting agency for one or more purposes identified in 15 U.S.C. 1681b(a);

(iii) The set of data in an application for health insurance, long-term care insurance, professional liability insurance, mortgage insurance, or life insurance;

(iv) Data relating to the physical, mental, or psychological health condition of an individual;

(v) Non-public electronic communications, including email, messaging, or chat communications, between or among users of a U.S. business's products or services if a primary purpose of such product or service is to facilitate third-party user communications;

(vi) Geolocation data collected using positioning systems, cell phone towers, or WiFi access points such as via a mobile application, vehicle GPS, other onboard mapping tool, or wearable electronic device;

(vii) Biometric enrollment data including facial, voice, retina/iris, and palm/fingerprint templates;

(viii) Data stored and processed for generating a Federal, State, Tribal, Territorial, or other government identification card;

(ix) Data concerning U.S. Government personnel security clearance status; or

(x) The set of data in an application for a U.S. Government personnel security clearance or an application for employment in a position of public trust; or

(2) Genetic information, which includes the results of an individual's genetic tests, including any related genetic sequencing data, whenever such results, in isolation or in combination with previously released or publicly available data, constitute identifiable data. Such results shall not include data derived from databases maintained by the U.S. Government and routinely provided to private parties for purposes of research. For purposes of this paragraph, ''genetic test'' shall have the meaning provided in 42 U.S.C. 300gg–91(d)(17).

Undue or unacceptable risk means those risks identified in Section 1(a)(ii) of the Executive Order.

United States person means any United States citizen; any permanent resident alien; or any entity organized under the laws of the United States or any jurisdiction within the United States (including such entity's foreign branches).

§ 7.3 Scope of Covered ICTS Transactions.

(a) This part applies only to an ICTS Transaction that:

(1) Is conducted by any person subject to the jurisdiction of the United States or involves property subject to the jurisdiction of the United States;

(2) Involves any property in which any foreign country or a national thereof has an interest (including through an interest in a contract for the provision of the technology or service);

(3) Is initiated, pending, or completed on or after January 19, 2021, regardless of when any contract applicable to the transaction is entered into, dated, or signed or when any license, permit, or authorization applicable to such transaction was granted. Any act or service with respect to an ICTS Transaction, such as execution of any provision of a managed services contract, installation of software updates, or the conducting of repairs, that occurs on or after January 19, 2021 may be deemed an ICTS Transaction within the scope of this part, even if the contract was initially entered into, or the activity commenced, prior to January 19, 2021; and

(4) Involves one of the following ICTS:

(i) ICTS that will be used by a party to a transaction in a sector designated as critical infrastructure by Presidential Policy Directive 21—Critical Infrastructure Security and Resilience, including any subsectors or subsequently designated sectors;

(ii) Software, hardware, or any other product or service integral to:

(A) Wireless local area networks, including:

(*1*) Distributed antenna systems; and

(*2*) Small-cell or micro-cell base stations;

(B) Mobile networks, including:

(*1*) eNodeB based stations;

(*2*) gNodeB or 5G new radio base stations;

(*3*) NodeB base stations;

(*4*) Home location register databases;

(*5*) Home subscriber servers;

(*6*) Mobile switching centers;

(*7*) Session border controllers; and

(*8*) Operation support systems;

(C) Satellite payloads, including:

(1) Satellite telecommunications systems;

(*2*) Satellite remote sensing systems; and

(*3*) Satellite position, navigation, and timing systems;

(D) Satellite operations and control, including:

(*1*) Telemetry, tracking, and control systems;

(*2*) Satellite control centers;

(*3*) Satellite network operations;

(*4*) Multi-terminal ground stations; and

(*5*) Satellite uplink centers;

(E) Cable access points, including:

(*1*) Core routers;

(*2*) Core networks; and

(*3*) Core switches;

(F) Wireline access points, including:

(*1*) Access infrastructure datalinks; and

(*2*) Access infrastructure digital loops;

(G) Core networking systems, including:

(*1*) Core infrastructure synchronous optical networks and synchronous digital hierarchy systems;

(*2*) Core infrastructure dense wavelength division multiplexing or optical transport network systems;

(*3*) Core infrastructure internet protocol and internet routing systems;

(*4*) Core infrastructure content delivery network systems;

(*5*) Core infrastructure internet protocol and multiprotocol label switching systems;

(*6*) Data center multiprotocol label switching routers; and

(*7*) Metropolitan multiprotocol label switching routers; or

(H) Long- and short-haul networks, including:

(*1*) Fiber optical cables; and

(*2*) Repeaters;

(iii) Software, hardware, or any other product or service integral to data hosting or computing services, to include software-defined services such as virtual private servers, that uses, processes, or retains, or is expected to use, process, or retain, sensitive personal data on greater than one million U.S. persons at any point over the twelve (12) months preceding an ICTS Transaction, including:

(A) Internet hosting services;

(B) Cloud-based or distributed computing and data storage;

(C) Managed services; and

(D) Content delivery services;

(iv) Any of the following ICTS products, if greater than one million units have been sold to U.S. persons at any point over the twelve (12) months prior to an ICTS Transaction:

(A) Internet-enabled sensors, webcams, and any other end-point surveillance or monitoring device;

(B) Routers, modems, and any other home networking device; or

(C) Drones or any other unmanned aerial system;

(v) Software designed primarily for connecting with and communicating via the internet that is in use by greater than one million U.S. persons at any point over the twelve (12) months preceding an ICTS Transaction, including:

(A) Desktop applications;

(B) Mobile applications;

(C) Gaming applications; and

(D) Web-based applications; or

(vi) ICTS integral to:

(A) Artificial intelligence and machine learning;

(B) Quantum key distribution;

(C) Quantum computing;

(D) Drones;

(E) Autonomous systems; or

(F) Advanced Robotics.

(b) This part does not apply to an ICTS Transaction that:

(1) Involves the acquisition of ICTS items by a United States person as a party to a transaction authorized under a U.S. government-industrial security program; or

(2) The Committee on Foreign Investment in the United States (CFIUS) is actively reviewing, or has reviewed, as a covered transaction or covered real estate transaction or as part of such a transaction under section 721 of the Defense Production Act of 1950, as amended, and its implementing regulations.

(c) (c) Notwithstanding the exemption in paragraph (b)(2) of this section, ICTS Transactions conducted by parties to transactions reviewed by CFIUS that were not part of the covered transaction or covered real estate transaction reviewed by CFIUS remain fully subject to this part.

§ 7.4 Determination of foreign adversaries.

(a) The Secretary has determined that the following foreign governments or foreign non-government persons have engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons and, therefore, constitute foreign adversaries solely for the purposes of the Executive Order, this rule, and any subsequent rule:

(1) The People's Republic of China, including the Hong Kong Special Administrative Region (China);

(2) Republic of Cuba (Cuba);

(3) Islamic Republic of Iran (Iran);

(4) Democratic People's Republic of Korea (North Korea);

(5) Russian Federation (Russia); and

(6) Venezuelan politician Nicolás Maduro (Maduro Regime).

(b) The Secretary's determination of foreign adversaries is solely for the purposes of the Executive Order, this rule, and any subsequent rule promulgated pursuant to the Executive Order. Pursuant to the Secretary's discretion, the list of foreign adversaries will be revised as determined to be necessary. Such revisions will be effective immediately upon publication in the **Federal Register** without prior notice or opportunity for public comment.

(c) The Secretary's determination is based on multiple sources, including:

(1) National Security Strategy of the United States;

(2) The Director of National Intelligence's 2016–2019 Worldwide Threat Assessments of the U.S. Intelligence Community;

(3) The 2018 National Cyber Strategy of the United States of America; and

(4) Reports and assessments from the U.S. Intelligence Community, the U.S. Departments of Justice, State and Homeland Security, and other relevant sources.

(d) (d) The Secretary will periodically review this list in consultation with appropriate agency heads and may add to, subtract from, supplement, or otherwise amend this list. Any amendment to this list will apply to any ICTS Transaction that is initiated, pending, or completed on or after the date that the list is amended.

§ 7.5 Effect on other laws.

Nothing in this part shall be construed as altering or affecting any other authority, process, regulation, investigation, enforcement measure, or review provided by or established under any other provision of Federal law, including prohibitions under the National Defense Authorization Act of 2019, the Federal Acquisition Regulations, or IEEPA, or any other authority of the President or the Congress under the Constitution of the United States.

§ 7.6 Amendment, modification, or revocation.

Except as otherwise provided by law, any determinations, prohibitions, or decisions issued under this part may be amended, modified, or revoked, in whole or in part, at any time.

§ 7.7 Public disclosure of records.

Public requests for agency records related to this part will be processed in accordance with the Department of Commerce's Freedom of Information Act regulations, 15 CFR part 4, or other applicable law and regulation.

Subpart B—Review of ICTS Transactions

§ 7.100 General.

In implementing this part, the Secretary of Commerce may:

(a) Consider any and all relevant information held by, or otherwise made available to, the Federal Government that is not otherwise restricted by law for use for this purpose, including:

(1) Publicly available information;

(2) Confidential business information, as defined in 19 CFR 201.6, or proprietary information;

(3) Classified National Security Information, as defined in Executive Order 13526 (December 29, 2009) and its predecessor executive orders, and Controlled Unclassified Information, as defined in Executive Order 13556 (November 4, 2010);

(4) Information obtained from state, local, tribal, or foreign governments or authorities;

(5) Information obtained from parties to a transaction, including records related to such transaction that any party uses, processes, or retains, or would be expected to use, process, or retain, in their ordinary course of business for such a transaction;

(6) Information obtained through the authority granted under sections 2(a) and (c) of the Executive Order and IEEPA, as set forth in U.S.C. 7.101;

(7) Information provided by any other U.S. Government national security body, in each case only to the extent necessary for national security purposes, and subject to applicable confidentiality and classification requirements, including the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector and the Federal Acquisitions Security Council and its designated information-sharing bodies; and

(8) Information provided by any other U.S. Government agency, department, or other regulatory body, including the Federal Communications Commission, Department of Homeland Security, and Department of Justice;

(b) Consolidate the review of any ICTS Transactions with other transactions already under review where the Secretary determines that the transactions raise the same or similar issues, or that are otherwise properly consolidated;

(c) In consultation with the appropriate agency heads, in determining whether an ICTS Transaction involves ICTS designed, developed, manufactured, or supplied, by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, consider the following:

(1) Whether the person or its suppliers have headquarters, research, development, manufacturing, test, distribution, or service facilities, or other operations in a foreign country, including one controlled by, or subject to the jurisdiction of, a foreign adversary;

(2) Ties between the person—including its officers, directors or similar officials, employees, consultants, or contractors—and a foreign adversary;

(3) Laws and regulations of any foreign adversary in which the person is headquartered or conducts operations, including research and development, manufacturing, packaging, and distribution; and

(4) Any other criteria that the Secretary deems appropriate;

(d) In consultation with the appropriate agency heads, in determining whether an ICTS Transaction poses an undue or unacceptable risk, consider the following:

(1) Threat assessments and reports prepared by the Director of National Intelligence pursuant to section 5(a) of the Executive Order;

(2) Removal or exclusion orders issued by the Secretary of Homeland Security, the Secretary of Defense, or the Director of National Intelligence (or their designee) pursuant to recommendations of the Federal Acquisition Security Council, under 41 U.S.C. 1323;

(3) Relevant provisions of the Defense Federal Acquisition Regulation (48 CFR ch. 2) and the Federal Acquisition Regulation (48 CFR ch. 1), and their respective supplements;

(4) The written assessment produced pursuant to section 5(b) of the Executive Order, as well as the entities, hardware, software, and services that present vulnerabilities in the United States as determined by the Secretary of Homeland Security pursuant to that section;

(5) Actual and potential threats to execution of a ''National Critical Function'' identified by the Department of Homeland Security Cybersecurity and Infrastructure Security Agency;

(6) The nature, degree, and likelihood of consequence to the United States public and private sectors that could occur if ICTS vulnerabilities were to be exploited; and

(7) Any other source or information that the Secretary deems appropriate; and

(e) In the event the Secretary finds that unusual and extraordinary harm to the national security of the United States is likely to occur if all of the procedures specified herein are followed, the Secretary may deviate from these procedures in a manner tailored to protect against that harm.

§ 7.101 Information to be furnished on demand.

(a) Pursuant to the authority granted to the Secretary under sections 2(a), 2(b), and 2(c) of the Executive Order and IEEPA, persons involved in an ICTS Transaction may be required to furnish under oath, in the form of reports or otherwise, at any time as may be required by the Secretary, complete information relative to any act or transaction, subject to the provisions of this part. The Secretary may require that such reports include the production of any books, contracts, letters, papers, or other hard copy or electronic documents relating to any such act, transaction, or property, in the custody or control of the persons required to make such reports. Reports with respect to transactions may be required either before, during, or after such transactions. The Secretary may, through any person or agency, conduct investigations, hold hearings, administer oaths, examine witnesses, receive evidence, take depositions, and require by subpoena the attendance and testimony of witnesses and the production of any books, contracts, letters, papers, and other hard copy or documents relating to any matter under investigation, regardless of whether any report has been required or filed in connection therewith.

(b) For purposes of paragraph (a) of this section, the term ''document'' includes any written, recorded, or graphic matter or other means of preserving thought or expression (including in electronic format), and all tangible things stored in any medium from which information can be processed, transcribed, or obtained directly or indirectly, including correspondence, memoranda, notes, messages, contemporaneous communications such as text and instant messages, letters, emails, spreadsheets, metadata, contracts, bulletins, diaries, chronological data, minutes, books, reports, examinations, charts, ledgers, books of account, invoices, air waybills, bills of lading, worksheets, receipts, printouts, papers, schedules, affidavits, presentations, transcripts, surveys, graphic representations of any kind, drawings, photographs, graphs, video or sound recordings, and motion pictures or other film.

(c) Persons providing documents to the Secretary pursuant to this section must produce documents in a format useable to the Department of Commerce, which may be detailed in the request for documents or otherwise agreed to by the parties.

§ 7.102 Confidentiality of information.

(a) Information or documentary materials, not otherwise publicly or commercially available, submitted or filed with the Secretary under this part will not be released publicly except to the extent required by law.

(b) The Secretary may disclose information or documentary materials that are not otherwise publicly or commercially available and referenced in paragraph (a) in the following circumstances:

(1) Pursuant to any administrative or judicial proceeding;

(2) Pursuant to an act of Congress;

(3) Pursuant to a request from any duly authorized committee or subcommittee of Congress;

(4) Pursuant to any domestic governmental entity, or to any foreign governmental entity of a United States ally or partner, information or documentary materials, not otherwise publicly or commercially available and important to the national security analysis or actions of the Secretary, but only to the extent necessary for national security purposes, and subject to appropriate confidentiality and classification requirements;

(5) Where the parties or a party to a transaction have consented, the information or documentary material that are not otherwise publicly or commercially available may be disclosed to third parties; and

(6) Any other purpose authorized by law.

(c) This section shall continue to apply with respect to information and documentary materials that are not otherwise publicly or commercially available and submitted to or obtained by the Secretary even after the Secretary issues a final determination pursuant to § 7.109 of this part.

(d) The provisions of 18 U.S.C. 1905, relating to fines and imprisonment and other penalties, shall apply with respect to the disclosure of information or documentary material provided to the Secretary under these regulations.

§ 7.103 Initial review of ICTS Transactions.

(a) Upon receipt of any information identified in § 7.100(a), upon written request of an appropriate agency head, or at the Secretary's discretion, the Secretary may consider any referral for review of a transaction (referral).

(b) In considering a referral pursuant to paragraph (a), the Secretary shall assess whether the referral falls within the scope of § 7.3(a) of this part and involves ICTS designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of a foreign adversary, and determine whether to:

(1) Accept the referral and commence an initial review of the transaction;

(2) Request additional information, as identified in § 7.100(a), from the referring entity regarding the referral; or

(3) Reject the referral.

(c) Upon accepting a referral pursuant to paragraph (b) of this section, the Secretary shall conduct an initial review of the ICTS Transaction and assess whether the ICTS Transaction poses an undue or unacceptable risk, which may be determined by evaluating the following criteria:

(1) The nature and characteristics of the information and communications technology or services at issue in the ICTS Transaction, including technical capabilities, applications, and market share considerations;

(2) The nature and degree of the ownership, control, direction, or jurisdiction exercised by the foreign adversary over the design, development, manufacture, or supply at issue in the ICTS Transaction;

(3) The statements and actions of the foreign adversary at issue in the ICTS Transaction;

(4) The statements and actions of the persons involved in the design, development, manufacture, or supply at issue in the ICTS Transaction;

(5) The statements and actions of the parties to the ICTS Transaction;

(6) Whether the ICTS Transaction poses a discrete or persistent threat;

(7) The nature of the vulnerability implicated by the ICTS Transaction;

(8) Whether there is an ability to otherwise mitigate the risks posed by the ICTS Transaction;

(9) The severity of the harm posed by the ICTS Transaction on at least one of the following:

(i) Health, safety, and security;

(ii) Critical infrastructure;

(iii) Sensitive data;

(iv) The economy;

(v) Foreign policy;

(vi) The natural environment; and

(vii) National Essential Functions (as defined by Federal Continuity Directive-2 (FCD–2)); and

(10) The likelihood that the ICTS Transaction will in fact cause threatened harm.

(d) If the Secretary finds that an ICTS Transaction does not meet the criteria of paragraph (b) of this section:

(1) The transaction shall no longer be under review; and

(2) Future review of the transaction shall not be precluded, where additional information becomes available to the Secretary.

§ 7.104 First interagency consultation.

Upon finding that an ICTS Transaction likely meets the criteria set forth in § 7.103(c) during the initial review under § 7.103, the Secretary shall notify the appropriate agency heads and, in consultation with them, shall determine whether the ICTS Transaction meets the criteria set forth in § 7.103(c).

§ 7.105 Initial determination.

(a) If, after the consultation required by § 7.104, the Secretary determines that the ICTS Transaction does not meet the criteria set forth in § 7.103(c):

(1) The transaction shall no longer be under review; and

(2) Future review of the transaction shall not be precluded, where additional information becomes available to the Secretary.

(b) If, after the consultation required by § 7.104, the Secretary determines that the ICTS Transaction meets the criteria set forth in § 7.103(c), the Secretary shall:

(1) Make an initial written determination, which shall be dated and signed by the Secretary, that:

(i) Explains why the ICTS Transaction meets the criteria set forth in § 7.103(c); and

(ii) Sets forth whether the Secretary has initially determined to prohibit the ICTS Transaction or to propose mitigation measures, by which the ICTS Transaction may be permitted; and

(2) Notify the parties to the ICTS Transaction either through publication in the **Federal Register** or by serving a copy of the initial determination on the parties via registered U.S. mail, facsimile, and electronic transmission, or third-party commercial carrier, to an addressee's last known address or by personal delivery.

(c) Notwithstanding the fact that the initial determination to prohibit or propose mitigation measures on an ICTS Transaction may, in whole or in part, rely upon classified national security information, or sensitive but unclassified information, the initial determination will contain no classified national security information, nor reference thereto, and, at the Secretary's discretion, may not contain sensitive but unclassified information.

§ 7.106 Recordkeeping requirement.

Upon notification that an ICTS Transaction is under review or that an initial determination concerning an ICTS Transaction has been made, a notified person must immediately take steps to retain any and all records relating to such transaction.

§ 7.107 Procedures governing response and mitigation.

Within 30 days of service of the Secretary's notification pursuant to § 7.105, a party to an ICTS Transaction may respond to the Secretary's initial determination or assert that the circumstances resulting in the initial determination no longer apply, and thus seek to have the initial determination rescinded or mitigated pursuant to the following administrative procedures:

(a) A party may submit arguments or evidence that the party believes establishes that insufficient basis exists for the initial determination, including any prohibition of the ICTS Transaction;

(b) A party may propose remedial steps on the party's part, such as corporate reorganization, disgorgement of control of the foreign adversary, engagement of a compliance monitor, or similar steps, which the party believes would negate the basis for the initial determination;

(c) Any submission must be made in writing;

(d) A party responding to the Secretary's initial determination may request a meeting with the Department, and the Department may, at its discretion, agree or decline to conduct such meetings prior to making a final determination pursuant to § 7.109;

(e) This rule creates no right in any person to obtain access to information in the possession of the U.S. Government that was considered in making the initial determination to prohibit the ICTS Transaction, to include classified national security information or sensitive but unclassified information; and

(f) (f) If the Department receives no response from the parties within 30 days after service of the initial determination to the parties, the Secretary may determine to issue a final determination without the need to engage in the consultation process provided in section 7.108 of this rule.

§ 7.108 Second interagency consultation.

(a) Upon receipt of any submission by a party to an ICTS Transaction under § 7.107, the Secretary shall consider

whether and how any information provided—including proposed mitigation measures—affects an initial determination of whether the ICTS Transaction meets the criteria set forth in § 7.103(c).

(b) After considering the effect of any submission by a party to an ICTS Transaction under § 7.107 consistent with paragraph (a), the Secretary shall consult with and seek the consensus of all appropriate agency heads prior to issuing a final determination as to whether the ICTS Transaction shall be prohibited, not prohibited, or permitted pursuant to the adoption of negotiated mitigation measures.

(c) If consensus is unable to be reached, the Secretary shall notify the President of the Secretary's proposed final determination and any appropriate agency head's opposition thereto.

(d) After receiving direction from the President regarding the Secretary's proposed final determination and any appropriate agency head's opposition thereto, the Secretary shall issue a final determination pursuant to § 7.109.

§ 7.109 Final determination.

(a) For each transaction for which the Secretary issues an initial determination that an ICTS Transaction is prohibited, the Secretary shall issue a final determination as to whether the ICTS Transaction is:

(1) Prohibited;

(2) Not prohibited; or

(3) Permitted, at the Secretary's discretion, pursuant to the adoption of negotiated mitigation measures.

(b) Unless the Secretary determines in writing that additional time is necessary, the Secretary shall issue the final determination within 180 days of accepting a referral and commencing the initial review of the ICTS Transaction pursuant to § 7.103.

(c) If the Secretary determines that an ICTS Transaction is prohibited, the Secretary shall have the discretion to direct the least restrictive means necessary to tailor the prohibition to address the undue or unacceptable risk posed by the ICTS Transaction.

(d) The final determination shall:

(1) Be written, signed, and dated;

(2) Describe the Secretary's determination;

(3) Be unclassified and contain no reference to classified national security information;

(4) Consider and address any information received from a party to the ICTS Transaction;

(5) Direct, if applicable, the timing and manner of the cessation of the ICTS Transaction;

(6) Explain, if applicable, that a final determination that the ICTS Transaction is not prohibited does not preclude the future review of transactions related in any way to the ICTS Transaction;

(7) Include, if applicable, a description of the mitigation measures agreed upon by the party or parties to the ICTS Transaction and the Secretary; and

(8) State the penalties a party will face if it fails to comply fully with any mitigation agreement or direction, including violations of IEEPA, or other violations of law.

(e) The written, signed, and dated final determination shall be sent to:

(1) The parties to the ICTS Transaction via registered U.S. mail and electronic mail; and

(2) The appropriate agency heads.

(f) The results of final written determinations to prohibit an ICTS Transaction shall be published in the **Federal Register**. The publication shall omit any confidential business information.

§ 7.110 Classified national security information.

In any review of a determination made under this part, if the determination was based on classified national security information, such information may be submitted to the reviewing court *ex parte* and *in camera.* This section does not confer or imply any right to review in any tribunal, judicial or otherwise.

Subpart C—Enforcement

§ 7.200 Penalties.

(a) Maximum penalties.

(1) *Civil penalty.* A civil penalty not to exceed the amount set forth in Section 206 of IEEPA, 50 U.S.C. 1705, may be imposed on any person who violates, attempts to violate, conspires to violate, or causes any knowing violation of any final determination or direction issued pursuant to this part, including any violation of a mitigation agreement issued or other condition imposed under this part. IEEPA provides for a maximum civil penalty not to exceed the greater of $250,000, subject to inflationary adjustment, or an amount that is twice the amount of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(2) *Criminal penalty.* A person who willfully commits, willfully attempts to commit, or willfully conspires to commit, or aids and abets in the commission of a violation of any final determination, direction, or mitigation agreement shall, upon conviction of a violation of IEEPA, be fined not more than $1,000,000, or if a natural person, may be imprisoned for not more than 20 years, or both.

(3) The Secretary may impose a civil penalty of not more than the maximum statutory penalty amount, which, when adjusted for inflation, is $307,922, or twice the amount of the transaction that is the basis of the violation, per violation on any person who violates any final determination, direction, or mitigation agreement issued pursuant to this part under IEEPA.

(i) Notice of the penalty, including a written explanation of the penalized conduct specifying the laws and regulations allegedly violated and the amount of the proposed penalty, and notifying the recipient of a right to make a written petition within 30 days as to why a penalty should not be imposed, shall be served on the notified party or parties.

(ii) The Secretary shall review any presentation and issue a final administrative decision within 30 days of receipt of the petition.

(4) Any civil penalties authorized in this section may be recovered in a civil action brought by the United States in U.S. district court.

(b) Adjustments to penalty amounts.

(1) The civil penalties provided in IEEPA are subject to adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note).

(2) The criminal penalties provided in IEEPA are subject to adjustment pursuant to 18 U.S.C. 3571.

(c) The penalties available under this section are without prejudice to other penalties, civil or criminal, available under law. Attention is directed to 18 U.S.C. 1001, which provides that whoever, in any matter within the jurisdiction of any department or agency in the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry, shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 738, 740, 742, 748, 750, 772, 774

[Docket No. 201221–0350]

RIN 0694–AI33

Implementation in the Export Administration Regulations of the United States' Rescission of Sudan's Designation as a State Sponsor of Terrorism

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to implement the rescission of Sudan's designation as a State Sponsor of Terrorism (SSOT). The Secretary of State rescinded this designation effective December 14, 2020 in accordance with established statutory procedures, including the President's October 26, 2020 submission to Congress of a report justifying the rescission and certifying Sudan had not provided any support for acts of international terrorism during the preceding six month period and that Sudan had provided assurances that it would not support acts of international terrorism in the future. Accordingly, BIS amends the EAR by removing Anti-Terrorism (AT) controls on the country and by removing Sudan from Country Group E:1 (Terrorist supporting countries). These actions render the country eligible for a general 25 percent *de minimis* level. As a consequence of these actions, as well as the addition of the country to Country Group B, Sudan is also potentially eligible for several new license exceptions under the EAR. However, pursuant to this rule, two license exceptions will be unavailable for exports and reexports to Sudan. BIS also makes conforming amendments in other applicable EAR provisions as part of this rule.

DATES: This rule is effective January 14, 2021.

FOR FURTHER INFORMATION CONTACT: Foreign Policy Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Compliance, U.S. Department of Commerce, by email at *Foreign.Policy@bis.doc.gov,* or by phone at 202–482–4252.

SUPPLEMENTARY INFORMATION:

Background

I. Brief History of Anti-Terrorism Controls on Sudan

A. Overview

Sections 1753, 1754, and 1768 of the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852, provide the legal authority for BIS's AT controls on SSOT destinations. On August 12, 1993, in accordance with Section 6(j) of the Export Administration Act of 1979, then codified at 50 U.S.C. App. 2405(j), the Secretary of State designated Sudan as a SSOT, citing his determination that Sudan, then led by Omar al-Bashir, had repeatedly provided support for acts of international terrorism. *See* 58 FR 52523 (Oct. 8, 1993). Consistent with this designation, BIS imposed AT controls on Sudan in accordance with the Export Administration Act of 1979, as amended, formerly codified at 50 U.S.C. Sections 4601–4623, the legal authority at the time for BIS's export control regime. 61 FR 12714 (March 25, 1996). Pursuant to § 742.10 (Anti-Terrorism) of the EAR, a license was also required for the export or reexport to Sudan of nearly all items on the Commerce Control List (CCL), Supp. No. 1 to part 774 of the EAR. License applications for such exports and reexports were reviewed under a general policy of denial. Consistent with Sudan's designation as a SSOT, the country was also placed in Country Group E (now Country Group E:1): (terrorist-supporting countries) in Supplement No. 1 to part 740 of the EAR and made subject to a 10 percent *de minimis* threshold for controlled U.S.-origin content (*see* § 734.4 of the EAR). Most license exceptions were also unavailable for exports and reexports of CCL items destined for Sudan due to its status as an ''E:1'' country.

B. Changes to Certain Licensing Policies and License Exceptions

Notwithstanding the general policy of denial set forth in § 742.10 of the EAR, prior to the publication of this rule, BIS reviewed certain categories of CCL items proposed for export or reexport to Sudan under less stringent review policies. In particular, applications for the export and reexport of medical items to Sudan were subject to case-by-case review. Over time, consistent with U.S. foreign policy initiatives, BIS instituted case-by case review or a general policy of approval for additional categories of items. For example, acting in coordination with the Department of the Treasury's Office of Foreign Assets Control (OFAC), in order to promote the free flow of communications among the Sudanese people, in February 2015, BIS amended § 742.10 to establish a case-by-case review policy for telecommunication equipment and associated items for civil end use, including items useful for the development of civil telecommunications infrastructure. *See* 80 FR 8520 (Feb. 18, 2015). Two years later, in January 2017, in response to positive developments in the U.S.-Sudan bilateral relationship, BIS amended § 742.10, again in coordination with OFAC, to institute a general policy of approval for certain items, including parts, components, and equipment, that are controlled on the CCL solely for AT reasons and are intended to ensure the safety of civil aviation or the safe operation of fixed-wing commercial passenger aircraft, as well as items controlled on the CCL solely for AT reasons intended for use in the inspection and repair, among other activities, of railroads in Sudan. *See* 82 FR 4781 (Jan. 17, 2017).

BIS also made changes to license exception eligibility in connection with foreign policy considerations and developments. In February 2005, BIS amended License Exception Temporary imports, exports, reexports, and transfers (in-country) (TMP) to permit temporary exports to Sudan of certain computers, communication devices, and global positioning devices as ''tools of trade'' by employees and staff of certain organizations engaged in humanitarian work in Sudan. *See* 70 FR 8257 (Feb. 18, 2005) and 70 FR 9703 (Feb. 28, 2005). In February 2008, BIS amended TMP again in connection with exports and reexports destined for Sudan, including by expanding the number of activities and commodities eligible under the ''tools of trade'' category, an action taken in part to reflect the changing nature of humanitarian work undertaken in the country by nongovernmental organizations. *See* 73 FR 10668 (Feb. 28, 2008). In January 2017, as part of the same regulatory action described above that created a more favorable license review policy for certain items for use in civil aviation and railroad infrastructure in Sudan, BIS made License Exception Consumer Communications Devices (CCD) eligible for the export and reexport of certain consumer communications devices to Sudan.

C. Dual Licensing—BIS and OFAC

For nearly twenty years, licenses from both BIS and OFAC were required to export and reexport items on the CCL to Sudan as a consequence of broad trade restrictions imposed in November 1997,

including restrictions on U.S. persons' exports of U.S.-origin items to Sudan. Pursuant to Executive Order (E.O.) 13067 of November 3, 1997, the U.S. Government imposed a comprehensive trade embargo in response to the Government of Sudan's policies and activities, including its support for terrorism, efforts to destabilize neighboring governments, and the prevalence of human rights violations. Specifically, this E.O. blocked the property of the Government of Sudan subject to U.S. jurisdiction and imposed restrictions on U.S. persons' activities with respect to Sudan. On July 1, 1998, OFAC published the Sudanese Sanctions Regulations, 31 CFR part 538 (SSR), implementing these restrictions. *See* 63 FR 35809 (July 1, 1998). Notably, as implemented in the SSR, E.O. 13067 required the Department of the Treasury to restrict the export or reexport to Sudan of goods, technology, or services from the U.S. or by a U.S. person, wherever located, or ''requiring the issuance of a license by a Federal agency.'' *See* Section 2(b) of E.O. 13067 and 31 CFR 538.205 (2017). This language provided the basis for a dual licensing regime pursuant to which the export and reexport of CCL items to Sudan required authorization by both BIS and OFAC.

On October 13, 2006, President George W. Bush issued E.O. 13412 following the enactment of the Darfur Peace and Accountability Act of 2006, a response to continuing atrocities in Sudan's Darfur Region. This E.O. exempted certain regions in Sudan from several prohibitions established pursuant to E.O. 13067, including those applicable to exports, thereby effectively narrowing the scope of exports and reexports of CCL items subject to dual licensing.

D. Termination of the Embargo

In recognition of positive actions sustained by the Government of Sudan in several areas, including enhanced cooperation with the U.S. on counterterrorism efforts, effective October 12, 2017, President Donald J. Trump revoked Sections 1 and 2 of E.O. 13067, along with E.O. 13412 in its entirety, pursuant to E.O. 13761 of January 13, 2017, as amended by E.O. 13804 of July 11, 2017. Consequently, as of October 12, 2017, U.S. persons were no longer prohibited from engaging in transactions with respect to Sudan, including exports and reexports of items destined for Sudan, or with the Government of Sudan, that had been prohibited by the SSR. These actions generally established BIS as the sole licensing agency for exports and reexports of items subject to the EAR to Sudan. To reflect the revocation of these authorities, OFAC removed the SSR from the Code of Federal Regulations on June 29, 2018. OFAC only retained jurisdiction over certain exports and reexports of agricultural commodities, medicine, and medical devices destined for Sudan pursuant to the Trade Sanctions Reform and Export Enhancement Act of 2000, 22 U.S.C. Section 7201 *et seq.,* and authorized the export and reexport of such items through a general license incorporated into Section 596.506 of the Terrorism List Governments Sanctions Regulations, 31 CFR part 596.

II. Rescission-Related Developments

Once a country is designated a State Sponsor of Terrorism, the designation remains in effect until it is rescinded in accordance with applicable law. On October 26, 2020, the President submitted to Congress the statutorily-required report justifying the rescission, and certifying that Sudan had not provided any support for acts of international terrorism during the preceding six month period and that Sudan had provided assurances that it would not support acts of international terrorism in the future. Effective December 14, 2020, the Secretary of State rescinded Sudan's designation as a SSOT, in accordance with Sections 1754(c) and 1768(c) of the National Defense Authorization Act for Fiscal Year 2019 (50 U.S.C. 4813(c) and 4826(c)), and in satisfaction of the provisions of Section 620A(c) of the Foreign Assistance Act of 1961 (22. U.S.C. 2371(c)), Section 40(f) of the Arms Export Control Act of 1976 (22 U.S.C. 2708(f)), and, to the extent applicable, section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), as continued in effect by Executive Order 13222 of August 17, 2001. BIS is publishing this rule amending the EAR to implement the rescission.

On October 23, 2020, the date that President Trump notified Congress of his intention to rescind the SSOT designation, the White House heralded the development as marking the advancement of the United States' bilateral relationship with Sudan and the ongoing efforts of the civilian-led Sudanese transitional government toward democracy and the achievement of regional peace. *See* October 23, 2020 Statement of the Press Secretary on Sudan, available at *https://www.whitehouse.gov/briefings-statements/statement-press-secretary-sudan/.* As noted by Secretary of State Michael R. Pompeo, President's Trump decision ''reflect[ed] the . . . transitional government's sustained efforts to make sure there is no support for acts of international terrorism.'' *See* November 2, 2020 State Department Press Statement, ''Sudan Making Progress,'' available at *https://www.state.gov/sudan-making-progress/.*

III. Specific Amendments in This Rule

A. Overview

Consistent with the Secretary of State's rescission of Sudan's designation as a SSOT, effective December 14, 2020, this rule removes AT controls on the country and makes conforming changes to various EAR provisions. First, this rule removes Sudan from Country Group E:1 in Supplement No. 1 to part 740, the Country Group placement for terrorist supporting countries. This action raises the *de minimis* level from 10 percent to 25 percent for most foreign-origin items located abroad that are destined for Sudan. These changes make Sudan potentially eligible for new license exceptions under the EAR. Second, this rule removes EAR § 742.10 (Anti-Terrorism: Sudan) in its entirety. Additionally, it adds Sudan to Country Group B in Supplement No. 1 to part 740. As a general matter, countries in Country Group B are eligible for a greater number of license exceptions, and they are subject to relatively less stringent license review policies. However, pursuant to this rule, two license exceptions, License Exception Shipments to Country Group B countries (GBS) (§ 740.4) and License Exception Technology and software under restriction (TSR) (§ 740.6), will be unavailable for exports and reexports to Sudan. Moreover, Sudan's continued placement in Country Group D:5 (U.S. Arms Embargoed Countries) impacts the availability of certain license exceptions in connection with items controlled under certain Export Control Classification Numbers (ECCNs). Finally, this rule makes conforming amendments to parts 734, 738, 748, 750, 772 and 774 of the EAR, and additional amendments to parts 740 and 742, consistent with the removal of AT controls, the country's removal from Country Group E:1, and addition to Country Group B. Other previously-existing license requirements remain intact.

Conforming changes include the removal of all references to Sudan from Supplement No. 2 to part 742, which specifies contract sanctity dates and related licensing review policies for certain items destined for countries subject to AT controls. This rule also amends License Exceptions GBS and

TSR set forth in part 740 (License Exceptions) to state that they are not available for Sudan. Additionally, it amends part 740 to remove references to Sudan from three license exceptions. As detailed below, these license exceptions had authorized exports and reexports of certain CCL items to Sudan notwithstanding the imposition of AT controls and the country's related placement in Country Group E:1.

B. Highlights of Key Changes

1. Changes to the Applicable De Minimis Level for Controlled U.S.-Origin Content

The EAR apply to foreign-made items located outside the United States that contain more than a *de minimis* amount of controlled U.S.-origin content by value. For most items, the *de minimis* level is 10 percent if the destination of the foreign-made item is in Country Group E:1 and 25 percent if the destination is in any other Country Group. The removal of Sudan from Country Group E:1 raises the *de minimis* level to 25 percent for most items destined for Sudan. Additionally, this 25 percent *de minimis* level will apply to certain foreign-made encryption items destined for Sudan that meet the criteria specified in § 734.4(b)(1) of the EAR. Foreign-made items destined for Sudan that incorporate U.S.-origin 9x515 or ''600 series'' paragraphs a. through .x content will continue to be subject to the EAR regardless of the level of U.S.-origin content, *i.e.,* there is no *de minimis* level for such items when they are destined for Sudan.

2. Applicable Controls and Related Licensing Policies

Sudan will be subject to licensing requirements that apply to the export and reexport of items on the multilateral export control regime lists (the Wassenaar Arrangement, the Nuclear Suppliers Group, the Australia Group and the Missile Technology Control Regime) and sensitive items controlled unilaterally for Crime Control (CC) or Regional Stability (RS) reasons. These license requirements are set forth in part 742 of the EAR and are reflected in the relevant columns of the Country Chart in Supplement No. 1 to part 738 of the EAR. (*See* ''Xs'' reflecting the applicability of various multilateral and unilateral controls on Sudan.) Other categories of items that are controlled for reasons not included on the Country Chart *(e.g.,* encryption (EI) and Chemical Weapons (CW)) will also require a license for export or reexport to Sudan. End User and End-Use-based controls set forth in part 744 of the EAR will also continue to apply. BIS will review license applications for exports or reexports to Sudan on a case-by-case basis pursuant to applicable licensing policies set forth in parts 742 and 744, or elsewhere in the EAR. Exporters should also be aware that the United States continues to maintain an arms embargo on Sudan, as implemented in Country Group D:5, which also implements the United Nations arms embargo, imposed in 2004, that applies to certain items controlled for United Nations (UN) reasons that are destined for the Darfur region in Sudan, as implemented in § 746.1 of the EAR.

3. Changes to License Exceptions

Consistent with the removal of AT controls on Sudan (and the related removal of the country from Country Group E:1), BIS is amending four license exceptions that make specific reference to Sudan or to Sudanese nationals. Through revising three of these license exceptions to reflect policy changes that occurred following Sudan's designation as a SSOT, BIS had authorized certain categories of transactions that were destined for Sudan notwithstanding the imposition of AT controls and the country's related placement in Country Group E:1. BIS also removes restrictions on releases to Sudanese nationals of technology and source code pertaining to computers from a fourth license exception.

License Exception Computers (APP)

Sudan is removed from § 740.7, paragraph (b)(2)(ii), which restricts technology and source code from release to nationals of Country Groups E:1 and E:2. The country is added to paragraph (d)(1) (Computer Tier 3 destinations), which will permit the release of technology and source code to Sudanese nationals up to the prescribed limit.

License Exception Temporary Imports, Exports, Reexports, and Transfers (In-Country) (TMP)

Paragraph (a)(2) of § 740.9, which referred to tools of the trade (as identified in § 740.19(b)) as exempted from paragraph (a)(1) restrictions on Country Group E:1 when destined for Sudan, is no longer applicable and is deleted.

License Exception Additional Permissive Reexports (APR)

Paragraph (i) of § 740.16, which authorized certain exports and reexports of Anti-Terrorism controlled items to Sudan, is no longer applicable and is deleted.

License Exception Consumer Communications Devices (CCD)

Section 740.19 (Consumer Communications Devices) no longer requires any reference to Sudan, as the eligible commodities and software specified therein may now be exported and reexported (barring end-use or end-user restrictions) to Sudan, including to the Sudanese Government. In light of the U.S. Government's ''unblocking'' of the Government of Sudan effective October 2017, the license exception's reference to restrictions on the Government of Sudan is inapplicable. This rule consequently removes the reference to Sudan in paragraph (a), and in the introductory text to paragraph (b), which identified Sudan as an eligible destination for this license exception. It also removes paragraph (c)(iii), which identified the Government of Sudan as an ineligible end-user for the license exception. Additionally, this rule removes altogether paragraph (b)(18), which permitted the export and reexport of items controlled under Export Control Classification Number 7A994 to Sudan only.

4. Availability of Other License Exceptions

As an E:1 country, Sudan was eligible for only a limited number of license exceptions. Many license exceptions contain restrictions that apply to countries in Country Group E:1 or to nationals of such countries. As a consequence of Sudan's removal from Country Group E:1, Sudan and/or Sudanese nationals are newly eligible for several license exceptions. No changes are required to the text of these license exceptions, as they do not refer specifically to Sudan or to Sudanese nationals. Additionally, as noted above, Sudan's addition to Country Group B by this rule makes the country potentially available for a broader range of license exceptions. However, BIS has determined that exports and reexports to Sudan are not eligible for License Exceptions GBS and TSR. This rule makes conforming changes in part 740 consistent with that policy. Specifically, amendments in §§ 740.4 and 740.6 clearly set forth that License Exceptions GBS and TSR, respectively, are unavailable for Sudan. As with all license exceptions, a specific transaction must meet all enumerated criteria, and persons should ensure that the restrictions set forth in § 740.2 (Restrictions on all license exceptions) do not apply. In particular, persons should be aware of limitations on the availability of license exceptions for exports and reexports to Sudan of items

in a 9x515 or ''600 series'' ECCN as set forth in paragraphs (a)(12) and (13) of § 740.2 that stem from Sudan's placement in Country Group D:5.

5. Other U.S. Government Regulatory Obligations

The amendments to the EAR made in this final rule do not apply to regulatory requirements administered by other U.S. Government agencies, such as OFAC and the Department of State's Directorate of Defense Trade Controls. In particular, U.S. persons should be aware of restrictions that may apply to transactions involving the Darfur region of Sudan. On October 30, 2020, President Trump continued in effect the national emergency initially declared with respect to the Government of Sudan in E.O. 13067, as expanded by subsequent E.O.s, including E.O. 13400 of April 26, 2006, due to violence in Sudan's Darfur region. *See* Presidential Notice, 85 FR 69463 (Nov. 2, 2020). OFAC administers sanctions on individuals and entities in connection with the conflict in Darfur based on this national emergency. *See* Darfur Sanctions Regulations, 31 CFR part 546. OFAC may also designate Sudanese persons under authorities apart from E.O. 13067 and E.O. 13400 and add such persons to the list of Specially Designated Nationals and Blocked Persons (SDN List), available at *https://www.treasury.gov/ofac.* Additional information regarding OFAC's sanctions programs may be located at *https://www.treasury.gov/ofac.*

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

2. This final rule is not subject to the requirements of E.O. 13771 (82 FR 9339 (February 3, 2017)) because it is issued with respect to a national security function of the United States. In particular, this rule implements an important U.S. foreign policy change, the rescission of Sudan's designation as a State Sponsor of Terrorism, that is closely linked with U.S. national security and regional security objectives. The amendments to the EAR made by this rule are consistent with the rescission and therefore serve U.S. foreign policy and national security interests.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

6. Notwithstanding any other provision of law, no person may be required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves a collection currently approved by OMB under control number 0694–0088, Simplified Network Application Processing System. The collection includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission for a total burden estimate of 31,878 hours. BIS expects the burden hour estimates associated with this collection to decrease slightly, as the removal of Anti-terrorism controls on Sudan should result in the submission of fewer license applications. Any comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, should be sent within 30 days of publication of this notice to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

List of Subjects

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Parts 738 and 772

Exports.

15 CFR Parts 740, 748 and 750

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 742

Exports, Terrorism.

15 CFR 746

Exports, Reporting and recordkeeping requirements.

15 CFR Parts 774

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, parts 734, 738, 740, 742, 748, 750, 772, 774 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 1. The authority citation for part 734 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 12, 2019, 84 FR 61817, 3 CFR, 2019 Comp., p. 479.

§ 734.4 [Amended]

■ 2. Amend § 734.4 by removing ''Sudan,'' from paragraph (a)(1).

PART 738—COMMERCE CONTROL LIST OVERVIEW AND THE COUNTRY CHART

■ 3. The authority citation for part 738 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824;

50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

Supplement No. 1 to Part 738 [Amended]

■ 4. In Supplement No. 1 to part 738, the entry for ''Sudan [1]'' is amended by removing the ''X'' from Anti-Terrorism Columns 1 and 2.

PART 740—LICENSE EXCEPTIONS

■ 5. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 6. Section 740.4 is revised to read as follows:

§ 740.4 Shipments to Country Group B countries (GBS).

License Exception GBS authorizes exports and reexports to Country Group B (see Supplement No. 1 to part 740), except Sudan and Ukraine, of those commodities where the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) indicates a license requirement to the ultimate destination for national security reasons only and identified by ''GBS—Yes'' on the CCL. See § 743.1 of the EAR for reporting requirements for exports of certain commodities under License Exception GBS.

■ 7. Section 740.6 is amended by revising paragraph (a) introductory text to read as follows:

§ 740.6 Technology and software under restriction (TSR).

(a) *Scope.* License Exception TSR permits exports and reexports of technology and software where the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) indicates a license requirement to the ultimate destination for national security reasons only and identified by ''TSR—Yes'' in entries on the CCL, provided the software or technology is destined to Country Group B, except Sudan and Ukraine. (See Supplement No. 1 to part 740.) A written assurance is required from the consignee before exporting or reexporting under this License Exception.

* * * * *

§ 740.7 [Amended]

■ 8. Amend § 740.7 by

■ a. Removing ''Sudan,'' from paragraph (b)(2)(ii); and

■ b. Adding ''Sudan,'' between ''Serbia,'' and ''Tajikistan,'' in paragraph (d)(1).

§ 740.9 [Amended]

■ 9. Amend § 740.9 by

■ a. Removing and reserving paragraph (a)(2);

■ b. Removing ''Sudan,'' from paragraph (a)(9)(i); and

■ c. In paragraph (c)(2), removing the phrase '',and Sudan'' and adding ''and'' in front of ''Iran''.

§ 740.16 [Amended]

■ 10. Amend § 740.16 by removing and reserving paragraph (i).

§ 740.19 [Amended]

■ 11. Amend § 740.19 by

■ a. Removing ''or Sudan'' from paragraphs (a), (b), and (c)(i);

■ b. Removing paragraph (b)(18); and

■ c. Removing and reserving paragraph (c)(iii).

■ 12. Amend Supplement No. 1 to part 740 by:

■ a. Amending the ''Country Group B'' table, by adding Sudan in alphabetical order.

■ b. Revising the ''Country Group E [1]'' table.

The revision reads as follows:

Supplement No. 1 to Part 740

* * * * *

COUNTRY GROUP E [1]

Country	[E:1] Terrorist supporting countries [2]	[E:2] Unilateral embargo
Cuba		X
Iran	X	
Korea, North	X	
Syria	X	

[1] In addition to the controls maintained by the Bureau of Industry and Security pursuant to the EAR, note that the Department of the Treasury administers:

(a) A *comprehensive embargo* against Cuba and Iran; and

(b) An *embargo against certain persons, e.g.,* Specially Designated Terrorists (SDT), Foreign Terrorist Organizations (FTO), Specially Designated Global Terrorists (SDGT), and Specially Designated Narcotics Traffickers (SDNT). Please see part 744 of the EAR for controls maintained by the Bureau of Industry and Security on these and other persons.

[2] The President made inapplicable with respect to Iraq provisions of law that apply to countries that have supported terrorism.

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 13. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 12, 2019, 84 FR 61817, 3 CFR, 2019 Comp., p. 479.

■ 14. Amend § 742.1 by revising paragraph (d) to read as follows:

§ 742.1 Introduction.

* * * * *

(d) *Anti-terrorism Controls on Iran, North Korea, and Syria.* Commerce maintains anti-terrorism controls on Iran, North Korea, and Syria under section 6(a) of the Export Administration Act. Items controlled under section 6(a) to Iran, Syria, and North Korea are described in §§ 742.8, 742.9, 742.10, and 742.19, respectively, and in Supplement No. 2 to part 742. Commerce also maintains controls under section 6(j) of the EAA to Iran, North Korea, and Syria. Items controlled to these countries under EAA section 6(j) are also described in Supplement 2 to part 742. The Secretaries of Commerce and State are required to notify appropriate Committees of the Congress 30 days before issuing a license for an item controlled under section 6(j) to North Korea, Iran, or Syria. If you are exporting or reexporting to Iran, North Korea, or Syria, you should review part 746 of the EAR, Embargoes and Other Special Controls.

* * * * *

§ 742.10 [Removed and Reserved]

■ 15. Remove and reserve § 742.10.

■ 16. Amend Supplement No. 2 to Part 742 by:

■ a. Removing ''and Sudan'' from the heading;

■ b. Removing ''Sudan'' from paragraph (a);

■ c. Removing ''Sudan,'' from paragraph (b)(1);

■ d. Removing ''Sudan'' from paragraph (b)(3) introductory text;

■ e. Removing ''for Sudan, items in paragraphs (c)(6) through (c)(14) and (c)(16) through (c)(44) of this Supplement:'' from paragraph (b)(3)(ii);

■ f. Revising paragraph (c) introductory text;

■ g. Removing and reserving paragraph (c)(1)(iii);

■ h. Revising paragraphs (c)(2) and (3);

■ i. Removing paragraphs (c)(10)(iii), (c)(11)(iii), (c)(12)(iii), (c)(13)(iii),

(c)(14)(iii), (c)(16)(iii), (c)(17)(iii), (c)(18)(iii), (c)(19)(iii), (c)(20)(ii), (c)(21)(ii), (c)(22)(iii), (c)(23)(iii), (c)(24)(iii), (c)(25)(iv), (c)(26)(i)(C), (c)(27)(iii), (c)(28)(iii), (c)(29)(iii), (c)(30)(iii), (c)(31)(iii), (c)(32)(iii), (c)(33)(iii), (c)(34)(iii), (c)(35)(iii), (c)(36)(iii), (c)(37)(iii), (c)(38)(iii), (c)(39)(i)(C), (c)(40)(iii), (c)(41)(iii), (c)(42)(iii), (c)(43)(iii), (c)(44)(iii), (c)(46)(ii), (c)(47)(ii), and (c)(48)(ii).

Supplement No. 2 to Part 742—Anti-Terrorism Controls: North Korea and Syria

* * * * *

(c) The license requirements and licensing policies for items controlled for anti-terrorism reasons to Syria and North Korea are generally described in §§ 742.9 and 742.19 of this part, respectively. This Supplement provides guidance on licensing policies for North Korea and Syria and related contract sanctity dates that may be available for transactions benefiting from pre-existing contracts involving Syria.

* * * * *

(2) *All items subject to chemical and biological weapons proliferation controls.* Applications for all end-users in North Korea and Syria of these items will generally be denied. See Supplement No. 1 to part 742 for contract sanctity dates for Syria.

(3) *All items subject to missile proliferation controls (MTCR).* Applications for all end-users in North Korea and Syria will generally be denied. Contract sanctity provisions for Syria are not available.

* * * * *

PART 748—APPLICATIONS (CLASSIFICATION, ADVISORY, AND LICENSE) AND DOCUMENTATION

■ 17. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 13, 2020, 85 FR 49939 (August 14, 2020).

Supplement No. 2 to Part 748 [Amended]

■ 18. Amend Supplement No. 2 to part 748 by removing ''Sudan,'' from paragraph (c)(2).

§ 750.4 [Amended]

■ 19. Amend § 750.4 by removing ''Sudan,'' from paragraph (b)(6)(i).

PART 772—DEFINITIONS OF TERMS

■ 20. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

§ 772.1 [Amended]

■ 21. Amend § 772.1 by

■ a. Removing ''and Sudan'' from ''NOTE 3'' to the definition of '''Agricultural commodities''.';

■ b. Removing ''Sudan,'' from the definition of ''Countries supporting international terrorism.''.

■ c. Removing ''Sudan,'' from the definition of ''Medical devices''; and

■ d. Removing ''Sudan,'' from the definition of ''Medicines.''.

PART 774—THE COMMERCE CONTROL LIST

■ 22. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 23. Supplement 1 to part 774 is amended in category 1 by revising ECCN 1C350 and ECCN 1C355 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

Category 1—Special Materials and Related Equipment, Chemicals, ''Microorganisms,'' and ''Toxins''

* * * * *

1C350 Chemicals that may be used as precursors for toxic chemical agents (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT.

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2

CW applies to 1C350 .b, and .c. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required, for CW reasons, to export or reexport Schedule 2 chemicals and mixtures identified in 1C350.b to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR). A license is required, for CW reasons, to export Schedule 3 chemicals and mixtures identified in 1C350.c to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country has been obtained by the exporter prior to export. A license is required, for CW reasons, to reexport Schedule 3 chemicals and mixtures identified in 1C350.c from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons. See § 745.2 of the EAR for End-Use Certificate requirements that apply to exports of Schedule 3 chemicals to countries not listed in Supplement No. 2 to part 745 of the EAR.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to a country in Country Group E:1 of Supplement No. 1 to part 740 of the EAR. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, and Syria. See part 746 of the EAR for additional information on sanctions that apply to Iran, North Korea, and Syria.)

License Requirement Notes

1. *SAMPLE SHIPMENTS: Subject to the following requirements and restrictions, a license is not required for sample shipments when the cumulative total of these shipments does not exceed a 55-gallon container or 200 kg of a single chemical to any one consignee during a calendar year. A consignee that receives a sample shipment under this exclusion may not resell, transfer, or reexport the sample shipment, but may use the sample shipment for any other legal purpose unrelated to chemical weapons.*

a. Chemicals Not Eligible:

A. [Reserved]

B. CWC Schedule 2 chemicals (States not Party to the CWC). No CWC Schedule 2 chemical or mixture identified in 1C350.b is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license.

b. Countries Not Eligible: Countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR are not eligible to receive sample shipments of any chemicals controlled by this ECCN without a license.

c. Sample shipments that require an End-Use Certificate for CW reasons: No CWC Schedule 3 chemical or mixture identified in 1C350.c is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export (see § 745.2 of the EAR for End-Use Certificate requirements).

d. Sample shipments that require a license for reasons set forth elsewhere in the EAR: Sample shipments, as described in this Note 1, may require a license for reasons set forth elsewhere in the EAR. See, in particular, the end-use/end-user restrictions in part 744 of the EAR, and the restrictions that apply to embargoed countries in part 746 of the EAR.

e. Annual report requirement. The exporter is required to submit an annual written report for shipments of samples made under this Note 1. The report must be on company letterhead stationery (titled ''Report of

Sample Shipments of Chemical Precursors'' at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date of export for all sample shipments that were made during the previous calendar year. The report must be submitted no later than February 28 of the year following the calendar year in which the sample shipments were made, to: U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Ave., NW, Room 2099B, Washington, DC 20230, Attn: ''Report of Sample Shipments of Chemical Precursors.''

2. MIXTURES:

a. Mixtures that contain precursor chemicals identified in ECCN 1C350, in concentrations that are below the levels indicated in 1C350.b through .d, are controlled by ECCN 1C395 or 1C995 and are subject to the licensing requirements specified in those ECCNs.

b. A license is not required under this ECCN for a mixture, when the controlled chemical in the mixture is a normal ingredient in consumer goods packaged for retail sale for personal use. Such consumer goods are designated EAR99. However, a license may be required for reasons set forth elsewhere in the EAR.

Note to Mixtures: *Calculation of concentrations of AG-controlled chemicals:*

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of ingredients in a chemical mixture, include all ingredients of the mixture, including those that act as solvents.

3. COMPOUNDS. Compounds created with any chemicals identified in this ECCN 1C350 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

4. TESTING KITS: Certain medical, analytical, diagnostic, and food testing kits containing small quantities of chemicals identified in this ECCN 1C350, are excluded from the scope of this ECCN and are controlled under ECCN 1C395 or 1C995. (Note that replacement reagents for such kits are controlled by this ECCN 1C350 if the reagents contain one or more of the precursor chemicals identified in 1C350 in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.)

Technical Notes:

1. For purposes of this entry, a ''mixture'' is defined as a solid, liquid or gaseous product made up of two or more ingredients that do not react together under normal storage conditions.

2. The scope of this control applicable to Hydrogen Fluoride (see 1C350.d.14 in the List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

3. Precursor chemicals in ECCN 1C350 are listed by name, Chemical Abstract Service (CAS) number and CWC Schedule (where applicable). Precursor chemicals of the same structural formula (e.g., hydrates) are controlled by ECCN 1C350, regardless of name or CAS number. CAS numbers are shown to assist in identifying whether a particular precursor chemical or mixture is controlled under ECCN 1C350, irrespective of nomenclature. However, CAS numbers cannot be used as unique identifiers in all situations because some forms of the listed precursor chemical have different CAS numbers, and mixtures containing a precursor chemical listed in ECCN 1C350 may also have different CAS numbers.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: See USML Category XIV(c) for related chemicals ''subject to the ITAR'' (see 22 CFR parts 120 through 130).
Related Definitions: See § 770.2(k) of the EAR for synonyms for the chemicals listed in this entry.
Items:

a. [Reserved]

b. Australia Group-controlled precursor chemicals also identified as Schedule 2 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

b.1. (C.A.S. #7784–34–1) Arsenic trichloride;
b.2. (C.A.S. #76–93–7) Benzilic acid;
b.3. (C.A.S. #78–38–6) Diethyl ethylphosphonate;
b.4. (C.A.S. #683–08–9) Diethyl methylphosphonate;
b.5. (C.A.S. #15715–41–0) Diethyl methylphosphonite;
b.6. (C.A.S. #2404–03–7) Diethyl-N,N-dimethylphosphoroamidate;
b.7. (C.A.S. #41480–75–5) N,N-Diisopropylaminoethanethiol hydrochloride;
b.8. (C.A.S. #5842–07–9) N,N-Diisopropyl-beta-aminoethane thiol;
b.9. (C.A.S. #96–80–0) N,N-Diisopropyl-beta-aminoethanol;
b.10. (C.A.S. #96–79–7), N,N-Diisopropyl-beta-aminoethyl chloride;
b.11. (C.A.S. #4261–68–1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride;
b.12. (C.A.S. #6163–75–3) Dimethyl ethylphosphonate;
b.13. (C.A.S. #756–79–6) Dimethyl methylphosphonate;
b.14. (C.A.S. #677–43–0) N,N-dimethylamino-phosphoryl dichloride;
b.15. (C.A.S. #1498–40–4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride];
b.16. (C.A.S. #430–78–4) Ethyl phosphonus difluoride [Ethyl phosphinyl difluoride];
b.17. (C.A.S. #1066–50–8) Ethyl phosphonyl dichloride;
b.18. (C.A.S. #993–13–5) Methylphosphonic acid;
b.19. (C.A.S. #676–98–2) Methylphosphonothioic dichloride.
b.20. (C.A.S. #464–07–3) Pinacolyl alcohol;
b.21. (C.A.S. #1619–34–7) 3-Quinuclidinol;
b.22. (C.A.S. #111–48–8) Thiodiglycol.

c. Australia Group-controlled precursor chemicals also identified as Schedule 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

c.1. (C.A.S. #762–04–9) Diethyl phosphite;
c.2. (C.A.S. #868–85–9) Dimethyl phosphite (dimethyl hydrogen phosphite);
c.3. (C.A.S. #139–87–7) Ethyldiethanolamine;
c.4. (C.A.S. #10025–87–3) Phosphorus oxychloride;
c.5. (C.A.S. #10026–13–8) Phosphorus pentachloride;
c.6. (C.A.S. #7719–12–2) Phosphorus trichloride;
c.7. (C.A.S. #10545–99–0) Sulfur dichloride;
c.8. (C.A.S. #10025–67–9) Sulfur monochloride;
c.9. (C.A.S. #7719–09–7) Thionyl chloride;
c.10. (C.A.S. #102–71–6) Triethanolamine;
c.11. (C.A.S. #122–52–1) Triethyl phosphite;
c.12. (C.A.S. #121–45–9) Trimethyl phosphite.

d. Other Australia Group-controlled precursor chemicals not also identified as Schedule 1, 2, or 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

d.1. (C.A.S. #1341–49–7) Ammonium hydrogen fluoride;
d.2. (C.A.S. #107–07–3) 2-Chloroethanol;
d.3. (C.A.S. #109–89–7) Diethylamine;
d.4. (C.A.S. #100–37–8) N,N-Diethylaminoethanol;
d.5. (C.A.S. #589–57–1) Diethyl chlorophosphite;
d.6. (C.A.S. #298–06–6) O,O-Diethyl phosphorodithioate;
d.7. (C.A.S. #2465–65–8) O,O-Diethyl phosphorothioate;
d.8. (C.A.S. #108–18–9) Di-isopropylamine;
d.9. (C.A.S. #124–40–3) Dimethylamine;
d.10. (C.A.S. #506–59–2) Dimethylamine hydrochloride;
d.11. (C.A.S. #762–77–6) Ethyl chlorofluorophosphate;
d.12. (C.A.S. #1498–51–7) Ethyl dichlorophosphate;
d.13. (C.A.S. #460–52–6) Ethyl difluorophosphate;
d.14. (C.A.S. #7664–39–3) Hydrogen fluoride;
d.15. (C.A.S. #3554–74–3) 3-Hydroxyl-1-methylpiperidine;
d.16. (C.A.S. #76–89–1) Methyl benzilate;
d.17. (C.A.S. #754–01–8) Methyl chlorofluorophosphate;
d.18. (C.A.S. #677–24–7) Methyl dichlorophosphate;
d.19. (C.A.S. #22382–13–4) Methyl difluorophosphate;
d.20. (C.A.S. #14277–06–6) N,N Diethylacetamidine;
d.21. (C.A.S. #53510–30–8) N,N-Diethylbutanamidine;
d.22. (C.A.S. #90324–67–7) N,N-Diethylformamidine;
d.23. (C.A.S. #1342789–47–2) N,N Diethylisobutanamidine;

d.24. (C.A.S. #84764–73–8) N,N-Diethylpropanamidine;
d.25. (C.A.S. #1315467–17–4) N,N-Diisopropylbutanamidine;
d.26. (C.A.S. #857522–08–8) N,N-Diisopropylformamidine;
d.27. (C.A.S. #2909–14–0) N,N-Dimethylacetamidine;
d.28. (C.A.S. #1340437–35–5) N,N-Dimethylbutanamidine;
d.29. (C.A.S. #44205–42–7) N,N-Dimethylformamidine;
d.30. (C.A.S. #321881–25–8) N,N-Dimethylisobutanamidine;
d.31. (C.A.S. #56776–14–8) N,N-Dimethylpropanamidine;
d.32. (C.A.S. #1339586–99–0) N,N-Dipropylacetamidine;
d.33. C.A.S. #1342422–35–8) N,N-Dipropylbutanamidine;
d.34. (C.A.S. #48044–20–8) N,N-Dipropylformamidine;
d.35. (C.A.S. #1342700–45–1) N,N-Dipropylisobutanamidine;
d.36. (C.A.S. #1341496–89–6) N,N-Dipropylpropanamidine;
d.37. (C.A.S. #1314–80–3) Phosphorus pentasulfide;
d.38. (C.A.S. #75–97–8) Pinacolone;
d.39. (C.A.S. #7789–29–9) Potassium bifluoride;
d.40. (C.A.S. #151–50–8) Potassium cyanide;
d.41. (C.A.S. #7789–23–3) Potassium fluoride;
d.42. (C.A.S. #3731–38–2) 3-Quinuclidone;
d.43. (C.A.S. #1333–83–1) Sodium bifluoride;
d.44. (C.A.S. #143–33–9) Sodium cyanide;
d.45. (C.A.S. #7681–49–4) Sodium fluoride;
d.46. (C.A.S. #16893–85–9) Sodium hexafluorosilicate;
d.47. (C.A.S. #1313–82–2) Sodium sulfide;
d.48. (C.A.S. #637–39–8) Triethanolamine hydrochloride;
d.49. (C.A.S. #116–17–6) Tri-isopropyl phosphite.

* * * * *

1C355 Chemical Weapons Convention (CWC) Schedule 2 and 3 chemicals and families of chemicals not controlled by ECCN 1C350 or ''subject to the ITAR'' (see 22 CFR parts) (see List of Items Controlled).

License Requirements

Reason for Control: CW, AT.
Control(s)

CW applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required to export or reexport CWC Schedule 2 chemicals and mixtures identified in 1C355.a to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR). A license is required to export CWC Schedule 3 chemicals and mixtures identified in 1C355.b to States not Party to the CWC, unless an End Use Certificate issued by the government of the importing country is obtained by the exporter, prior to export. A license is required to reexport CWC Schedule 3 chemicals and mixtures identified in 1C355.b from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to a country in Country Group E:1 of Supplement No. 1 to part 740 of the EAR. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, and Syria. See part 746 of the EAR for additional information on sanctions that apply to Iran, North Korea, and Syria.)

License Requirements Notes:

1. MIXTURES:

a. Mixtures containing toxic and precursor chemicals identified in ECCN 1C355, in concentrations that are below the control levels indicated in 1C355.a and .b, are controlled by ECCN 1C995 and are subject to the license requirements specified in that ECCN.

b. Mixtures containing chemicals identified in this entry are not controlled by ECCN 1C355 when the controlled chemical is a normal ingredient in consumer goods packaged for retail sale for personal use or packaged for individual use. Such consumer goods are classified as EAR99.

Note to mixtures: *Calculation of concentrations of CW-controlled chemicals:*

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of ingredients in a chemical mixture, include all ingredients of the mixture, including those that act as solvents.

2. COMPOUNDS: Compounds created with any chemicals identified in this ECCN 1C355 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

Technical Notes: *For purposes of this entry, a ''mixture'' is defined as a solid, liquid or gaseous product made up of two or more ingredients that do not react together under normal storage conditions.*

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: See also ECCNs *1C350 1C351, 1C395,* and *1C995.* See §§ 742.18 and 745.2 of the EAR for End-Use Certification requirements.
Related Definitions: N/A
Items:

a. CWC Schedule 2 chemicals and mixtures containing Schedule 2 chemicals:

a.1. Toxic chemicals, as follows, and mixtures containing toxic chemicals:

a.1.a. PFIB: 1,1,3,3,3-Pentafluoro-2-(trifluoromethyl)-1-propene (C.A.S. 382–21–8) and mixtures in which PFIB constitutes more than 1 percent of the weight of the mixture;

a.1.b. [Reserved]

a.2. Precursor chemicals, as follows, and mixtures in which at least one of the following precursor chemicals constitutes more than 10 percent of the weight of the mixture:

a.2.a. Chemicals, except for those listed in Schedule 1, containing a phosphorus atom to which is bonded one methyl, ethyl, or propyl (normal or iso) group but not further carbon atoms.

Note: *1C355.a.2.a does not control Fonofos: O-Ethyl S-phenyl ethylphosphonothiolothionate (C.A.S. 944–22–9).*

a.2.b. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) phosphoramidic dihalides;

a.2.c. FAMILY: Dialkyl (Me, Et, n-Pr or i-Pr) N,N-dialkyl (Me, Et, n-Pr, or i-Pr)-phosphoramidates;

a.2.d. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethyl-2-chlorides and corresponding protonated salts;

a.2.e. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-ols and corresponding protonated salts;

Note: *1C355.a.2.e. does not control N,N-Dimethylaminoethanol and corresponding protonated salts (C.A.S. 108–01–0) or N,N-Diethylaminoethanol and corresponding protonated salts (C.A.S. 100–37–8).*

a.2.f. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-thiols and corresponding protonated salts.

b. CWC Schedule 3 chemicals and mixtures containing Schedule 3 chemicals:

b.1. Toxic chemicals, as follows, and mixtures in which at least one of the following toxic chemicals constitutes 30 percent or more of the weight of the mixture:

b.1.a. Phosgene: Carbonyl dichloride (C.A.S. 75–44–5);

b.1.b. Cyanogen chloride (C.A.S. 506–77–4);

b.1.c. Hydrogen cyanide (C.A.S. 74–90–8);

b.1.d. Chloropicrin: Trichloronitromethane (CAS 76–06–2).

b.2. Precursor chemicals, as follows, and mixtures in which at least one of the following precursor chemicals constitutes 30 percent or more of the weight of the mixture:

b.2.a. [Reserved];

b.2.b. Methyldiethanolamine (C.A.S. 105–59–9).

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–29037 Filed 1–14–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 210107–0004]

RIN 0648–BA21

Expansion of Flower Garden Banks National Marine Sanctuary

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) issues final regulations to implement the expansion of the boundaries of Flower Garden Banks National Marine Sanctuary (FGBNMS or sanctuary) and revise the sanctuary's terms of designation. The purpose of this action is to expand the sanctuary to include portions of 14 additional reefs and banks in the northwestern Gulf of Mexico, representing approximately a 104 square mile increase in area. With this action, the existing FGBNMS regulations will apply to the expanded locations.

DATES: *Effective Date:* Pursuant to section 304(b) of the National Marine Sanctuaries Act (NMSA) (16 U.S.C. 1434(b)), the designation and regulations shall take effect and become final after the close of a review period of forty-five days of continuous session of Congress, beginning on the date on which this document is published. The public can track the days of Congressional session at *https://www.congress.gov/days-in-session.* After the close of the forty-five days of continuous session of Congress, NOAA will publish a document announcing the effective date of the final regulations in the **Federal Register**.

ADDRESSES: Copies of the Final Environmental Impact Statement (FEIS) described in this rule and the record of decision (ROD) are available at *https://flowergarden.noaa.gov/management/sanctuaryexpansion.html.*

FOR FURTHER INFORMATION CONTACT: George P. Schmahl, Superintendent, Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Building 216, Galveston, Texas 77551, at 409–356–0383, or *fgbexpansion@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

1. Flower Garden Banks National Marine Sanctuary

Located in the northwestern Gulf of Mexico, 70 to 115 nautical miles (130 to 213 kilometers) off the coasts of Texas and Louisiana, FGBNMS encompasses approximately 56 square miles and includes three separate undersea features: East Flower Garden Bank, West Flower Garden Bank, and Stetson Bank. The banks range in depth from 55 feet (17 meters) to nearly 500 feet (152 meters), and are geological formations created by the movement of ancient salt deposits pushed up through overlying sedimentary layers.

The banks provide a wide range of habitat conditions that support several distinct biological communities, including the northernmost coral reefs in the continental United States and mesophotic coral habitats. These and similar formations throughout the northwestern Gulf of Mexico provide the foundation for essential habitat for numerous marine species, including a variety of fish species of commercial and recreational importance, and several endangered or threatened species, including sea turtles and mobula rays. The combination of location and geology makes the sanctuary an extremely productive and diverse ecosystem.

NOAA issued a final rule to implement the designation of FGBNMS on December 5, 1991 (56 FR 63634). Congress subsequently passed a law recognizing the designation on January 17, 1992 (Pub. L. 102–251, Title I, Sec. 101). At that time, the sanctuary consisted of two areas known as East and West Flower Garden Banks (56 FR 63634). Among other things, FGBNMS regulated a narrow range of activities, established permit and certification procedures, and exempted certain U.S. Department of Defense (DOD) activities from the sanctuary's prohibitions (56 FR 63634). Those regulations became effective on January 18, 1994 (58 FR 65664). In 1996, Congress added Stetson Bank to the sanctuary (Pub. L. 104–283). The boundaries of Stetson Bank and West Flower Garden Bank were later amended to improve administrative efficiencies and increase the precision of all boundary coordinates based on new positioning technology (65 FR 81175, Dec. 22, 2000). FGBNMS regulations can be found at 15 CFR part 922, subpart L, and the sanctuary management plan may be found on the FGBNMS website.[1] As a result of this action, FGBNMS is being expanded to a total of 160.4 square miles, with the existing regulations applying to the expansion area.

2. Need for Action

The NMSA authorizes the Secretary of Commerce (Secretary) to designate and protect, as national marine sanctuaries, areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or aesthetic qualities. Day-to-day management of national marine sanctuaries is delegated by the Secretary to ONMS. The primary objective of the NMSA is to protect nationally significant marine resources, including biological features such as coral reefs, and cultural resources, such as historic shipwrecks and archaeological sites. The mission of FGBNMS is to identify, protect, conserve, and enhance the natural and cultural resources, values, and qualities of the sanctuary and its regional environment for this and future generations.

This action responds to the need to provide comprehensive and coordinated management of, and additional regulatory protection for, sensitive underwater features and marine habitats associated with continental shelf-edge reefs and banks in the northwestern Gulf of Mexico. The current jurisdictional regime divides authority among several governmental entities that regulate offshore energy exploration (Bureau of Ocean Energy Management (BOEM)), fishing (Gulf of Mexico Fishery Management Council (GMFMC)), and water quality (Environmental Protection Agency (EPA)), but does not provide comprehensive and effective management for the full range of activities that impact the sensitive reefs and banks in the region. For example, BOEM has established No Activity Zones (NAZs) that prohibit anchoring only by vessels engaged in development activities and platform services specific to a particular lease, while anchoring by other vessels remains unregulated. Further, these anchoring regulations in the NAZs apply only on a lease-by-lease basis. Other vessel ground tackle (including anchors, chains, and cables) and marine salvage activities were unregulated and have caused significant injury to sensitive biological communities. Sanctuary designation will allow for additional protection of these reefs and banks from other bottom-disturbing activities, which are otherwise unregulated at this time.

[1] *https://flowergarden.noaa.gov/management/2012mgmtplan.html.*

The sanctuary expansion areas are recognized as hotspots of marine biodiversity that provide vital habitat for many important species in the Gulf of Mexico region. They are home to the most significant examples of coral and algal reefs, mesophotic and deepwater coral communities, and other biological assemblages in the Gulf of Mexico. Furthermore, these areas provide important habitat for vulnerable species such as mobula rays, sea turtles, and whale sharks, while serving as nurseries for numerous fish species of commercial and recreational importance. As such, most of these areas have also been identified as nationally significant through their designation as Habitat Areas of Particular Concern (HAPC) by the GMFMC and as NAZs by BOEM. These habitats are vulnerable to a variety of known and potential impacts, including large vessel anchoring, marine salvage operations, fishing techniques that may injure benthic habitat (*e.g.,* trawling, bottom-tending gear), and certain oil and gas exploration and development activities. These impacts will more effectively be addressed within the expanded areas through the comprehensive habitat conservation and management authorities under the NMSA. The protection of these ecologically significant sites would increase the resilience of marine ecosystems and enhance the sustainability of the region's thriving recreation, tourism, and commercial economies. Ultimately, expanding FGBNMS will help ensure that valuable marine resources remain available for the use and enjoyment of future generations of Americans.

This sanctuary expansion is the outcome of decades of scientific research and growing public recognition of the need for coordinated protection of significant offshore marine places in the northwestern Gulf of Mexico region. Protecting additional habitat in the northwestern Gulf of Mexico emerged as one of the highest priorities identified during a vigorous public review process of FGBNMS management issues. Subsequently, ''Sanctuary Expansion'' was incorporated as a discrete action plan in the 2012 revision of the sanctuary's management plan. The region is utilized for a variety of recreational, commercial, and industrial purposes, and there are ongoing impacts from bottom-disturbing activities, such as large vessel anchoring and marine salvage, on the sensitive biological resources and geological features associated with many reefs and banks in the area. Therefore, pursuant to the NMSA's purpose to ''facilitate to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas,'' FGBNMS can further resource protection while balancing multiple uses. This action will expand FGBNMS by incorporating portions of selected reefs and banks in the northwestern Gulf of Mexico. In doing so, this action will provide management of and protection for nationally significant areas with biological, ecological, and/or structural links to the existing sanctuary, including vulnerable mesophotic and deep benthic habitat sites, while providing important opportunities for research and recovery of resources from observed impacts. These areas contain the most significant examples of mesophotic coral communities in the United States, including some of the highest known densities (colonies per square meter) and species richness of mesophotic corals (Cairns et al. 2017). In addition, and as noted above, many banks in the expansion area have also been recognized by BOEM and GMFMC as nationally significant and designated as HAPCs and NAZs.

II. History of the FGBNMS Expansion Process

1. Management Plan Review

NOAA is required by NMSA Section 304(e) to periodically review sanctuary management plans to ensure that sanctuary management continues to effectively conserve, protect, and enhance the nationally significant living and cultural resources at each site. Management plans generally outline regulatory goals, describe boundaries, identify staffing and budgetary needs, and set priorities and performance measures for resource protection, research, and education programs. Management plans also guide the development of future management activities.

The FGBNMS management plan review process began in 2006 with a series of scoping meetings to obtain information about the public's interests and priorities for FGBNMS management (71 FR 52757; September 7, 2006). Subsequently, NOAA worked with the FGBNMS Advisory Council to prioritize issues and develop appropriate management strategies and activities for the preparation of a draft revised management plan. Protecting additional nationally significant habitat in the northwestern Gulf of Mexico emerged as one of the highest priority issues for the sanctuary during the FGBNMS management plan review process.

In 2007, the FGBNMS Advisory Council, using information developed by its Boundary Expansion Working Group (BEWG), recommended a range of sanctuary boundary expansion alternatives. Based on this input, and information obtained through a subsequent public process, NOAA prepared a revised management plan (77 FR 25060, April 27, 2012) that contained six action plans, including one that specifically addressed sanctuary expansion. The Sanctuary Expansion Action Plan outlined a strategy to expand the protected areas to include additional reefs and banks in the northwestern Gulf of Mexico, and to develop a Draft Environmental Impact Statement (DEIS) to evaluate appropriate expansion alternatives. The recommended expansion alternative, as identified by the FGBNMS Advisory Council in 2007, was included in the Sanctuary Expansion Action Plan. This recommendation included nine additional reefs and banks, encompassing approximately 281 square miles.

2. Boundary Expansion Notice of Intent

On February 3, 2015, NOAA published a Notice of Intent (NOI) to prepare a DEIS for expanding FGBNMS boundaries (80 FR 5699). The NOI solicited public input on the range and significance of issues related to sanctuary expansion, including potential boundary configurations, resources to be protected, other issues NOAA should consider, and any information that should be included in the resource analysis. The public scoping period was open through April 6, 2015, during which time ONMS held three public hearings and interested parties submitted both written and oral comments.

NOAA received approximately 200 comments during the scoping period. Most commenters were strongly supportive of the concept of sanctuary expansion. In addition to broad general support, some comments expressed conditional support while raising user concerns primarily relating to the potential impact of sanctuary expansion on the offshore oil and gas industry and historic fishing practices. Other commenters recommended that NOAA consider a broader geographical area than the Sanctuary Expansion Action Plan identified, especially in light of the 2010 BP/Deepwater Horizon oil spill and new information that became available since the 2007 FGBNMS Advisory Council recommendation. This information was considered during the development of the expansion alternatives in the DEIS.

3. Draft Environmental Impact Statement

In accordance with the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) and the NMSA (16 U.S.C. 1434), NOAA prepared and released a DEIS (81 FR 37576, June 10, 2016). The DEIS considered alternatives for the proposed expansion of boundaries at FGBNMS and application of the existing sanctuary regulations and management actions to the expanded area. The DEIS evaluated the environmental consequences of the alternatives and provided an in-depth resource assessment. The action alternatives in the DEIS would expand the network of protected areas within FGBNMS by incorporating selected reefs, banks, and other features throughout the north central Gulf of Mexico.

The DEIS evaluated five alternatives, ranging from ''no action'' (maintaining the current boundaries) to one that included a total of 45 discrete boundary units and encompassed approximately 935 square miles. The action discussed in this rulemaking falls within the bounds of the DEIS alternatives as discussed below in part II, section 5 of this final rule and in the supplemental information report which is available at the FGBNMS website.[2] NOAA's preferred alternative in the 2016 DEIS (Alternative 3) sought to expand the existing sanctuary from approximately 56 square miles to approximately 383 square miles, including additional important and sensitive marine habitat areas in the northwestern Gulf of Mexico. This alternative would have applied the existing sanctuary regulations and management actions to the expanded area. The 2016 preferred alternative included 15 reefs and banks (in addition to those contained within the existing 3 sanctuary units) encompassed within 11 discrete boundary polygons, including multi-bank complexes. No significant adverse impacts to the human environment were identified under any alternative considered in the DEIS.

In June 2016, NOAA opened a public comment period on the DEIS for sixty-nine (69) days, which closed on August 19, 2016. During this public comment period, NOAA also held five (5) in person public hearings in Galveston, TX; Houston, TX; New Orleans, LA; Lafayette, LA; and Mobile, AL. NOAA received 1,421 separate comments, including three letter campaigns and one petition, each with multiple signatories. All written comments on the DEIS are available at the *Regulations.gov* website.[3] NOAA's response to the public comments are set forth in Appendix A of the FEIS, which was made available to the public on December 11, 2020 (85 FR 80093).

4. NOAA's Revised Preferred Alternative and Supplemental Information Report

In response to concerns raised primarily by the oil and gas industry regarding the potential impacts to offshore energy operations arising from the Preferred Alternative presented in the 2016 DEIS, the FGBNMS Advisory Council (Advisory Council) established a new BEWG to review NOAA's expansion proposal and make a recommendation. Between July 2016 and May 2018, the BEWG met 21 times, and considered a variety of topics, including a range of boundary and regulatory issues. The BEWG recommended revised FGBNMS expansion boundaries that tracked the BOEM-designated NAZs. NAZs are areas within which no operations, anchoring, or structures are allowed for oil and gas operations. The NAZs were developed in the 1970–1980's to protect the shallowest portion of the reefs and banks. Based primarily on the May 2018 FGBNMS Advisory Council recommendation, along with input received from public comments and consultation with the GMFMC and various Federal agencies, NOAA revised the preferred alternative.

In the revised preferred alternative, NOAA reduced the size of the expansion areas proposed in the 2016 DEIS preferred alternative to promote compatibility with users and reduce potential economic impacts to the offshore energy and fishing industries. On March 22, 2019, NOAA evaluated changes to the 2016 DEIS preferred alternative in a Supplemental Information Report (SIR). Through this review, NOAA determined that preparing a supplement to the 2016 DEIS is neither required nor necessary under NEPA. The SIR is available on the FGBNMS website.[4] Pursuant to applicable Council on Environmental Quality (CEQ) guidance, NOAA's rationale for the revised preferred alternative is now presented as NOAA's Final Preferred Alternative in the FEIS and part II, section 7 of this final rule and the ROD.

5. The Proposed Rule

On May 1, 2020, NOAA published a proposed rule which would expand the boundaries of FGBNMS from approximately 56 square miles to 160 square miles (85 FR 25359 May 1, 2020). This action would add 14 banks, for a total of 17 banks, represented in 19 polygons (including 3 banks with multi-polygons), and apply the existing sanctuary regulations and management plan to the expanded sanctuary boundaries. Under the existing sanctuary regulations, only conventional hook and line gear would be permissible in the expanded sanctuary boundaries.

NOAA solicited public comment on the proposed rule from May 1, 2020 to July 3, 2020, including specifically on whether to provide exemptions for spearfishing and pelagic longline in the expanded area. NOAA accepted comments in the form of letters and written comments through electronic submissions to *http://regulations.gov,* letters submitted by mail, and public hearings. As a result of the Coronavirus global pandemic and restrictions on public gatherings, three virtual public hearings were held via Gotowebinar®.

NOAA received 485 separate comments, including four letter campaigns and four petitions, each with multiple signatories, for a total of 36,111 comments. All written public comments on the proposed expansion are available on the *Regulations.gov* website.[5] NOAA's responses to the public comments are available in Appendix A of the FEIS, and in section IV of this final rule.

III. Summary of Final Regulations

With this final rule, NOAA is revising the FGBNMS regulations at 15 CFR part 922, subpart L, as follows.

1. Sanctuary Boundary Expansion

NOAA is amending the sanctuary boundary descriptions at 15 CFR part 922, subpart L, and the terms of designation in order to expand the boundaries of FGBNMS to include portions of 14 additional reefs and banks in the sanctuary, adding approximately 104 square miles, bringing the total area to 160.4 square miles and encompassing 17 banks. The boundary changes were selected through a public process to identify and assess marine areas that could more effectively complement current management authorities or enhance natural and cultural resource values.

[2] *https://flowergarden.noaa.gov/management/expansionnpr.html.*

[3] *https://www.regulations.gov/docket?D=NOAA-NOS-2016-0059.*

[4] *https://nmsflowergarden.blob.core.windows.net/flowergarden-prod/media/archive/doc/expansion/deissupplementalinforeport.pdf.*

[5] *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&D=NOAA-NOS-2019-0033.*

Collectively, these new areas capture a greater diversity of habitats and biological resources than currently protected by FGBNMS. Inclusion of these areas within the sanctuary system will provide additional regulatory protection, additional management actions and initiatives, and improved public awareness of their natural resource values. Detailed maps of these boundary changes are available on the FGBNMS website.[6]

Under this action, NOAA is expanding the boundaries of the sanctuary by 104.2 square miles from 56.2 square miles to 160.4 square miles as follows:

a. Stetson Bank—increase of area by 0.6 square miles from 0.8 square miles to 1.4 square miles

b. West Flower Garden Bank—increase of area by 7.22 square miles from 29.94 square miles to 37.16 square miles

c. East Flower Garden Bank—increase of area by 2.4 square miles from 25.4 square miles to 27.8 square miles

d. Horseshoe Bank—28.7 square miles

e. MacNeil Bank—2.7 square miles

f. Rankin/28 Fathom Banks—5.6 square miles

g. Bright Bank—7.7 square miles

h. Geyer Bank—11.5 square miles

i. Elvers Bank—4.6 square miles

j. McGrail Bank—4.7 square miles

k. Sonnier Bank—3.1 square miles

l. Bouma Bank—7.7 square miles

m. Rezak Bank—3.7 square miles

n. Sidner Bank—2.0 square miles

o. Alderdice Bank—5.0 square miles

p. Parker Bank—7.0 square miles

2. Apply the Existing Sanctuary Regulations and Management Action to the Expanded Area

NOAA will apply the existing sanctuary regulations (including regulatory prohibitions set forth in § 922.122) and the existing management plan[7] to the expanded sanctuary boundary in order to provide for more comprehensive management and protection of sensitive underwater features and marine habitats associated with continental shelf-edge reefs and banks in the northwestern Gulf of Mexico. Accordingly, 15 CFR 922.122(e) will be updated to reflect the effective date of the sanctuary expansion, and no further amendments of the regulatory text in 15 CFR part 922 are necessary to implement this action.

3. Department of Defense Activities

NOAA's decision to amend the effective date in § 922.122(e) addresses concerns raised by the Department of the Navy (DON) during coordination in development of this final rule. In the final rule, NOAA clarifies that the prohibitions in § 922.122(a)(2) through (11) do not apply to the activities being carried out by the Department of Defense as of the date of sanctuary expansion.

4. Terms of Designation

Section 304(a)(4) of the NMSA requires that the terms of designation include the geographic area of the sanctuary; the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or aesthetic value; and the types of activities that will be subject to regulation by the Secretary of Commerce to protect these characteristics. Section 304(a)(4) also specifies that the terms of designation may be modified only by the same procedures by which the original designation was made.

The terms of designation for FGBNMS was first published in 1991 (56 FR 63637), and became effective in 1994 (58 FR 65664). The terms of designation were not incorporated into the Code of Federal Regulations, and, whenever there was a proposed regulatory change, NOAA and the general public had to refer to the preamble of the 1991 final rule to understand the nature and scope of the terms of designation. With this final rule, NOAA is making the terms of designation more readily available to the general public by amending the FGBNMS regulations at 15 CFR part 922, subpart L, to incorporate the terms of designation as a new appendix B to the FGBNMS regulations. NOAA is amending Article II. Description of the Area to include Stetson Bank (added by Congress in 1996 pursuant to Pub. L. 104–283) and the additional reefs and banks included in this expansion, add a new section relating to the U.S. Department of Defense (DoD) exemption, and revising the ''Consistency with International Law'' section of the terms of designation in order to address comments raised by the U.S. Department of State during interagency consultation.

5. No Exemptions for Spearfishing and Pelagic Longline Fishing in the Expanded Sanctuary

Based on the public comments received on the proposed rule, NOAA has decided not to provide exemptions for spearfishing or pelagic longline fishing. The rationale for the decisions not to provide exemptions for spearfishing or pelagic longline fishing are addressed below in section IV. Responses to Comments.

IV. Response to Comments

NOAA received 1,421 individual (8,491 campaigns and petitions) public comments on the DEIS and 485 individual (36,111 including campaigns and petitions) public comments on the proposed rule. The majority of comments expressed general support for sanctuary expansion, others expressed concerns about the reduced size of the boundaries, and few comments were received opposing the expansion of FGBNMS. Of the comments received during this action, approximately one third supported the revised preferred alternative in the proposed rule (which is identified as NOAA's Final Preferred Alternative in the FEIS). Public comments identified specific geographic locations of concern that were not included in the revised preferred alternative. Comments raised concerns about boundary enforcement, essential fish habitat, preservation of biodiversity, connectivity between bank areas, mesophotic/deepwater coral ecosystems, mobula rays, whale sharks, sea turtles, sharks, marine mammals, and commercial and recreationally important fish. Many of the comments supportive of the proposed expansion referred to industrial, environmental, and global impacts.

In response to NOAA's request for public comment on fishery exemptions for pelagic longline fishing and spearfishing with sanctuary expansion, 25,641 comments opposed an exemption for pelagic longline fishing, 23,353 opposed an exemption for spearfishing, 2 comments supported allowing pelagic longline fishing, and 8 comments indicated conditional support for spearfishing. Conditional support for spearfishing included an exemption for breath-hold only spearfishing, establishing an initial limited capacity fishery that could be assessed at a reduced number of banks, and an exemption for lionfish only. NOAA analyzed comments received during this process and considered them in preparation of this FEIS, as well as developed agency responses. NOAA's responses to the public comments are included in Appendix A of the FEIS and in this document (Part IV).

NOAA has consolidated public comments from the DEIS and proposed rule and collectively responds to those comments here and in Appendix A of the FEIS.

[6] *https://flowergarden.noaa.gov/management/sanctuaryexpansion.html.*

[7] *https://flowergarden.noaa.gov/management/2012mgmtplan.html.*

General Support and Opposition of Proposed Sanctuary Expansion

1. *Comment:* NOAA received comments that supported the proposed expansion of the sanctuary and encouraged NOAA to proceed with the expansion process. Comments also supported the Revised Preferred Alternative (NOAA's Final Preferred Alternative).

Response: Comment accepted. NOAA has considered these comments in carrying the Revised Preferred Alternative forward to the Final Environmental Impact Statement (FEIS) and final rule as NOAA's Final Preferred Alternative.

2. *Comment:* NOAA received comments that opposed the overall sanctuary expansion process citing reasons including: (1) Existing protections for sensitive resources; (2) concern of restricting use/access to the public; (3) safety, budget, and management limitations; and (4) socioeconomic consequences to certain industries.

Response: NOAA determined the proposed action responds to the need to provide additional protection and management of sensitive underwater features and marine habitats associated with continental shelf-edge reefs and banks in the northwestern Gulf of Mexico. The current jurisdictional regime divides authority among several governmental entities that regulate offshore energy exploration (Bureau of Ocean and Energy Management (BOEM)), fishing (Gulf of Mexico Fishery Management Council (GMFMC)), and water quality (Environmental Protection Agency (EPA)). NOAA has determined the current jurisdictional regime does not provide comprehensive and effective management for the full range of activities that impact the sensitive reefs and banks in the region. Chapter 2 of the FEIS and Part I, Section 2 of the preamble to the final rule describe the purpose and need for this proposed expansion. Extending the sanctuary boundary to new reefs and banks in the northwestern Gulf of Mexico promotes ecological conservation and biodiversity, expands sanctuary management efforts in the region, and helps to balance multiple uses.

Boundaries

3. *Comment:* NOAA received comments that generally supported expansion, but opposed the boundaries in the Revised Preferred Alternative (NOAA's Final Preferred Alternative). These comments indicated that the proposed boundaries of the Revised Preferred Alternative were too small or would exclude some ''topographic highs'' and reduce migratory corridors, or that NOAA should select a larger boundary alternative. Additionally, comments noted the removal of buffer zones entirely in the Revised Preferred Alternative and that very small areas were created at some banks (*e.g.,* Elvers, McGrail), which results in fragmented connectivity and diminished ecological and species function. Comments also stated NOAA's Preferred Alternative in the DEIS (Alternative 3) excluded 39 nationally significant areas and 9 nationally significant shipwrecks.

Response: NOAA developed the Final Preferred Alternative in response to public comments and recommendations from the Sanctuary Advisory Council. NOAA's Final Preferred Alternative was based on boundary configurations developed by the Advisory Council's Boundary Expansion Working Group and the Advisory Council's 2018 recommendation. It was also based on research conducted by the Office of National Marine Sanctuaries, consultation with other Federal and state agencies, strong public support and comment during public meetings preceding this proposal, and extensive input from oil and gas, and fishing interests. The Final Preferred Alternative further follows the National Marine Sanctuaries Act's goal of facilitating, to the extent compatible with the primary objective of resource protection, all public and private uses of the resources.

NOAA modified DEIS Alternative 3 to develop the Final Preferred Alternative under which the boundaries were drawn more tightly around the shallowest portions of the geological features identified in Alternative 3. The new boundaries closely follow the BOEM No Activity Zones, which have prohibitions on oil and gas exploration and development, but allow other bottom-disturbing activities that can cause severe negative impacts to the benthic areas. NOAA's Final Preferred Alternative expands the sanctuary by approximately 104 square miles, to include additional important and sensitive marine habitat areas outside the current sanctuary boundary, which will offer additional protection not provided by BOEM's current regulations. NOAA has determined the Final Preferred Alternative minimizes the impact to offshore energy exploration and production while providing substantial protection to sensitive marine habitats of national significance and meeting the expansion objectives as identified in the 2012 FGBNMS management plan and 2016 DEIS. Refer also to FEIS Chapter 3, Section 3.2 for additional details on the development of NOAA's proposed action.

NOAA submits there were more environmentally preferable alternatives assessed in the DEIS; however, ONMS has identified the Final Preferred Alternative as one that, based on strong input from the public and the Sanctuary Advisory Council, provides a significant environmental benefit, can be managed with current FGBNMS operational capacity, and minimizes negative impact to industry activities.

NOAA has determined the Final Preferred Alternative remains within the range of alternatives and impacts analyzed in the 2016 DEIS. Also refer to NOAA's Supplemental Information Report and FEIS Chapter 3, Section 3.2 for additional details on the development of the Final Preferred Alternative.

4. *Comment:* NOAA received comments requesting additional areas and banks to be considered in the proposed expansion process, including: Coffee Lump, 32 Fathom, Claypile, Applebaum, 29 Fathom, Fishnet, Phleger, Sweet, and Jakkula Banks, Florida Middle Grounds, Madison/Swanson, and Alabama Pinnacles, north central Gulf of Mexico, Ewing Bank (whale shark aggregation), Bryant Bank, more of Bright Bank complex, and the Deep Water Horizon (Deepwater Horizon) rig/well area.

Response: NOAA rejects the requests to add these additional banks and areas for two primary reasons, (1) there was insufficient data to characterize these areas as nationally significant, or (2) they were too far from the existing sanctuary. NOAA considered including 32 Fathom Bank, Applebaum Bank, Coffee Lump Bank, Fishnet Bank, Phleger Bank, Sweet Bank, Diaphus Bank, and Sackett Bank but determined either insufficient data were available to adequately characterize the sites or available data does not indicate sufficiently unique, diverse, productive, or otherwise nationally significant biological communities or geologic features.

Sites in biogeographic regions other than the north central Gulf of Mexico were also eliminated from further consideration; areas to both the east and west of the area roughly defined by the 87th and 95th west meridians reflect geologic/sedimentary and hydrologic/oceanographic settings, as well as biological communities, that are distinctly different from those of the north central Gulf of Mexico and are faced with distinctly different threats or other conservation issues. Features

eliminated from further consideration based on this distinction include Big Dunn Bar, Small Dunn Bar, Blackfish Ridge, Mysterious Bank, the South Texas Banks (Dream Bank, Southern Bank, Hospital Bank, North Hospital Bank, Aransas Bank, Baker Bank, and South Baker Bank), Madison-Swanson, the Florida Middle Grounds, and Pulley Ridge. Bryant Bank and more areas of the Bright Bank Complex were primarily excluded from the Final Preferred Alternative because of concerns raised from the oil and gas industry.

Although these additional areas were rejected for consideration in the current FEIS, FGBNMS will consider extending sanctuary protection and management to these additional biogeographic regions and habitat types during the next management plan review.

For more information on how the Final Preferred Alternative was developed and selected, refer to FEIS Chapter 1, Sections 1.5 and Chapter 3, Sections 3.1 and 3.2.

5. *Comment:* NOAA received a comment that requested the agency identify areas to redraw boundaries to reduce impact on fishing (*i.e.,* northern boundary of MacNeil, northern boundary of Sonnier, and northeast boundary of Bouma).

Response: NOAA considered this request, and following the DEIS, slightly reduced the boundaries at these banks to more closely align with BOEM designated NAZs. The decrease in proposed expansion area in the Final Preferred Alternative was partly in response to requests, such as this, to reduce impacts to historical fishing activities. Moreover, ONMS has completed consultation with the GMFMC pursuant to NMSA section 304(a)(5) regarding the boundaries and fishing regulations in the Final Preferred Alternative, and GMFMC concurred with this action. See Appendix G of the FEIS for more details on the 304(a)(5) consultation.

6. *Comment:* NOAA received a comment that requested coordinates for all proposed alternatives be included.

Response: NOAA disagrees. NOAA provided the coordinates of NOAA's Final Preferred Alternative in Appendix H of the FEIS. Additionally, the coordinates of NOAA's Final Preferred Alternative are included as appendix A to the final rule which will be codified in 15 CFR part 922, subpart L. NOAA does not believe inclusion of coordinates for all other alternatives is necessary. However, maps of all alternatives can be reviewed in FEIS Chapter 3 and Appendix D.

7. *Comment:* NOAA received comments requesting an explanation of how the FGBNMS Advisory Council's recommendations were incorporated throughout the expansion process.

Response: The Sanctuary Advisory Council was involved in developing DEIS Alternative 2, reviewing DEIS Alternative 3, and providing recommendations to modify the alternative. Ultimately, NOAAs Final Preferred Alternative was largely developed by recommendations proposed by the Sanctuary Advisory Council. Refer to FEIS Chapter 1, Section 1.5, which provides background information on development of the DEIS alternatives and the process by which NOAA modified DEIS Alternative 3 to develop the Final Preferred Alternative, including information of the Sanctuary Advisory Council's involvement. See response to comment #3 pertaining to the Revised Preferred Alternative.

8. *Comment:* NOAA received comments that requested a buffer around reefs to enhance connectivity, compliance, and enforcement, as well as to keep out any structure that may act as a vector for invasive species spread.

Response: Buffers were considered during the FGBNMS Advisory Council's Boundary Expansion Working Group meetings and were rejected due to potential impacts to the oil and gas and fisheries industries. The 2018 Sanctuary Advisory Council recommendation for sanctuary expansion did not include buffers. Refer to FEIS Chapter 1, Section 1.5 for details regarding development of the Final Preferred Alternative and associated interagency consultations and coordination.

9. *Comment:* NOAA received comments suggesting the boundaries proposed in the Revised Preferred Alternative (NOAA's Final Preferred Alternative) were too complicated for enforcement purposes, stating that simpler boundaries make enforcement easier, which results in better compliance of user groups.

Response: Along with input for NOAA's Office of Law Enforcement (OLE), ONMS considered this concern and determined the expansion boundaries are enforceable as proposed in NOAA's Final Preferred Alternative. The boundaries achieve a polygonal configuration, which is recommended by the OLE, and closely follow the existing BOEM designated NAZ boundaries. This polygonal approach uses fewer vertices, simplifying the NAZ boundaries and allowing for heightened enforceability and user compliance.

ONMS believes that vessels visiting the sanctuary are likely to be equipped with onboard mapping technology (*e.g.,* Global Positioning System) that would inform operators of their vessel's position relative to the expanded sanctuary boundary. In light of the technological capabilities of onboard positioning systems, ONMS decided to continue with the boundary configuration of the Final Preferred Alternative, confident that user compliance and agency enforcement can be achieved.

Please refer to FEIS Chapter 3, Section 3.2 for more details regarding development of the Final Preferred Alternative boundaries.

10. *Comment:* NOAA received comments related to the influence of the oil and gas industry on the boundary configurations of the proposed expansion of banks and reefs, including a claim that the FGBNMS Advisory Council's Boundary Expansion Working Group was biased (towards the oil and gas industry).

Response: The BEWG included Advisory Council members representing multiple stakeholder groups including the oil and gas industry, commercial and recreational fishing industries, recreational diving, science, and conservation. The BEWG presented its revised FGBNMS expansion boundaries recommendation to the full FGBNMS Advisory Council, representing all user groups, on May 9, 2018, and the recommendation was accepted by the Advisory Council and subsequently by ONMS as proposed. Refer to responses to comments #3 and #7 and FEIS Chapter 3, Section 3.2, which details the Sanctuary Advisory Council's BEWG process for developing the Revised Preferred Alternative.

Purpose and Need for Proposed Expansion/Regulations

11. *Comment:* NOAA received comments suggesting that the purpose and/or need for the proposed expansion was not warranted, citing several reasons including: (1) Need for protection was not demonstrated; (2) expansion would offer no benefit of protection; (3) government overreach; (4) majority of sites are already protected from oil and gas development by the existing BOEM's No Activity Zones; and (5) proposed expansion areas are not nationally significant or unique.

Response: Pursuant to the National Environmental Policy Act (NEPA), NOAA has established a strong purpose and need to expand FGBNMS (See FEIS Chapter 2). Through the management plan review and scoping process, NOAA identified several gaps in management of reefs and banks near the current sanctuary where habitats were experiencing damage from anchoring

and fishing gear in addition to potential for further industrial development. NOAA determined that extending sanctuary management to these areas would assist in addressing these gaps in protections by supplementing and complementing existing authorities established by BOEM and the GMFMC. While BOEM-designated NAZ's protect from oil and gas development, without sanctuary management efforts, habitats would remain vulnerable to anchor damage, detrimental fishing impacts, and other threats.

NOAA disagrees with the comment that the expansion demonstrates government overreach. The NMSA provides NOAA with the authority to designate, as marine sanctuaries, areas of the marine environment, which are of special national significance that possess conservation, ecological, and scientific qualities. Through decades of scientific research and exploration, NOAA has determined that the sanctuary expansion areas contain some of the highest reported densities of corals in the U.S. and other unique deepwater habitats that are not found elsewhere in the world, making them nationally significant and worthwhile to protect.

Sanctuary Regulations and Enforcement

12. *Comment:* NOAA received comments requesting changes to existing regulations including: (1) Allow anchoring for fishing; (2) a reasonable range of alternative management actions; (3) allow spearfishing; and (4) an exemption for pelagic longline fishing.

Response: NOAA rejected these requests because it was determined that granting them would negate the overall effectiveness of the existing regulations in the expansion areas. Current sanctuary regulations will address gaps in protection of the expansion areas. In the NPRM for sanctuary expansion, NOAA requested public comments on two fishery exemption requests: to allow pelagic longlining and spearfishing. NOAA received very limited support for exempting these activities (see fishing section below) and has determined that extension of existing fishing regulations to the expansion area is appropriate. Refer to FEIS Chapter 3, Section 3.1.2 for alternatives considered but rejected.

13. *Comment:* NOAA received comments that suggested the agency should provide enforcement policies to enhance the effectiveness of sanctuary expansion.

Response: The FGBNMS management plan details the enforcement policy for the expansion areas. NOAA will continue to work with Federal and state enforcement partners to maintain water and aerial surveillance, update patrol guides and regulatory handbooks, and conduct interpretive/outreach patrols within all of FGBNMS.

Air Quality and Climate Change

14. *Comment:* NOAA received comments requesting that NOAA evaluate how the sanctuary expansion would affect the climate (*i.e.,* potential impacts to greenhouse gas emissions within sanctuary expansion areas).

Response: NOAA agrees with the need to evaluate the impacts of sanctuary expansion on the climate and has provided analysis of the potential beneficial effects of the expansion on physical and biological resources, including beneficial impacts derived from prohibiting harmful activities. NOAA also estimates that this action will help offset impacts of climate change (see FEIS Chapter 5, Section 5.3.1).

15. *Comment:* NOAA received comments requesting an assessment of how climate change affects FGBNMS, how it will affect proposed additions, and methods to reduce greenhouse gases with sanctuary expansion areas. One comment also requested a program-wide evaluation of climate adaption management gaps and needs.

Response: The management plan for FGBNMS contains Conservation Science Action Plans, which include goals to increase knowledge and understanding of the sanctuary's ecosystem, develop new and continue ongoing research and monitoring programs to identify and address specific resource management issues, and encourage information exchange, and cooperation. FGBNMS participated in development of the Ocean Acidification Action Plan [8] for national marine sanctuaries. The plan has numerous research recommendations for studying ocean acidification, a common consequence expected of future climate change. Please also visit NOAA's website [9] for program-wide climate change initiatives, data, observations, and outreach materials. ONMS is standing up a Focus Group on climate, with the goal to develop the ONMS Climate Strategic Plan. FGBNMS is an active participant in this initiative, and the sanctuary, including the expansion areas, will be integrated into the overall plan. Ocean Acidification, specifically, has been integrated into FGBNMS long-term monitoring programs.

16. *Comment:* NOAA received recommendations that the agency use newer emissions inventory for the analysis on air monitoring and pollutants.

Response: NOAA used the best available data for their environmental analysis of air emissions and pollutants when developing the FEIS. Please refer to FEIS Chapter 4, Section 4.2.1 for detailed information about the data and resources used for air quality and climate change.

17. *Comment:* NOAA received a comment that suggested the No Action Alternative (Alternative 1) does contribute to climate change over time as it does not prevent climate change from progressing, and requested the agency amend the analysis in DEIS Section 5.3.1.

Response: Since implementation of the No Action Alternative is expected to leave the existing environment unchanged except for continuation of existing impacts, including on-going impacts of climate change, the effect of this alternative is the same as described in Chapter 4. The ''No Action'' Alternative served as a baseline for the impact analysis to compare all other alternatives. As such, there would be no additional change to climate expected under this alternative. The text has been slightly amended in FEIS Chapter 5, Section 5.2 to offer clarification in response to this comment.

Biological Resources

18. *Comment:* NOAA received comments related to biological resource concerns. Biological comments focused on how sanctuary expansion would protect resources against damages (*e.g.,* anchoring, invasive species), the benefits sanctuary protection would provide (*e.g.,* improvements in fish stocks and productivity, preservation of biodiversity, continued discovery of new species), and requests for protection of specific species/groups (*e.g., Mobula* rays, sea turtles, sharks, coral).

Response: NOAA concurs with the importance of protecting vulnerable biological resources and believes that this action helps to address many of the remaining gaps that threaten biological resources in the expanded sanctuary. With this action, NOAA is prohibiting the following activities in the sanctuary: Anchoring; drilling into, dredging, or altering the seabed; discharging or depositing of material; any injury to coral, rays, or whale sharks; fishing except for with conventional hook and line gear; and take of marine mammals and turtles except when permitted under the Marine Mammal Protection Act (MMPA) and Endangered Species Act (ESA). Collectively, these

[8] *https://oceanacidification.noaa.gov/Home.aspx.*

[9] *https://www.noaa.gov/climate.*

prohibitions will help to protect fishes from unsustainable harvest by limiting fishing; help to maintain biodiversity of benthic habitats by protecting the seafloor; and allow further protection of many vulnerable living marine resources including rays, sea turtles and other ESA and MMPA-listed species. Please also refer to FEIS Chapter 5, Section 5.3.6 and 5.3.8 for additional details regarding impacts of sanctuary expansion to biological resources.

19. *Comment:* NOAA received comments requesting the sanctuary protect resources from negative impacts of fishing. Commenters noted the vulnerability of the expansion area to fishing injury, and urged protection of fish species in order to achieve fishing sustainability. Requests for fishery management included: (1) Limiting fishing locations; (2) prohibiting bottom-dragging gear; and (3) continuing to limit fishing to hook and line only. Some of the comments received in support of expansion were from members of the fishing sector.

Response: NOAA intends to extend the current sanctuary regulations to the proposed expansion areas, which includes restricting fishing activities to conventional hook and line techniques only (*i.e.,* any fishing apparatus operated aboard a vessel and composed of a single line terminated by a combination of sinkers and hooks or lures and spooled upon a reel that may be hand- or electrically-operated, hand-held or mounted). NOAA prohibits the use of any bottom tending fishing gear to protect delicate corals and important benthic habitat from fishing impacts, which will continue in the expansion areas. A detailed list of the current regulations can be reviewed in Table 1.1, Chapter 1, Section 1.4.

20. *Comment:* NOAA received a comment requesting projections of ecosystem services (*i.e.,* estimates for the increase in value of managing protected species and habitats such as hard and soft corals, fish, and mesophotic reefs) be included in the final analysis.

Response: Analysis of ecosystem services is beyond the scope of the environmental analysis necessary for this action, and thus, NOAA rejects this request. Instead, NOAA provided an economic analysis in the FEIS that estimated a passive economic value (*i.e.* non-use value) of the sanctuary expansion. For details on the economic analysis, please refer to Chapter 4, Section 4.4.7 of the FEIS or the peer-reviewed publication that resulted from this study, Stefanski and Shimshack (2016).

21. *Comment:* NOAA received a comment which indicated that the BEWG was informed that higher coral counts had been observed outside of the NAZs, than inside NAZs, and requested an explanation for why this was not considered during the boundary configuration of the Revised Preferred Alternative.

Response: Additional areas containing higher coral colony counts were quantified during remotely operated vehicle (ROV) surveys, and the data was considered during the National Centers for Coastal Ocean Sciences (NCCOS) collaboration with the FGBNMS Advisory Council's BEWG. The BEWG selected smaller boundaries, which closely follow the NAZs, primarily to reduce impacts to the oil and gas industry and to retain access for historical fishing practices. Outside of the expansion process, NOAA will provide the processed data and associated publication to both BOEM and NMFS, for consideration during review of regulations, and for future oil and gas, and fishing activities. While this will not provide blanket protection measures, it will be valuable in protections from potential major impacts.

22. *Comment:* NOAA received comments requesting an analysis of the impacts sustained to the environment from run-off of toxic and hazardous elements, sewage, pollution, and potential expansion of the Gulf of Mexico hypoxic zone, or 'dead zone', into the proposed sanctuary expansion areas.

Response: NOAA used the best available data to evaluate the environmental impacts to the expansion areas as required under NEPA and the Council of Environmental Quality's (CEQ's) 1978 NEPA regulations. NOAA, however, is studying these issues and plans to continue analyzing the impacts in its next management plan review process.

23. *Comment:* NOAA received comments regarding disturbances (vessel traffic) related to the noise environment, including a request to quantify the additional impact from an increased number of boaters.

Response: NOAA continues to study the issue of noise impacts on sanctuary resources. Sanctuary regulations prohibit the disturbance of marine mammals and turtles except when permitted under the MMPA and ESA. With respect to sonar testing, Section 304(d) of the NMSA provides for consultation with other federal agencies if their actions have the likelihood to injure sanctuary resources. NOAA has previously used this mechanism in consultations to minimize impacts of noise on marine mammals and other species. FGBNMS is actively engaged in a vessel traffic and noise assessment and monitoring program within the sanctuary, which will be expanded to the new areas.

Please refer to FEIS Chapter 4, Section 4.2.2 for detailed information about the noise environment in the current FGBNMS, as well as expansion areas. Additionally, refer to FEIS Chapter 5, Section 5.3.2 for NOAA's analysis of environmental consequences to marine resources with respect to noise disturbances.

24. *Comment:* NOAA received comments requesting protection for fish spawning aggregations with the expansion.

Response: NOAA concurs with commenters and believes the expansion of the sanctuary will assist in the protection of fish spawning aggregations in the northwestern Gulf of Mexico. With this action, NOAA will extend sanctuary regulations to the expansion areas which limit fishing activities to conventional hook and line techniques, prohibit bottom tending gear, and restrict the use of anchors within sanctuary boundaries. This action will thereby complement protections for fish spawning habitats provided under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). Fish spawning aggregations have been observed and recorded during ROV explorations at reefs and banks included in the expansion areas. Therefore, NOAA determined that sanctuary designation will directly protect habitat where the aggregations occur. NOAA intends to consider further protection of spawning aggregations during the next management plan review.

25. *Comment:* NOAA received a comment requesting NOAA consider designating areas within the sanctuary as ''no take'' marine reserves.

Response: NOAA considered this request and does not intend to designate any ''no-take'' marine reserves within the sanctuary through this action. With this action, NOAA extends the current fishing regulations to the expansion areas which limit fishing activities to conventional hook and line techniques and exclude any bottom tending gear. Anchoring will also be prohibited in the expanded sanctuary, and mooring buoys will be installed so that fishers and vessels (<100 feet long) can safely moor within the sanctuary boundaries.

To evaluate the impact of conventional hook and line fishing to managed fish species in the sanctuary, NOAA conducted an environmental impact analysis on living marine

resources, including fish in relation to the different expansion alternatives (see FEIS Chapter 5, Section 5.36). Overall, NOAA determined none of these resources would sustain any significant adverse impacts with sanctuary designation. However, NOAA determined that this action will provide benefit to fish, given the added protection to critical habitat and restrictions to fishing techniques. Mesophotic and deep water reefs have been shown to have low resilience and slow recovery potential, and harbor greater fish biomass than their shallower counterparts, underlining the importance of their protection (Lindfield et al. 2016, Huvenne et al. 2016). By reducing fishing pressure through sanctuary protection, fish size, biomass, and abundance could increase, while also enhancing coral reef resiliency (Reed 2002, 2007, Bozec et al. 2016, Chirico et al. 2017). Impacts to the resources may be reduced due to limitations on fishing that can otherwise alter predator-prey relationships, disturb bottom habitats, and increase loss of fish biomass. The added prohibition of spearfishing further protects fish from direct extraction (Lindfield et al. 2014).

Sanctuary management actions could reduce marine debris and impacts of debris on corals and other organisms, such as entanglement in derelict fishing gear and incidental catch of fish in ''ghost'' fishing gears. Moreover, extending to the expansion areas the prohibition of bottom-tending fishing gear, limits on anchoring and the discharge of pollutants, removal of marine debris such as derelict fishing gear, and invasive species removal, would all improve habitat for benthic coral communities and fish communities.

Designating areas as a ''no take'' marine reserve is an important issue and NOAA plans to consider it in the next review of the FGBNMS management plan.

26. *Comment:* NOAA received a comment requesting that a Gulf Sperm Whale/Pelagic Ecosystem national marine sanctuary be established.

Response: NOAA does not intend to establish a Gulf Sperm Whale/Pelagic Ecosystem National Marine Sanctuary. The request is beyond the scope of this proposed action.

Visual Resources

27. *Comment:* NOAA received a comment on DEIS Section 5.3.2.3—Scenic and Visual Resources requesting that negative impacts to scenic and visual resources that could occur because of an increased number of boaters and/or increased use of fishing line be considered in the analysis.

Response: NOAA evaluated both beneficial and adverse impacts to each resource area and determined there would be no adverse impacts to scenic and visual resources. NOAA predicts beneficial impacts on the scenic and visual resources of the proposed expansion areas by reducing marine debris including derelict fishing gear, vessel traffic, and industrial infrastructure. Refer to FEIS Chapter 5, Section 5.3.3.

Fishing, Fishery Regulations, and Fishery Management

28. *Comment:* NOAA received a comment that requested the agency to analyze recreational fishing activities in the proposed expansion areas.

Response: NOAA addressed the request for this analysis by evaluating the level of recreational fishing activity expected to occur in the proposed expansion areas, using the best available data, to capture the socioeconomic impact to this industry. Ultimately, NOAA determined that there would be no significant adverse impacts to recreational fishers. For analysis of recreational fishing activities, please refer to FEIS Chapter 4, Section 4.4.1.2 for a description of the data used and Chapter 5, Section 5.3.9.2 for the expected environmental impact.

29. *Comment:* NOAA received a comment that requested the agency clarify benefits of the expansion to commercial fishers and improve the socioeconomic analysis of commercial fishers.

Response: NOAA updated FEIS Chapter 4, Section 4.4.1 to supplement the analysis on commercial fisheries with additional and current VMS data to assess socioeconomic impacts imposed by the expansion on commercial (Section 4.4.1.1) and recreational (Section 4.4.1.2) fishers. Overall, NOAA determined that no significant adverse impacts to fishers would result from the proposed expansion (See Chapter 5, Section 5.3.9.1 and 5.3.9.2). NOAA concluded minor benefits to commercial fishers may occur with the expansion of the sanctuary (see Chapter 5, Section 5.3.9.1) as fish production may increase in general with the decreased fishing pressure and habitat protections of specific locations.

Broadly, it is well documented by the scientific community that coral reef and mesophotic coral communities provide necessary habitat for a significant number of fish species, and the prevention of loss of these habitats will help to maintain and enhance fish populations dependent on these areas. More specifically, higher biomass and abundance of fish are often associated with greater habitat coverage and/or complexity, such that, protecting habitat has an increased likelihood to improve fish stocks (Jones et al. 2004, Coker et al. 2014, Lindfield et al. 2016, Komyakova et al. 2018, Carminatto et al. 2020, Russ et al. 2020). Additionally, reducing fishing pressure could lead to an increased monetary value of commercial fisheries, partly due to the presence of larger individuals (thus more valuable) and higher densities of high-value species (Chirico et al. 2017). Mesophotic reefs have been found to harbor greater biomass of fishery-targeted species than shallower reefs, suggesting these habitats are important to protect for the longevity of commercial harvests (Lindfield et al. 2016). In essence, sanctuary expansion is protecting critical habitat which may result in increased fish biomass (Edgar et al. 2011, Harborne et al. 2008) or abundance (Jeffrey et al. 2012), particularly where fishing pressure is reduced (Edgar et al. 2011, Kramer and Heck 2007), which could benefit commercial fishers.

30. *Comment:* NOAA received comments regarding spearfishing, with the majority requesting a prohibition on this activity. Some commenters offered conditional support of spearfishing, suggesting allowing the activity: (1) In a limited capacity with access at a limited number of banks and reefs in the expansion area; (2) only for the removal of lionfish, an invasive species present in the current and proposed sanctuary areas; or (3) by breath hold only.

Response: NOAA intends to extend the current sanctuary regulations to the expansion areas proposed in the Final Preferred Alternative. As such, NOAA will not be implementing any additional fishing regulations as part of the final rulemaking. NOAA prohibits spearfishing in the current boundary to protect delicate corals, including threatened species, and important benthic habitat from fishing impacts, which will continue in the expansion areas. Spearfishing for lionfish is not a permissible activity within sanctuary borders. However, spearfishing with pole spears has been performed opportunistically by research staff through permitted long-term monitoring activities at FGBNMS. Additionally, lionfish invitational research cruises have been a permitted activity since 2015 at FGBNMS to remove the invasive species with highly skilled, qualified recreational divers and contribute to a variety of research projects with external academic and agency partners. NOAA intends to continue to permit

lionfish removals, with restrictions and obligations to properly train divers in effective removal techniques that prioritize coral and ecosystem health. A detailed description of sanctuary regulations is described in FEIS Table 1.1, Chapter 1, Section 1.4.

31. *Comment:* NOAA received a comment that suggested the spearfishing community has been excluded from access to the sanctuary.

Response: NOAA solicited public comment to exempt spearfishing in the proposed sanctuary boundary with the release of the NPRM. In response, NOAA received overwhelming support to continue prohibition of this activity. Please see additional information provided in comment #30. This will restrict access to the sanctuary expansion areas for the spearfishing community.

32. *Comment:* In response to the DEIS, NOAA received a request seeking a pelagic longline exemption from the otherwise applicable sanctuary fishing prohibitions proposed for the expansion areas. NOAA also received a few similar comments in response to the NPRM. However, there were also a significant number of NPRM commenters that opposed this exemption.

Response: NOAA considered the request made during the public review of the DEIS for a pelagic longline exemption to the proposed fishing prohibitions in the expansion area. In response, NOAA solicited public comments pertaining to pelagic longline fishing in the NPRM. Based on strong public support to prohibit this activity, NOAA has rejected the request for an exemption for pelagic longlining and, instead, intends to extend the current sanctuary regulations to the expansion areas. Under existing regulations, fishing will only be allowed with conventional hook and line gear (*i.e.,* any fishing apparatus operated aboard a vessel and composed of a single line terminated by a combination of sinkers and hooks or lures and spooled upon a reel that may be hand- or electrically operated, hand-held or mounted). NOAA believes the expansion of FGBNMS to additional reefs and banks in the northwestern Gulf of Mexico will add critical protection for fish, marine mammals, threatened and endangered species, as well as their habitat. NOAA determined the existing regulations would best accomplish this protection and fulfill the NMSA obligation to protect nationally significant environmental features.

A detailed description of sanctuary regulations is described in the FEIS Table 1.1, Chapter 1, Section 1.4. NOAA has been in consultation with NMFS and GMFMC throughout the entire scoping process of sanctuary expansion, please refer to FEIS Chapter 1, Section 1.5.4.2, for additional details on these consultations.

33. *Comment:* NOAA received a comment requesting its fisheries analysis in the DEIS include more types of fishing gear and data to determine what areas were used by fishers and the value of these areas to those fisheries.

Response: NOAA provided a detailed list of the types of commercial vessel and recreation vessels that operate within the proposed sanctuary boundaries in the DEIS. NOAA has added a new table to the FEIS to include gear types used by commercial fishers that were observed in the vicinity of the Final Preferred Alternative. Please review Section 5.3.9.1 and 5.3.9.2 for a description of the commercial and recreational fishing vessels that operate within the proposed sanctuary boundaries based on permit or gear type. This analysis estimates the number of vessels within the vicinity of the boundaries under each alternative.

34. *Comment:* NOAA received a comment requesting an analysis of the potential impact(s) of weights used in bandit reel gear configurations on the benthic habitat and corals, as well as more information on the types of gear used in this type of fishing configuration.

Response: FGBNMS intends to continue investigating impacts of recreational and commercial fishing in the sanctuary, including bandit reel gear, and will address this in more detail during the next management plan review.

35. *Comment:* NOAA received a comment requesting a comprehensive commercial endorsement and certification program be developed to allow commercial fishers to continue to operate within the proposed boundaries. Additionally, there was a request to create an exemption for shrimpers in the Royal Red Shrimp industry to continue their historical practices.

Response: NOAA has considered this request, and following consultation with GMFMC pursuant to NMSA section 304(a)(5), decided not to establish a commercial endorsement and certification program or provide an exemption for shrimpers or other fishers in the sanctuary, based on the reduction in size of the new areas. Facilitating commercial fishing in the sanctuary, even through an endorsement and certification process, could make corals and other sensitive bottom habitats vulnerable to injury. NOAA believes that the reduction in boundaries between the 2016 original preferred alternative and the Final Preferred Alternative, in addition to allowing conventional hook and line fishing in the expanded sanctuary, facilitates an appropriate balance between environmental protection and user access dictated as mandated by the NMSA. A detailed description of sanctuary regulations is described in FEIS Table 1.1, Chapter 1, Section 1.4. FEIS Chapter 1, Section 1.5.2 provides additional details on this consultation.

36. *Comment:* NOAA received a comment that suggested specific language be added for the discharge of natural waste of farmed fish related to open gulf mariculture, stating that fish farming operations outside of sanctuary boundaries may discharge sinking organic material that deposit within the sanctuary with prevailing currents.

Response: NOAA determined this request is outside the scope of this action. While sanctuary regulations do not specifically prohibit aquaculture, some associated activities are prohibited such as discharge of certain material, alteration of the seabed, and injury to sanctuary resources. Furthermore, the suitability of the area for aquaculture is being separately considered under other authorities including E.O. 13921, (October 23, 2020; 85 FR 67519). FGBNMS will further consider aquaculture and its potential impacts during the next management plan review.

Military Uses

37. *Comment:* A comment related to the Department of the Navy's activities within the proposed sanctuary areas suggested to: (1) Include in the FEIS, Department of Defense (DoD) use of water space in the vicinity of proposed expansion and current sanctuary; (2) provide a map of the Gulf of Mexico warning areas for military use; (3) add military uses to marine-use categories; and (4) add an analysis of the potential impact to military uses.

Response: Homeland security and military uses of the expanded sanctuary are subject to compliance with NEPA and NMSA, in addition to all applicable environmental regulations. DoD would be required to consult with ONMS pursuant to NMSA section 304(d) on any new military activities in the expansion area that are likely to injure sanctuary resources. NOAA believes the existing regulatory framework sufficiently addresses DoD impacts on sanctuary resources. Existing military uses and an analysis of their environmental effects in the expansion area have been added to Chapter 4, Section 4.4.5 and Chapter 5, Section 5.3.9.7 of the FEIS.

NEPA Process

38. *Comment:* NOAA received comments regarding the NEPA process. Commenters requested NOAA conduct a new NEPA analysis because of: (1) The difference in methodologies used to configure the Final Preferred Alternative and Alternative 3 in the DEIS; and (2) new circumstances and/or information available (*e.g.,* fishing exemptions, removal of buffer zones).

Response: NOAA evaluated the changes made from the 2016 original preferred alternative (Alternative 3) to the Final Preferred Alternative presented in the NPRM and this FEIS. The Final Preferred Alternative revised Alternative 3 boundaries to be more tightly drawn near the shallowest portions of the geological features of interest, largely in response to existing fishing activity and oil and gas activity (see response to comment #3). The new polygons included all of the same reefs and banks, excluding Bryant Bank, which is not included in the Final Preferred Alternative. Ultimately, NOAA determined that the changes reflected in the Final Preferred Alternative were not ''substantial changes in the proposed action that are relevant to environmental concerns'' (40 CFR 1502.9(c)(1)(i)). NOAA further determined the comments received on the 2016 DEIS did not ''constitute significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts'' (40 CFR 1502.9(c)(1)(ii)). As such, NOAA concluded that preparing a supplemental environmental impact statement or new NEPA analysis is neither required nor necessary under NEPA. NOAA has documented the agency's rationale for revising the Final Preferred Alternative (see Chapter 3, Section 3.2) and provided updated information on the affected environment in FEIS Chapter 5, Section 5.3, and related Record of Decision. Please refer to NOAA's Supplemental Information Report that was provided with the release of the NPRM for further information.

39. *Comment:* NOAA received a comment that requested that the Protected Species analysis in Section 5.3.2.7 of the DEIS be public and open for review/comment.

Response: ONMS conducted an ESA Section 7 consultation with NMFS in conjunction with the development of both the DEIS and NPRM. In the DEIS, ONMS included a list of protected species which may be affected by the proposed action, and the DEIS was subsequently submitted for public comment. Additional species were included in the NPRM consultation. See FEIS Chapter 4, Section 4.3.4 for additional information on protected species with an updated list of protected species and Appendix G for a summary of how ONMS satisfied ESA consultation requirements including ONMS's ESA consultation correspondence.

40. *Comment:* NOAA received a comment stating that the Notices to Lessees are not simply guidance because they contain requirements for oil and gas.

Response: NOAA disagrees. Please refer to the Bureau of Safety and Environmental Enforcement Notice to Lessees 2009–G39,[10] which provides and consolidates guidance for oil and gas.

National Marine Sanctuaries Act

41. *Comment:* NOAA received comments that suggested the expansion of sanctuaries must be conducted through an act of Congress, otherwise it violates Congressional intent found in the NMSA.

Response: NOAA disagrees. NOAA can administratively designate and expand sanctuaries pursuant to Section 303 of the NMSA (16 U.S.C. 1433), using procedures set forth in section 304 (16 U.S.C. 1434). It is also possible for Congress to legislatively designate a sanctuary; Stetson Bank (Pub. L. 104–283) in the current FGBNMS serves as an example of a legislatively designated sanctuary.

42. *Comment:* NOAA received comments stating the NPRM did not comply with the NMSA and the FGBNMS 2012 management plan to prioritize conservation of surrounding reefs and banks.

Response: The proposed action responds to the need to provide additional protection of sensitive underwater features and marine habitats associated with continental shelf-edge reefs and banks in the northwestern Gulf of Mexico. NOAA adds 14 additional reefs and banks, for a total of 17 features to be protected, expanding the sanctuary by approximately three times its current spatial extent. In addition to prioritizing the conservation of nationally significant biological features, the NMSA section 301 (16 U.S.C. 1431) directs NOAA to facilitate, to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas not prohibited pursuant to other authorities. Thus, compliant with the NMSA, NOAA believes the current expansion in this FEIS and final rule, as proposed in the NPRM, maximizes conservation and user group interests to allow for greater protection of these areas.

Oil & Gas Exploration and Development

43. *Comment:* NOAA received comments from the oil and gas industry in response to the 2016 DEIS alternatives regarding recognition and inclusion of existing oil and gas leases. Commenters expressed concern that sanctuary expansion could be more costly or difficult for oil and gas production, new leases would be precluded, and the loss of oil and gas exploration may lead to reliance on foreign oil. Industry representatives noted their reliance on the 2007 Sanctuary Advisory Council recommendation for expansion (Alternative 2) to inform their investment in resources for the industry's development and growth, or their decision to relinquish certain lease blocks. Industry representatives requested oil and gas access, leasing, produced water discharge requirements, and seismic acquisition should remain as is, with no additional regulations.

Response: To address concerns from the oil and gas industry, the FGBNMS Sanctuary Advisory Council's BEWG underwent an extensive process to evaluate how protecting biologically significant areas may impact the oil and gas industry. They proposed modifying DEIS Alternative 3 to develop the Revised Preferred Alternative (see comment #3). This process also involved input from the Sanctuary Advisory Council, the GMFMC, and coordination within NOAA. The new boundaries closely follow BOEM's NAZs, encompassing the shallowest portions of the banks, which are already protected from oil and gas exploration and development. Furthermore, ONMS consulted with BOEM pursuant to E.O. 13795—Implementing an America-First Offshore Energy Strategy and determined that expanding the sanctuary would not have a significant economic impact on oil and gas exploration and development. BOEM's analysis is summarized in the NPRM and in FEIS Chapter 5, Section 5.3.9.5.

44. *Comment:* NOAA received a comment requesting an analysis of the inclusion of four oil and gas platforms within the expansion areas for advantages and disadvantages, especially in the context of Sanctuary Expansion Action Plan Objective 6C.

Response: NOAA's Final Preferred Alternative does not include any

[10] *https://www.bsee.gov/notices-to-lessees-ntl/notices-to-lessees/ntl-2009-g39-biologically-sensitive-underwater-features.*

additional oil and gas platforms within the existing or expanded sanctuary boundaries, thus, the requested analysis is not necessary. NOAA did, however, consider inclusion of certain oil and gas platforms as part of the alternatives considered in the NEPA analysis for this action. See Alternatives 4 and 5 of this FEIS. Please also refer to FEIS Chapter 5, Section 5.3.9.5 for analysis of impacts to offshore energy resources. Finally, NOAA intends to continue analyzing the advantages and disadvantages of oil and gas structure inclusion within FGBNMS as part of its ongoing management plan review process.

45. *Comment:* NOAA received a comment that requested an economic analysis of: (1) Impacts to oil and gas resources due to directional drilling; (2) affected lease blocks; and (3) a comparison in area between NAZs and proposed sanctuary expansion areas. There was also a request to identify any future management actions/mitigations which may affect oil and gas activities.

Response: BOEM analyzed potential impacts to oil and gas resources pursuant to E.O. 13795, and these results are available on the sanctuary website.[11] BOEM determined that expanding the sanctuary would not have significant economic impacts on the oil and gas industry, and NOAA accepted BOEM's findings. NOAA will continue to coordinate with BOEM to co-manage these resources and mitigate any impacts to oil and gas activities, including the 11 active Outer Continental Shelf (OCS) oil and gas leases that will lie wholly or partially within the boundaries of the expanded FGBNMS. For new leases, approvals or permits, licenses, or other authorizations in existence prior to the date in which the FGBNMS expansion is finalized, lessees or operators will be required to obtain from NOAA a certification to authorize the oil and gas activities within the FGBNMS. The certification will require compliance with the FGBNMFS regulations, as well as the permits or plan approvals issued by BOEM and/or BSEE, and the topographic features stipulation (as applicable) in the lease.

Refer to FEIS Section 5.3.9.5 for additional analysis of the impacts to oil and gas activities.

46. *Comment:* NOAA received a comment to incorporate BOEM lease sales and stipulations into BOEM's Record of Decision and Final Notice of Sale.

Response: As a non-voting member on the Sanctuary Advisory Council, and a cooperating agency in the preparation of the 2016 DEIS, BOEM has incorporated lease sales and stipulations into BOEM's Record of Decision and Final Notice. FEIS Chapter 5, Section 5.3.9.5 shows that there were 13 active lease blocks, as reported by BOEM in their 2019 report. However, since publication of that report, two leases were relinquished. There are currently 11 active leases in the expansion area, averaging approximately 17% of the lease blocks falling within the Final Preferred Alternative boundaries. Lease sales issued between 1996 and 2001 provided Information for Lessees indicating ''Minimizing Oil and Gas Structures near Flower Garden Banks''. Lease sales issued between 2002 through 2014 did not specifically mention FGBNMS, but the lease sales do refer to the Notice to Lessees outlining the topographic and live bottom stipulations. The sanctuary regulations track the operational requirements established by BOEM in those stipulations. Lease sales issued between 2015 to the present provide notice to prospective leaseholders of the proposed expansion. More information regarding BOEM lease sales may be found on BOEM's website.[12]

47. *Comment:* NOAA received a comment that requested the agency develop an appropriate regulatory ''firewall'' that will set a precedent for other sanctuaries to protect those areas from offshore drilling practices.

Response: NOAA believes this request is beyond the scope of this action but will continue to work toward balancing multiple user interests with the NMSA's primary goal of resource protection.

48. *Comment:* NOAA received comments related to environmental impacts of the oil and gas industry. Of these, nearly half requested the sanctuary update the regulations to prohibit oil and gas development and to ensure management protects against damages from this industry. Concerns raised included: (1) Oil spills and leaks; (2) extraction practices; (3) encroaching drilling and exploration; and (4) the vulnerability of biological resources to oil and gas activities. Comments also requested that NOAA prohibit fracking and analyze the potential for fracking fluids and directional hydraulic fracturing to impact the area in and near the sanctuary. A few comments related specifically to methane hydrate extraction.

Response: NOAA determined the Final Preferred Alternative balances protecting vulnerable habitats with multiple uses of the region. See FEIS Chapter 3, Section 3.2 for more details regarding the Final Preferred Alternative. NOAA intends to extend the current FGBNMS regulations to the new expansion areas. Please refer to FEIS Table 1.1 in Chapter 1, Section 1.4 for a list of current sanctuary regulations and management efforts from impacts of oil and gas activities. Additionally, sanctuary regulations prohibit discharge of any kind from oil and gas activities that may be harmful to the benthic environment.

BOEM assessed the potential for offshore energy resources including oil and gas and methane hydrate resources in the proposed expansion areas. BOEM determined that due to the shallow-water depth of the proposed expansion areas, the formation of methane hydrate in the subsurface is unlikely. BOEM's E.O. 13795 report is available on the sanctuary website.[13]

The FEIS describes damages related to oil and gas activities observed at banks proposed in the expansion, as well as potential impacts that could be sustained to these resources. Please review Chapter 4, Section 4.4.3 of the FEIS for additional information.

Furthermore, in 2016, the NOAA Office of Response and Restoration Gulf of Mexico Disaster Response Center convened with the Department of Interior and a variety of environmental, regulatory, and resource protection agencies to develop a document outlining ''Oil Spill Response Options for FGBNMS.'' This document may be found at the University of New Hampshire, Coastal Response Research Center and the Center for Spills and Environmental Hazards website.[14]

49. *Comment:* NOAA received comments related to the prohibition of oil and gas development. Specifically, NOAA was requested to prohibit: (1) New oil and gas directional drilling, infrastructure, and transport; (2) oil and gas leasing within new boundary areas; and (3) directional drilling under new boundary areas.

Response: With this action, NOAA intends to extend existing sanctuary prohibitions, which allow and regulate oil and gas exploration and development to the expansion areas. Directional drilling permits for oil and gas will continue to be considered for surface operations in the expansion

[11] *https://nmsflowergarden.blob.core.windows.net/flowergarden-prod/media/archive/doc/expansion/boemenergyanalysis.pdf.*

[12] *https://www.boem.gov/oil-gas-energy/lease-sale-information.*

[13] *https://nmsflowergarden.blob.core.windows.net/flowergarden-prod/media/archive/doc/expansion/boemenergyanalysis.pdf.*

[14] *https://crrc.unh.edu/sites/crrc.unh.edu/files/nrpt_oil_spill_response_impacting_fgbnms_tx_report.pdf.*

areas, given existing prohibitions, outside of the BOEM-designated No Activity Zones. Pursuant to NMSA Section 301(b)(6), NOAA will continue ''to facilitate to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas not prohibited pursuant to other authorities''. Please also refer to comment #49 and FEIS Table 1.1, Section 1.4 for current sanctuary regulations.

50. *Comment:* NOAA received comments from oil and gas industry companies in support of this expansion that recognized the balance between conservation, extraction, and user groups achieved through the Sanctuary Advisory Council's process in developing the Revised Preferred Alternative (NOAA's Final Preferred Alternative).

Response: NOAA has carried forward the 2018 BEWG's recommendation, which is now NOAA's Final Preferred Alternative. Please refer above to the Boundaries section and to FEIS Chapter 3, Sections 3.1 and 3.2 for more information regarding the development of alternatives and selection of the Final Preferred Alternative.

Sanctuary Management and Administration, Funding, Education and Outreach, and Sanctuary Advisory Council

51. *Comment:* NOAA received comments requesting that FGBNMS develop a Resilient Habitat Plan, which seeks to enhance habitat resilience to uncertain and unpredictable effects of future change, such as climate change.

Response: The current FGBNMS management plan serves as a framework for addressing issues facing the sanctuary and lays the foundation for protecting, conserving, and enhancing FGBNMS and its regional environment in the Gulf of Mexico. Following this expansion, NOAA will begin the process to review and update the FGBNMS Management Plan as needed. NOAA acknowledges the growing need to integrate resiliency plans into their habitat management schemes and are beginning to implement sanctuary climate assessment and adaptations plans sitewide. As determined during management plan review, FGBNMS will aim to integrate adaptation and resiliency strategies into their habitat and resource management. Additionally, FGBNMS will begin development of a Condition Report describing the current status of sanctuary resources, including the expansion areas. As described in the FEIS Executive Summary, NOAA will be extending the existing sanctuary management plan and regulations to the newly expanded area.

52. *Comment:* NOAA received a comment on DEIS Section 5.3.6—Irreversible and Irretrievable Commitments of Resources requesting NOAA include costs of expansion and evaluate potential impacts to conservation and management activities.

Response: NEPA requires an analysis of the extent to which the proposed project's primary and secondary effects would commit nonrenewable resources to uses that future generations would be unable to reverse (42 U.S.C. 4332(C)(v); 40 CFR 1502.16). See FEIS Chapter 5, Section 5.6.4 which describes any impacts, or losses, to resources that cannot be recovered or reversed associated with the proposed action or alternatives. Alternatives 1–3 and the Final Preferred Alternative are within the current operational budget, and NOAA expects field operations to continue at current intensity in the expanded sanctuary. Also refer to the 2012 FGBNMS Management Plan for additional budgetary information.

53. *Comment:* NOAA received comments requesting the FEIS to clearly describe ''best diving practices'' in Section 5.3.9.4, how they will be implemented, how they will protect FGBNMS, and how NOAA will enforce their use.

Response: The existing sanctuary regulations (15 CFR 922.122(a)(2)(iii)) require any vessel moored in the sanctuary to exhibit the blue and white International Code flag ''A'' (''alpha'' dive flag) or red and white ''sports diver'' flag whenever a scuba diver from that vessel is in the water and remove the ''alpha'' dive flag or ''sports diver'' flag after all divers exit the water and return on board the vessel, consistent with U.S. Coast Guard guidelines relating to sports diving as contained within ''Special Notice to Mariners'' (00–2008) for the Gulf of Mexico. This final rule will apply that requirement to the expanded areas and must be followed. The FGBNMS Trip Prep web page [15] provides recreational divers with information to prepare for their trip to the sanctuary, information about the challenging diving conditions that can be experienced at FGBNMS, and how to safely prepare for these visits, and includes information on best diving and boating practices to ensure the safety of visitors. Additionally, the FGBNMS Trip Prep web page includes a link to reef etiquette, which provides information about the best diving practices to ensure the protection of the environment. A link to this reef etiquette web page [16] has been added to Section 5.3.6. NOAA believes when these practices are followed, reefs sustain very minimal, if any, damage. While compliance with the sanctuary regulations is mandatory, some of the best diving practices set forth on the FGBNMS Trip Prep web page are voluntary.

FGBNMS also has regulations prohibiting resources from being taken from the sanctuary (*e.g.,* shells, coral, invertebrates) and restricting harassment of marine wildlife (*e.g., Mobula* rays, whale sharks). A list of the regulations is provided in FEIS Chapter 1, Section 1.4, Table 1.1. The USCG and NOAA's OLE are jointly responsible for enforcing regulations at FGBNMS.

54. *Comment:* NOAA received comments regarding sharing its coral and habitat information with the GMFMC so the data could be included in the coral portal. Also, FGBNMS was asked to collaborate with NOAA's National Resource Damage Assessment's (NRDA) Trustee Council's Open Ocean Trustee Implementation Group to restore mesophotic and deep benthic communities (MDBC).

Response: NOAA welcomes the opportunity to collaborate with organizations to build community partnerships for education, outreach, research, monitoring, and resource protection. Before, during, and after the release of the DEIS and the NPRM, the FGBNMS Superintendent presented information to the GMFMC on the FGBNMS proposed sanctuary expansion. Additionally, FGBNMS provides benthic (*e.g.,* coral) data from the current and expanded FGBNMS, as well as other offshore banks and reefs in the northwestern Gulf of Mexico to GMFMC for its publicly accessible coral portal.[17] FGBNMS has been intently involved as an Active Management Project Partner with NRDA's Mesophotic Deepwater Benthic Community's planning projects. Project goals include: (1) Enhancing public awareness and performing active management and protection activities by undertaking education and outreach targeting MDBC resource users and the general public; (2) engaging stakeholders and developing socioeconomic analyses to evaluate potential impacts of management or protection actions; and (3) directly

[15] *https://flowergarden.noaa.gov/visiting/tripprep.html.*

[16] *https://flowergarden.noaa.gov/visiting/reefetiquette.html.*

[17] *https://portal.gulfcouncil.org/cp/.*

addressing threats to MDBC through management activities.

55. *Comment:* NOAA received a comment requesting a Critical Habitat Assessment of the banks be included in the proposed expansion as required in the International Finance Corporation (IFC) Performance Standard 6 (Biodiversity Conservation and Sustainable Management of Living Natural Resources).

Response: To develop each alternative, NOAA identified nationally significant coral habitats that are vulnerable to multiple threats as detailed in the FEIS and final rule's Need for Action sections. For more detail regarding how specific habitats were selected in the alternatives, refer to Chapter 3 of the FEIS. In summary, ONMS determined the selected habitats were most in need of protection based on the best available scientific information as well as through public comment and interagency coordination.

56. *Comment:* NOAA received a comment that requested the agency incorporate and address management of artificial reefs within sanctuary boundaries, specifically decommissioning of oil and gas platforms.

Response: NOAA's Final Preferred Alternative does not include any artificial reef structures. Federal policy on artificial reefs is discussed in the FEIS Appendix G and in the 2012 FGBNMS Management Plan.

57. *Comment:* NOAA received a comment requesting the use of collaborative, consensus-building, transparent processes for selection and management of sanctuary resources.

Response: ONMS uses several public, stakeholder-driven processes to ensure collaborative, transparent selection and management of resources. National marine sanctuaries have sanctuary advisory councils, composed of voting and non-voting members that represent a variety of government agencies; local user groups; and the general public, that advise sanctuary superintendents on priority issues. Sanctuary advisory councils may choose to establish committees and working groups to further delve into issues; working groups provide an opportunity to involve more stakeholders from the community in developing recommendations for consideration by the full sanctuary advisory councils. Additionally, through NEPA and the federal rulemaking processes, ONMS is required to solicit, consider, and respond to public comments during each stage in an expansion, designation, or regulatory update. All comments received are made available and considered by ONMS.

58. *Comment:* NOAA received comments requesting the use of British Petroleum (BP) restoration funds to justify expansion to Alternatives 4 and 5. One comment noted specific issues affecting FGBNMS' operational capacity to manage alternatives with greater environmental benefit had changed (*i.e.* substantial resources have since been dedicated to managing mesophotic and deep benthic communities in the Gulf of Mexico through the Deepwater Horizon NRDA).

Response: FGBNMS is engaged in collaborative efforts with NOAA Fisheries through the MDBC project funded through NRDA. NOAA has determined, for the purpose of this action, that Alternatives 4 and 5 are beyond the geographic scope that is feasible for the sanctuary to effectively manage (see comment #54 and refer to Chapter 3 of the FEIS).

59. *Comment:* NOAA received a comment requesting FGBNMS design, develop, and commission a research vessel dedicated to studying marine mammal population growth in the pelagic environment.

Response: FGBNMS currently operates the R/V *Manta,* a research vessel that can be used as a platform to research marine mammals, and thus rejects this request. NOAA Fisheries conducts marine mammal population studies and their Southeast Fisheries Science Center develops a report every 5 years. Further, the sanctuary collaborates with external organizations and partners to support marine mammal research.

60. *Comment:* NOAA received a comment requesting the creation of an interpretive center in support of the sanctuary.

Response: NOAA will evaluate opportunities for an interpretive center through the next FGBNMS management plan review process.

61. *Comment:* NOAA received a comment requesting inclusion of a user education and enforcement program to ensure the public is aware of new boundaries and requirements.

Response: Existing online and print materials created for the proposed action contain select maps and several photographs. When the proposed action becomes final, NOAA will work to update and distribute printed and online materials to reflect the features and boundaries of FGBNMS.

62. *Comment:* NOAA received comments regarding input from the FGBNMS Sanctuary Advisory Council and other stakeholders. More specifically, commenters asked why the FGBNMS Sanctuary Advisory Council was not informed of new information and proposed boundaries for NOAA's original preferred alternative in the DEIS (Alternative 3) prior to publication, and asked why NOAA selected Alternative 3 instead of the 2007 FGBNMS Advisory Council's recommendation (Alternative 2).

Response: FGBNMS received input from its Sanctuary Advisory Council through a Boundary Expansion Working Group comprised of stakeholders from varied constituent seats. In 2007, the working group presented its recommendation for sanctuary expansion to the full Advisory Council, after which the 2007 Sanctuary Advisory Council recommendation (Alternative 2) was approved, based on the criteria developed by the original BEWG. Their recommendation became the foundation for NOAA's original preferred alternative (Alternative 3), which also included additional research in the northwestern Gulf of Mexico. After the release of the DEIS, a Sanctuary Advisory Council working group reformed. Based on the Sanctuary Advisory Council recommendations in response to the DEIS, NOAA made a number of changes to the boundaries of the polygons surrounding the banks and submerged features. In 2018, the BEWG brought forth its recommendation for sanctuary expansion to the full Advisory Council, which was approved and became NOAA's Revised Preferred Alternative for the NPRM and the Final Preferred Alternative in this FEIS.

NOAA's Final Preferred Alternative represents the collaborative efforts between constituent/stakeholder groups and the sanctuary's multi-use management. Refer to FEIS Chapter 3, Sections 3.2 and 3.5 which details development of the Final Preferred Alternative and provides the rationale for the selection of Alternative 3 as the original preferred alternative in the DEIS, respectively.

63. *Comment:* NOAA received a comment suggesting FGBNMS form an Advisory Council working group on maritime shipping traffic regarding shipping routes.

Response: NOAA will consider this suggestion in the future.

64. *Comment:* NOAA received comments claiming science was disregarded during the development of the boundary configuration for the Revised Preferred Alternative presented in the NPRM.

Response: The bank boundaries of the Revised Preferred Alternative presented in the NPRM (NOAA's Final Preferred Alternative) closely follow BOEM's NAZs, which were based on information

available in 1970–1980's, and designated to protect active reef building benthic communities, associated with the shallowest portions of the geographic features. NOAA reduced the size of the expansion areas proposed in the 2016 DEIS original preferred alternative to minimize user conflicts and potential economic impacts to the offshore energy industry in accordance with NMSA section 301 (16 U.S.C. 1431), which supports establishing compatible uses with public and private resource users.

Socioeconomic Issues and Access

65. *Comment:* NOAA received comments stating that the economic impact analysis in the DEIS was insufficient and requested updates to data pertaining to scuba diving, commercial fishing, air emissions, and oil and gas.

Response: NOAA used the best available scientific information to conduct the economic analysis for the DEIS and incorporated updated data and analysis, if available, in the FEIS (see Chapter 5). Specifically, ONMS updated analyses of impacts to commercial and recreational fishing and impacts to oil and gas resources in the FEIS.

66. *Comment:* NOAA received comments related to the positive socioeconomic impacts resulting from sanctuary expansion on local tourism/businesses and the recreation industry. Commenters noted some fishing practices were harmful and therefore, fishing restrictions in the expansion areas would benefit the recreational fishing industry, the commercial fishing industry, and fisheries/seafood production.

Response: Potential positive and adverse impacts to socioeconomic resources (*e.g.,* recreation, fishing) are detailed in FEIS Chapter 5. NOAA does not anticipate any significant adverse impacts to be incurred on the commercial or recreational fishing industry as a result of this expansion. Rather, fishers may find a minor beneficial impact with an increase in fish production with the protection of these important areas. Please review FEIS Chapter 5, Section 5.3.9.1 and 5.3.9.2 for more details on the expected impact to commercial and recreational fishing industries, respectively.

67. *Comment:* NOAA received comments suggesting that the proposed action removes an asset from public use for both commercial and recreational purposes, restricts recreational diving access, and restricts recreational fishing opportunities. Commenters urged NOAA to allow for multiple use of the sanctuary, with reasonable access regulations and reasonable mitigation measures that directly address threats.

Response: By expanding the sanctuary's boundaries and extending existing regulations to the expansion areas, NOAA is not restricting access to divers or hook and line fishers in any part of the sanctuary as long as users do not injure or possess any sanctuaries resources (see FEIS regulations Table 1.1, Chapter 1, Section 1.4). NOAA determined through the Sanctuary Advisory Council process and through public input that the expansion would allow for multiple uses of the sanctuary while addressing threats to sanctuary resources, as is set forth in NMSA Section 301. For additional details pertaining to impacts to socioeconomic resources such as recreational diving, please refer to FEIS Chapter 5.

68. *Comment:* NOAA received comments from the diving industry and scuba divers supporting sanctuary expansion. Divers urged NOAA to install mooring buoys in the expansion areas to increase access and to provide better maintenance of the mooring buoys and longlines.

Response: NOAA intends to extend the current management regime to the expansion areas, under which the sanctuary would provide and maintain mooring buoys so that vessels (< 100 feet long) could safely moor in the sanctuary boundaries, as is logistically feasible. See the current FGBNMS Management Plan.

Regulatory Impact Review (RIR)

NOAA received eight comments on the Bureau of Ocean Management's (BOEM) analysis (the RIR) (85 FR 74630, November 23, 2020) and collectively responds to those comments here.

69. *Comment:* NOAA received comments expressing concern about the short length of the period provided for public comment, suggesting (1) it was not long enough to provide substantive feedback; (2) no similar National Marine Sanctuary System has offered a 15-day comment period; and (3) that it was not circulated with other documents prior to this period. NOAA also received a request to provide justification for the legality of the 15-day comment period, and further requested that NOAA extend the comment period for 60 days.

Response: The request to extend the comment period is denied. Prior to soliciting public comment for the RIR, a 60-day comment period was open for the proposed rule, including a fulsome summary of the RIR, which allowed the public to comment on the proposed action in its entirety (85 FR 25359, May 1, 2020). On November 23, 2020, NOAA acknowledged the oversight of not circulating the RIR, and reopened the public comment period (85 FR 74630). Given that NOAA provided 60 days for public comment period on the proposed rule, which contained a summary of the BOEM analysis, the additional comment period is reasonable.

70. *Comment:* NOAA received comments suggesting that the RIR was outdated and requesting a new analysis, suggesting that a decline in the current value of oil and gas and other hydrocarbon resources leads to mistaken assumptions in the current RIR. Additionally, commenters suggest that the RIR is no longer an accurate portrayal of expected impacts to the oil and gas industry. According to the commenters, lower oil and gas prices reduce the desire to explore and develop resources in the region and, thus, oil and gas resources cannot be considered economically recoverable.

Response: NOAA disagrees with this comment due to the uncertainty in determining future oil prices, and because BOEM's February 2019 report provides the best available economic information. NOAA summarized this analysis in the proposed rule for sanctuary expansion and further evaluated impacts of this action on the oil and gas industry in their Final Environmental Impact Statement (FEIS); see Chapter 5, Section 5.3.9.5.

71. *Comment:* NOAA received comments requesting the other alternatives be re-evaluated in light of the analysis presented in the RIR.

Response: NOAA updated the analyses of all alternatives in the FEIS; see Chapters 4 and 5. Ultimately, NOAA decided to move forward with the Revised Preferred Alternative, as presented in the proposed rule, as their Final Preferred Alternative.

VI. Classification

A. National Marine Sanctuaries Act

Section 301(b) of the NMSA (16 U.S.C. 1431) provides authority for comprehensive and coordinated conservation and management of national marine sanctuaries in coordination with other resource management authorities. Section 304(a)(4) of the NMSA (16 U.S.C. 1434) requires that the procedures specified in Section 304 for designating a national marine sanctuary be followed for modifying any term of designation. This action, in addition to expanding the sanctuary, is revising the terms of designation (*e.g.,* scope of regulations) for the FGBNMS. In accordance with Section 304, the documents relevant to the expansion of Flower Garden Banks

are being submitted to the House Resources Committee and the Senate Committee on Commerce, Science, and Transportation. Section 304(a)(5) of the NMSA also requires that NOAA consult with the appropriate Federal fishery management council on any action proposing to regulate fishing in federal waters. Consultation with the Gulf of Mexico Fishery Management Council (GMFMC) is discussed above in part II sections 4 and 5. NOAA solicited comments on potential exemptions for pelagic longline and spearfishing in the expanded area, and based on public comment and coordination with NOAA fisheries, determined to not grant these exemptions and to extend existing fishing regulations into the expansion areas.

B. National Environmental Policy Act

In accordance with Section 304(a)(2) of the NMSA (16 U.S.C. 1434(a)(2)), and the provisions of NEPA (42 U.S.C. 4321–4370), NOAA has prepared a FEIS to evaluate the impacts of this action. Because this environmental review began before September 14, 2020, which was the effective date of the amendments to the Council on Environmental Quality (CEQ) regulations implementing NEPA (85 FR 43372 (Jul. 16, 2020)), the FEIS was prepared using the 1978 CEQ NEPA regulations. The Notice of Availability (December 11, 2020, 85 FR 80093) of the FGBNMS FEIS is available on the FGBNMS website.[18] NEPA reviews initiated prior to the effective date of the 2020 revised CEQ regulations may be conducted using the 1978 version of the regulations. NOAA has also prepared a ROD. Copies of the FEIS and ROD are available at the address and website listed in the **ADDRESSES** section of this final rule.

C. Executive Order 12866: Regulatory Impact

This final rule has been determined to be ''significant'' within the meaning of Executive Order 12866. Details on the estimated costs of this rule are discussed in BOEM's E.O. 13795 report, which is available on *regulations.gov* at docket NOAA–NOS–2019–033, and serves as a substitute for the Regulatory Impact Review (RIR). NOAA inadvertently omitted this report in the public docket for this action when the NPRM was published. NOAA subsequently published a **Federal Register** notice on November 23, 2020 (85 FR 74630), making the RIR available for public comments. Refer to section V of this rule for comments received on the RIR. Details on the estimated benefits of this action are discussed in Chapter 5, section 5.3 of the FEIS.

D. Executive Order 13132: Federalism Assessment

NOAA has concluded this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132. The area that is the subject of the final rule is located entirely within federal waters outside of state or local jurisdiction. This rule will not have a substantial or direct effect on states or local governments.

E. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This Executive Order reaffirms the Federal government's commitment to tribal sovereignty, self-determination, and self-government. Its purpose is to ensure that all Executive departments and agencies consult with Indian tribes and respect tribal sovereignty as they develop policies on issues that impact Indian communities. This action is not anticipated to have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibility between the Federal Government and Indian tribes.

F. Executive Order 13795: Implementing an America-First Offshore Energy Strategy

Executive Order 13795 directs the Secretary of Commerce to refrain from designating or expanding any national marine sanctuary unless the proposal includes a full accounting from the DOI of any energy or mineral resource potential (including offshore energy from wind, oil, natural gas, methane hydrates, and any other sources that the Secretary of Commerce deems appropriate) within the expansion area, and the potential impact of the expansion on energy or mineral resource potential within the designated area. On February 25, 2019, BOEM provided NOAA with a review of offshore energy and mineral resource potential located within the revised expansion areas in accordance with Executive Order 13795. BOEM's report is available at the Supporting Document section of the docket identified by NOAA–NOS–2019–033, and posted at *https://www.regulations.gov/document?D=NOAA-NOS-2019-0033-1630.*

G. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not a significant energy action under the definition in E.O. 13211. It is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Moreover, the Administrator of OIRA has not otherwise designated this action as a significant energy action. A Statement of Energy Effects, therefore, is not required.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires Federal agencies to prepare an analysis of a rule's impact on small entities whenever the agency is required to publish a rule, unless the head of the agency can certify, pursuant to 5 U.S.C. 605(b), that the action will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, if the head of an agency (or his or her designee) certifies that a rule will not have a significant impact on a substantial number of small entities, then the agency is not required to prepare a regulatory flexibility analysis.

Pursuant to section 605(b), the Chief Counsel for Regulations for the Department of Commerce, through delegation by the head of the agency, certified to the Office of Advocacy of the Small Business Administration during the proposed rule stage that the regulations would not have a significant economic impact on a substantial number of small entities. The factual basis for certification was published in the proposed rule (85 FR 25367). No public comments were received regarding this certification. Therefore, a regulatory flexibility analysis was not required and none was prepared.

I. Paperwork Reduction Act

The existing FGBNMS regulations contain a collection-of-information requirement subject to the Paperwork Reduction Act (PRA), approved by The Office of Management and Budget (OMB), under control number 0648–0141, for collection-of-information for reporting and recordkeeping requirements under 15 CFR part 922. This final rule would not increase or otherwise revise the existing paperwork burdens.

The public reporting burden for national marine sanctuary general permit applications is estimated to average 1 hour 30 minutes per application, including the time for reviewing the application instructions,

[18] *https://flowergarden.noaa.gov/management/sanctuaryexpansion.html.*

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. For special use permits, a collection-of information requirement is necessary to determine whether the activities are consistent with the terms and conditions of special use permits prescribed by the NMSA. The public reporting burden for this collection of information is estimated to average twenty four (24) hours per response (application, annual report, and financial report), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This estimate does not include additional time that may be required should the applicant be required to provide information to NOAA for the preparation of documentation that may be required under NEPA (16 U.S.C. 1431 *et seq.*).

NOAA determined that this final rule would not appreciably change the average annual number of respondents or the reporting burden for the information requirements supporting special use or research permits because few activities requiring new permits are expected for the new areas. Much of the research is expected to be conducted by the sanctuary, and other uses that require permits are anticipated with very low intensity in the proposed expansion areas. NOAA also determined that these regulations do not necessitate a modification to its information collection approval by the Office of Management and Budget under the Paperwork Reduction Act. Comments on this determination were solicited in the proposed rule, and no public comments were received. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

J. National Historic Preservation Act

The National Historic Preservation Act (NHPA; 16 U.S.C. 470 *et seq.*) is intended to preserve historical and archaeological sites in the United States of America. The act created the National Register of Historic Places, the list of National Historic Landmarks, and the State Historic Preservation Offices. Section 106 of the NHPA requires Federal agencies to take into account the effects of their undertakings on historic properties, and afford the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment. The historic preservation review process mandated by Section 106 is outlined in regulations issued by ACHP (36 CFR part 800). Pursuant to 36 CFR 800.16(l)(1), historic properties include: ''any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in the National Register of Historic Places maintained by the Secretary of the Interior.'' The term includes artifacts, records, and remains that are related to and located within such properties. NOAA did not identify any known historic properties within the boundaries of the Final Preferred Alternative, and received no public comments regarding historic properties in the Final Preferred Alternative boundaries.

K. Coastal Zone Management Act

Section 307 of the Coastal Zone Management Act (CZMA; 16 U.S.C. 1456) requires Federal agencies carrying out an activity that would affect any land or water use or natural resource of the coastal zone to provide a consistency determination to the relevant state agencies before final approval of the agency action. Copies of the Draft Environmental Impact Statement were provided to five Gulf Coast States (Texas, Louisiana, Alabama, Florida, and Mississippi), soliciting feedback on reasonably foreseeable effects on coastal resources and uses. Responses were received from Mississippi Department of Marine Resources and the Texas General Land Office indicating no objection to the proposed boundary changes or the DEIS. With this information in addition to analysis provided in the FEIS, NOAA determined this action would have no effect on coastal resources. On November 16, 2020, NOAA prepared a consistency determination, which was submitted to the five Gulf Coast States along with the proposed rule. In response to this request, the five Gulf States of Alabama, Florida, Louisiana, Mississippi, and Texas concurred with NOAA's consistency determination.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Fishing gear, Marine resources, Natural resources, Penalties, Recreation and recreation areas, Wildlife.

Nicole R. LeBoeuf,

Acting Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service.

Accordingly, for the reasons set forth above, NOAA amends part 922, title 15 of the Code of Federal Regulations as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

Subpart L—Flower Garden Banks National Marine Sanctuary

■ 2. Revise § 922.120 to read as follows:

§ 922.120 Boundary.

The Flower Garden Banks National Marine Sanctuary (sanctuary) boundary encompasses a total area of approximately 121 square nautical miles (160.35 square miles) of offshore ocean waters, and submerged lands thereunder, along the continental shelf and shelf edge in the northwestern Gulf of Mexico. The entire sanctuary boundary is comprised of 19 unique polygons. The precise boundary coordinates for each polygon are listed in appendix A to this subpart.

■ 3. In § 922.121, revise the term ''No-activity zone'' to read as follows:

§ 922.121 Definitions.

* * * * *

No-activity zone (applicable only to oil and gas industry activities) means the geographic areas delineated by the Department of the Interior in Topographic Features Stipulations for Outer Continental Shelf (OCS) lease sales as defined by a bathymetric contour (isobath) ranging from 55–85m in depth, with the exception of Stetson Bank (52m) and East and West Flower Garden Banks (100m). The Notice to Lessees (NTL) No. 2009–G39 provides and consolidates guidance for the avoidance and protection of biologically sensitive features and areas (*i.e.* topographic features, pinnacles, live bottoms (low relief features)) and other potentially sensitive biological features (PSBFs) when conducting operations in water depths shallower than 980 feet (300 meters) in the Gulf of Mexico. NTL 2009–G39 remains in effect pursuant to NTL No. 2015–N02. The no-activity zones are based on depth contours as noted for the following Banks: Stetson Bank (52 meters), MacNeil Bank (82

meters), Rankin Banks (including 28 Fathom Bank) (85 meters), Bright Bank (85 meters), Geyer Bank (85 meters), Elvers Bank (85 meters), McGrail Bank (85 meters), Bouma Bank (85 meters), Rezak Bank (85 meters), Sidner Bank (85 meters), Sonnier Bank (55 meters), Alderdice Bank (80 meters), and Parker Bank (85 meters). For East and West Flower Garden Banks, the no-activity zones are based on the ''¼ ¼ ¼'' aliquot system formerly used by the Department of the Interior, a method that delineates a specific portion of a block rather than the actual underlying isobath. The precise aliquot part description of these areas around East and West Flower Garden Banks are provided in appendix A of this subpart.

■ 4. Revise § 922.122(e)(1) to read as follows:

§ 922.122 Prohibited or otherwise regulated activities.

* * * * *

(e)(1) The prohibitions in paragraphs (a)(2) through (11) of this section do not apply to activities being carried out by the Department of Defense as of the effective date of the revised terms of sanctuary designation. Such activities shall be carried out in a manner that minimizes any adverse impact on Sanctuary resources or qualities. The prohibitions in paragraphs (a)(2) through (11) of this section do not apply to any new activities carried out by the Department of Defense that do not have the potential for any significant adverse impact on Sanctuary resources or qualities. Such activities shall be carried out in a manner that minimizes any adverse impact on Sanctuary resources or qualities. New activities with the potential for significant adverse impact on Sanctuary resources or qualities may be exempted from the prohibitions in paragraphs (a)(2) through (11) of this section by the Director after consultation between the Director and the Department of Defense. If it is determined that an activity may be carried out, such activity shall be carried out in a manner that minimizes any adverse impact on Sanctuary resources or qualities.

* * * * *

■ 5. Revise appendix A to subpart L to read as follows:

Appendix A to Subpart L of Part 922—Flower Garden Banks National Marine Sanctuary Boundary Coordinates

Flower Garden Banks National Marine Sanctuary

Coordinates listed in this appendix are unprojected (Geographic Coordinate System) and based on the North American Datum of 1983 (NAD83).

Point ID No.	Polygon ID No.	Bank(s)	Latitude	Longitude
1	1	Stetson Bank	28.15673	−94.29673
2	1	Stetson Bank	28.15661	−94.30312
3	1	Stetson Bank	28.15862	−94.30888
4	1	Stetson Bank	28.16950	−94.30839
5	1	Stetson Bank	28.17386	−94.30257
6	1	Stetson Bank	28.17583	−94.29445
7	1	Stetson Bank	28.17543	−94.29327
8	1	Stetson Bank	28.17284	−94.28952
9	1	Stetson Bank	28.16924	−94.28677
10	1	Stetson Bank	28.16428	−94.28681
11	1	Stetson Bank	28.16274	−94.28756
12	1	Stetson Bank	28.15796	−94.29047
13	1	Stetson Bank	28.15673	−94.29673
1	2	West Flower Garden Bank	27.84363	−93.78549
2	2	West Flower Garden Bank	27.81750	−93.81056
3	2	West Flower Garden Bank	27.81752	−93.84752
4	2	West Flower Garden Bank	27.83069	−93.86271
5	2	West Flower Garden Bank	27.81735	−93.87490
6	2	West Flower Garden Bank	27.83220	−93.89185
7	2	West Flower Garden Bank	27.85854	−93.89369
8	2	West Flower Garden Bank	27.87925	−93.87853
9	2	West Flower Garden Bank	27.92626	−93.82011
10	2	West Flower Garden Bank	27.92620	−93.81759
11	2	West Flower Garden Bank	27.91801	−93.80801
12	2	West Flower Garden Bank	27.90969	−93.77939
13	2	West Flower Garden Bank	27.88644	−93.77939
14	2	West Flower Garden Bank	27.84363	−93.78549
1	3	Horseshoe Bank	27.82317	−93.62789
2	3	Horseshoe Bank	27.80927	−93.63578
3	3	Horseshoe Bank	27.80568	−93.65541
4	3	Horseshoe Bank	27.79429	−93.66555
5	3	Horseshoe Bank	27.78357	−93.68846
6	3	Horseshoe Bank	27.79640	−93.70534
7	3	Horseshoe Bank	27.81855	−93.75198
8	3	Horseshoe Bank	27.82742	−93.74743
9	3	Horseshoe Bank	27.81868	−93.68868
10	3	Horseshoe Bank	27.83143	−93.68941
11	3	Horseshoe Bank	27.84699	−93.70079
12	3	Horseshoe Bank	27.87165	−93.73947
13	3	Horseshoe Bank	27.88602	−93.73294
14	3	Horseshoe Bank	27.87252	−93.64648
15	3	Horseshoe Bank	27.85861	−93.63908
16	3	Horseshoe Bank	27.82317	−93.62789
1	4	East Flower Garden Bank	27.89455	−93.57040
2	4	East Flower Garden Bank	27.87999	−93.61309
3	4	East Flower Garden Bank	27.88003	−93.62961

Point ID No.	Polygon ID No.	Bank(s)	Latitude	Longitude
4	4	East Flower Garden Bank	27.89330	−93.64172
5	4	East Flower Garden Bank	27.92101	−93.64747
6	4	East Flower Garden Bank	27.95899	−93.64490
7	4	East Flower Garden Bank	27.97485	−93.63086
8	4	East Flower Garden Bank	27.98177	−93.60996
9	4	East Flower Garden Bank	27.98554	−93.58188
10	4	East Flower Garden Bank	27.95206	−93.57810
11	4	East Flower Garden Bank	27.92151	−93.56880
12	4	East Flower Garden Bank	27.89455	−93.57040
1	5	MacNeil Bank	28.00226	−93.51550
2	5	MacNeil Bank	27.99707	−93.52669
3	5	MacNeil Bank	28.00136	−93.52423
4	5	MacNeil Bank	28.00518	−93.52425
5	5	MacNeil Bank	28.01694	−93.52233
6	5	MacNeil Bank	28.01883	−93.51264
7	5	MacNeil Bank	28.03670	−93.50300
8	5	MacNeil Bank	28.03724	−93.49844
9	5	MacNeil Bank	28.03113	−93.49199
10	5	MacNeil Bank	28.01300	−93.49624
11	5	MacNeil Bank	28.00331	−93.50725
12	5	MacNeil Bank	28.00226	−93.51550
1	6	Rankin Bank & 28—Fathom Bank	27.92554	−93.40593
2	6	Rankin Bank & 28—Fathom Bank	27.92039	−93.41021
3	6	Rankin Bank & 28—Fathom Bank	27.92035	−93.42474
4	6	Rankin Bank & 28—Fathom Bank	27.91387	−93.43165
5	6	Rankin Bank & 28—Fathom Bank	27.90829	−93.42234
6	6	Rankin Bank & 28—Fathom Bank	27.90641	−93.42535
7	6	Rankin Bank & 28—Fathom Bank	27.90489	−93.44219
8	6	Rankin Bank & 28—Fathom Bank	27.89549	−93.44396
9	6	Rankin Bank & 28—Fathom Bank	27.88892	−93.43403
10	6	Rankin Bank & 28—Fathom Bank	27.88072	−93.42805
11	6	Rankin Bank & 28—Fathom Bank	27.87676	−93.42787
12	6	Rankin Bank & 28—Fathom Bank	27.88449	−93.44458
13	6	Rankin Bank & 28—Fathom Bank	27.88803	−93.45159
14	6	Rankin Bank & 28—Fathom Bank	27.88794	−93.45905
15	6	Rankin Bank & 28—Fathom Bank	27.89234	−93.46410
16	6	Rankin Bank & 28—Fathom Bank	27.89971	−93.45571
17	6	Rankin Bank & 28—Fathom Bank	27.90910	−93.45343
18	6	Rankin Bank & 28—Fathom Bank	27.92847	−93.45335
19	6	Rankin Bank & 28—Fathom Bank	27.93407	−93.44743
20	6	Rankin Bank & 28—Fathom Bank	27.93599	−93.44215
21	6	Rankin Bank & 28—Fathom Bank	27.92554	−93.40593
1	7	Bright Bank	27.87310	−93.27056
2	7	Bright Bank	27.86549	−93.29462
3	7	Bright Bank	27.87300	−93.31055
4	7	Bright Bank	27.89058	−93.32193
5	7	Bright Bank	27.89839	−93.31987
6	7	Bright Bank	27.90336	−93.30953
7	7	Bright Bank	27.91010	−93.30562
8	7	Bright Bank	27.91634	−93.29292
9	7	Bright Bank	27.91263	−93.28816
10	7	Bright Bank	27.90354	−93.28386
11	7	Bright Bank	27.90253	−93.27238
12	7	Bright Bank	27.89927	−93.26729
13	7	Bright Bank	27.87310	−93.27056
1	8	Geyer Bank	27.78848	−93.07794
2	8	Geyer Bank	27.79458	−93.08448
3	8	Geyer Bank	27.83313	−93.07913
4	8	Geyer Bank	27.85306	−93.08279
5	8	Geyer Bank	27.86328	−93.07885
6	8	Geyer Bank	27.86908	−93.06974
7	8	Geyer Bank	27.86556	−93.05944
8	8	Geyer Bank	27.85211	−93.05391
9	8	Geyer Bank	27.83713	−93.05725
10	8	Geyer Bank	27.82540	−93.04312
11	8	Geyer Bank	27.82490	−93.04276
12	8	Geyer Bank	27.80846	−93.03412
13	8	Geyer Bank	27.78997	−93.04096
14	8	Geyer Bank	27.78602	−93.05384
15	8	Geyer Bank	27.78848	−93.07794
1	9A	Elvers Bank—A	27.82285	−92.88605
2	9A	Elvers Bank—A	27.82087	−92.88600
3	9A	Elvers Bank—A	27.82009	−92.88670

Point ID No.	Polygon ID No.	Bank(s)	Latitude	Longitude
4	9A	Elvers Bank—A	27.81869	−92.89235
5	9A	Elvers Bank—A	27.81690	−92.89404
6	9A	Elvers Bank—A	27.81615	−92.89653
7	9A	Elvers Bank—A	27.80645	−92.90884
8	9A	Elvers Bank—A	27.81221	−92.92082
9	9A	Elvers Bank—A	27.81599	−92.93908
10	9A	Elvers Bank—A	27.81934	−92.93940
11	9A	Elvers Bank—A	27.82250	−92.92465
12	9A	Elvers Bank—A	27.82809	−92.91359
13	9A	Elvers Bank—A	27.83973	−92.89876
14	9A	Elvers Bank—A	27.83972	−92.88038
15	9A	Elvers Bank—A	27.83003	−92.86983
16	9A	Elvers Bank—A	27.82285	−92.88605
1	9B	Elvers Bank—B	27.85645	−92.92310
2	9B	Elvers Bank—B	27.85662	−92.91922
3	9B	Elvers Bank—B	27.85334	−92.91631
4	9B	Elvers Bank—B	27.85076	−92.91727
5	9B	Elvers Bank—B	27.84903	−92.92097
6	9B	Elvers Bank—B	27.85145	−92.92524
7	9B	Elvers Bank—B	27.85645	−92.92310
1	10A	McGrail Bank—A	27.97684	−92.58489
2	10A	McGrail Bank—A	27.97749	−92.57716
3	10A	McGrail Bank—A	27.97475	−92.56753
4	10A	McGrail Bank—A	27.97304	−92.56191
5	10A	McGrail Bank—A	27.95173	−92.53902
6	10A	McGrail Bank—A	27.94849	−92.54254
7	10A	McGrail Bank—A	27.96632	−92.56116
8	10A	McGrail Bank—A	27.96792	−92.58152
9	10A	McGrail Bank—A	27.95989	−92.58187
10	10A	McGrail Bank—A	27.95409	−92.57057
11	10A	McGrail Bank—A	27.94951	−92.57135
12	10A	McGrail Bank—A	27.94920	−92.57994
13	10A	McGrail Bank—A	27.95846	−92.60274
14	10A	McGrail Bank—A	27.97286	−92.61901
15	10A	McGrail Bank—A	27.98096	−92.60158
16	10A	McGrail Bank—A	27.97684	−92.58489
1	10B	McGrail Bank—B	27.94116	−92.54750
2	10B	McGrail Bank—B	27.94180	−92.54543
3	10B	McGrail Bank—B	27.94010	−92.54202
4	10B	McGrail Bank—B	27.93616	−92.54151
5	10B	McGrail Bank—B	27.93481	−92.54398
6	10B	McGrail Bank—B	27.93529	−92.54803
7	10B	McGrail Bank—B	27.93859	−92.54901
8	10B	McGrail Bank—B	27.94116	−92.54750
1	11	Bouma Bank	28.07909	−92.47305
2	11	Bouma Bank	28.07370	−92.44900
3	11	Bouma Bank	28.07370	−92.44891
4	11	Bouma Bank	28.06544	−92.43518
5	11	Bouma Bank	28.05162	−92.43380
6	11	Bouma Bank	28.03846	−92.44065
7	11	Bouma Bank	28.03463	−92.45289
8	11	Bouma Bank	28.03114	−92.45537
9	11	Bouma Bank	28.02915	−92.46338
10	11	Bouma Bank	28.03154	−92.47259
11	11	Bouma Bank	28.04166	−92.47229
12	11	Bouma Bank	28.04525	−92.46717
13	11	Bouma Bank	28.04751	−92.47310
14	11	Bouma Bank	28.04676	−92.48308
15	11	Bouma Bank	28.04866	−92.48462
16	11	Bouma Bank	28.05687	−92.48145
17	11	Bouma Bank	28.06388	−92.49262
18	11	Bouma Bank	28.07018	−92.49141
19	11	Bouma Bank	28.06974	−92.48613
20	11	Bouma Bank	28.06594	−92.48098
21	11	Bouma Bank	28.07109	−92.47708
22	11	Bouma Bank	28.07683	−92.48071
23	11	Bouma Bank	28.07909	−92.47305
1	12	Sonnier Bank	28.32652	−92.45356
2	12	Sonnier Bank	28.32495	−92.45647
3	12	Sonnier Bank	28.32501	−92.45965
4	12	Sonnier Bank	28.32796	−92.46626
5	12	Sonnier Bank	28.33523	−92.47536
6	12	Sonnier Bank	28.34453	−92.47511

Point ID No.	Polygon ID No.	Bank(s)	Latitude	Longitude
7	12	Sonnier Bank	28.34840	−92.47439
8	12	Sonnier Bank	28.35256	−92.47181
9	12	Sonnier Bank	28.35416	−92.46784
10	12	Sonnier Bank	28.35456	−92.46135
11	12	Sonnier Bank	28.35351	−92.45729
12	12	Sonnier Bank	28.35174	−92.45107
13	12	Sonnier Bank	28.34852	−92.44564
14	12	Sonnier Bank	28.34303	−92.44045
15	12	Sonnier Bank	28.34048	−92.44024
16	12	Sonnier Bank	28.33584	−92.44669
17	12	Sonnier Bank	28.33068	−92.44985
18	12	Sonnier Bank	28.32652	−92.45356
1	13	Rezak Bank	27.95420	−92.36641
2	13	Rezak Bank	27.95847	−92.37739
3	13	Rezak Bank	27.95629	−92.38599
4	13	Rezak Bank	27.97297	−92.39248
5	13	Rezak Bank	27.97892	−92.39845
6	13	Rezak Bank	27.98869	−92.39964
7	13	Rezak Bank	27.99372	−92.38244
8	13	Rezak Bank	27.98603	−92.36697
9	13	Rezak Bank	27.98022	−92.36429
10	13	Rezak Bank	27.97442	−92.36996
11	13	Rezak Bank	27.96006	−92.36854
12	13	Rezak Bank	27.95420	−92.36641
1	14	Sidner Bank	27.93046	−92.36762
2	14	Sidner Bank	27.91368	−92.37398
3	14	Sidner Bank	27.91462	−92.38530
4	14	Sidner Bank	27.91976	−92.39427
5	14	Sidner Bank	27.92306	−92.38792
6	14	Sidner Bank	27.94525	−92.38305
7	14	Sidner Bank	27.94166	−92.37565
8	14	Sidner Bank	27.94231	−92.37189
9	14	Sidner Bank	27.93046	−92.36762
1	15A	Parker Bank—A	27.95067	−92.00294
2	15A	Parker Bank—A	27.94177	−91.99762
3	15A	Parker Bank—A	27.93547	−91.99568
4	15A	Parker Bank—A	27.92937	−91.99981
5	15A	Parker Bank—A	27.93224	−92.02999
6	15A	Parker Bank—A	27.93401	−92.03946
7	15A	Parker Bank—A	27.93958	−92.05015
8	15A	Parker Bank—A	27.95012	−92.05050
9	15A	Parker Bank—A	27.96214	−92.05407
10	15A	Parker Bank—A	27.96630	−92.04745
11	15A	Parker Bank—A	27.96869	−92.04120
12	15A	Parker Bank—A	27.96925	−92.02758
13	15A	Parker Bank—A	27.96678	−92.02175
14	15A	Parker Bank—A	27.95067	−92.00294
1	15B	Parker Bank—B	27.96082	−91.99450
2	15B	Parker Bank—B	27.96432	−91.99285
3	15B	Parker Bank—B	27.96566	−91.99014
4	15B	Parker Bank—B	27.96385	−91.98600
5	15B	Parker Bank—B	27.96149	−91.98639
6	15B	Parker Bank—B	27.95931	−91.98760
7	15B	Parker Bank—B	27.95824	−91.99183
8	15B	Parker Bank—B	27.96082	−91.99450
1	16	Alderdice Bank	28.09726	−91.99328
2	16	Alderdice Bank	28.09474	−91.98619
3	16	Alderdice Bank	28.09569	−91.97526
4	16	Alderdice Bank	28.09184	−91.97361
5	16	Alderdice Bank	28.08410	−91.97273
6	16	Alderdice Bank	28.07506	−91.97457
7	16	Alderdice Bank	28.07053	−91.98465
8	16	Alderdice Bank	28.06959	−91.99347
9	16	Alderdice Bank	28.06819	−92.00512
10	16	Alderdice Bank	28.07026	−92.01321
11	16	Alderdice Bank	28.07562	−92.02032
12	16	Alderdice Bank	28.08058	−92.02436
13	16	Alderdice Bank	28.08463	−92.02577
14	16	Alderdice Bank	28.09024	−92.02296
15	16	Alderdice Bank	28.09487	−92.01231
16	16	Alderdice Bank	28.09627	−92.00735
17	16	Alderdice Bank	28.09507	−92.00008
18	16	Alderdice Bank	28.09726	−91.99328

■ 6. Revise appendix B to subpart L to read as follows:

Appendix B to Subpart L of Part 922—Flower Garden Banks National Marine Sanctuary—Terms of Designation

Preamble

Under the authority of title III of the Marine Protection, Research, and Sanctuaries Act, as amended (''the Act''), 16 U.S.C. 1431 *et seq.,* 19 separate unique polygon areas of ocean waters and the submerged lands thereunder, along the continental shelf and shelf edge in the northwestern Gulf of Mexico, as described in Article II, are hereby designated as Flower Garden Banks National Marine Sanctuary for the purposes of protecting and managing the conservation, ecological, recreation, research, education, historic and aesthetic resources and qualities of these areas.

Article I—Effect of Designation

The Act authorizes the Secretary of Commerce to issue such final regulations as are necessary and reasonable to implement the designation, including managing and protecting the conservation, recreational, ecological, historical, research, educational, and esthetic resources and qualities of a sanctuary. Section 1 of Article IV of this Designation Document lists those activities that may be regulated on the effective date of designation or at some later date in order to protect Sanctuary resources and qualities. Thus, the act of designation empowers the Secretary of Commerce to regulate the activities listed in Section 1. Listing does not necessarily mean that an activity will be regulated. However, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original designation was made.

Article II—Description of the Area

The Flower Garden Banks National Marine Sanctuary (Sanctuary) boundary encompasses a total area of approximately 121 square nautical miles (160 square miles) of offshore ocean waters, and submerged lands thereunder, along the continental shelf and shelf edge in the northwestern Gulf of Mexico. The entire sanctuary boundary is composed of 19 unique polygons. The precise boundary coordinates for each polygon are listed in appendix A to this subpart.

The sanctuary boundary for Polygon 1 begins at Point 1 and continues in numerical order to Point 13 and contains the submerged feature of Stetson Bank with an area of approximately 1.1 square nautical miles (1.5 square miles), located approximately 71 nautical miles (82 miles) south-southeast of Galveston, Texas. The sanctuary boundary for Polygon 2 begins at Point 1 and continues in numerical order to Point 14 and contains the submerged feature of West Flower Garden Bank with an area of approximately 28.0 square nautical miles (37.1 square miles), located approximately 97 nautical miles (111 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 3 begins at Point 1 and continues in numerical order to Point 16 and contains the submerged feature of Horseshoe Bank with an area of approximately 21.7 square nautical miles (28.7 square miles), located approximately 102 nautical miles (117 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 4 begins at Point 1 and continues in numerical order to Point 12 and contains the submerged feature of East Flower Garden Bank with an area of approximately 21.0 square nautical miles (27.8 square miles), located approximately 101 nautical miles (116 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 5 begins at Point 1 and continues in numerical order to Point 12 and contains the submerged feature of MacNeil Bank with an area of approximately 2.1 square nautical miles (2.7 square miles), located approximately 103 nautical miles (118 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 6 begins at Point 1 and continues in numerical order to Point 21 and contains the submerged features of Rankin Bank and 28 Fathom Bank with an area of approximately 4.2 square nautical miles (5.6 square miles), located approximately 109 nautical miles (126 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 7 begins at Point 1 and continues in numerical order to Point 13 and contains the submerged features of Bright Bank with an area of approximately 5.8 square nautical miles (7.6 square miles), located approximately 115 nautical miles (133 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 8 begins at Point 1 and continues in numerical order to Point 15 and contains the submerged feature of Geyer Bank within an area of approximately 8.7 square nautical miles (11.5 square miles), located approximately 126 nautical miles (145 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 9A begins at Point 1 and continues in numerical order to Point 16 and contains part of the submerged feature of Elvers Bank within an area of approximately 3.3 square nautical miles (4.4 square miles), located approximately 134 nautical miles (154 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 9B begins at Point 1 and continues in numerical order to Point 7 and also contains part of the submerged feature of Elvers Bank within an area of approximately 0.1 square nautical miles (0.2 square miles), located approximately 133 nautical miles (153 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 10A begins at Point 1 and continues in numerical order to Point 16 and contains part of the submerged feature of McGrail Bank with an area of approximately 3.4 square nautical miles (4.5 square miles), located approximately 142 nautical miles (163 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 10B begins at Point 1 and continues in numerical order to Point 8 and also contains part of the submerged feature of McGrail Bank with an area of approximately 0.1 square nautical miles (0.2 square miles), located approximately 146 nautical miles (168 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 11 begins at Point 1 and continues in numerical order to Point 23 and contains the submerged feature of Bouma Bank with an area of approximately 5.8 square nautical miles (7.7 square miles), located approximately 145 nautical miles (167 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 12 begins at Point 1 and continues in numerical order to Point 18 and contains the submerged feature of Sonnier Bank with an area of approximately 2.3 square nautical miles (3.1 square miles), located approximately 138 nautical miles (159 miles) east-southeast of Galveston, Texas. The sanctuary boundary for Polygon 13 begins at Point 1 and continues in numerical order to Point 12 and contains the submerged feature of Rezak Bank with an area of approximately 2.8 square nautical miles (3.7 square miles), located approximately 151 nautical miles (174 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 14 begins at Point 1 and continues in numerical order to Point 9 and contains the submerged feature of Sidner Bank with an area of approximately 1.5 square nautical miles (2.0 square miles), located approximately 153 nautical miles (177 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 15A begins at Point 1 and continues in numerical order to Point 14 and contains part of the submerged feature of Parker Bank within an area of approximately 5.2 square nautical miles (6.8 square miles), located approximately 168 nautical miles (194 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 15B begins at Point 1 and continues in numerical order to Point 8 and also contains part of the submerged feature of Parker Bank within an area of approximately 0.1 square nautical miles (0.2 square miles), located approximately 171 nautical miles (197 miles) southeast of Galveston, Texas. The sanctuary boundary for Polygon 16 begins at Point 1 and continues in numerical order to Point 18 and contains the submerged feature of Alderdice Bank within an area of approximately 3.8 square nautical miles (5.0 square miles), located approximately 166 nautical miles (191 miles) east-southeast of Galveston, Texas.

Article III—Characteristics of Area That Give it Particular Value

The Sanctuary contains a series of underwater features located along the edge of the continental shelf in the northwestern Gulf of Mexico. These features are of interest from both a geological and biological perspective. Formed primarily as the result of the movement of underlying salt deposits (also called salt domes or salt diapirs), and bathed by waters of tropical origin, they contain important geological features, biological habitats and other marine resources of national significance. They contain highly productive marine ecosystems that support a variety of fish and invertebrate communities of biological and economic importance.

The reefs and banks of the northwestern Gulf of Mexico are structurally complex and contain a range of marine habitats, including coral reefs, coralline algal reefs, algal nodule beds, mesophotic and deepwater reefs, and soft bottom communities. The composition,

diversity and vertical distribution of benthic communities on the banks are strongly influenced by the physical environment, including water temperature, turbidity and current regime. Geological features of interest include brine seeps, exposed basalt, methane seeps, and mud volcanoes. East and West Flower Garden Banks, the most well-known of the features, sustain the northernmost living coral reefs on the U.S. continental shelf, considered among the healthiest coral reefs in the Caribbean and Western Atlantic region. A deeper water coral reef also exists at McGrail Bank, consisting primarily of large colonies of blushing star coral (*Stephanocoenia intersepta*) at depths between 140 and 160 feet. These coral reefs are isolated from other reef systems by over 300 nautical miles (342 miles) and exist under hydrographic conditions generally near the northern limit for tropical reef formation. Several other banks, including Stetson, Sonnier, Geyer, and Bright Banks, contain various combinations of non-reef building coral species known collectively as coral communities, comprised of sponges, stony corals, fire coral, leafy algae and coralline algae. The deeper portions of the banks host thriving mid-depth (or ''mesophotic'') coral habitats characterized by the presence of both light-dependent and deepwater corals, including black corals, gorgonian corals, and associated organisms. Biological communities are distributed among several interrelated biotic zones, including a coralline algae zone, deep reef rocky outcrops, and soft bottom communities. The complex and biologically productive ecological communities of the banks offer a combination of aesthetic appeal and recreational and research opportunity matched in few other ocean areas.

The following are qualitative descriptions of the individual reefs and banks within the Sanctuary; specific boundary coordinates can be found in appendix A to this subpart.

a. Stetson Bank, Depth Range 56ft–194ft

Boundaries encompass a claystone/siltstone ring feature of mesophotic coral habitat revealed by high resolution multibeam bathymetric surveys, and subsequently ground-truthed by remotely operated vehicle surveys. These features are surface expressions of the salt dome associated with the feature, and provide habitat for sponges, gorgonians, stony branching corals, black corals, and associated fish and mobile invertebrates.

b. West Flower Garden Bank, Depth Range 59ft–545ft

Boundaries encompass mesophotic coral patch reefs to the north, southwest, and east of the existing sanctuary. These reefs provide coralline algae reef habitat for black corals, gorgonians, stony branching corals, and associated fish and mobile invertebrates.

c. East Flower Garden Bank, Depth Range 52ft–446ft

Boundaries to encompass mesophotic coral patch reefs to the north and southeast of the existing sanctuary. These reefs provide deep coral habitat for dense populations of black corals, gorgonians, stony branching corals, and associated fish and mobile invertebrates.

d. Horseshoe Bank, Depth Range 243ft–614ft

Extensive deepwater habitat and coralline algae reefs in the form of hundreds of patchy outcroppings covering an area of approximately 1.9 miles (3km) wide and having 16.4–49.2ft (5–15m) of relief above the seafloor, with dense assemblages of mesophotic black coral, gorgonians, stony branching corals, sponges, algae invertebrates, and fish; several conical-shaped mud volcanoes clustered near the center of the feature, with one rising 328ft (100m) above the sea floor.

e. MacNeil Bank, Depth Range 210ft–315ft

Deep reef bedrock outcrops and coralline algae patch reefs harboring populations of black corals and gorgonians, sponges, fish, and mobile invertebrates.

f. Rankin/28 Fathom Banks, Depth Range 164ft–571ft

Rankin Bank is just north of 28 Fathom Bank, and separated from it by a long trough, approximately 1,640-foot (500 m) wide, approximately 6,070-foot (1,850 m) which extends to a depth of approximately 570ft (174 m). The boundaries encompass the shallowest portions of Rankin and 28 Fathom Banks, which harbor coral algae reefs and deep coral reefs with populations of gorgonians, black corals, sponges, and associated fish and mobile invertebrates.

g. Bright Bank, Depth Range 112ft–384ft

Bright Bank previously harbored a coral reef on the very shallowest portions of the bank, which sustained extensive damage from salvage and mining activities employing dynamite for excavation activities. The cap is now considered a coral community, and in spite of these impacts, nine species of shallow water scleractinian corals survive, along with two deeper water species. The feature also harbors extensive coralline algae reefs, providing habitat for populations of gorgonians, black corals, sponges, and associated fish and mobile invertebrates.

h. Geyer Bank, Depth Range 128ft–722ft

Geyer Bank is a broad, relatively flat fault-bounded structure situated on an active salt diaper. This feature supports a coral community, as well as extensive coralline algae reefs and fields of algal nodules including dense fields of macro-algae, black corals, gorgonians, sponges, and associated fish and mobile invertebrates. Seasonal spawning aggregations of fish are associated with this bank, including enormous numbers of reef butterflyfish.

i. Elvers Bank, Depth Range 213ft–686ft

Two discreet polygons have been developed to protect portions of Elvers Bank: A larger polygon encompassing 4.43 square miles on the south side of the feature, and a small polygon, encompassing 0.19 square miles on the north side of the feature. The shallow areas of the bank feature coralline algae reefs and algal nodule fields, and the deeper areas in the southern polygon harbor large deep reef outcroppings, both providing habitat for black corals, gorgonians, sponges, and associated fish and mobile invertebrates. The deep reefs also harbor glass sponge fields, a feature not documented in any other areas of the sanctuary, as well as a previously undescribed species of black coral.

j. McGrail Bank, Depth Range 144ft–512ft

Two discreet polygons have been developed to protect portions of McGrail Bank: A larger claw shaped polygon reaching from northwest to southeast, encompassing 4.54 square miles, and a smaller polygon, encompassing 0.17 square miles, situated on the southeast of the feature that wraps around a conical shaped mound. This bank features unique areas of coral reefs dominated by large colonies of the blushing star coral, *Stephanocoenia intersepta,* with 28% live coral cover in discrete areas (no other known coral reef is dominated by this species). Pinnacles varying in diameter from ~80 to 395 feet (24–120 m) and as tall as ~25 feet (8 m) are found on the southwest rim of the main feature, along east- and southeast-trending scarps leading away from the bank and in concentric fields to the south and southeast of the bank. A significant portion of the depth zone between 145 and 170 feet is dominated by coral colonies up to 5 feet tall, covering an area of approximately 37 acres. At least 14 species of stony corals have been recorded. Deeper portions of this site harbor mesophotic coral habitat for deep coral, coralline algae reefs, and fields of algal nodules. Dense populations of black corals, gorgonians, macro-algae fields, and associated fish and mobile invertebrates are present.

k. Sonnier Bank, Depth Range 62ft–210ft

Sonnier Bank consists of a series of isolated clusters of pinnacles comprised of uplifted siltstone and claystone, that rise mostly around the perimeter of a single, roughly circular ring 1.9 miles (3.2km) in diameter. Two peaks are accessible and popular with recreational scuba divers. The peaks are dominated by coral communities featuring fire coral, sponges, and algae. The deeper portions of the feature are fairly heavily silted, but provide habitat for black corals, gorgonians, and associated fish and mobile invertebrates.

l. Bouma Bank, Depth Range 187ft–322ft

Bouma Bank is dominated by coralline algae reefs and algal nodule fields, providing habitat for populations of black corals, gorgonians, algae, branching stony coral, clusters of cup coral, and associated fish and mobile invertebrates.

m. Rezak Bank, Depth Range 197ft–430ft

Rezak Bank is dominated by coralline algae reefs and extensive algal nodule fields, providing habitat for populations of black corals, gorgonians, algae, and associated fish and mobile invertebrates.

n. Sidner Bank, Depth Range 190ft–420ft

Dominated by coralline algae reefs and extensive algal nodule fields providing habitat for populations of black corals, gorgonians, algae, sponges, and associated fish and mobile invertebrates.

o. Alderdice Bank, Depth Range 200ft–322ft

This feature includes spectacular basalt outcrops of Late Cretaceous origin

(approximately 77 million years old) representing the oldest rock exposed on the continental shelf offshore of Louisiana and Texas. The outcrops at Alderdice Bank bear diverse, extremely dense assemblages of gorgonians and black corals, sponges, and swarms of reef fish. Mesophotic coralline algae reef habitats below the spires, silted over in areas, provide habitat for dense populations of black corals, gorgonians, sponges, branching stony corals, fields of macro-algae, and associated fish and mobile invertebrates.

p. Parker Bank, Depth Range 187ft–387ft

Two discreet polygons have been developed to protect portions of Parker Bank. A larger polygon bounding the central portion of the features, encompassing 6.82 square miles, and a smaller polygon to the east, encompassing 0.14 square miles. These boundaries protect the shallowest portions of the bank, which harbor coralline algae reefs and algal nodule fields and support populations of plating stony corals, black corals, gorgonians, sponges, macro-algae, and associated fish and mobile invertebrates.

Article IV—Scope of Regulations

Section 1. Activities Subject to Regulation

The following activities are subject to regulation, including prohibition, to the extent necessary and reasonable to ensure the protection and management of the conservation, recreational, ecological, historical, research, educational and esthetic resources and qualities of the area:

a. Anchoring or otherwise mooring within the Sanctuary;

b. Discharging or depositing, from within the boundaries of the Sanctuary, any material or other matter;

c. Discharging or depositing, from beyond the boundaries of the Sanctuary, any material or other matter;

d. Drilling into, dredging or otherwise altering the seabed of the Sanctuary; or constructing, placing or abandoning any structure, material or other matter on the seabed of the Sanctuary;

e. Exploring for, developing or producing oil, gas or minerals within the Sanctuary;

f. Taking, removing, catching, collecting, harvesting, feeding, injuring, destroying or causing the loss of, or attempting to take, remove, catch, collect, harvest, feed, injure, destroy or cause the loss of, a Sanctuary resource;

g. Possessing within the Sanctuary a Sanctuary resource or any other resource, regardless of where taken, removed, caught, collected or harvested, that, if it had been found within the Sanctuary, would be a Sanctuary resource.

h. Possessing or using within the Sanctuary any fishing gear, device, equipment or other apparatus.

i. Possessing or using airguns or explosives or releasing electrical charges within the Sanctuary.

j. Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation or permit issued under the Act.

Section 2. Consistency With International Law

Any regulation of activities listed in Section 1 of this Article will be applied and enforced as mandated by 16 U.S.C. 1435(a).[1]

Section 3. Emergency Regulations

Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality, or minimize the imminent risk of such destruction, loss or injury, any and all activities, including those not listed in section 1 of this Article, are subject to immediate temporary regulation, including prohibition.

Article V—Effect on Other Regulations, Leases, Permits, Licenses, and Rights

Section 1. Fishing Regulations, Licenses, and Permits

The regulation of fishing is authorized under Article IV. All regulatory programs pertaining to fishing, including fishery management plans promulgated under the Magnuson Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* shall remain in effect. Where a valid regulation promulgated under these programs conflicts with a Sanctuary regulation, the regulation deemed by the Secretary of Commerce or designee as more protective of Sanctuary resources and qualities shall govern.

Section 2. Other Licenses, Regulations, and Permits

If any valid regulation issued by any Federal authority of competent jurisdiction, regardless of when issued, conflicts with a Sanctuary regulation, the regulation deemed by the Secretary of Commerce or designee as more protective of Sanctuary resources and qualities shall govern.

Pursuant to section 304(c)(1) of the Act, 16 U.S.C. 1434(c)(1), no valid lease, permit, license, approval, or other authorization issued by any Federal authority of competent jurisdiction, or any valid right of subsistence use or access, may be terminated by the Secretary of Commerce or designee as a result of this designation or as a result of any Sanctuary regulation if such authorization or right was in existence on the effective date of this designation. However, the Secretary of Commerce or designee may regulate the exercise of such authorization or right consistent with the purposes for which the Sanctuary is designated.

Accordingly, the prohibitions set forth in the Sanctuary regulations shall not apply to any activity authorized by any valid lease, permit, license, approval, or other authorization in existence on the effective date of Sanctuary designation and issued by any Federal authority of competent jurisdiction, or by any valid right of subsistence use or access in existence on the effective date of Sanctuary designation, provided that the holder of such authorization or right complies with Sanctuary regulations regarding the certification of such authorizations and rights (*e.g.,* notifies the Secretary or designee of the existence of, requests certification of, and provides requested information regarding such authorization or right) and complies with any terms and conditions on the exercise of such authorization or right imposed as a condition of certification by the Secretary or designee as he or she deems necessary to achieve the purposes for which the Sanctuary was designated.

Pending final agency action on the certification request, such holder may exercise such authorization or right without being in violation of any prohibitions set forth in the Sanctuary regulations, provided the holder is in compliance with Sanctuary regulations regarding certifications.

The prohibitions set forth in the Sanctuary regulations shall not apply to any activity conducted in accordance with the scope, purpose, terms, and conditions of the National Marine Sanctuary permit issued by the Secretary or designee in accordance with the Sanctuary regulations. Such permits may only be issued if the Secretary or designee finds that the activity for which the permit is applied will: Further research related to Sanctuary resources; further the educational, natural or historical resource value of the Sanctuary; further salvage or recovery operations in or near the Sanctuary in connection with a recent air or marine casualty; or assist in managing the Sanctuary.

The prohibitions set forth in the sanctuary regulations shall not apply to any activity conducted in accordance with the scope, purpose, terms, and conditions of a Special Use permit issued by the Secretary or designee in accordance with section 310 of the Act. However, in areas where sanctuary regulations prohibit oil, gas, or mineral exploration, development or production, the Secretary or designee may in no event, permit or otherwise, approve such activities in that area. Any leases, licenses, permits, approvals, or other authorizations issued after the effective date of designation authorizing the exploration or production of oil, gas, or minerals in that area shall be invalid.

Section 3. Department of Defense Activities

The prohibitions in § 922.122(a)(2) through (11) do not apply to activities being carried out by the Department of Defense as of the effective date of designation. Such activities shall be carried out in a manner that minimizes any adverse impact on Sanctuary resources and qualities. The prohibitions in § 922.122(a)(2) through (11) do not apply to any new activities carried out by the Department of Defense that do not have the potential for any significant adverse impact on Sanctuary resources and qualities. Such activities shall be carried out in a manner that minimizes any adverse impact on Sanctuary resources and qualities. New activities with the potential for significant adverse impact on Sanctuary resources and qualities may be exempted from the prohibitions in § 922.122(a)(2) through (11) of this section by the Director after consultation between the Director and the Department of Defense. If it is determined that an activity may be carried out, such activity shall be

[1] Based on the legislative history of the NMSA, NOAA has long interpreted the text of 16 U.S.C. 1435(a) as encompassing international law, including customary international law.

carried out in a manner that minimizes any adverse impact on Sanctuary resources and qualities. In the event of threatened or actual destruction of, loss of, or injury to a Sanctuary resource or quality resulting from an untoward incident, including but not limited to spills and groundings, caused by a component of the Department of Defense, the cognizant component shall promptly coordinate with the Director for the purpose of taking appropriate actions to respond to and mitigate the harm and, if possible, restore or replace the Sanctuary resource or quality.

Article VI—Alterations to This Designation

The terms of designation may be modified only by the same procedures by which the original designation is made, including public hearings; consultation with any appropriate Federal, State, regional and local agencies; review by the appropriate Congressional committees; and approval by the Secretary of Commerce or designee.

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BILLING CODE 3510–NK–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1223

[Docket No. CPSC–2013–0025]

Revisions to Safety Standard for Infant Swings

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In November 2012, the U.S. Consumer Product Safety Commission (CPSC) published a consumer product safety standard for infant swings under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The standard incorporated by reference the ASTM voluntary standard that was in effect for infant swings at the time. The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, when a voluntary standards organization revises the standard. Consistent with the CPSIA update process, the Commission issued a direct final rule in October 2013, to revise the incorporation by reference for the mandatory swings standard, to reflect ASTM'S revised voluntary standard. Since 2013, ASTM has revised the voluntary standard for infant swings three times. This direct final rule updates the mandatory standard for infant swings to incorporate by reference ASTM's 2020 version of the voluntary standard.

DATES: The rule is effective on April 3, 2021, unless CPSC receives a significant adverse comment by February 18, 2021. If CPSC receives such a comment, it will publish a notice in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of April 3, 2021.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2013–0025, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (email), except through *https://www.regulations.gov.* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. Alternatively, as a temporary option during the COVID–19 pandemic, you may email such submissions to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically: Confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2013–0025, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–6820; email: *kwalker@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products and adopt mandatory standards for these products. 15 U.S.C. 2056a(b)(1). The mandatory standard must be ''substantially the same as'' the voluntary standard, or may be ''more stringent than'' the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. *Id.*

Section 104(b)(4)(B) of the CPSIA specifies the process for when a voluntary standards organization revises a standard that the Commission incorporated by reference under section 104(b)(1). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. The Commission may reject the revised standard by notifying the voluntary standards organization that it has determined that the revised standard does not improve the safety of the consumer product and that it is retaining the existing standard. When rejecting a revision, the Commission must notify the voluntary standards organization of this determination within 90 days of receiving notice of the revision. If the Commission does not take this action to reject the revised standard, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision (or a later date specified by the Commission in the **Federal Register**). 15 U.S.C. 2056a(b)(4)(B).

2. Safety Standard for Infant Swings

Under section 104(b)(1) of the CPSIA, the Commission adopted a mandatory rule for infant swings, codified in 16 CFR part 1223. The rule incorporated by reference ASTM F2088–12a, *Standard Consumer Safety Specification for Infant Swings,* with modifications to the labeling and test method requirements.[1] 77 FR 66703 (Nov. 7, 2012). At the time the Commission published the final rule, ASTM F2088–12a was the current version of the voluntary standard.

In April 2013, ASTM notified CPSC that it had issued a revised standard for infant swings, ASTM F2088–13. In accordance with the procedures set out in section 104(b)(4)(B) of the CPSIA, the revised standard became the new

[1] The modifications included changes to the required warning label content and a revised test method to address an omission in the voluntary standard for toy mobiles attached to swings.

mandatory standard for infant swings. The Commission published a direct final rule to update 16 CFR part 1223, incorporating by reference ASTM F2088–13, without modification. 78 FR 37706 (June 24, 2013). After the Commission issued the revised mandatory standard in 2013, ASTM approved two more revisions: ASTM F2088–15 and ASTM F2088–19. However, ASTM did not officially notify CPSC of these revisions under CPSIA section 104(b)(4)(B). Consequently, these revised standards did not become the mandatory standards by operation of law, and the Commission did not update the mandatory standard to incorporate by reference these revised ASTM standards. Therefore, ASTM F2088–13 remained the mandatory standard.

On October 5, 2020, ASTM notified CPSC that it had revised the voluntary standard for infant swings, approving ASTM F2088–20 on June 15, 2020.[2] As this preamble discusses, based on CPSC staff's review of ASTM F2088–20,[3] the Commission will allow the revised voluntary standard to become the mandatory standard because the revised requirements in the voluntary standard either improve the safety of infant swings, or are safety neutral. Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F2088–20 will become the mandatory consumer product safety standard for infant swings on April 3, 2021. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1223 to incorporate by reference the revised voluntary standard, ASTM F2088–20.

B. Revisions to ASTM F2088

The ASTM standard for infant swings includes performance requirements, test methods, and requirements for warning labels and instructional literature, to address hazards to infants associated with infant swings. ASTM has revised the voluntary standard for infant swings three times since ASTM F2088–13, which is the current mandatory standard. This section describes the changes in these three editions of the standard—ASTM F2088–15, ASTM F2088–19, and ASTM F2088–20. The revisions that ASTM included in the 2015 and 2019 versions of the standard are also in the newly revised version, ASTM F2088–20, although some section and figure numbers have changed to accommodate other revisions.

1. ASTM F2088–15

On October 1, 2015, ASTM approved a revised version of the standard, ASTM F2088–15. ASTM did not notify the Commission of this revision. ASTM F2088–15 included one substantive change, several revisions to clarify existing requirements, and editorial revisions that did not alter substantive requirements in the standard or affect safety. The revisions that ASTM included in the 2015 version of the standard are also in the newly revised version, ASTM F2088–20.

a. Substantive Revisions

Section 6.5.2 of ASTM F2088–15 states: ''Swings with a maximum seat back angle greater than 50 degrees from horizontal measured in accordance with 7.13 shall include shoulder straps as part of the restraint system.'' This requirement was already in the standard in ASTM F2088–13. However, ASTM F2088–15 added revised procedures for measuring the seat back and bottom angles for seat designs without a defined intersection of the seat bottom and back (*i.e.,* curved seats), by adding a new figure to indicate how to determine the intersection for curved seats (Figure 11, sections 7.13–7.15). ASTM F2088–15 also added the word ''gently'' to the direction to ''gently place the Hinged Weight Gage—Infant'' in this procedure (sections 7.13–7.15).

ASTM F2088–13 did not address how to measure seat angles for curved seat designs. Without a defined method, test laboratories were left to interpret how to place the Hinged Weight Gauge—Infant in the seat, resulting in inconsistent measurements among test laboratories. Inconsistent measurements among test laboratories are problematic because these seat back angle measurements determine whether the product requires shoulder straps. Shoulder straps provide additional safety for infant swings, by preventing infant occupants from slumping forward when the seat back angle is greater than 50 degrees. Therefore, greater consistency in seat back measurements for curved seat designs improves the safety of infant swings, by ensuring that shoulder straps are included for infant swings with larger seat back angles.

b. Non-Substantive Revisions

ASTM F2088–15 also added information to provide greater clarity to consumers. ASTM F2088–13 already required a warning statement to ''discontinue use of swing when infant attempts to climb out.'' ASTM F2088–15 added ''(approximately 9 months)'' to this warning, to provide additional guidance to consumers on when to stop using the product (section 8.3.1.1(3)). ASTM F2088–15 also added minor formatting changes to align with ASTM form and style guidelines (*e.g.,* changed ''in'' to ''in.''). These revisions are neutral regarding the safety of infant swings because they do not change any substantive requirements.

2. ASTM F2088–19

On November 15, 2019, ASTM approved a revised version of the standard, ASTM F2088–19. ASTM did not notify the Commission of this revision. ASTM F2088–19 included one substantive change, as well as several editorial revisions that did not alter substantive requirements in the standard or affect safety. The revisions that ASTM included in the 2019 version of the standard are also in the newly revised version, ASTM F2088–20.

a. Substantive Revisions

ASTM F2088–19 added a definition for ''tethered strap'' (section 3.1.11), a performance requirement (section 6.9), and a test method (section 7.16) to address possible entanglement of non-occupant children in exposed tethered straps that connect the underside of the seat to the product frame or to other straps. The new requirements only apply to tethered straps, and not straps that are loose or hanging from the product (*i.e.,* not connected to other components). The new requirement limits the length of tethered straps to a maximum of 16 inches, when measured from the back of the seat to the first attachment point (*e.g.,* another strap or part of the product frame) in accordance with the test method in section 7.16.

ASTM based the 16-inch limit on the approximate perimeter of the small head probe described in ASTM F406–19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards,* which is 16.3 inches (section X1.4). The small head probe represents a 5th percentile 6-month-old child, which is the youngest child with the developmental ability to become entrapped in a tethered strap.[4] The ASTM ballot that lead to these requirements stated that they were intended to prevent a 6-month-old or older child from becoming entangled if exposed tethered straps under the seat of an infant swing formed a loop.

[2] ASTM published ASTM F2088–20 in July 2020.

[3] CPSC staff's briefing memorandum regarding ASTM F2088–20 is available at: *https://cpsc.gov/s3fs-public/ASTMs-Revised-Safety-Standard-for-Infant-and-Cradle-Swings.pdf?dTN6hRTePdlXPZ8oDFUd8DGAFHvUmP5i.*

[4] ASTM F406–19, Section 5.15.3 states: ''The small head probe represents the 5th percentile 6-month-old child because that is the youngest child having the developmental abilities to become entrapped.''

The new test method regarding tethered straps first assesses whether, over the course of five attempts, the tethered straps separate from the seat using a pull force of 5 pounds. If the tethered straps separate in all five attempts, the tethered straps are exempt from the length limit. If the tethered straps remain attached in any one of the five attempts, the tethered straps under the seat are subject to the 16-inch maximum length limit. The test method also explains how to measure the length of the strap to determine whether it complies with the 16-inch limit, and refers to the new Figures 14 and 15 as examples. These figures illustrate how to measure the exposed length on two types of tethered strap configurations. For straps that attach to a rigid portion of the product, the length is measured from the point where the strap connects with the rigid surface (Figure 14). For straps that attach to another strap, the length is measured from the point where the strap first attaches to the other strap (Figure 15).

ASTM F2088–15 did not address the entanglement hazard for non-occupant children associated with tethered straps. As such, these added requirements improve the safety of infant swings by addressing this hazard for certain tethered strap designs.[5]

b. Non-Substantive Revisions

ASTM F2088–19 also included minor additions and revisions that did not affect the substantive requirements in the standard. The following revisions are neutral regarding the safety of infant swings because they do not change any substantive requirements:

- Section 1.5 says ''safety, health and environmental,'' instead of ''safety and health'';
- a new section 1.6 indicates that ASTM developed the standard in accordance with principles recognized by the World Trade Organization;
- in section 2.1, the list of referenced ASTM standards reflects a change to the title of ASTM D3359 and adds ASTM F406, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;*
- revised unit expressions align with ASTM form and style guidelines (*e.g.,* changed ''hour'' to ''h''; changed ''73 ± 9 °F'' to ''73 °F ± 9 °F'');
- minor spelling changes (*e.g.,* changed ''a/c'' to ''AC''); and
- updated section numbers to reflect added sections.

3. ASTM F2088–20

On June 15, 2020, ASTM approved a revised version of the standard, ASTM F2088–20. In accordance with CPSIA section 104(b)(4)(B), ASTM notified CPSC of this revision on October 5, 2020. ASTM F2088–20 includes several substantive changes, several revisions to clarify existing requirements, and editorial revisions that do not alter substantive requirements in the standard or affect safety. The revisions that ASTM included in the 2015 and 2019 versions of the standard are also in the newly revised version, ASTM F2088–20.[6]

Several changes in ASTM F2088–20 are intended to align with wording changes ASTM initiated for all of its juvenile products standards. After publishing ASTM F2088–13, ASTM convened a task group, the ASTM Ad Hoc Wording Task Group (Ad Hoc TG) to harmonize the wording of common provisions (*e.g.,* introduction, scope, protective components), as well as warning label requirements, across durable infant and toddler product voluntary standards. The Ad Hoc TG consists of members of various durable nursery products voluntary standards committees, including CPSC staff. The final Ad Hoc TG recommendations are in a reference document, titled, ''Recommended Language Approved by Ad Hoc Task Group, Revision E, May 28, 2019,'' and are part of the F15 Committee Documents. ASTM F15 committees have used these recommendations to update juvenile products standards so that common provisions and requirements for warnings are consistent across the standards.[7] There are substantive and non-substantive revisions in ASTM F2088–20 that are intended to align with the Ad Hoc TG recommendations; these revisions are explained in more detail in subsections *a. Substantive Revisions* and *b. Non-Substantive Revisions,* below.

a. Substantive Revisions

ASTM F2088–20 includes revisions and additions to substantive requirements, as well as changes that make existing requirements clearer or more explicit.

Scope. A new section 1.3 specifies that the standard covers products with a powered mechanism that provides a swinging or gliding seat/cradle in any direction relative to the frame. Section 1.3 also notes that swinging or gliding mechanisms can be powered by batteries, AC adapters, wind-up mechanisms, or other means. These revisions do not expand or modify the scope of the standard. Other sections of the standard already addressed the listed features (*e.g.,* requirements regarding battery compartments and AC adapters), indicating that products with those features are within the scope of the standard. This revision merely highlights and clarifies that the standard covers this range of products. Accordingly, these changes to section 1.3 are neutral to the safety of infant swings because they do not alter any substantive requirements.

Section 1.3 also specifies that the standard does not cover products that are intended to provide sleeping accommodations for the occupant. This revision does not alter the scope of the standard. However, explicitly stating that the infant swing standard does not cover products intended for infant sleep will assist manufacturers to recognize that the swing standard is not applicable to products intended for sleep, which are subject to other standards. As such, this revision improves the safety of infant swings because it clarifies the types of products that are subject to the standard.

Referenced Documents. Section 2.1 includes a new reference to ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles,* because this standard is referenced as part of a new requirement (see *General Requirements,* below).

Terminology. ASTM F2088–20 updates two definitions and adds a third to align with the Ad Hoc TG recommendations. The terms ''conspicuous'' (Section 3.1.2) and ''static load'' (Section 3.1.11) were already defined in the standard; the revisions simply modify wording and do not alter the substantive meaning of the terms. ''Protective component'' (Section 3.1.10) was not previously defined in the standard, but there were already requirements for ''protective components'' in the standard, and those provisions described the meaning of the term. The revision moves that description to a formal definition.

ASTM F2088–20 also includes updated definitions for ''cradle swing'' (Section 3.1.3) and ''infant swing'' (Section 3.1.5) to specify the maximum developmental and age limit for each product. This information was already in the warning requirements; the revisions only add these details to the formal definitions.

[5] See staff's briefing memorandum, available at *https://cpsc.gov/s3fs-public/ASTMs-Revised-Safety-Standard-for-Infant-and-Cradle-Swings.pdf?dTN6hRTePdlXPZ8oDFUd8DGAFHvUmP5i,* for discussion of staff's assessment that these added requirements only address the hazard for certain tethered strap designs.

[6] Some section and figure numbers may differ in ASTM F2088–20 due to other revisions.

[7] This process is ongoing, and ASTM has not yet updated all of its juvenile products standards to reflect these changes.

ASTM also added a new definition for ''combination swing'' (Section 3.1.1.) to address products with both a cradle swing and infant swing use, mode, or position. The standard already addressed ''combination swings''—Section 8.5 describes them as products with both a cradle mode and a seated mode, and applies labeling requirements to them. However, the standard did not previously contain a formal definition of the term.

ASTM also revised the definition of ''travel swing'' (Section 3.1.14). Previously, ASTM defined ''travel swing'' as a ''low-profile, compact swing,'' grouping all compact swing products into a single term. The revised definition does the same, but because of the revised definitions of ''infant swing,'' ''cradle swing,'' and ''combination swing,'' the revised definition of ''travel swing'' lists the compact versions of each product type (*i.e.,* ''low-profile, compact infant, cradle, or combination swing'').

These revisions to the terminology in ASTM F2088–20 are neutral to the safety of infant swings because they do not alter the meaning of the terms or the substantive requirements that apply to these products.

General Requirements. ASTM F2088–20 includes revised requirements for protective components (Section 5.8). The standard already required testing to assess the potential removal of protective components. The revision specifies that all protective components that are accessible to a child in or around the product must be evaluated according to the requirements for protective components. As such, the revision clarifies which protective components to assess. This revision improves the safety of infant swings because it ensures that all accessible protective components are tested for potential removal.

The standard also includes a new requirement that cradle swings or combination swings in a cradle swing use, mode, or position, while in the rest (*i.e.,* non-rocking) position, comply with the requirements of ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles* (section 5.11). As a general matter, ASTM F2088–20 does not cover products that are intended as sleeping accommodations (section 1.3) and the standard requires swings to display warnings that the products are not safe for unattended sleep (section 8.5.1). However, cradle swings, when at rest, have characteristics that are consistent with a stationary bassinet or cradle, where the occupant is lying flat, and is not being rocked. As such, cradle swings, while at rest, may serve as a sleep surface, despite the on-product warnings. If used as a sleep surface, these swings may present hazards consistent with a bassinet or cradle. ASTM F2194 addresses these hazards, including requirements to provide a safe sleep environment. This addition improves the safety of infant swings because it requires swings that function like bassinets or cradles to meet the safety requirements for such products.

Performance Requirements. Section 6.5 already included requirements for restraint systems and specified that a restraint system is required to secure an occupant in the seated position in any manufacturer-recommended use positions. However, ASTM F2088–20 adds to this requirement that cradle swings and combination swings, when in all manufacturer's use positions as a cradle swing, shall not have a restraint system. This prevents occupants of cradle swings (which are intended for infants from birth to approximately 5 months old) from getting entangled in restraints while lying flat, and is consistent with the bassinet standard (ASTM F2194). This revision improves the safety of infant swings by addressing a potential entanglement hazard.

Marking and Labeling. ASTM F2088–20 does not include the previous requirement that manufacturers mark each product and its retail packaging with a model number and change the model number when they make changes to the product that affect conformance with the safety standard (previous Section 8.1.2). The ASTM ballot that led to removing this requirement suggested that the rationale was to provide consistency with other juvenile products standards, which do not contain this requirement. This requirement likely was intended to facilitate recalls, by providing a way to identify products made during a certain time. However, other remaining requirements accomplish this purpose. Section 8.1.2 still requires manufacturers to mark products with the month and year of manufacture, and 16 CFR 1130.4 requires manufacturers that use model names or numbers to permanently mark that identifying information on their infant or toddler products. Therefore, the revision is neutral with respect to the safety of infant swings because other requirements accomplish the same purpose.

ASTM F2088–20 also includes revised marking and labeling requirements, including warning formatting and wording, to align with the Ad Hoc TG recommendations.

Revised wording of warnings statements (Section 8.5) includes changing ''Always secure infant in the restraint system provided'' to ''ALWAYS use restraints. Adjust to fit snugly,'' and changing ''Never leave infant unattended in swing'' to ''Stay near and watch infant during use.'' This revised language more directly indicates to caregivers what actions to take.

The revised standard also includes two new warning subsections, for combination swings (Section 8.5.3) and travel swings (Section 8.5.4). The standard already included the warning requirements for these swing designs, but they were embedded in the general warning requirements. Moving them to individual sections based on product type highlights the importance of these warnings and clearly matches warnings with the corresponding product design.

The revised marking and labeling requirements in ASTM F2088–20 improve the safety of infant swings by providing clear, direct, and product-specific requirements, and providing consistency across juvenile product standards.

Instructional Literature. ASTM F2088–20 includes revised requirements for instructional literature (Section 9) for consistency with the Ad Hoc TG recommendations and the revised warning label requirements in Section 8. These revisions improve the safety of infant swings by providing clear warning information and instructional literature that is consistent with the corresponding on-product warnings and across juvenile product standards.

b. Non-Substantive Revisions

ASTM F2088–20 also includes minor additions and revisions that are editorial and do not alter any substantive requirements in the standard. Because they do not change any substantive requirements, these revisions are neutral regarding the safety of infant swings.

Title. ASTM F2088–20 revises the title for the standard, changing it from ''Standard Consumer Safety Specification for Infant Swings'' to ''Standard Consumer Safety Specification for Infant and Cradle Swings.'' This title change does not alter the scope of the standard; performance requirements and test methods for cradle swings have been in the standard since ASTM first adopted it. This revision makes it clear in the title that the standard applies to cradle swings.

Introduction. The revised standard includes updated introduction language to align with the Ad Hoc TG recommendations. This includes replacing the statements regarding reasonably foreseeable misuse or abuse

with a single statement that conveys the same information. Specifically, the revision retains the existing statement that the voluntary standard covers normal and reasonably foreseeable misuse or abuse of infant swings, and removes an additional sentence about careless or blatant misuse. This revision clarifies, and does not alter, the type of use covered by the standard. In addition, the introduction includes minor wording changes (*e.g.,* ''infant swing incidents'' changed to ''incidents associated with swings intended for infants'').

Scope. ASTM F2088–20 includes minor wording changes in the scope section (*e.g.,* deleting ''consumer safety'' from ''this consumer safety specification'') to harmonize with the Ad Hoc TG recommendations (Section 1.6).

Referenced Documents. ASTM F2088–20 includes a revised list of referenced documents. ASTM updated the title of Section 2.2 from ''Federal Standards'' to ''Federal Regulations,'' and added a new section 2.3 to include ANSI standards. These revisions are consistent with other ASTM standards and aligns with the Ad Hoc TG recommendations.

General Requirements. ASTM F2088–20 includes several revisions to section 5 to harmonize the wording with the Ad Hoc TG recommendations. These revisions include minor wording changes in the sections on ''Scissoring, Shearing, and Pinching'' (Section 5.5), ''Protective Components'' (Section 5.8), and ''Toys'' (Section 5.10) (*e.g.,* changing ''component'' to ''component(s),'' changing ''must meet'' to ''shall comply with'').

Test Methods. Minor editorial revisions in the test methods section (Section 7) maintain consistency with wording and unit expressions in the rest of the standard and other ASTM standards (*e.g.,* adding a space after the number to change ''68 °F ± 9 °F'' to ''68 °F ± 9 °F,'' changing ''0.040'' to ''0.04,'' and correcting the spelling of ''Gauge''). In addition, ASTM harmonized the ''*Removal of Protective Components Test*'' wording (Section 7.2) with the Ad Hoc TG recommendations. These revisions do not alter the substance of the requirements.

C. Incorporation by Reference

Section 1223.2 of the direct final rule incorporates by reference ASTM F2088–20. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B. Revisions to ASTM F2088, of this preamble summarizes the major provisions of ASTM F2088–20 that the Commission incorporates by reference into 16 CFR part 1223. The standard is reasonably available to interested parties and interested parties can purchase a copy of ASTM F2088–20 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone; 610–832–9585; *www.astm.org.* Additionally, until the direct final rule takes effect, a read-only copy of ASTM F2088–20 is available for viewing on ASTM's website at: *https://www.astm.org/CPSC.htm.* Once the rule takes effect, a read-only copy of the standard will be available for viewing on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: 301–504–7479; email: *cpsc-os@cpsc.gov.*

D. Certification

Section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051–2089) requires manufacturers of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are ''consumer product safety standards.'' Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because infant swings are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1223 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,[8] the phthalates prohibitions in section 108 of the CPSIA [9] and 16 CFR part 1307, the tracking label requirements in section 14(a)(5) of the CPSA,[10] and the consumer registration form requirements in section 104(d) of the CPSIA.[11]

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(iv) of the CPSIA, the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing infant swings. 78 FR 15836 (Mar. 12, 2013). The NOR provided the criteria and process for CPSC to accept accreditation of third party conformity assessment bodies for testing infant swings to 16 CFR part 1223. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies,'' codified in 16 CFR part 1112. *Id.*

ASTM F2088–20 includes revised requirements for testing infant swings. However, these revisions to test requirements do not require additional equipment or test protocols beyond those that already exist in the standard. Accordingly, the revisions do not significantly change the way that third party conformity assessment bodies test these products for compliance with the infant swings standard. Laboratories will begin testing to the new standard when ASTM F2088–20 goes into effect, and the existing accreditations that the Commission has accepted for testing to this standard will cover testing to the revised standard. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F2088–13 to be capable of testing to ASTM F2088–20 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

F. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and

[8] 15 U.S.C. 1278a.
[9] 15 U.S.C. 2057c.
[10] 15 U.S.C. 2063(a)(5).
[11] 15 U.S.C. 2056a(d).

an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency, ''for good cause finds,'' that notice and comment are ''impracticable, unnecessary, or contrary to the public interest.'' *Id.* 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

Under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference under section 104(b)(1)(B) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's standard by operation of law. The Commission is allowing ASTM F2088–20 to become CPSC's new standard. The purpose of this direct final rule is to update the reference in the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the terms of the CPSIA, ASTM F2088–20 takes effect as the new CPSC standard for infant swings, even if the Commission does not issue this rule. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the ''unnecessary'' prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on April 3, 2021. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be ''one where the commenter explains why the rule would be inappropriate,'' including an assertion challenging ''the rule's underlying premise or approach,'' or a claim that the rule ''would be ineffective or unacceptable without change.'' 60 FR 43108, 43111. As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section F. Direct Final Rule Process of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The current mandatory standard for infant swings includes requirements for marking, labeling, and instructional literature that constitute a ''collection of information,'' as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). The revised mandatory standard does not alter these requirements. The Commission took the steps required by the PRA for information collections when it adopted 16 CFR part 1223, including obtaining approval and a control number. Because the information collection is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the Federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision ''consumer product safety standards.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for infant swings. Therefore, ASTM F2088–20 automatically will take effect as the new mandatory standard for infant swings on April 3, 2021, 180 days after the Commission received notice of the revision on October 5, 2020. As a direct final rule, unless the Commission receives a significant adverse comment within 30 days of this notice, the rule will become effective on April 3, 2021.

L. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states

that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1223

Consumer protection, Imports, Incorporation by reference, Imports, Infants and children, Law enforcement, Safety, Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1223—SAFETY STANDARD FOR INFANT SWINGS

■ 1. Revise the authority citation for part 1223 to read as follows:

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec 3, Pub. L. 112–28, 125 Stat. 273.

■ 2. Revise § 1223.2 to read as follows:

§ 1223.2 Requirements for infant swings.

Each infant swing shall comply with all applicable provisions of ASTM F2088–20, *Standard Consumer Safety Specification for Infant and Cradle Swings,* approved on June 15, 2020. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; phone: (610) 832–9585; *www.astm.org.* A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email: *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2020–28362 Filed 1–15–21; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Canada; Correction

AGENCY: Office of the Secretary, U.S. Department of Homeland Security; U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: Notification of continuation of temporary travel restrictions; correction.

SUMMARY: The Department of Homeland Security (DHS) is making corrections to a notice that appeared in the **Federal Register** on December 22, 2020. The document contained incorrect dates.

DATES: The corrections apply to the notification published in the **Federal Register** December 22, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations Coronavirus Coordination Cell, U.S. Customs and Border Protection (CBP) at 202–325–0840.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 22, 2020, in FR Doc. 2020–28381—

- On page 83432, in the first column, correct the words ''January 21, 2020.'' to read, ''January 21, 2021.''; and
- On page 83433, in the second column, correct the words ''January 21, 2020.'' to read, ''January 21, 2021.''

Christina E. McDonald,

Associate General Counsel for Regulatory Affairs.

[FR Doc. 2020–28875 Filed 1–15–21; 8:45 am]

BILLING CODE 9111–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Mexico; Correction

AGENCY: Office of the Secretary, U.S. Department of Homeland Security; U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: Notification of continuation of temporary travel restrictions; correction.

SUMMARY: The Department of Homeland Security (DHS) is making corrections to a notice that appeared in the **Federal Register** on December 22, 2020. The document contained incorrect dates.

DATES: The corrections apply to the notification published in the **Federal Register** December 22, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations Coronavirus Coordination Cell, U.S. Customs and Border Protection (CBP) at 202–325–0840.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 22, 2020, in FR Doc. 2020–28375—

- On page 83433, in the third column, correct the words ''January 21, 2020.'' to read, ''January 21, 2021.''; and
- On page 83434, in the third column, correct the words ''January 21, 2020.'' to read, ''January 21, 2021.''

Christina E. McDonald,

Associate General Counsel for Regulatory Affairs, U.S. Department of Homeland Security.

[FR Doc. 2020–28876 Filed 1–15–21; 8:45 am]

BILLING CODE 9112–FP–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Mexico

AGENCY: Office of the Secretary, U.S. Department of Homeland Security; U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: Notification of continuation of temporary travel restrictions.

SUMMARY: This document announces the decision of the Secretary of Homeland Security (Secretary) to continue to temporarily limit the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border. Such travel will be limited to ''essential travel,'' as further defined in this document.

DATES: These restrictions go into effect at 12 a.m. Eastern Standard Time (EST) on January 22, 2021 and will remain in effect until 11:59 p.m. EST on February 21, 2021.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations Coronavirus Coordination Cell, U.S. Customs and Border Protection (CBP) at 202–325–0840.

SUPPLEMENTARY INFORMATION:

Background

On March 24, 2020, DHS published notice of the Secretary's decision to temporarily limit the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border to ''essential travel,'' as further defined in that document.[1] The document described the developing circumstances regarding the COVID–19 pandemic and stated that, given the outbreak and continued transmission and spread of the virus associated with COVID–19 within the United States and globally, the Secretary had determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Mexico posed a ''specific threat to human life or national interests.'' The Secretary later published a series of notifications continuing such limitations on travel until 11:59 p.m. EST on January 21, 2021.[2]

The Secretary has continued to monitor and respond to the COVID–19 pandemic. As of the week of January 4, there have been over 83.3 million confirmed cases globally, with over 1.8 million confirmed deaths.[3] There have been over 20.7 million confirmed and probable cases within the United States,[4] over 587,000 confirmed cases in Canada,[5] and over 1.4 million confirmed cases in Mexico.[6]

Notice of Action

Given the outbreak and continued transmission and spread of COVID–19 within the United States and globally, the Secretary has determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Mexico poses an ongoing ''specific threat to human life or national interests.''

U.S. and Mexican officials have mutually determined that non-essential travel between the United States and Mexico poses additional risk of transmission and spread of the virus associated with COVID–19 and places the populace of both nations at increased risk of contracting the virus associated with COVID–19. Moreover, given the sustained human-to-human transmission of the virus, returning to previous levels of travel between the two nations places the personnel staffing land ports of entry between the United States and Mexico, as well as the individuals traveling through these ports of entry, at increased risk of exposure to the virus associated with COVID–19. Accordingly, and consistent with the authority granted in 19 U.S.C. 1318(b)(1)(C) and (b)(2),[7] I have determined that land ports of entry along the U.S.-Mexico border will continue to suspend normal operations and will only allow processing for entry into the United States of those travelers engaged in ''essential travel,'' as defined below. Given the definition of ''essential travel'' below, this temporary alteration in land ports of entry operations should not interrupt legitimate trade between the two nations or disrupt critical supply chains that ensure food, fuel, medicine, and other critical materials reach individuals on both sides of the border.

For purposes of the temporary alteration in certain designated ports of entry operations authorized under 19 U.S.C. 1318(b)(1)(C) and (b)(2), travel through the land ports of entry and ferry terminals along the United States-Mexico border shall be limited to ''essential travel,'' which includes, but is not limited to—

- U.S. citizens and lawful permanent residents returning to the United States;
- Individuals traveling for medical purposes (*e.g.,* to receive medical treatment in the United States);
- Individuals traveling to attend educational institutions;
- Individuals traveling to work in the United States (*e.g.,* individuals working in the farming or agriculture industry who must travel between the United States and Mexico in furtherance of such work);
- Individuals traveling for emergency response and public health purposes (*e.g.,* government officials or emergency responders entering the United States to support federal, state, local, tribal, or territorial government efforts to respond to COVID–19 or other emergencies);
- Individuals engaged in lawful cross-border trade (*e.g.,* truck drivers supporting the movement of cargo between the United States and Mexico);
- Individuals engaged in official government travel or diplomatic travel;
- Members of the U.S. Armed Forces, and the spouses and children of members of the U.S. Armed Forces, returning to the United States; and
- Individuals engaged in military-related travel or operations.

The following travel does not fall within the definition of ''essential travel'' for purposes of this Notification—

- Individuals traveling for tourism purposes (*e.g.,* sightseeing, recreation, gambling, or attending cultural events).

At this time, this Notification does not apply to air, freight rail, or sea travel between the United States and Mexico, but does apply to passenger rail, passenger ferry travel, and pleasure boat travel between the United States and Mexico. These restrictions are

[1] 85 FR 16547 (Mar. 24, 2020). That same day, DHS also published notice of the Secretary's decision to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border to ''essential travel,'' as further defined in that document. 85 FR 16548 (Mar. 24, 2020).

[2] *See* 85 FR 83433 (Dec. 22, 2020); 85 FR 74604 (Nov. 23, 2020); 85 FR 67275 (Oct. 22, 2020); 85 FR 59669 (Sept. 23, 2020); 85 FR 51633 (Aug. 21, 2020); 85 FR 44183 (July 22, 2020); 85 FR 37745 (June 24, 2020); 85 FR 31057 (May 22, 2020); 85 FR 22353 (Apr. 22, 2020). DHS also published parallel notifications of the Secretary's decisions to continue temporarily limiting the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border to ''essential travel.'' *See* 85 FR 83432 (Dec. 22, 2020); 85 FR 74603 (Nov. 23, 2020); 85 FR 67276 (Oct. 22, 2020); 85 FR 59670 (Sept. 23, 2020); 85 FR 51634 (Aug. 21, 2020); 85 FR 44185 (July 22, 2020); 85 FR 37744 (June 24, 2020); 85 FR 31050 (May 22, 2020); 85 FR 22352 (Apr. 22, 2020). Both December notices contained typos with respect to the end date of the extension; as of December 23, 2020, correction notices were pending publication in the **Federal Register**.

[3] WHO, Coronavirus disease 2019 (COVID–19) Weekly Epidemiological Update (Jan. 5, 2021), available at *https://www.who.int/publications/m/item/weekly-epidemiological-update—5-january-2021.*

[4] CDC, COVID Data Tracker (accessed Jan. 6, 2021), available at *https://covid.cdc.gov/covid-data-tracker/.*

[5] WHO, COVID–19 Weekly Epidemiological Update (Jan. 5, 2021).

[6] *Id.*

[7] 19 U.S.C. 1318(b)(1)(C) provides that ''[n]otwithstanding any other provision of law, the Secretary of the Treasury, when necessary to respond to a national emergency declared under the National Emergencies Act (50 U.S.C. 1601 *et seq.*) or to a specific threat to human life or national interests,'' is authorized to ''[t]ake any . . . action that may be necessary to respond directly to the national emergency or specific threat.'' On March 1, 2003, certain functions of the Secretary of the Treasury were transferred to the Secretary of Homeland Security. *See* 6 U.S.C. 202(2), 203(1). Under 6 U.S.C. 212(a)(1), authorities ''related to Customs revenue functions'' were reserved to the Secretary of the Treasury. To the extent that any authority under section 1318(b)(1) was reserved to the Secretary of the Treasury, it has been delegated to the Secretary of Homeland Security. *See* Treas. Dep't Order No. 100–16 (May 15, 2003), 68 FR 28322 (May 23, 2003). Additionally, 19 U.S.C. 1318(b)(2) provides that ''[n]otwithstanding any other provision of law, the Commissioner of U.S. Customs and Border Protection, when necessary to respond to a specific threat to human life or national interests, is authorized to close temporarily any Customs office or port of entry or take any other lesser action that may be necessary to respond to the specific threat.'' Congress has vested in the Secretary of Homeland Security the ''functions of all officers, employees, and organizational units of the Department,'' including the Commissioner of CBP. 6 U.S.C. 112(a)(3).

temporary in nature and shall remain in effect until 11:59 p.m. EST on February 21, 2021. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.[8]

The Commissioner of U.S. Customs and Border Protection (CBP) is hereby directed to prepare and distribute appropriate guidance to CBP personnel on the continued implementation of the temporary measures set forth in this Notification. The CBP Commissioner may determine that other forms of travel, such as travel in furtherance of economic stability or social order, constitute ''essential travel'' under this Notification. Further, the CBP Commissioner may, on an individualized basis and for humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

Peter T. Gaynor,

Acting Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–01029 Filed 1–15–21; 8:45 am]

BILLING CODE 9112–FP–P

[8] DHS is working closely with counterparts in Mexico and Canada to identify appropriate public health conditions to safely ease restrictions in the future and support U.S. border communities.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Chapter I

Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Canada

AGENCY: Office of the Secretary, U.S. Department of Homeland Security; U.S. Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: Notification of continuation of temporary travel restrictions.

SUMMARY: This document announces the decision of the Secretary of Homeland Security (Secretary) to continue to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border. Such travel will be limited to ''essential travel,'' as further defined in this document.

DATES: These restrictions go into effect at 12 a.m. Eastern Standard Time (EST) on January 22, 2021 and will remain in effect until 11:59 p.m. EST on February 21, 2021.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations Coronavirus Coordination Cell, U.S. Customs and Border Protection (CBP) at 202–325–0840.

SUPPLEMENTARY INFORMATION:

Background

On March 24, 2020, DHS published notice of the Secretary's decision to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada border to ''essential travel,'' as further defined in that document.[1] The document described the developing circumstances regarding the COVID–19 pandemic and stated that, given the outbreak and continued transmission and spread of the virus associated with COVID–19 within the United States and globally, the Secretary had determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Canada posed a ''specific threat to human life or national interests.'' The Secretary later published a series of notifications continuing such limitations on travel until 11:59 p.m. EST on January 21, 2021.[2]

The Secretary has continued to monitor and respond to the COVID–19 pandemic. As of the week of January 4, there have been over 83.3 million confirmed cases globally, with over 1.8 million confirmed deaths.[3] There have been over 20.7 million confirmed and probable cases within the United States,[4] over 587,000 confirmed cases in Canada,[5] and over 1.4 million confirmed cases in Mexico.[6]

Notice of Action

Given the outbreak and continued transmission and spread of COVID–19 within the United States and globally, the Secretary has determined that the risk of continued transmission and spread of the virus associated with COVID–19 between the United States and Canada poses an ongoing ''specific threat to human life or national interests.''

U.S. and Canadian officials have mutually determined that non-essential travel between the United States and Canada poses additional risk of transmission and spread of the virus associated with COVID–19 and places the populace of both nations at increased risk of contracting the virus associated with COVID–19. Moreover, given the sustained human-to-human transmission of the virus, returning to previous levels of travel between the two nations places the personnel staffing land ports of entry between the United States and Canada, as well as the individuals traveling through these ports of entry, at increased risk of exposure to the virus associated with COVID–19. Accordingly, and consistent with the authority granted in 19 U.S.C. 1318(b)(1)(C) and (b)(2),[7] I have

[1] 85 FR 16548 (Mar. 24, 2020). That same day, DHS also published notice of the Secretary's decision to temporarily limit the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border to ''essential travel,'' as further defined in that document. 85 FR 16547 (Mar. 24, 2020).

[2] *See* 85 FR 83432 (Dec. 22, 2020); 85 FR 74603 (Nov. 23, 2020); 85 FR 67276 (Oct. 22, 2020); 85 FR 59670 (Sept. 23, 2020); 85 FR 51634 (Aug. 21, 2020); 85 FR 44185 (July 22, 2020); 85 FR 37744 (June 24, 2020); 85 FR 31050 (May 22, 2020); 85 FR 22352 (Apr. 22, 2020). DHS also published parallel notifications of the Secretary's decisions to continue temporarily limiting the travel of individuals from Mexico into the United States at land ports of entry along the United States-Mexico border to ''essential travel.'' *See* 85 FR 83433 (Dec. 22, 2020); 85 FR 74604 (Nov. 23, 2020); 85 FR 67275 (Oct. 22, 2020); 85 FR 59669 (Sept. 23, 2020); 85 FR 51633 (Aug. 21, 2020); 85 FR 44183 (July 22, 2020); 85 FR 37745 (June 24, 2020); 85 FR 31057 (May 22, 2020); 85 FR 22353 (Apr. 22, 2020). Both December notices contained typos with respect to the end date of the extension; as of December 23, 2020, correction notices were pending publication in the **Federal Register**.

[3] WHO, Coronavirus disease 2019 (COVID–19) Weekly Epidemiological Update (Jan. 5, 2021), available at *https://www.who.int/publications/m/item/weekly-epidemiological-update—5-january-2021.*

[4] CDC, COVID Data Tracker (accessed Jan. 6, 2021), available at *https://covid.cdc.gov/covid-data-tracker/.*

[5] WHO, COVID–19 Weekly Epidemiological Update (Jan. 5, 2021).

[6] *Id.*

[7] 19 U.S.C. 1318(b)(1)(C) provides that ''[n]otwithstanding any other provision of law, the Secretary of the Treasury, when necessary to respond to a national emergency declared under the National Emergencies Act (50 U.S.C. 1601 *et seq.*) or to a specific threat to human life or national interests,'' is authorized to ''[t]ake any . . . action that may be necessary to respond directly to the national emergency or specific threat.'' On March 1, 2003, certain functions of the Secretary of the Treasury were transferred to the Secretary of Homeland Security. *See* 6 U.S.C. 202(2), 203(1). Under 6 U.S.C. 212(a)(1), authorities ''related to Customs revenue functions'' were reserved to the Secretary of the Treasury. To the extent that any authority under section 1318(b)(1) was reserved to the Secretary of the Treasury, it has been delegated to the Secretary of Homeland Security. *See* Treas. Dep't Order No. 100–16 (May 15, 2003), 68 FR 28322 (May 23, 2003). Additionally, 19 U.S.C. 1318(b)(2) provides that ''[n]otwithstanding any other provision of law, the Commissioner of U.S. Customs and Border Protection, when necessary to respond to a specific threat to human life or national interests, is authorized to close temporarily any Customs office or port of entry or take any other lesser action that may be necessary to respond to the specific threat.'' Congress has vested in the Secretary of Homeland Security the ''functions of all officers, employees, and organizational units of

Continued

determined that land ports of entry along the U.S.-Canada border will continue to suspend normal operations and will only allow processing for entry into the United States of those travelers engaged in ''essential travel,'' as defined below. Given the definition of ''essential travel'' below, this temporary alteration in land ports of entry operations should not interrupt legitimate trade between the two nations or disrupt critical supply chains that ensure food, fuel, medicine, and other critical materials reach individuals on both sides of the border.

For purposes of the temporary alteration in certain designated ports of entry operations authorized under 19 U.S.C. 1318(b)(1)(C) and (b)(2), travel through the land ports of entry and ferry terminals along the United States-Canada border shall be limited to ''essential travel,'' which includes, but is not limited to—

- U.S. citizens and lawful permanent residents returning to the United States;
- Individuals traveling for medical purposes (*e.g.,* to receive medical treatment in the United States);
- Individuals traveling to attend educational institutions;
- Individuals traveling to work in the United States (*e.g.,* individuals working in the farming or agriculture industry who must travel between the United States and Canada in furtherance of such work);
- Individuals traveling for emergency response and public health purposes (*e.g.,* government officials or emergency responders entering the United States to support federal, state, local, tribal, or territorial government efforts to respond to COVID–19 or other emergencies);
- Individuals engaged in lawful cross-border trade (*e.g.,* truck drivers supporting the movement of cargo between the United States and Canada);
- Individuals engaged in official government travel or diplomatic travel;
- Members of the U.S. Armed Forces, and the spouses and children of members of the U.S. Armed Forces, returning to the United States; and
- Individuals engaged in military-related travel or operations.

The following travel does not fall within the definition of ''essential travel'' for purposes of this Notification—

- Individuals traveling for tourism purposes (*e.g.,* sightseeing, recreation, gambling, or attending cultural events).

At this time, this Notification does not apply to air, freight rail, or sea travel between the United States and Canada, but does apply to passenger rail, passenger ferry travel, and pleasure boat travel between the United States and Canada. These restrictions are temporary in nature and shall remain in effect until 11:59 p.m. EST on February 21, 2021. This Notification may be amended or rescinded prior to that time, based on circumstances associated with the specific threat.[8]

The Commissioner of U.S. Customs and Border Protection (CBP) is hereby directed to prepare and distribute appropriate guidance to CBP personnel on the continued implementation of the temporary measures set forth in this Notification. The CBP Commissioner may determine that other forms of travel, such as travel in furtherance of economic stability or social order, constitute ''essential travel'' under this Notification. Further, the CBP Commissioner may, on an individualized basis and for humanitarian reasons or for other purposes in the national interest, permit the processing of travelers to the United States not engaged in ''essential travel.''

Peter T. Gaynor

Acting Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–01028 Filed 1–15–21; 8:45 am]

BILLING CODE 9112–FP–P

the Department,'' including the Commissioner of CBP. 6 U.S.C. 112(a)(3).

[8] DHS is working closely with counterparts in Mexico and Canada to identify appropriate public health conditions to safely ease restrictions in the future and support U.S. border communities.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9946]

RIN 1545–BO67

Denial of Deduction for Certain Fines, Penalties, and Other Amounts; Related Information Reporting Requirements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations providing guidance on section 162(f) of the Internal Revenue Code (Code), as amended in 2017, concerning the deduction of certain fines, penalties, and other amounts. This document also contains final regulations providing guidance relating to the information reporting requirements under new section 6050X of the Code with respect to those fines, penalties, and other amounts. The final regulations affect taxpayers that pay or incur amounts to, or at the direction of, governments, governmental entities or certain nongovernmental entities treated as governmental entities relating to the violation of any law or investigations or inquiries by such governments, governmental entities, or nongovernmental entities into the potential violation of any law. The final regulations also affect governments, governmental entities, and nongovernmental entities subject to the related reporting requirements.

DATES:

Effective date: These regulations are effective on January 14, 2021.

Applicability dates: For dates of applicability, see §§ 1.162–21(g) and 1.6050X–1(g).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations on amended section 162(f), Sharon Y. Horn (202) 317–4426; concerning the information reporting requirement, Nancy L. Rose (202) 317–5147. The phone numbers above may also be reached by individuals who are deaf or hard of hearing, or who have speech disabilities, through the Federal Relay Service toll-free at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Prior to its amendment in 2017, section 162(f) disallowed an ordinary and necessary business expense deduction under section 162(a) for any fine or similar penalty paid to a government for the violation of any law. On February 20, 1975, the Treasury Department and the IRS issued final regulations under the prior version of section 162(f) (TD 7345, 40 FR 7437), which were amended on July 11, 1975 (T.D. 7366, 40 FR 29290) (together the 1975 regulations).

Section 162(f) was amended by section 13306(a) of Public Law 115–97, 131 Stat. 2054 (2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA). Section 6050X was added to the Code by section 13306(b) of the TCJA.

As amended by the TCJA, the general rule of section 162(f)(1) provides that no deduction otherwise allowable under chapter 1 of the Code (chapter 1) shall be allowed for any amount paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry by such government or governmental entity into the potential violation of any law. Section 162(f)(5) describes certain self-regulating nongovernmental entities that are treated as governmental entities for

purposes of section 162(f). As used in this preamble, the term ''governmental entities'' includes nongovernmental entities treated as governmental entities under section 162(f)(5).

Section 162(f)(2) provides an exception to the general disallowance rule in section 162(f)(1) for certain amounts paid or incurred for restitution, remediation, or to come into compliance with a law. Under section 162(f)(2)(A)(i) and (ii), section 162(f)(1) does not apply to amounts that (i) the taxpayer establishes were paid or incurred as restitution (including remediation of property) or to come into compliance with a law (establishment requirement), and (ii) are identified in a court order (order) or settlement agreement (agreement) as restitution, remediation, or amounts paid or incurred to come into compliance with a law (identification requirement). Section 162(f)(2)(B) provides that amounts paid for restitution, remediation, and to come into compliance with a law do not include any amount paid or incurred as reimbursement to a government or governmental entity for the costs of any investigation or litigation.

Section 162(f)(3) provides an exception to the general rule for amounts paid or incurred related to private party suits and section 162(f)(4) provides an exception for certain taxes due.

Section 6050X(a)(1) and 6050X(a)(2)(A) requires the appropriate official of any government or governmental entity involved in a suit or agreement described in section 6050X(a)(2)(A)(i) to file an information return if the aggregate amount involved in all orders or agreements with respect to the violation, investigation, or inquiry is $600 or more. Section 6050X(a)(2)(B) authorizes the Secretary of the Treasury or his delegate (Secretary) to adjust the threshold amount for filing the information return as necessary to ensure the efficient administration of the internal revenue laws. Pursuant to section 6050X(a)(1), the information return must set forth (1) the amount required to be paid as a result of the order or agreement to which section 162(f)(1) applies; (2) any amount required to be paid as a result of the order or agreement that constitutes restitution or remediation of property; and (3) any amount required to be paid as a result of the order or agreement for the purpose of coming into compliance with a law that was violated or involved in the investigation or inquiry.

Section 6050X(a)(3) provides that the government or governmental entity shall file the information return at the time the agreement is entered into, as determined by the Secretary. Section 6050X(b) requires the government or governmental entity to furnish to each person who is a party to the suit or agreement a written statement, at the time the information return is filed with the IRS, that includes (1) the name of the government or entity and (2) the information submitted to the IRS.

Under section 13306(a)(2) and (b)(3) of the TCJA, the amendments to section 162(f) and new section 6050X apply to amounts paid or incurred on or after December 22, 2017, the date of enactment of the TCJA. However, they do not apply to amounts paid or incurred under any binding order issued or agreement entered into, before December 22, 2017, and, if such order or agreement requires court approval, the required approval is obtained before December 22, 2017.

On May 13, 2020, the Internal Revenue Service published a notice of proposed rulemaking (REG–104591–18) in the **Federal Register** (85 FR 28524) providing guidance on the deduction disallowance rules in section 162(f) and the associated reporting requirements in section 6050X. No public hearing on the proposed regulations was requested and accordingly no public hearing was held.

The Treasury Department and the IRS received written comments in response to the proposed regulations. All comments were considered and are available at *www.regulations.gov* or upon request. After full consideration of the comments received on the proposed regulations, this Treasury decision adopts the proposed regulations with modifications in response to such comments as described in the Summary of Comments and Explanation of Revisions.

Summary of Comments and Explanation of Revisions

Most of the comments addressing the proposed regulations are summarized in this Summary of Comments and Explanation of Revisions. However, comments merely summarizing or interpreting the proposed regulations, recommending statutory revisions, or addressing issues that are outside the scope of the final regulations are not discussed.

Part I of this Summary of Comments and Explanation of Revisions addresses § 1.162–21 and Part II addresses § 1.6050X–1.

I. Denial of Deduction for Certain Fines, Penalties, and Other Amounts

A. General Rule

The proposed regulations revise § 1.162–21 and provide operational and definitional guidance concerning the application of section 162(f), as amended by the TCJA. The proposed regulations provide generally that a taxpayer may not take a deduction under any provision of chapter 1 for amounts (1) paid or incurred by suit, agreement, or otherwise; (2) to, or at the direction of, a government or governmental entity; (3) in relation to the violation, or investigation or inquiry into the potential violation, of any civil or criminal law. The proposed regulations also describe an exception to the general rule, under section 162(f)(2), which allows a deduction for certain amounts identified in the order or agreement as restitution, remediation, or paid or incurred to come into compliance with a law and the taxpayer establishes that the amount was paid or incurred for the purpose identified.

The final regulations provide generally that a taxpayer may not take a deduction under any provision of chapter 1 for amounts (1) paid or incurred by suit, agreement, or otherwise; (2) to, or at the direction of, a government or governmental entity; (3) in relation to the violation, or investigation or inquiry by such government or governmental entity into the potential violation, of any civil or criminal law. This general rule applies whether or not the taxpayer admits guilt or liability or pays the amount imposed for any other reason, including to avoid the expense or uncertain outcome of an investigation or litigation. An admission of guilt or liability is not necessary because section 162(f)(1) contemplates a broader disallowance, as demonstrated by the disallowance of any amount paid or incurred, to, or at the direction of, a government or governmental entity in relation to the ''investigation or inquiry'' into the ''potential violation of any law.''

1. Suit, Agreement, or Otherwise

Under the proposed regulations, suit, agreement, or otherwise includes, but is not limited to, settlement agreements; non-prosecution agreements; deferred prosecution agreements; judicial proceedings; administrative adjudications; decisions issued by officials, committees, commissions, or boards of a government or governmental entity; and any legal actions or hearings in which a liability for the taxpayer is determined or pursuant to which the taxpayer assumes liability.

Commenters asked that the final regulations exclude administrative and certain other categories of proceedings from the definition of suit, agreement, or otherwise. The final regulations do not adopt this recommendation because the

statute's use of the phrase ''suit, agreement, or otherwise'' indicates that Congress intended for section 162(f)(1) to apply broadly to both formal legal proceedings as well as other less formal proceedings.

The preamble to the proposed regulations under section 6050X explains that an order or agreement is treated as binding under applicable law even if all appeals have not been exhausted with respect to the suit, agreement, or otherwise. A commenter recommended that the final regulations provide that the same meaning applies for the term ''binding'' order or agreement under section 162(f). The final regulations generally adopt this recommendation.

2. To, or at the Direction of, a Government or Governmental Entity

One commenter asked for clarification that, if a deduction is otherwise allowable under chapter 1, section 162(f)(1) does not disallow a deduction for amounts paid for the taxpayer's own legal fees and related expenses incurred in defending a prosecution or other action or proceeding, including an investigation or inquiry into a potential violation of any law. Legal fees and other expenses, such as stenographic and printing charges, paid or incurred in the defense of a prosecution or civil action arising from a violation of any law, or an investigation or inquiry into a potential violation of any law, are not amounts paid or incurred to, or at the direction of, a government or governmental entity. Thus it is clear that section 162(f)(1) does not disallow a deduction for such amounts, and there is no need to clarify this rule in final regulations.

The proposed regulations provide a definition of ''government or governmental entity.'' The definition in the final regulations has been reorganized to provide a definition of a government in § 1.162–21(e)(1) and to provide a definition of a ''governmental entity'' in § 1.162–21(e)(2). The definitions are based on the definition in the proposed regulations but clarify that a political subdivision of a government includes a local government unit. No comments were received on the definition of ''government or governmental entity'' in the proposed regulations.

The proposed regulations define a nongovernmental entity treated as a governmental entity as an entity that exercises self-regulatory powers (including imposing sanctions) in connection with a qualified board or exchange, as defined in section 1256(g)(7), or exercises self-regulatory powers, including adopting, administering, or enforcing laws and imposing sanctions, as part of performing an essential governmental function. The final regulations revise the definition to clarify that self-regulatory powers include enforcing rules, not laws. A commenter recommended that the definition of ''essential governmental function'' under section 115 should apply to section 162(f)(5). The final regulations do not adopt this recommendation because section 115 does not define the term ''essential governmental function.'' The final regulations clarify that a governmental entity includes a nongovernmental entity treated as a governmental entity.

3. Violation of Any Law

Commenters asked that the final regulations provide a definition of a ''violation of any law.'' The final regulations do not adopt this recommendation because they are intended to provide broad rules of general application based on the underlying principles of section 162(f) rather than narrow rules with limited application. The final regulations provide several examples to illustrate the application of section 162(f) to violations of any law.

Commenters also requested clarification that ''technical violations'' of any law, such as vendor overcharge errors remedied in the ordinary course of business, are not violations of any law. The commenters did not further define what constitutes a ''technical violation.'' Without a more comprehensive definition, the commenters' requests may be inconsistent with the general rule in the final regulations. Therefore, the final regulations do not adopt this comment.

Commenters recommended that the final regulations clarify that the phrase ''in relation to the violation of any law or the investigation or inquiry by such government or [governmental] entity into the potential violation of any law'' do not apply to a government or governmental entity enforcing its legal rights, including defending against claims, as a private party. The Treasury Department and the IRS agree that, in general, unless a government contracting or similar statute provides otherwise, a government's recovery of vendor overcharge errors are in the nature of private party recoveries and not payments made to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry in to the potential violation of any law. Similarly, as discussed with respect to private party suits in Part I.B.6 of this Summary of Comments and Explanation of Revisions, a violation of any law does not include any order or agreement in a suit in which a government or governmental entity enforces rights as a private party.

Commenters asked the Treasury Department and the IRS how section 162(f) applies to amounts paid or incurred pursuant to certain statutes that contain provisions that may apply without any finding of a violation of law, such as the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). CERCLA contains cleanup requirements and reimbursement provisions that generally apply even though there has been no violation of law. CERCLA also contains penalty provisions for specific violations of law. Although section 162(f) and the final regulations generally will not apply to CERCLA cleanup requirements and reimbursements required to be paid or incurred by provisions that apply without any violation of law, section 162(f) and the final regulations will apply to penalties required to be paid or incurred for violations of law, including penalties required to be paid or incurred by reason of a violation of specific CERCLA provisions.

4. Investigation or Inquiry Into the Potential Violation of Any Law

The Treasury Department and the IRS received several requests for additional guidance concerning ''the investigation or inquiry by [a] government or [governmental] entity into the potential violation of any law.'' Commenters requested that the final regulations: (1) Provide that an investigation or inquiry by such government into the potential violation of any law does not include a routine investigation, inquiry, audit, review, or inspection; (2) clarify when a routine investigation, inquiry, audit, review, or inspection ends and a non-routine investigation or inquiry begins; (3) clarify whether payments related to an investigation or inquiry are deductible if the investigation or inquiry ends without a finding of a violation of any law; and (4) provide examples of routine investigations, inquiries, audits, reviews, or inspections that are not non-routine investigations or inquiries. In addition, some of the commenters requested guidance that is unique to an industry or a statute.

The Treasury Department and the IRS agree that, in general, section 162(f)(1) does not disallow a deduction for amounts paid or incurred in connection with investigations or inquiries of regulated businesses or industries

conducted in the ordinary course of business if the payment is otherwise deductible as an ordinary and necessary business expense. Accordingly, the final regulations provide, in general, that amounts paid or incurred for routine investigations or inquiries, such as audits or inspections, required to ensure compliance with rules and regulations applicable to the business or industry, which are not related to any evidence of wrongdoing or suspected wrongdoing, are not amounts paid or incurred relating to the potential violation of any law. Therefore, section 162(f)(1) will not apply to disallow an otherwise deductible ordinary and necessary business expense for amounts paid or incurred for these routine investigations or inquiries. Examples to illustrate the application of this rule are provided in the final regulations.

In contrast, section 162(f)(1) explicitly disallows a deduction for amounts paid or incurred for an investigation or inquiry by the government or governmental entity relating to the potential violation of any law. Therefore, the final regulations do not adopt the commenters' recommendation that section 162(f)(1) does not apply to amounts paid or incurred where, at the conclusion of the investigation or inquiry, there is no finding of wrongdoing, because the recommendation is inconsistent with section 162(f)(1).

The final regulations clarify that the investigation or inquiry must be one that is conducted by the government or governmental entity. Examples to illustrate the application of this rule are provided in the final regulations.

5. Fine or Penalty

The proposed regulations disallow a deduction for payments made, at the taxpayer's election, in lieu of a fine or penalty. No comments were received regarding this provision and it is retained in the final regulations. One commenter asked that the final regulations adopt a definition for ''fine or penalty,'' and expressly state that both are not deductible. Although the final regulations do not provide a definition of ''fine or penalty,'' they provide that an amount that is paid or incurred in relation to the violation of any civil or criminal law includes a fine or penalty.

B. Exception to General Rule

Section 162(f)(2) provides an exception to the general disallowance rule for certain amounts identified in the order or agreement as, and established by the taxpayer to be, paid or incurred for restitution or remediation, or to come into compliance with a law. The final regulations provide definitions and other guidance on the operation of this exception.

1. Restitution and Remediation

a. General

The proposed regulations provide that an amount is paid or incurred for restitution or remediation if it restores, in whole or in part, the person, as defined in section 7701(a)(1); the government; the governmental entity; or property harmed by the violation or potential violation of any law. Commenters requested clarification as to what comprises restitution or remediation and requested modifications to the proposed definitions. A commenter recommended that the final regulations distinguish between civil and criminal restitution and disallow the deduction for amounts paid as criminal restitution. The final regulations do not adopt this rule because section 162(f)(2) does not distinguish between civil and criminal restitution and applies to ''restitution (including remediation of property) for damage or harm which was or may be caused by the violation of *any* law or the potential violation of *any* law.'' Emphasis added. Nonetheless, it may be harder for a taxpayer to establish that an amount paid is restitution in the criminal context because of the punitive purpose underlying most criminal liability.

b. Restitution or Remediation of the Environment

One commenter asked whether the definition of ''property'' for which restitution or remediation may be provided includes the environment. Another commenter noted that restitution or remediation cannot redress irreparable harms to the environment or natural resources, such as, killing wildlife or destroying a species or an ecosystem caused by the violation of any law. The commenter recommended that the final regulations provide a special restitution and remediation rule to address amounts paid or incurred for irreparable harm to the environment, natural resources, or wildlife. The Treasury Department and the IRS agree, provided the identification and establishment requirements are met and the restitution or remediation has a strong nexus or connection to the harm to the environment, natural resources, or wildlife that the taxpayer has caused or is alleged to have caused. The final regulations revise the definition of ''*restitution, remediation of property, and amounts paid to come into compliance with a law*'' to clarify that, if otherwise deductible under chapter 1, an amount is paid or incurred for restitution or remediation of the environment, wildlife, or natural resources if it is paid or incurred for the purpose of conserving soil, air, or water resources, protecting or restoring the environment or an ecosystem, improving forests, or providing a habitat for fish, wildlife, or plants, and has the requisite nexus with the harm that the taxpayer has caused or is alleged to have caused. Such amounts may include payments described in § 1.162–21(e)(4)(A), to be used exclusively for the restitution or remediation of a harm to the environment, wildlife, or natural resources that the taxpayer has caused or is alleged to have caused or paid to a segregated fund or account established by, or at the direction of, the government or governmental entity for the restitution or remediation of harm to the environment, wildlife, or natural resources that the taxpayer has caused or is alleged to have caused, provided, pursuant to the order or agreement, the amounts are not disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes.

c. Disgorgement or Forfeiture

Under the proposed regulations, the section 162(f)(2) exception to the general deduction disallowance rule does not apply to forfeiture or disgorgement. Therefore, the proposed regulations treat any amount paid or incurred as forfeiture or disgorgement as, per se, disallowed under section 162(f)(1). To support excluding disgorgement from the definition of restitution, remediation, or amounts paid to come into compliance with a law, the preamble to the proposed regulations quote *Kokesh* v. *Securities and Exchange Commission,* 137 S. Ct. 1635, 1643 (2017) (''[t]he primary purpose of disgorgement orders is to deter violations of the securities laws by depriving violators of their ill-gotten gains'''). In *Kokesh,* the Supreme Court determined that disgorgement, when imposed as a sanction for violating a Federal securities law, constitutes a penalty under the related five-year statute of limitations because disgorgement is imposed to deter violations of securities laws by depriving violators of their ill-gotten gains and because the funds are dispersed to the United States Treasury to redress a wrong to the public at large caused by the violation. *Kokesh,* 137 S. Ct. at 1642–44. However, in *Kokesh,* the

Supreme Court recognized that disgorgement may serve a compensatory purpose as well (''wrong sought to be redressed is . . . a wrong to the individual;'' ''[s]ome disgorged funds are paid to victims''). *Id.*

To support excluding forfeiture from the definition of restitution, remediation, or amounts paid to come into compliance with a law, the preamble to the proposed regulations quotes *Nacchio* v. *United States,* 824 F.3d 1370, 1379 (Fed. Cir. 2016) (''[w]hile restitution seeks to make victims whole by reimbursing them for their losses, forfeiture is meant to punish the defendant by transferring his ill-gotten gains to the United States Department of Justice.'') In *Nacchio,* the United States Court of Appeals for the Federal Circuit disallowed the taxpayer's deduction for the amount of mandatory forfeiture pursuant to a criminal conviction for insider trading, even though the government, in its discretion, subsequently used the forfeited funds to compensate victims.

Several commenters asked the Treasury Department and the IRS to reconsider the rule in the proposed regulations, which excludes disgorgement and forfeiture from the definition of ''restitution, remediation, and coming into compliance.'' One commenter explained the exclusion is contrary to the expressed intent of Congress because the statute provides an exception to the disallowance rule of section 162(f)(1) for restitution and that, in *Kokesh,* the Supreme Court stated, ''[g]enerally, disgorgement is a form of '[r]estitution measured by the defendant's wrongful gain.'' *Kokesh,* 137 S. Ct. at 1640. Commenters noted that, in *Liu* v. *Securities and Exchange Commission,* 140 S. Ct. 1936 (2020), which was decided after the publication of the proposed regulations, the Supreme Court recognized that, amounts paid through disgorgement that do not exceed the wrongdoer's net profits and that are awarded to individual victims may constitute an equitable remedy. Commenters also noted that, in *Liu,* the Supreme Court expressly declined to answer whether under *Kokesh* disgorgement necessarily constitutes a penalty. *Liu,* 140 S. Ct. at 1946.

In consideration of the comments submitted with respect to disgorgement and the Supreme Court's decision in *Liu,* the final regulations will not treat disgorgement of net profits as, per se, nondeductible under section 162(f)(1). Instead, taxpayer's claim for a deduction for amounts paid or incurred through disgorgement will not be disallowed if the amount is otherwise deductible under chapter 1; the order or agreement identifies the payment, not in excess of net profits, as restitution, remediation, or an amount paid to come into compliance with a law; the taxpayer establishes that the amount was paid as restitution, remediation, or an amount paid to come into compliance with a law; and the origin of the taxpayer's liability is restitution, remediation, or an amount paid to come into compliance with a law. However, amounts paid or incurred through disgorgement will be disallowed if, pursuant to the order or agreement, the amounts are disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes. The final regulations provide an example to illustrate the application of section 162(f) to disgorgement.

Commenters also requested that the Treasury Department and the IRS reconsider the rule in the proposed regulations that excludes forfeiture from the definition of ''restitution, remediation, and coming into compliance,'' but did not address forfeiture independently from their discussion of disgorgement. Virtually all states have some form of asset recovery legislation and the United States Code contains many forfeiture provisions. Because the final regulations cannot provide specific rules about the application of section 162(f) to every asset recovery statute, the final regulations will not treat forfeiture of net profits as, per se, nondeductible under section 162(f)(1). Instead, taxpayer's claim for a deduction for an amount paid or incurred through forfeiture will not be disallowed if the amount is otherwise deductible under chapter 1; the order or agreement identifies the payment, not in excess of net profits, as restitution, remediation, or an amount paid to come into compliance with a law; the taxpayer establishes that the amount was paid as restitution, remediation, or an amount paid to come into compliance with a law; and the origin of the taxpayer's liability is restitution, remediation, or an amount paid to come into compliance with a law. However, amounts paid or incurred through forfeiture will be disallowed if, pursuant to the order or agreement, the amounts are disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes. The final regulations provide an example to illustrate the application of section 162(f) to forfeiture.

d. Payment to a Fund

Under the proposed regulations, restitution, remediation, and amounts paid to come into compliance with a law do not include any amount paid or incurred to an entity; to a fund, including a restitution, remediation, or other fund; to a group; or to a government or governmental entity, to the extent it was not harmed by the taxpayer's violation or potential violation of a law. Commenters asked that the Treasury Department and the IRS reconsider this rule. In consideration of the comments, the final regulations remove the per se exclusion. However, the final regulations provide that restitution and remediation do not include amounts paid or incurred pursuant to an order or agreement to the general account or treasury of the government or governmental entity for general enforcement efforts or other discretionary purposes or amounts paid or incurred that do not meet the requirements of § 1.162–21(e)(4)(i). In addition, the final regulations provide that if amounts paid or incurred pursuant to an order or agreement to an entity, fund, group, or government or governmental entity are subsequently returned to the taxpayer, the taxpayer will be required to include those amounts in income under the tax benefit rule.

Several commenters noted that restitution funds may not be exhausted if, for example, there are unclaimed amounts or when less than the entire fund is required to be used to make harmed parties whole. One commenter recommended that the final regulations provide an example to illustrate that when unclaimed amounts revert to a government or governmental entity's general account the nature of those amounts does not change as long as it was reasonably expected, at the time the taxpayer made the payment to the fund, that the amount would be used for restitution payments to harmed parties. Although the final regulations do not provide this example, the Treasury Department and the IRS generally agree that, if the order or agreement identifies the payment to a fund, described in § 1.162–21(e)(4)(A) or (e)(4)(B), as restitution or remediation, and the taxpayer establishes that it made the payment to a fund for the purpose identified, for example, by providing the canceled check making the payment to the fund, a deduction will not be disallowed if, after the taxpayer makes the payment, the amount paid to the fund is not used for the purpose identified as long as the amount does

not revert to the taxpayer or for the benefit of the taxpayer.

2. Coming Into Compliance With a Law

The proposed regulations provide that an amount is paid or incurred to come into compliance with a law by performing specific services, taking a specific corrective action, providing specific property, or a combination thereof. The final regulations also list amounts that will not be treated as paid or incurred to come into compliance with a law. The final regulations clarify that the services performed, actions taken, and the provision of property must be done to come into compliance with the law that has been violated, or potentially violated.

One commenter requested that the final regulations treat amounts paid or incurred pursuant to an order or agreement to upgrade equipment or property to a higher standard than required by law as coming into compliance with a law. The final regulations modify an example in the proposed regulations to clarify that if an order or agreement requires a taxpayer to come into compliance with a law and the taxpayer elects to upgrade equipment or property to a higher than required standard, any amount paid or incurred in excess of the amount paid or incurred to come into compliance with a law will not be disallowed by section 162(f)(1) or the related final regulations because it is not an amount paid or incurred to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry into the potential violation of any law.

Another commenter requested that the final regulations define the class of services and actions that qualify as having been made to come into compliance with a law under section 162(f)(2)(A)(i)(II). The final regulations do not adopt this recommendation because they are intended to provide broad rules of general application based on the underlying principles of section 162(f) rather than narrow rules with limited application that risk excluding certain services or actions. The commenter also suggested that the government or governmental entity not be required to verify the accuracy of the amount expended by a taxpayer to perform the activities to come into compliance. The regulations do not require the government or governmental entity to verify the accuracy of the amount expended by a taxpayer to perform the activities to come into compliance.

3. Identification Requirement

Section 162(f)(2)(A)(ii) requires an order or agreement to identify an amount paid or incurred as restitution, remediation, or to come into compliance with a law. Under the proposed regulations, an order or agreement identifies a payment by stating the nature of, or purpose for, each payment each taxpayer is obligated to pay and the amount of each payment identified.

To satisfy the identification requirement, the proposed regulations require the order or agreement to specifically state the amount of the payment and that the payment constitutes restitution, remediation, or an amount paid to come into compliance with a law. The proposed rule provides that the identification requirement may be met if the order or agreement uses a different form of the requisite words, such as ''remediate'' or ''comply with a law.''

The Treasury Department and the IRS received several recommendations and requests for clarification regarding how orders or agreements may meet the identification requirement when the payment amount is not identified. One commenter suggested that, if the total amount to be paid is known at the time the agreement is entered into or the order is issued, the order or agreement must identify separately the amount to be paid as restitution, remediation, or to come into compliance with a law in order to meet the identification requirement. In contrast, several other commenters asked whether the identification requirement may be met if the order or agreement identifies the total payment as restitution, remediation, or paid to come into compliance with a law without allocating the payment amount among ''restitution,'' ''remediation,'' and ''coming into compliance.'' Some commenters expressed the concern that it may not be possible to satisfy the identification requirement in an order or agreement that imposes lump-sum judgments or settlements, involves multiple taxpayers, or multiple damage awards, because the order or agreement may not segregate the amounts to be paid as restitution, remediation, or to come into compliance with a law from the disallowed amounts, or allocate the payments among the multiple taxpayers.

The final regulations do not adopt a rule that a total payment amount must be allocated in an order or agreement among ''restitution,'' ''remediation,'' and/or ''coming into compliance'' in order to meet the identification requirement under section 162(f)(2)(A)(ii) because it could be burdensome on governments and governmental entities and taxpayers and would be difficult for the IRS to administer. Instead, the final regulations modify the proposed rule for payment amounts not identified so that it applies to orders or agreements that impose lump-sum payment judgments for ''restitution, remediation, and coming into compliance,'' or that involve multiple taxpayers or multiple damage awards. The payment amount not identified rule provides that the identification requirement may be met even if the order or agreement does not allocate the total lump-sum payment amount or multiple damage award among restitution, remediation, or to come into compliance or allocate the total payment among multiple taxpayers. The final regulations also clarify that the identification requirement may be met even if the order or agreement does not provide an estimated payment amount.

Several commenters asked for clarification about how a taxpayer may meet the identification requirement. Consistent with section 162(f)(2)(A)(ii), the final regulations provide that the order or agreement, not the taxpayer, must meet the identification requirement with language specifically stating, or describing, that the amount will be paid or incurred as restitution, remediation, or to come into compliance with a law.

Under the proposed regulations, the identification requirement is presumed to be met if an order or agreement specifically states that the payment, and the amount of the payment, constitutes restitution, remediation, or an amount paid to come into compliance with a law. Commenters requested that the final regulations adopt a more permissive rule pursuant to which the identification requirement is presumed to be met if the order or agreement uses words other than ''restitution,'' ''remediation'' or ''remediate,'' and ''come into compliance'', or ''comply.'' In addition, a commenter also asked for a more permissive rule if an order or agreement is in a foreign language. The final regulations provide that the identification requirement is met, not presumed to be met, if the order or agreement specifically states that the payment constitutes restitution, remediation, or an amount paid to come into compliance with a law. In response to the comments, the final regulations also provide a similar result if the order or agreement uses a different form of the required words, such as, ''remediate'' or ''comply with a law.'' An order or agreement in a foreign language may meet the identification requirement if

the taxpayer provides a complete and accurate certified English translation of the order or agreement that describes the nature and purpose of the payment using the foreign language equivalent of restitution, remediation, or coming into compliance with the law.

An order or agreement will also meet the identification requirement, despite not using the words ''restitution,'' ''remediation,'' ''remediate,'' ''come into compliance'', or ''comply,'' if the nature and purpose of the payment, as described in the order or agreement, are clearly and unambiguously to restore the injured party or property or to correct the non-compliance. The final regulations provide that an order or agreement will also meet the identification requirement if the order or agreement describes the damage done, harm suffered, or manner of noncompliance with a law, and describes the action required of the taxpayer to (i) restore, in whole or in part, the party, property, environment, wildlife, or natural resources harmed, injured, or damaged by the violation or potential violation of that law or (ii) to perform services, take action, provide property, or doing any combination thereof to come into compliance with that law.

The proposed regulations provide that the IRS may challenge an order or agreement's identification of the payment amount as restitution, remediation, or made to come into compliance with a law for the purposes of meeting the identification requirement. One commenter recommended that a substantive challenge to the characterization of a payment would more appropriately fit under the establishment requirement, rather than under the identification requirement. To address this comment, the identification requirement in the final regulations does not include a rebuttable presumption.

4. Establishment Requirement

Section 162(f)(2)(A)(i) requires that a taxpayer establish that an amount was paid as restitution or remediation, or that the amount was paid to come into compliance with a law. The proposed regulations provide that the taxpayer may satisfy the establishment requirement by providing documentary evidence (1) that the taxpayer was legally obligated to pay the amount the order or agreement identified as restitution, remediation, or to come into compliance with a law; (2) of the amount paid or incurred; and (3) of the date on which the amount was paid or incurred. A commenter recommended that the final regulations clarify what the taxpayer must prove to meet the establishment requirement. The commenter also advised that it would be more appropriate for the IRS to challenge the characterization of the payment amount as restitution, remediation, or made to come into compliance with a law under the establishment requirement rather than under the identification requirement. The final regulations clarify that the establishment requirement is met if the documentary evidence submitted by the taxpayer proves that the taxpayer was legally obligated to pay the amount identified in the order or agreement as restitution, remediation, or to come into compliance with a law and that it was paid or incurred for the nature and purpose identified.

If the order or agreement identifies a lump sum payment or a multiple damage award that includes some combination of restitution, remediation, and coming into compliance with a law, the taxpayer must establish the exact amount paid or incurred for each purpose. Likewise, if an order or agreement involves multiple taxpayers, each taxpayer must establish the amount that taxpayer paid or incurred as restitution, remediation, or to come into compliance.

The proposed regulations provided a non-exhaustive list of documents that taxpayers may use to satisfy the establishment requirement. Commenters requested that the final regulations include additional examples of such documents. The final regulations expand the list of documentary evidence that may be used to meet the establishment requirement. The taxpayer may be able to use documentary evidence in a foreign language to satisfy the establishment requirement if the taxpayer provides a complete and accurate certified English translation of the documentary evidence.

5. Information Return May Not Satisfy the Identification Requirement or the Establishment Requirement

The proposed regulations provide that reporting of the amount by a government or governmental entity under section 6050X does not satisfy the identification requirement or the establishment requirement. A commenter requested that the final regulations provide that a government or governmental entity's submission of an information return under section 6050X can satisfy the identification requirement under section 162(f)(2)(A)(ii) and/or the establishment requirement under section 162(f)(2)(A)(i). The final regulations do not adopt this recommendation. The reporting requirement imposed by section 6050X is for tax administration purposes and does not serve as documentation that the taxpayer has met the identification requirement or the establishment requirement. Therefore, the taxpayer may not use the information reported on the Form 1098–F to satisfy the identification requirement or the establishment requirement.

6. Private Party Suit

Under section 162(f)(3), the general rule that disallows a deduction does not apply to any amount paid or incurred pursuant to an order in a suit in which no government or governmental entity is a party. Like the proposed regulations, the final regulations clarify that section 162(f)(1) does not apply to any amount paid or incurred by reason of any order or agreement in a suit in which no government or governmental entity is a party. A commenter asked for clarification in the final regulations that section 162(f)(1) does not apply to any amount paid or incurred by reason of any order or agreement in a suit in which a government or governmental entity enforces rights as a private party. For example, payments pursuant to contract disputes that are not due to fraud or other potentially illegal activity wherein the government or governmental entity enforces its rights as a private party contracting for goods and/or services, and not in its enforcement, regulatory, or administrative capacity, generally are not payments made at the direction of a government or governmental entity. The final regulations generally adopt this recommendation. An example has been provided in the final regulations to illustrate the application of this rule.

A commenter asked for clarification about the application of section 162(f) to qui tam cases brought by private citizens on behalf of a government or governmental entity. The final regulations do not adopt a single rule concerning qui tam cases, but certain principles apply to determine whether a deduction for the amounts paid or incurred will be allowed. In general, a government or governmental entity is the real party in interest in the suit and receives any funds paid pursuant to the order or agreement, including any share ultimately paid by the government or governmental entity to the relator, whether or not the government or governmental entity intervenes in the suit. Accordingly, any amount paid or incurred to a government or governmental entity as a result of the

suit will likely be disallowed unless an exception to section 162(f)(1) applies.

7. Pre and Postjudgment Interest

A commenter asked whether section 162(f)(1) disallows a deduction for prejudgment and postjudgment interest. Section 162(f)(1) applies to prejudgment interest paid or incurred to, or at the direction of, a government or governmental entity for the violation of any law or for the investigation or inquiry into a violation or potential violation of any law. However, a deduction for prejudgment interest will not be disallowed if the prejudgment interest is identified as a component of the total amount identified in the order or agreement as restitution and the taxpayer establishes that it was paid for this purpose. In general, section 162(f)(1) applies to postjudgment interest on amounts to be paid or incurred to, or at the direction of, a government or governmental entity for the violation of any law or investigation or inquiry into a potential violation of any law. However, if postjudgment interest is paid on an amount to which an exception under section 162(f)(2) applies, the exception also applies to that postjudgment interest.

8. Failure To Pay Tax and Related Interest and Penalties

The proposed regulations provide that section 162(f)(1) does not apply to amounts paid or incurred as otherwise deductible taxes or related interest. In accordance with section 162(f)(2)(A)(iii), the final regulations provide that, in the case of any amount paid or incurred as restitution for failure to pay any tax imposed under Title 26, section 162(f)(1) does not disallow a deduction for an amount equal to or less than the amount otherwise allowed under chapter 1 if the tax had been timely paid. For example, section 162(f)(1) does not disallow a deduction of an amount paid or incurred as restitution for failure to pay a tax imposed under Title 26 of the Code, such as certain excise or employment taxes otherwise deductible under chapter 1. However, a deduction for amounts paid or incurred as restitution for failure to pay a Federal income tax is disallowed because Federal income taxes are not otherwise deductible under chapter 1. *See* section 275(a)(1).

The Treasury Department and the IRS received several comments about the application of section 162(f) to federal, state and local taxes, and any related interest and penalties. Under the proposed regulations, if penalties are imposed with respect to otherwise deductible taxes, a taxpayer may not deduct the interest paid with respect to such penalties. A commenter requested clarification that the taxpayer also may not deduct the penalties. The Treasury Department and the IRS agree and the final regulations are revised accordingly to provide that if penalties are imposed with respect to otherwise deductible taxes, a taxpayer may not deduct the penalties or the interest paid with respect to such penalties.

9. Material Change

The proposed regulations contained a material change rule under which some orders issued, or agreements entered, before December 22, 2017, were subject to section 162(f)(1) as amended by the TCJA. Several commenters considered the definition of ''material change'' in the proposed regulations as ''overly broad,'' and suggested it could cause unnecessary administrative disputes and discourage taxpayers from negotiating with governments or governmental entities to clarify the terms of an order or agreement, resulting in increased litigation and burdening taxpayers, governments and governmental entities, and courts. One commenter argued that section 13306(a)(2) of the TCJA (the transition rule for section 162(f)) precludes adopting a material change rule for any binding orders issued or agreements entered into before December 22, 2017. The commenter recommended that the final regulations provide that the amendment to section 162(f) applies only to orders issued or agreements entered into after December 22, 2017.

In response to this comment, the Treasury Department and the IRS have determined that section 162(f), as amended by TCJA, does not apply to any pre-December 22, 2017 binding order or agreement even if modified on or after December 22, 2017. In addition, material changes to an order or agreement will generally result in a new order or agreement subject to section 162(f). For these reasons, the final regulations do not include the material change rule included in the proposed regulations.

II. Reporting Information for Certain Fines, Penalties, and Other Amounts

A. General Rule

The purpose of the regulations under section 6050X is to provide appropriate officials of governments or governmental entities the operational, administrative, and definitional rules for complying with the statutory information reporting requirements for suits or agreements to which section 6050X(a)(1) applies.

In general, under the final regulations, if the aggregate amount a payor is required to pay pursuant to an order or agreement for a violation, investigation, or inquiry to which section 6050X(a)(1) and (a)(2) applies equals or exceeds the threshold amount, the appropriate official of a government or governmental entity that is a party to the order or agreement must file an information return with the IRS regarding certain amounts paid or incurred pursuant to the order or agreement, the payor's taxpayer identification number (TIN), and other information required by the information return and the related instructions. The appropriate official of a government or governmental entity that is a party to the order or agreement must also furnish a written statement with the same information to the payor.

1. Government, Governmental Entity, or Nongovernmental Entity Treated as a Governmental Entity

The proposed regulations provided a definition of ''government or governmental entity.'' No comments were received on the definition of ''government or governmental entity'' in the proposed regulations. The definition in the final regulations has been reorganized to provide a definition of a government in § 1.6050X–(f)(2) and to provide a definition of a ''governmental entity'' in § 1.162–21(f)(3). The definitions are based on the definition in the proposed regulations but clarify that a political subdivision of a government includes a local government unit. The final regulations also clarify that a governmental entity includes a nongovernmental entity treated as a governmental entity.

The proposed regulations under section 6050X incorporate the definition of a ''nongovernmental entity'' in the proposed regulations under section 162(f). The final regulations clarify that, for purposes of the information reporting requirements in section 6050X, a nongovernmental entity treated as a governmental entity does not include a nongovernmental entity of a territory of the United States, including American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands, a foreign country, or an Indian tribe.

2. Suit or Agreement

The proposed regulations provided that the information reporting is required for a ''suit, agreement, or otherwise'' pursuant to section 162(f)(1). A commenter noted that this rule is inconsistent with the statutory language of section 6050X, which only concerns a ''suit or agreement.'' The final

regulations clarify that a government or governmental entity involved in a suit or agreement to which section 6050X(a)(2) applies must file an information return for payment amounts described in section 6050X(a)(1).

Another commenter recommended that the final regulations clarify that a suit or agreement is treated as binding under applicable law even if all appeals have not been exhausted. The final regulations generally adopt this recommendation.

3. Payor

The final regulations define ''payor'' as the person, as defined in section 7701(a)(1), which, pursuant to an order or agreement, has paid or incurred, or is liable to pay or incur, an amount to, or at the direction of, the government or governmental entity in relation to the violation or potential violation of any law. In general, the payor will be the person to which section 162(f) and § 1.162–21 apply.

One commenter recommended that the final regulations provide that governments and governmental entities do not have a reporting requirement, and do not need to furnish a written statement, pursuant to section 6050X for the amounts described in section 6050X(a)(1) that tax-exempt, non-profit payors are required to pay. Another commenter recommended that the final regulations provide that the information reporting requirement should apply only for civil, not criminal, cases. A third commenter recommended that the final regulations provide that the information reporting requirement applies only to payors involved in a trade or business and not to individual payors.

The final regulations do not adopt these recommendations because they are inconsistent with section 6050X. Section 6050X does not carve out an exception for criminal cases, individuals, including those not in a trade or business, and tax-exempt organizations.

The final regulations require the appropriate official to include the TIN of the payor on the information return filed regarding the payor. Commenters asked how the appropriate official of a government or governmental entity may secure a payor's TIN. If the appropriate official does not already have the payor's TIN, the appropriate official must request the TIN. The TIN may be requested in any manner. The appropriate official must notify the payor that the law requires the payor to furnish a TIN for inclusion on the information return and that failure to furnish the TIN may subject the payor to a penalty under section 6723. The payor may provide the TIN in any manner including orally, in writing, or electronically. If the payor furnishes the TIN in writing, no particular form is required.

4. Threshold Amount

Section 6050X(a)(2)(B) provides the Secretary with the authority to adjust the statutory reporting threshold of $600 as necessary to ensure the efficient administration of the internal revenue laws. Based on comments received prior to the publication of the proposed regulations from governments and governmental entities concerned about the burden of information reporting and to ensure the efficient administration of the internal revenue laws, the Treasury Department and the IRS determined that a threshold higher than $600 was appropriate to address these concerns. The proposed regulations provided that reporting is required if the aggregate amount of all orders and agreements for the violation, investigation, or inquiry equals or exceeds $50,000 (threshold amount). Anticipating possible compliance burdens on filers, the Treasury Department and the IRS requested comments about the proposed $50,000 threshold. In particular, the Treasury Department and the IRS requested data on the annual number of relevant orders issued, or agreements entered, by governments or governmental entities and the financial, time, and administrative burdens associated with different threshold amounts. After publication of the proposed regulations, the Treasury Department and the IRS received several requests from governments and governmental entities to raise the proposed $50,000 threshold amount, but none of the comments provided data to support those requests. As a result, the final regulations maintain the proposed threshold amount and provide that reporting is required for payment amounts equal to or in excess of $50,000.

Commenters described several situations in which the government or governmental entity may be uncertain about its reporting obligation because it is not clear that the suit or agreement requires the payor to make payments described in section 6050X(a)(1) that equal or exceed the threshold amount. In one situation, the order or agreement described in section 6050X(a)(1) requires the payor to make several payments for a violation, investigation, or inquiry, each described in section 6050X(a)(2) and each for less than the threshold amount, but the aggregate amount of all payments pursuant to the order or agreement equals or exceeds the threshold amount. In another situation, an order or agreement involving more than one violation, investigation, or inquiry, each described in section 6050X(a)(2), requires the payor to make several payments, each described in section 6050X(a)(1), and each for less than the threshold amount, but the aggregate amount of all payments pursuant to the order or agreement equals or exceeds the threshold amount.

The commenter recommended that, in these two situations, the final regulations should treat each payment amount separately to determine if the aggregate amount involved in the order or agreement equals or exceeds the threshold amount. The final regulations do not provide rules for every circumstance to which section 6050X(a)(2)(A)(ii) could apply. Form 1098–F and its instructions will contain additional guidance regarding the threshold amount.

Another commenter described a situation in which, pursuant to separate orders or agreements, the payor is required to pay separate amounts, all less than the threshold amount, for multiple acts or omissions in violation of the same law but the aggregate amount of the payments to be made pursuant to all orders and agreements equals or exceeds the threshold amount. The commenter requested that, in this situation, the final regulations treat each order and agreement separately. This situation is addressed by section 6050X(a)(2)(A)(ii), which provides that the government or governmental entity must file an information return for a suit or agreement if ''the aggregate amount involved in all court orders and agreements with respect to the violation, investigation, or inquiry'' equals or exceeds the threshold amount. Therefore, the final regulations do not adopt the rule proposed by the commenter. The final regulations also provide that in this situation, the appropriate official must file only one information return for all amounts the payor is required to pay pursuant to these orders or agreements.

5. Requirement To File Return

The appropriate official of a government or governmental entity must comply with the information reporting requirements of section 6050X and the related regulations by filing Form 1098–F, *Fines, Penalties, and Other Amounts,* or any successor form, as provided by the instructions, with Form 1096, *Annual Summary and Transmittal of U.S. Information Returns,* on or before the annual due date as

provided in the final regulations. Under the final regulations, the information return filed by the government or governmental entity with the IRS must provide the amount a payor is required to pay, pursuant to section 6050X(a)(1)(A) and § 1.6050X–1(b)(1)(i), as a result of the order or agreement, the separate amounts required to be paid as restitution, remediation, or to come into compliance with a law, pursuant to section 6050X(a)(1)(B) and (a)(1)(C) and § 1.6050X–1(b)(1)(ii), as a result of the order or agreement, the payor's TIN, and any additional information required by the information return and the related instructions.

The Treasury Department and the IRS received comments requesting that the final rules require information reporting only for amounts paid directly to a government or governmental entity. A commenter also requested final rules pursuant to which the government or governmental entity could provide the reporting information to the payor and require the payor to file the information return. None of these suggestions were adopted in the final regulations because they are inconsistent with the explicit language of section 6050X.

A commenter inquired whether the government or governmental entity reports the payment amount identified in the order or agreement, or only the amount the payor ultimately pays. Another commenter recommended that the reporting requirement apply only to payment amounts described in sections 162(f)(1) and 6050X(a)(1)(A) that are actually collected by governments and governmental entities. Section 6050X(a)(1) mandates reporting for ''the amount required to be paid as a result of the suit or agreement'' for a violation of any law, or an investigation or inquiry into the potential violation of any law, as well as for restitution, remediation, and to come into compliance with a law. Therefore, the final regulations do not adopt the commenter's recommendation. Instead, the final regulations clarify that governments and governmental entities have a reporting obligation for the amounts, described in section 6050X(a)(1) and § 1.6050X–1(b)(1)(i) and (ii), required to be paid pursuant to the order or agreement.

A commenter inquired whether the IRS would consider using website reporting instead of requiring reporting on a form. Section 6050X prescribes reporting that is more suitable on a form. Furthermore, section 6050X(b) also requires governments and governmental entities to furnish written statements to payors. Thus, even if the final regulations permitted governments and governmental entities to report information to the IRS via a website, they would still need to provide a written statement to payors, which could not be accomplished by a website. To minimize the burden on governments or governmental entities, the final regulations permit the appropriate official to comply with the requirements to furnish written statements to payors via the Form 1098–F or another document that contains the required information if the document conforms to applicable guidance relating to substitute statements.

A commenter expressed concerns about the information reporting requirements resulting from an order or agreement, pursuant to which payments are made over the course of several years. To minimize the burden on governments and governmental entities and to ensure the efficient administration of the internal revenue laws, the final regulations do not require an appropriate official to file information returns for each taxable year in which a payor makes a payment pursuant to a single order or agreement. Instead, the appropriate official must file only one information return to report the amounts required by section 6050X(a)(1).

Some commenters inquired about the application of the reporting obligation to governments and governmental entities for specific types of administrative and certain other categories of proceedings. The final regulations do not address the application of the reporting obligation to specific statutes or types of proceedings because the final regulations are intended to provide broad rules of general application based on the underlying principles of sections 162(f) and 6050X rather than narrow rules with limited application that risk excluding a certain ''violation of any law or the investigation or inquiry . . . into the potential violation of any law.''

One commenter observed that the payors and the governments and governmental entities may have incentives to enter into an agreement concerning the filing of information returns such that payors may improperly attempt to claim deductions to which they are not entitled and governments and governmental entities do not have to incur the burden of filing information returns and furnishing written statements. The commenter recommended that the final regulations treat any agreements between payors and governments or governmental entities not to file information returns as invalid and unenforceable. The final regulations do not adopt this recommendation because section 162(f) applies to the taxpayer regardless of whether the appropriate official files an information return with the IRS and furnishes a written statement to the payor.

6. Due Dates

Section 6050X(a)(3) provides that the information return shall be filed at the time the agreement is entered into, as determined by the Secretary, not at the time of payment, as recommended by a commenter. Further, section 6050X(b) requires the written statement to be furnished to the payor at the same time the information return is filed with the IRS. Under the proposed regulations, the information return was required to be filed on or before January 31 of the year following the calendar year in which the order or agreement, becomes binding under applicable law.

A commenter requested that appropriate officials of governments and governmental entities be given more time to comply with the requirement. As requested, the final regulations provide, pursuant to section 6071(a), that information returns filed with the IRS on paper are due on or before February 28 of the year following the calendar year in which the order or agreement, becomes binding under applicable law. In accordance with section 6071(b), information returns filed electronically are due on or before March 31 of such year. However, to increase the likelihood that payors have the information necessary to timely prepare their income tax returns and to avoid burdening governments and governmental entities with having to determine the tax year of each payor, the final regulations require the appropriate official to furnish the written statement on or before January 31 of such year.

7. Rules for Multiple Payors

The final regulations describe the application of the information reporting requirements if, pursuant to the order or agreement, the aggregate amount multiple payors are required to pay, or the costs to provide the property or the service, equals or exceeds the threshold amount. If, pursuant to the order or agreement, more than one payor is individually liable for some or all of the payment amount, the final regulations require the appropriate official to file an information return for the separate amount that each individually liable payor is required to pay, even if a payor's payment liability is less than the threshold amount, and to furnish a written statement containing this information to each payor. If more than one person, as defined in section

7701(a)(1), is a party to an order or agreement, there is no information reporting requirement, or requirement to furnish a written statement, with respect to any person who does not have a payment obligation or obligation for costs to provide services or to provide property.

The final regulations provide that, if an order or agreement, identifies multiple jointly and severally liable payors, the appropriate official must file an information return for each payor to report the information required by § 1.6050X–1(b)(1)(i) and (ii) on the amount to be paid by all jointly and severally liable payors. The appropriate official must furnish a written statement containing this information to each of those payors, regardless of which payor makes the payment.

A commenter wrote that the rules requiring reporting would be challenging to implement when multiple payors are required to make payments. However, under section 6050X(a)(1)(3), the appropriate official has an obligation to file an information return when an order or agreement becomes binding, not when the payments are made, so there is no need for governments or governmental entities to track the receipt of payments in order to comply with section 6050X or the related final regulations.

Another commenter recommended that the payment obligation of each payor be examined separately to determine whether the amount each payor is required to pay, or the costs to provide the property or the service, equals or exceeds the threshold amount. However, in the case of joint and several liability, each payor is responsible for the entire amount, which requires reporting of, and furnishing a statement to, each payor. In the case where a payor is individually liable for an amount below the threshold amount, the payor may still attempt to deduct some or all of the payment amount all of the payors are required to pay, so filing an information return for each of the payors' liabilities is useful for tax administration.

One commenter asked for clarification that the government or governmental entity is not obligated to file an information return with the IRS if, after an order or agreement has become binding under applicable law, the payor pursues another party for contribution. Because any payment the payor receives from another party in a subsequent proceeding will not be subject to section 162(f), the government or governmental entity will not have an obligation to file an information return for any payment made by the other party.

8. Payment Amount Not Identified

Commenters expressed concern that it is difficult for governments and governmental entities to estimate the payment amount pursuant to the order or agreement, and whether the aggregate amount equals or exceeds the information reporting threshold, when the order or agreement does not specify an amount. The Treasury Department and the IRS agree, which is why the regulations do not require governments or governmental entities to estimate payment amounts. Accordingly, if some or all of the payment amount is not identified in the order or agreement, the regulations direct governments and governmental entities to the instructions to Form 1098–F, or any successor form.

Some orders or agreements may identify a payment described in section 6050X(a)(1)(A) and identify a payment or an obligation to provide property or to provide services, as restitution, remediation, or an amount paid to come into compliance with a law, as described in section 6050X(a)(1)(B), but not identify some or all of the payment amounts the payor must pay, or some or all of the cost to provide property or services. The final regulations provide that, if the government or governmental entity reasonably expects that the aggregate amount the payor must pay, and the costs the payor will pay or incur to provide services or to provide property, pursuant to the order or agreement, will equal or exceed the threshold amount, the appropriate official of such government or governmental entity must file an information return on Form 1098–F, or any successor form, as provided in the instructions to the Form 1098–F, and furnish a written statement to the payor with the information supplied to the IRS on Form 1098–F.

Similarly, a commenter noted that some orders or agreements may require a payor to make payments described in section 6050X(a)(1) for which reporting is required and other payments for which reporting is not required under section 6050X. The commenter recommended that if it is not clear for which payment amount the government or governmental entity has a reporting requirement, the rule under the proposed regulations for a payment amount not identified should apply. The Treasury Department and the IRS generally agree with this recommendation. Therefore, if, under the circumstances described by the commenter, the government or governmental entity reasonably expects that the aggregate amount the payor must pay, and the costs the payor must pay to provide services or to provide property, will equal or exceed the threshold amount, the appropriate official of such government or governmental entity must file an information return.

9. Material Change

Under the proposed regulations, if there was a material change to the terms of an order or agreement for which an appropriate official of a government or governmental entity filed an information return, the appropriate official had to file a corrected information return with the IRS and furnish an amended written statement to the payor. The Treasury Department and the IRS have concluded that material changes to an order or agreement will generally result in a new order or agreement subject to the rules under section 6050X and § 1.6050X–1. For this reason, and because the final regulations under § 1.162–21 do not include a material change rule, the final regulations have removed the material change rule from § 1.6050X–1.

Applicability Dates

The rules of § 1.162–21 apply to taxable years beginning on or after the date of publication of this Treasury decision in the **Federal Register**, except that such rules do not apply to amounts paid or incurred under any order or agreement, pursuant to a suit, agreement, or otherwise, that became binding under applicable law before such date, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired. The rules of § 1.6050X–1 apply only to orders and agreements, pursuant to suits and agreements, that become binding under applicable law on or after January 1, 2022, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The regulations have been designated by the Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and by the Office of Management and Budget (OMB) regarding review of tax regulations.

A. Background

Prior to the Tax Cuts and Jobs Act (TCJA), section 162(f) of the Code disallowed a deduction for any fine or similar penalty paid to a government for the violation of any law. This provision, enacted in 1969, codified existing case law that denied business deductions for fines or similar penalties. The general rule of section 162(f)(1), as amended by section 13306(a) of the TCJA, disallows any deduction for amounts paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or governmental entity or certain nongovernmental entities treated as governmental entities, in relation to the violation of any law or the investigation or inquiry by such government or entity into the potential violation of any law. Section 13306(a) also provides certain exceptions to this disallowance. Section 162(f)(2)(A)(i) and (ii) does not disallow deduction for amounts that (1) the taxpayer establishes were paid or incurred as restitution (including remediation of property) or to come into compliance with a law, and (2) are identified in the court order or settlement agreement as restitution, remediation, or to come into compliance with a law.

In addition, under prior law, the Treasury Department and the IRS did not receive information returns from governments or governmental entities that received fines or penalties. Section 6050X of the Code, enacted by section 13306(b) of the TCJA, requires appropriate officials to file an information return if the aggregate amount involved in all orders or agreements relating to the violation, investigation, or inquiry is $600 or more. The information return must include (1) the amount required to be paid as a result of the order or agreement; (2) any amount that constitutes restitution or remediation of property; and (3) any amount required to be paid for the purpose of coming into compliance with a law that was violated or involved in the investigation or inquiry. Section 6050X provides the Secretary with the authority to adjust the $600 reporting threshold in order to ensure efficient tax administration.

Proposed regulations regarding these provisions were previously issued on May 13, 2020 (REG–104591–18) (proposed regulations).

B. Need for the Regulations

Following the passage of the TCJA, the Treasury Department and the IRS received several questions and comments from Federal, state, local, and tribal governments, as well as the public, regarding the meaning of various provisions in each section and issues not explicitly addressed in the statute. The Treasury Department and the IRS have determined that such comments warrant the issuance of further guidance.

In addition, the Treasury Department and the IRS have determined that increasing the reporting threshold to reduce the reporting burden and to enhance the efficiency of tax administration is appropriate.

C. Overview of the Regulations

The regulations provide guidance regarding sections 162(f) and 6050X. The following analysis provides further detail regarding the anticipated impacts of the regulations. Part I.D specifies the baseline for the economic analysis. Part I.E.1. summarizes the economic effects of the rulemaking, relative to this baseline. Part I.E.2. describes the economic effects of specific provisions covering (1) the reporting threshold, (2) the timing of information reporting, and (3) information reporting requirements when payment amounts are not identified.

D. Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

E. Economic Analysis of the Regulation

I. Summary of Economic Effects

The regulations under section 162(f) provide definitions for restitution, remediation, and amounts paid to come into compliance with the law. These definitions clarify for taxpayers which amounts paid or incurred may be deductible under the statute. The regulations also clarify (1) how the taxpayer meets the establishment requirement; and (2) how the order or agreement meets the identification requirement.

The Treasury Department and the IRS have determined that the burden reduction associated with the regulations for section 162(f) is modest. In addition, while the regulations reduce uncertainty for taxpayers, they are unlikely to affect economic decision-making because most of the amounts to be paid or incurred which are subject to section 162(f) are non-discretionary.

The regulations under section 6050X provide certainty and consistency for affected governments and governmental entities by defining and clarifying the statute's terms and rules. Further, the regulations use the authority provided by the statute to the Secretary to set information reporting requirements to minimize the burden on governments and governmental entities and to ensure the efficient administration of the internal revenue laws. Most importantly, the regulations increase the reporting threshold from $600 to $50,000, thereby eliminating information reporting requirements for approximately 1 to 5 million orders or agreements. Using the midpoint of this range (3 million), the estimated burden reduction from this exercise of regulatory discretion is $74 million (2018 dollars) per year relative to the no-action baseline.

This reduction in compliance burden is the only meaningful economic effect of the regulations. The regulations do not have meaningful effects on the tax liability of taxpayers, the deductibility of amounts paid to, or at the directions of, governments and governmental entities, or the incentive for individuals or businesses to engage in violations of the law.

II. Economic Analysis of Specific Provisions

A. Reporting Threshold

Section 6050X requires governments and governmental entities which enter orders or agreements to which section 162(f) applies to file an information return if the aggregate amount paid or incurred in all orders or agreements relating to the violation, investigation, or inquiry is equal to or exceeds a threshold of $600. Section 6050X also provides the Secretary with the authority to adjust the statutory reporting threshold as necessary to ensure efficient tax administration. In response to multiple comments received prior to the issuance of the proposed regulations from governments and governmental entities concerned about the burden of information reporting for smaller payments amounts pursuant to orders or agreements, the regulations raise the reporting threshold to $50,000. In the proposed regulations, the Treasury Department and the IRS solicited data on the annual number of orders or agreements by governments or governmental entities that could inform the determination of the appropriate

threshold amount. The Treasury Department and the IRS did not receive any such data.

The Treasury Department and the IRS considered a range of alternative thresholds including the statutory threshold of $600, along with much higher thresholds suggested by some commenters. Upon consideration of both the enforcement needs of the IRS and the reporting burden on governments and governmental entities, the Treasury Department and the IRS exercised the authority provided to the Secretary by the statute to set the reporting threshold amount at $50,000.

The Treasury Department and the IRS do not know of any data on the number of orders or agreements requiring taxpayers to pay amounts to, or at the direction of, governments or governmental entities, or the distribution of these amounts, such as the number that are above or below $600. Based on communications with stakeholders, the Treasury Department and the IRS estimate that the increase in reporting threshold from $600 to $50,000 will reduce the number of required information returns by approximately 1 to 5 million. The Treasury Department and the IRS further estimate that the average time to complete the information return is between 0.387 and 0.687 hours. Using the midpoint of each of these ranges (3 million information returns and .537 hours) and a labor cost of $46 per hour,[1] the Treasury Department and the IRS estimate that increasing the reporting threshold will reduce annual compliance burdens by $74 million dollars (2018 dollars) per year. It should be noted that many of the lower level fines and penalties are likely to be assessed on non-businesses that are not able to deduct business expenses so they would be unaffected by the extent to which governments or governmental entities are subject to reporting requirements.

Increasing the reporting threshold from $600 to $50,000 is unlikely to have a significant effect on revenues because fines over $50,000 likely account for the vast majority of fines and penalties in terms of dollar values. Based on financial reporting values disclosed on tax returns of C corporations, S corporations and partnerships, firms with over $50,000 in total fines and penalties account for 99 percent of all fines and penalties. However, these data should be interpreted with caution. Financial reporting of fines and penalties includes both international and domestic fines, and all fines and penalties are aggregated into yearly totals. Furthermore, firms with less than $10 million in assets are not required to provide financial reporting values with their tax returns.

B. Time of Reporting

Section 6050X provides that the government or governmental entity shall file the information return at the time the order is issued or the agreement is entered into, as determined by the Secretary. The Treasury Department and the IRS received comments from governments and governmental entities prior to the issuance of the proposed regulations observing that it would be burdensome and inefficient for them to file information returns each time an order or agreement becomes binding under applicable law. Several commenters suggested that annual filing of information returns would meaningfully reduce this reporting burden. The Treasury Department and the IRS agree with this comment and have adopted it in the regulations. The Treasury Department and the IRS have not estimated the difference in compliance burden between these two alternatives because they do not have suitable data or models to do so.

Several commenters also expressed uncertainty and concern about the information reporting requirements for an order or agreement pursuant to which payments are made over the course of several years. To reduce uncertainty, and to minimize the burden on governments and governmental entities, the regulations clarify that information reporting is required only for the year in which the order or agreement becomes binding under applicable law, and not required for each taxable year in which a payor makes a payment.

The Treasury Department and the IRS considered requiring information reporting at the time the order is issued or the agreement is entered. The Treasury Department and the IRS also considered requiring information reporting in each year in which an amount is paid or incurred pursuant to the order or agreement. However, both alternative approaches were determined to impose unnecessary burden for governments and governmental entities without creating accompanying benefits for tax administration or for taxpayers.

Under the proposed regulations, the information return was required to be filed with the IRS, and a written statement furnished to the payor, on or before January 31 of the year following the calendar year in which the order or agreement becomes binding under applicable law, even if all appeals have not been exhausted for the suit or agreement. In response to the proposed regulations, a commenter requested that governments and governmental entities be given more time to comply with the requirements. As requested, the final regulations are revised to provide that information returns filed with the IRS on paper are due on or before February 28 of the year following the calendar year in which the order or agreement becomes binding under applicable law and information returns filed electronically are due on or before March 31 of such year. However, to increase the likelihood that payors have the information necessary to timely prepare their income tax returns, the final regulations still require governments and governmental entities to furnish the written statements to payors on or before January 31 of such year.

C. Payment Amount Not Identified

When the expected amount paid or incurred pursuant to an order or agreement equals or exceeds the threshold amount, section 6050X requires governments or governmental entities to file an information return including: (1) The amount required to be paid as a result of the order or agreement; (2) any amount that constitutes restitution or remediation of property; and (3) any amount required to be paid for the purpose of coming into compliance with a law that was violated or involved in the investigation or inquiry. However, some orders or agreements may involve uncertain payments or costs to provide property or services without identifying some or all of the aggregate amount the payor must pay, or some or all of the aggregate cost to provide property or services. The Treasury Department and the IRS received comments expressing concern that amounts paid or incurred are often difficult to assess, and strict valuation requirements would impose undue burden on governments and governmental entities. For situations in which the amount is not identified, the regulations direct governments and governmental entities to the instructions to Form 1098–F. To address commenters' concerns, these instructions will permit governments and governmental entities to report the threshold amount of $50,000 when the amount is unknown but expected to equal or exceed $50,000. This rule is necessary to improve taxpayer compliance.

The Treasury Department and the IRS considered requiring governments and

[1] This data point is derived by the IRS as part of the burden analysis described in the Paperwork Reduction Act section below.

governmental entities to provide an estimate of each amount to be paid or incurred; however this approach was rejected because it would impose significant burden on governments and governmental entities. The Treasury Department and the IRS did not estimate the difference in compliance burden between the final regulation and this alternative approach because they do not have suitable data or models to do so.

Paperwork Reduction Act

Collection of Information—Form 1098–F

In general, the collection of information in the regulations is required under section 6050X of the Code. The collection of information in these regulations is set forth in § 1.6050X–1. The IRS intends that the collection of information pursuant to section 6050X will be conducted by way of Form 1098–F, *Fines, Penalties, and Other Amounts.* Form 1098–F will be used by all governments, governmental entities, and nongovernmental entities treated as governmental entities with a reporting requirement. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the regulations. In addition, when available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

The current status of the PRA submissions related to section 6050X are provided in the following table.

Form	Type of filer	OMB No.	Status
1098–F	Governments, Governmental Entities, And Certain Non-governmental Entities.	1545–2284	Form 1098–F is approved through 1/31/2023.

RELATED NEW OR REVISED TAX FORMS

	New	Revision of existing form	Number of respondents (2018, estimated)
Form 1098–F	Yes		90,100 (85,500 small governmental jurisdictions, 4,500 large governmental jurisdictions and 100 nongovernmental entities).

A reasonable burden estimate for the average time to complete Form 1098–F is between 0.387 and 0.687 hours (approximately 23 to 41 minutes). This estimate is based on survey data collected from similar information return filers. In addition, the increase in the reporting threshold under section 6050X will lead to a decrease in the number of information returns filed by approximately 1 million to 5 million returns. Using the midpoint of these ranges, or 3 million and 0.537 hours, the estimated burden reduction is $74 million per year.

Estimated average time per form: .537 hours.

Estimated number of respondents: 90,100.

Estimated total annual burden hours: 48,383.70.

Estimated change in number of information returns resulting from increased reporting threshold: (3,000,000).

Estimated change in burden (hours): (1,611,150).

Estimated change in burden (Dollars): ($74,161,235).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. chapter 6) requires agencies to ''prepare and make available for public comment an initial regulatory flexibility analysis,'' which will ''describe the impact of the rule on small entities.'' 5 U.S.C. 603(a). Section 605(b) of the RFA allows an agency to certify a rule if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the RFA, the Secretary of the Treasury hereby certifies that these regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the RFA.

The RFA generally applies to regulations that affect small businesses, small organizations, and small governmental jurisdictions. For purposes of the RFA, small governmental jurisdictions are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000. This rule would affect States, as well as local governments, some of which may meet the definition of small governmental jurisdiction. Approximately 90,100 governments, governmental entities, and nongovernmental entities treated as governmental entities may be subject to the reporting requirements of section 6050X. Of those governments and governmental entities, approximately 85,500 (or 95%) are small governmental jurisdictions.

Although the regulations may affect a substantial number of small governmental jurisdictions, the economic impact of the regulations is not expected to be significant. The regulations set a reporting threshold that is higher than the minimum required by statute and also provide for governments and governmental entities to file annual returns. Both of these provisions reduce the potential burden on small governmental jurisdictions. In particular, the increase in the reporting threshold will lead to a decrease in the number of information returns filed by approximately 1 million to 5 million returns. Using the midpoint of this range, or 3 million, the estimated burden reduction is $74 million per year (2018 dollars). It is estimated that after reading and learning about the requirements of the regulations, the burden associated with filing the annual form is approximately 23 to 41 minutes and the average cost per information return is approximately $24.72, which would not result in a significant economic impact on small entities.

Pursuant to section 7805(f) of the Code, the proposed rule preceding this rulemaking was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small entities and no comments were received.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)

requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

Executive Order 13132: Federalism

Executive Order 13132 (entitled *Federalism*) prohibits an agency from publishing any rule that has Federalism implications if the rule either imposes substantial direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. These rules do not have Federalism implications, and do not impose substantial direct compliance costs on state and local governments or preempt state law, within the meaning of the Executive Order. The compliance costs, if any, are imposed on state and local governments by section 6050X, as enacted by the TCJA. Notwithstanding, the Treasury Department and the IRS consulted with the National League of Cities and the National Governors Association prior to the issuance of the proposed regulations. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, the Treasury Department and the IRS certify that they have complied with the requirements of Executive Order 13132.

Congressional Review Act

The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (CRA)). Under 5 U.S.C. 801(3), a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Notwithstanding this requirement, 5 U.S.C. 808(2) allows agencies to dispense with the requirements of 5 U.S.C. 801 when the agency for good cause finds that such procedure would be impracticable, unnecessary, or contrary to the public interest and the rule shall take effect at such time as the agency promulgating the rule determines. Pursuant to 5 U.S.C. 808(2), the Treasury Department and the IRS find, for good cause, that a 60-day delay in the effective date is unnecessary and contrary to the public interest.

Following the amendments to section 162(f) and enactment of section 6050X by the TCJA, the Treasury Department and the IRS published IRS published Notice 2018–23, 2018–15 I.R.B. 474, to provide transitional guidance on the identification requirement of section 162(f) and the information reporting requirement under section 6050X and to solicit comments from the public and affected governments and governmental entities on issues related to the implementation of section 162(f) and section 6050X. Subsequently, on May 13, 2020, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–104591–18) in the **Federal Register** (85 FR 28524) providing additional guidance for taxpayers and governments and governmental entities on the deduction disallowance rules in section 162(f) and the associated reporting requirements in section 6050X. However, as demonstrated by the wide variety of public comments in response to the proposed regulations received, taxpayers and governments and governmental entities continue to express uncertainty regarding the proper application of the relevant statutory rules under section 162(f) and section 6050X. These final regulations provide crucial guidance for taxpayers and governments and governmental entities on how to apply the relevant statutory rules. In certain cases, failure to comprehend the proper application of the requirements of section 162(f) can prevent taxpayers from claiming appropriate deductions, resulting in them paying potentially higher taxes than required during a time of economic difficulty.[2] In addition, governments and governmental entities will require several months to update or develop data collection and reporting systems to comply with the rules under section 6050X. However, governments and governmental entities will need to know that the final regulations are effective before incurring necessary costs to timely comply with the final regulations. Accordingly, the Treasury Department and the IRS have determined that the rules in this Treasury decision will take effect on the date of filing for public inspection in the **Federal Register**.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, Notices and other guidance cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Drafting Information

The principal author of these regulations is Sharon Y. Horn of Associate Chief Counsel (Income Tax and Accounting), IRS. However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes; Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.6050X–1 also issued under 26 U.S.C. 6050X(a), (b).

* * * * *

■ **Par. 2.** Section 1.162–21 is revised to read as follows:

§ 1.162 –21 Denial of deduction for certain fines, penalties, and other amounts.

(a) *Deduction Disallowed.* Except as otherwise provided in this section, no deduction is allowed under chapter 1 of the Internal Revenue Code (Code) for any amount that is paid or incurred—

(1) By suit, settlement agreement (agreement), or otherwise, as defined in paragraph (e)(5) of this section;

(2) To, or at the direction of, a government, as defined in paragraph (e)(1) of this section, or a governmental entity, as defined in paragraph (e)(2) of this section; and

(3) In relation to the violation, or investigation or inquiry by such government or governmental entity into the potential violation, of any civil or criminal law.

(i) An amount that is paid or incurred in relation to the violation of any civil or criminal law includes a fine or penalty.

(ii) An investigation or inquiry into the potential violation of any law does not include routine investigations or inquiries, such as audits or inspections, of regulated businesses that are not related to any evidence of wrongdoing

[2] See Executive Order 13924 (May 19, 2020) 85 FR 31,353–54.

or suspected wrongdoing, but are conducted to ensure compliance with the rules and regulations applicable to those businesses.

(b) *Exception for restitution, remediation, and amounts paid to come into compliance with a law*—(1) *In general.* Paragraph (a) of this section does not apply to amounts paid or incurred for restitution (including remediation) or to come into compliance with a law, as defined in paragraphs (e)(4) of this section, provided that both the identification and the establishment requirements of paragraphs (b)(2) and (b)(3) of this section are met.

(2) *Identification requirement*—(i) *In general.* A court order (order) or an agreement, as defined in paragraph (e)(5) of this section, identifies a payment by stating the nature of, or purpose for, each payment each taxpayer is obligated to pay and the amount of each payment identified.

(ii) *Meeting the identification requirement.* The identification requirement is met if an order or agreement specifically states the amount of the payment described in paragraph (b)(2)(i) of this section and that the payment constitutes restitution, remediation, or an amount paid to come into compliance with a law. If the order or agreement uses a different form of the required words (such as ''remediate'' or ''comply with a law'') and describes the purpose for which restitution or remediation will be paid or the law with which the taxpayer must comply, the order or agreement will be treated as stating that the payment constitutes restitution, remediation, or an amount paid to come into compliance with a law. Similarly, if an order or agreement specifically describes the damage done, harm suffered, or manner of noncompliance with a law and describes the action required of the taxpayer to provide restitution, remediation, or to come into compliance with any law, as defined in paragraph (e)(4) of this section, the order or agreement will be treated as stating that the payment constitutes restitution, remediation, or an amount paid to come into compliance with any law. Meeting the establishment requirement of paragraph (b)(3) of this section alone is not sufficient to meet the identification requirement of paragraph (b)(2) of this section.

(iii) *Payment amount not identified.* (A) If the order or agreement identifies a payment as restitution, remediation, or to come into compliance with a law but does not identify some or all of the amount the taxpayer must pay or incur, the identification requirement may be met for any payment amount not identified if the order or agreement describes the damage done, harm suffered, or manner of noncompliance with a law, and describes the action required of the taxpayer, such as paying or incurring costs to provide services or to provide property.

(B) If the order or agreement identifies a lump-sum payment or multiple damages award as restitution, remediation, or to come into compliance with a law but does not allocate some or all of the amount the taxpayer must pay or incur among restitution, remediation, or to come into compliance with a law, or does not allocate the total payment amount among multiple taxpayers, the identification requirement may be met for any payment amount not specifically allocated if the order or agreement describes the damage done, harm suffered, or manner of noncompliance with a law, and describes the action required of the taxpayer, such as paying or incurring costs to provide services or to provide property.

(3) *Establishment requirement*—(i) *Meeting the establishment requirement.* The establishment requirement is met if the taxpayer, using documentary evidence, proves the taxpayer's legal obligation, pursuant to the order or agreement, to pay the amount identified as restitution, remediation, or to come into compliance with a law; the amount paid or incurred; the date the amount was paid or incurred; and that, based on the origin of the liability and the nature and purpose of the amount paid or incurred, the amount the taxpayer paid or incurred was for restitution or remediation, as defined in paragraph (e)(4)(i) of this section or to come into compliance with any law, as defined in paragraph (e)(4)(ii) of this section. If the amount is paid or incurred to a segregated fund or account, as described in paragraphs (e)(4)(i)(A)(*2*) and (*3*), (e)(4)(i)(B), or (e)(4)(i)(C) of this section, the taxpayer may meet the establishment requirement even if each ultimate recipient, or each ultimate use, of the payment is not designated or is unknown. A taxpayer will not meet the establishment requirement if the taxpayer fails to prove that the taxpayer paid or incurred the amount identified as restitution, remediation, or to come into compliance with a law; the amount paid; the date the amount was paid or incurred; or that the amount the taxpayer paid or incurred was for the nature and purpose identified in the order or agreement as required by paragraph (b)(2)(i) of this section, or was made for the damage done, harm suffered, noncompliance, or to provide property or services as described in (b)(2)(iii) of this section. Meeting the identification requirement of paragraph (b)(2) of this section is not sufficient to meet the establishment requirement of paragraph (b)(3) of this section.

(ii) *Substantiating the establishment requirement.* The documentary evidence described in paragraph (b)(3)(i) of this section includes, but is not limited to, receipts; the legal or regulatory provision related to the violation or potential violation of any law; documents issued by the government or governmental entity relating to the investigation or inquiry, including court pleadings filed by the government or governmental entity requesting restitution, remediation, or demanding that defendant take action to come into compliance with the law; judgment; decree; documents describing how the amount to be paid was determined; and correspondence exchanged between the taxpayer and the government or governmental entity before the order or agreement became binding under applicable law, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired.

(c) *Other exceptions*—(1) *Suits between private parties.* Paragraph (a) of this section does not apply to any amount paid or incurred by reason of any order or agreement in a suit in which no government or governmental entity is a party or any order or agreement in a suit pursuant to which a government or governmental entity enforces its rights as a private party.

(2) *Taxes and related interest.* Paragraph (a) of this section does not apply to amounts paid or incurred as otherwise deductible taxes or related interest. However, if penalties are imposed relating to such taxes, paragraph (a) of this section applies to disallow a deduction for such penalties and interest payments related to such penalties.

(3) *Failure to pay title 26 tax.* In the case of any amount paid or incurred as restitution for failure to pay tax imposed under title 26 of the United States Code, paragraph (a) of this section does not disallow a deduction for title 26 taxes, such as excise and employment taxes, which are equal to or less than the deduction otherwise allowed under chapter 1 of the Code if the tax had been timely paid.

(d) *Application of general principles of Federal income tax law*—(1) *Taxable year of deduction.* If, under paragraph (b) or (c) of this section, the taxpayer is allowed a deduction for the amount paid or incurred pursuant to an order or agreement, the deduction is taken into

account under the rules of section 461 and the related regulations, or under a provision specifically applicable to the allowed deduction, such as § 1.468B–3(c).

(2) *Tax benefit rule applies.* If the deduction allowed under paragraphs (b) or (c) of this section results in a tax benefit to the taxpayer, the taxpayer must include in income, under sections 61 and 111, the recovery of any amount deducted in a prior taxable year to the extent the prior year's deduction reduced the taxpayer's tax liability.

(i) A tax benefit to the taxpayer includes a reduction in the taxpayer's tax liability for a prior taxable year or the creation of a net operating loss carryback or carryover.

(ii) A taxpayer's recovery of any amount deducted in a prior taxable year includes, but is not limited to—

(A) Receiving a refund, recoupment, rebate, reimbursement, or otherwise recovering some or all of the amount the taxpayer paid or incurred, or

(B) Being relieved of some or all of the payment liability under the order or agreement.

(e) *Definitions.* For section 162(f) and § 1.162–21, the following definitions apply:

(1) *Government.* A *government* means—

(i) The government of the United States, a State, or the District of Columbia;

(ii) The government of a territory of the United States, including American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands;

(iii) The government of a foreign country;

(iv) An Indian tribal government, as defined in section 7701(a)(40), or a subdivision of an Indian tribal government, as determined in accordance with section 7871(d); or

(v) A political subdivision (such as a local government unit) of a government described in paragraph (e)(1)(i), (ii), or (iii) of this section.

(2) *Governmental entity.* A *governmental entity* means—

(i) A corporation or other entity serving as an agency or instrumentality of a government (as defined in paragraph (e)(1) of this section), or

(ii) A nongovernmental entity treated as a governmental entity as described in paragraph (e)(3) of this section.

(3) *Nongovernmental entity treated as a governmental entity.* A *nongovernmental entity treated as a governmental entity* is an entity that—

(i) Exercises self-regulatory powers (including imposing sanctions) in connection with a qualified board or exchange, as defined in section 1256(g)(7); or

(ii) Exercises self-regulatory powers, including adopting, administering, or enforcing rules and imposing sanctions, as part of performing an essential governmental function.

(4) *Restitution, remediation of property, and amounts paid to come into compliance with a law*—(i) *Amounts for restitution or remediation.* An amount is paid or incurred for restitution or remediation pursuant to paragraph (b)(1) of this section if it is paid or incurred to restore, in whole or in part, the person, as defined in section 7701(a)(1); government; governmental entity; property; environment; wildlife; or natural resources harmed, injured, or damaged by the violation or potential violation of any law described in paragraph (a)(3) of this section to the same or substantially similar position or condition as existed prior to such harm, injury or damage.

(A) *Environment, wildlife, or natural resources.* Restitution or remediation of the environment, wildlife, or natural resources includes amounts paid or incurred for the purpose of conserving soil, air, or water resources, protecting or restoring the environment or an ecosystem, improving forests, or providing a habitat for fish, wildlife, or plants. The amounts must be paid or incurred—

(*1*) To, or at the direction of, a government or governmental entity to be used exclusively for the restitution or remediation of a harm to the environment, wildlife, or natural resources;

(*2*) To a segregated fund or account established by a government or governmental entity and, pursuant to the order or agreement, the amounts are not disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes; or

(*3*) To a segregated fund or account established at the direction of a government or governmental entity.

(*4*) Paragraph (e)(4)(i)(A) of this section applies only if there is a strong nexus or connection between the purpose of the payment and the harm to the environment, natural resources, or wildlife that the taxpayer has caused or is alleged to have caused.

(B) *Disgorgement or forfeiture.* Provided the identification and establishment requirements of paragraphs (b)(2) and (b)(3) of this section are met, restitution may include amounts paid or incurred as disgorgement or forfeiture, if paid or incurred at the direction of a government or governmental entity directly to the person, as defined in section 7701(a)(1), harmed by the violation or potential violation of any law or to, or at the direction of, the government or governmental entity, to establish a segregated fund or account for the benefit of such harmed person. This paragraph (e)(4)(i)(B) does not apply if the order or agreement identifies the payment amount as in excess of the taxpayer's net profits or, pursuant to the order or agreement, the amounts are disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes.

(C) *Segregated funds or accounts.* Provided the identification and establishment requirements of paragraphs (b)(2) and (b)(3) of this section are met, restitution or remediation may include amounts paid or incurred, pursuant to an order or agreement, to a segregated fund or account to restore, in whole or in part, the person, as defined in section 7701(a)(1); government; governmental entity; property; environment; wildlife; or natural resources harmed, injured, or damaged by the violation or potential violation of any law described in paragraph (a)(3) of this section. This paragraph (e)(4)(i)(C) does not apply if, pursuant to the order or agreement, the amounts are disbursed to the general account of the government or governmental entity for general enforcement efforts or other discretionary purposes.

(ii) *Amounts to come into compliance with a law.* An amount is paid or incurred to come into compliance with a law that the taxpayer has violated, or is alleged to have violated, by performing services; taking action, such as modifying equipment; providing property; or doing any combination thereof to come into compliance with that law.

(iii) *Amounts not included.* Regardless of whether the order or agreement identifies them as such, restitution, remediation, and amounts paid to come into compliance with a law do not include any amount paid or incurred—

(A) As reimbursement to a government or governmental entity for investigation costs or litigation costs incurred in such government or governmental entity's investigation into, or litigation concerning, the violation or potential violation of any law; or

(B) At the taxpayer's election, in lieu of a fine or penalty.

(5) *Suit, agreement, or otherwise.* A suit, agreement, or otherwise includes,

but is not limited to, suits; settlement agreements; orders; non-prosecution agreements; deferred prosecution agreements; judicial proceedings; administrative adjudications; decisions issued by officials, committees, commissions, or boards of a government or governmental entity; and any legal actions or hearings which impose a liability on the taxpayer or pursuant to which the taxpayer assumes liability.

(f) *Examples.* The application of this section is illustrated by the following examples.

(1) *Example 1.* (i) *Facts.* Corp. A enters into an agreement with State Y's environmental enforcement agency (Agency) for violating state environmental laws. Pursuant to the agreement, Corp. A pays $40X to the Agency in civil penalties, $80X in restitution for the environmental harm that the taxpayer has caused, $50X for remediation of contaminated sites, and $60X to conduct comprehensive upgrades to Corp. A's operations to come into compliance with the state environmental laws.

(ii) *Analysis.* The identification requirement is satisfied for those amounts the agreement identifies as restitution, remediation, or to come into compliance with a law. If Corp. A meets the establishment requirement, as provided in paragraph (b)(3), paragraph (a) of this section will not disallow Corp. A's deduction for $80X in restitution and $50X for remediation. Under paragraph (a) of this section, Corp. A may not deduct the $40X in civil penalties. Paragraph (a) of this section will not disallow Corp. A's deduction for the $60X paid to come into compliance with the state environmental laws. See section 161, concerning items allowed as deductions, and section 261, concerning items for which no deduction is allowed, and the regulations related to sections 161 and 261.

(2) *Example 2.* (i) *Facts.* Corp. A enters into an agreement with State T's securities agency (Agency) for violating a securities law by inducing B to make a $100X investment in Corp. C stock, which B lost when the Corp. C stock became worthless. As part of the agreement, Corp. A agrees to pay $100X to B as restitution for B's investment loss, incurred as a result of Corp. A's actions. The agreement specifically states that the $100X payment by Corp. A to B is restitution. The agreement also requires Corp. A to pay a $40X penalty for violating Agency law. Corp. A pays the $140X.

(ii) *Analysis.* Corp. A's $100X payment to B is identified in the agreement as restitution. If Corp. A establishes, as provided in paragraph (b)(3) of this section, that the amount paid was for that purpose, paragraph (a) of this section will not disallow Corp. A's deduction for the $100X payment. Under paragraph (a) of this section, Corp. A may not deduct its $40X payment to the Agency because it was paid for Corp. A's violation of Agency law.

(3) *Example 3.* (i) *Facts.* Corp. B is under investigation by State X's environmental enforcement agency for a potential violation of State X's law governing emissions standards. Corp. B enters into an agreement with State X under which it agrees to upgrade the engines in a fleet of vehicles that Corp. B operates to come into compliance with State X's law. Although the agreement does not provide the specific amount Corp. B will incur to upgrade the engines to come into compliance with State X's law, it identifies that Corp. B must upgrade existing engines to lower certain emissions. Under the agreement, Corp. B also agrees to construct a nature center in a local park for the benefit of the community. Instead of paying $12X, to come into compliance with State X's law, Corp. B pays $15X to upgrade the engines to a standard higher than that which the law requires. Corp. B presents evidence to establish that it would cost $12X to upgrade the engines to come into compliance with State X's law.

(ii) *Analysis.* Because the agreement describes the specific action Corp. B must take to come into compliance with State X's law, and Corp. B provides evidence, as described in paragraph (b)(3)(ii) of this section, to establish that the agreement obligates it to incur costs to come into compliance with a law, paragraph (a) of this section will not disallow Corp. B's deduction for the $12X Corp. B incurs to come into compliance. Corp. B may also deduct the $3X if it is otherwise deductible under chapter 1 of the Code. However, Corp. B may not deduct the amounts paid to construct the nature center because no facts exist to establish that the amount was paid either to come into compliance with a law or as restitution or remediation.

(4) *Example 4.* (i) *Facts.* Corp. D enters into an agreement with governmental entity, Trade Agency, for engaging in unfair trade practices in violation of Trade Agency laws. The agreement requires Corp. D to pay $80X to a Trade Agency fund, through disgorgement of net profits, to be used exclusively to pay restitution to the consumers harmed by Corp. D's violation of Trade Agency law. Corp. D pays $80X to Trade Agency fund and Trade Agency disburses all amounts in the restitution fund to the harmed consumers.

(ii) *Analysis.* The agreement identifies the $80X payment to the fund as restitution. Trade Agency uses the funds exclusively to provide restitution to the harmed consumers and does not use it for discretionary or general enforcement purposes. If Corp. D establishes, as provided in paragraph (b)(3) of this section, that the $80X constitutes restitution under paragraph (e)(4)(i)(B) of this section, paragraph (a) of this section does not apply.

(5) *Example 5.* (i) *Facts.* B, a regulated banking institution, is subject to the supervision of, and annual examinations by governmental entity, R. In the ordinary course of its business, B is required to pay annual assessment fees to R, which fees are used to support R in supervising and examining banking institutions to ensure a safe and sound banking system. Following an annual examination conducted in the ordinary course of B's business, R issues a letter to B identifying concerns with B's internal compliance functions. B takes corrective action to address R's concerns by investing in its internal compliance functions. R does not conduct an investigation or inquiry into B's potential violation of any law.

(ii) *Analysis.* The payment of annual assessment fees by B to R in the ordinary course of business is not related to the violation of any law or the investigation or inquiry into the potential violation of any law. In addition, B's costs of taking the corrective action are not related to the violation of any law or the investigation or inquiry into the potential violation of any law as described in section 162(f)(1). Paragraph (a) of this section will not disallow the deduction of the annual assessment fees and the cost of the corrective actions.

(6) *Example 6.* (i) *Facts.* B, a regulated banking institution, is subject to the supervision of, and annual examinations by governmental entity, R. Following an annual examination conducted in the ordinary course of B's business, R pursues an enforcement action against B for violation of banking laws. B and R enter a settlement agreement, pursuant to which B agrees to undertake certain improvements to come into compliance with banking laws and to pay R $20X for violation of banking laws. B pays the $20X.

(ii) *Analysis.* If the agreement meets the identification requirement of paragraph (b)(2) of this section and B meets the establishment requirement of paragraph (b)(3) of this section, paragraph (a) of this section will not

disallow the deduction of the costs of the corrective actions to come into compliance with banking laws. However, B may not deduct the $20X paid to R because the amount was not paid to come into compliance with a law or as restitution or remediation.

(7) *Example 7.* (i) *Facts.* Corp. C contracts with governmental entity, Q, to design and build a rail project within five years. Corp. C does not complete the project. Q sues Corp. C for breach of contract and damages of $10X. A jury finds Corp. C breached the contract and Corp. C pays $10X to Q.

(ii) *Analysis.* The suit arose out of a proprietary contract, wherein Q enforced its rights as a private party. Paragraph (a) of this section will not disallow Corp. C's deduction of the payment of $10X pursuant to this suit.

(8) *Example 8.* (i) *Facts.* Corp. C contracts with governmental entity, Q, to design and build a rail project within five years. Site conditions cause construction delays and Corp. C asks Q to pay $50X in excess of the contracted amount to complete the project. After Q pays for the work, it learns that, at the time it entered the contract with Corp. C, Corp. C knew that certain conditions at the project site would make it challenging to complete the project within five years. Q sues Corp. C for withholding critical information during contract negotiations in violation of the False Claims Act (FCA). The court enters a judgment in favor of Q pursuant to which Corp. C will pay Q $50X in restitution and $150X in treble damages. Corp. C pays the $200X.

(ii) *Analysis.* The suit pertains to Corp. C's violation of the FCA. The order identifies the $50X Corp. C is required to pay as restitution, as described in paragraph (b)(2) of this section. If Corp. C establishes, as provided in paragraph (b)(3) of this section, that the amount paid was for restitution, paragraph (a) of this section will not disallow Corp. C's deduction for the $50X payment. Under paragraph (a) of this section, Corp. C may not deduct the $150X paid for the treble damages imposed for violation of the FCA because the order did not identify all or part of the payment as restitution.

(9) *Example 9.* (i) *Facts.* Corp. T operates a truck fleet company incorporated in State A. State A requires that all vehicles registered in State A have a vehicle emissions test every two years. Corp. T's 40 trucks take the emissions test on March 1 for which it pays the $15 per vehicle. Under State A law, if a vehicle fails the emissions test, the vehicle owner has 30 days to certify to State A that the vehicle has been repaired and has passed the emissions test. State A imposes a $1X penalty per vehicle for failure to comply with this 30-day rule. Twenty trucks pass; twenty trucks fail. Corp. T does not submit the required certification to State A for the twenty trucks that failed the emissions test. State A imposes a $40X penalty against Corp. T. Corp. T pays the $40X.

(ii) *Analysis.* Emissions tests are conducted in the ordinary course of operating a truck fleet company and, therefore, paragraph (a) of this section does not apply to the $600 Corp. T pays for the emissions tests. However, Corp. T may not deduct the $40X penalty for failure to comply with State A requirements because the amount is required to be paid to a government in relation to the violation of a law.

(10) *Example 10.* (i) *Facts.* Corp. G operates a chain of 20 grocery stores in County X. Under County X health and food safety code and regulations, Corp. G is subject to annual inspections for which Corp. G is required to pay an inspection fee of $40 per store. Pursuant to the annual inspection, the County X health inspector finds violations of County X's health and food safety code and regulations in three of Corp. G's 20 stores. County X bills Corp. G $800 for the annual inspection fees for the 20 stores and a $1,000 fine for each of the three stores, for a total fine of $3,000, for violations of the health and food safety code. Corp. G pays the fees and fines.

(ii) *Analysis.* Paragraph (a) of this section will not disallow Corp. G's deduction for the $800 inspection fees paid in the ordinary course of a regulated business. Under paragraph (a) of this section, Corp. G may not deduct the $3,000 fine for violation of the County X health code and food safety ordinances because it was paid to a government in relation to the violation of a law.

(11) *Example 11.* (i) *Facts.* Corp. G operates a chain of grocery stores in County X. Under County X health and food safety code and regulations, Corp. G is subject to annual inspections. Pursuant to an annual inspection, the County X health inspector finds that the refrigeration system in one of Corp. G's stores does not keep food at the temperature required by the health and food safety code and regulations. The County X health inspector issues a warning letter instructing Corp. G to correct the violation and bring the refrigeration system into compliance with the law before a reinspection in 60 days or face the imposition of fines if it fails to comply. Corp. G pays $10,000 to bring its refrigeration system into compliance with the law.

(ii) *Analysis.* Provided the identification and establishment requirements of paragraphs (b)(2) and (b)(3), respectively, of this section are met, paragraph (a) of this section will not disallow Corp. G's deduction for the $10,000 it pays to bring its refrigeration system into compliance with the law.

(12) *Example 12.* (i) *Facts.* Corp. G operates a chain of grocery stores in County X. Under County X health and food safety code and regulations, Corp. G is subject to annual inspections. Pursuant to an annual inspection, the County X health inspector finds that the refrigeration system in one of Corp. G's stores does not keep food at the temperature required by the health and food safety code and regulations. The County X health inspector issues a warning letter instructing Corp. G to correct the violation and bring the refrigeration system into compliance with the law before a reinspection in 60 days or face the imposition of fines if it fails to comply. The County X health inspector later reinspects the refrigeration system. Corp. G pays a reinspection fee of $80. During the reinspection, the health inspector finds that Corp. G did not bring its refrigeration system into compliance with the law. The health inspector issues a citation imposing a $250 fine on Corp. G. Corp. G pays the $250 fine.

(ii) *Analysis.* Paragraph (a) of this section will disallow Corp. G's deduction for the $80 inspection fee because it is paid in relation to the investigation or inquiry by County X into the potential violation of a law. Paragraph (a) of this section will also disallow Corp. G's deduction for the $250 fine paid for violation of the law.

(13) *Example 13.* (i) *Facts.* Accounting Firm was convicted of embezzling $500X from Bank in violation of State X law. The court issued an order requiring Accounting Firm to pay $100X in restitution to Bank. The court also issued an order of forfeiture and restitution for $400X, which was seized by the State X officials. Accounting Firm paid $100X to Bank. The $400X seized was deposited with Fund within the State X treasury and, at the discretion of the State X Attorney General, was used to support law enforcement programs.

(ii) *Analysis.* Although the order identified the amount forfeited as restitution, paragraph (a) of this section will disallow Accounting Firm's deduction for the $400X forfeited because, under paragraph (e)(4)(i)(B)(I) of this section, it does not constitute restitution. If Accounting Firm establishes, as provided in paragraph (b)(3) of this section, that the $100X constitutes restitution under paragraph (e)(4)(i), paragraph (a) of this section

will not disallow Accounting Firm's deduction for the $100X paid, provided the $100X is otherwise deductible under chapter 1.

(g) *Applicability date.* The rules of this section apply to taxable years beginning on or after January 19, 2021, except that such rules do not apply to amounts paid or incurred under any order or agreement pursuant to a suit, agreement, or otherwise, which became binding under applicable law before such date, determined without regard to whether all appeals have been exhausted or the time for filing appeals has expired.

■ **Par. 3.** Add § 1.6050X–1 to read as follows:

§ 1.6050X–1 Information reporting for fines, penalties, and other amounts by governments, governmental entities, and nongovernmental entities treated as governmental entities.

(a) *Information reporting requirement.* The appropriate official, as defined in paragraph (f)(1) of this section, of a government, as defined in paragraph (f)(2) of this section, a governmental entity, as defined in paragraph (f)(3) of this section, or nongovernmental entity treated as a governmental entity, as defined in paragraph (f)(4) of this section, that is a party to a suit or agreement to which section 6050X(a)(1) and (a)(2) applies, must—

(1) File an information return, as described in paragraph (b) of this section, if the aggregate amount the payor, as defined in paragraph (f)(5) of this section, is required to pay pursuant to all court orders (orders) and settlement agreements (agreements), relating to the violation of any law, or the investigation or inquiry into the potential violation of any law, equals or exceeds the threshold amount provided in paragraph (f)(6) of this section;

(2) Furnish a written statement as described in paragraph (c) of this section to each payor; and

(3) Request the payor's taxpayer identification number (TIN) if it is not already known, and notify the payor that the law requires the payor to furnish a TIN for inclusion on the information return and that the payor may be subject to a penalty for failure to furnish the TIN. See sections 6723, 6724(d)(3), and § 301.6723–1 of this chapter. The TIN may be requested in any manner, and the payor may provide the TIN in any manner, including orally, in writing, or electronically. If the TIN is furnished in writing, no particular form is required. Form W–9, Request for Taxpayer Identification Number and Certification, may be used, or the request may be incorporated into documents related to the order or agreement.

(b) *Requirement to file return*—(1) *Content of information return.* The information return must provide the following:

(i) The amount required to be paid to, or at the direction of, a government or governmental entity, pursuant to section 6050X(a)(1)(A), as a result of the orders and/or agreements;

(ii) The separate amounts required to be paid as restitution, remediation, or to come into compliance with a law, as described in section 6050X(a)(1)(B) and (C), as a result of the orders and/or agreements;

(iii) The payor's TIN; and

(iv) Any additional information required by the information return and the related instructions.

(2) *Form and manner of reporting.* The appropriate official required to file an information return, under paragraph (a)(1) of this section, must file Form 1098–F, Fines, Penalties, and Other Amounts, or any successor form, as provided by the instructions, with Form 1096, Annual Summary and Transmittal of U.S. Information Returns.

(3) *Multiple orders and/or agreements.* The appropriate official must file only one Form 1098–F for amounts required to be paid as a result of multiple orders and/or agreements with respect to the violation, investigation, or inquiry.

(4) *Time of reporting.* Returns required to be made under paragraph (a) of this section must be filed with the Internal Revenue Service (IRS) on or before February 28 (March 31 if filed electronically) of the year following the calendar year in which the orders and/or agreements become binding under applicable law, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired.

(c) *Requirement to furnish written statement*—(1) *In general.* The appropriate official must furnish a written statement to each payor for which it is required to file an information return under paragraphs (a)(1) and (b) of this section. The written statement must include:

(i) The information that was reported to the IRS relating to such payor; and

(ii) A legend that identifies the statement as important tax information that is being furnished to the IRS.

(2) *Copy of the Form 1098–F.* The appropriate official may satisfy the requirement of this paragraph (c) by furnishing a copy of the Form 1098–F, or any successor form, filed regarding the payor, or another document that contains the information required by paragraph (c)(1) of this section if the document conforms to applicable revenue procedures or other guidance relating to substitute statements. See § 601.601 of this chapter.

(3) *Time for furnishing written statement.* The appropriate official must furnish the written statement to the payor on or before January 31 of the year following the calendar year in which the order or agreement becomes binding under applicable law, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired.

(d) *Rules for multiple payors*—(1) *Multiple payors—individual liability.* If, pursuant to an order or agreement, multiple individually liable payors are liable to pay, for the violation of any law, or the investigation or inquiry into the potential violation of any law, an amount that, in the aggregate, equals, or exceeds, the threshold amount under paragraph (f)(6) of this section, the appropriate official must file an information return under paragraphs (a)(1) and (b) of this section to report the amount required to be paid by each payor, even if a payor's payment liability is less than the threshold amount. The appropriate official must furnish a written statement, under paragraph (c) of this section, to each payor. If more than one person, as defined in section 7701(a)(1), is a party to an order or agreement, there is no information reporting requirement, or requirement to furnish a written statement, with respect to any person who does not have a payment obligation or obligation for costs to provide services or to provide property.

(2) *Multiple payors—joint and several liability.* If, pursuant to an order or agreement, multiple payors are jointly and severally liable to pay, for the violation of any law, or the investigation or inquiry into the potential violation of any law, an amount that, in the aggregate, equals or exceeds the threshold amount under paragraph (f)(6) of this section, the appropriate official must file an information return, under paragraphs (a)(1) and (b) of this section for each of the jointly and severally liable payors. Each information return must report all amounts required to be paid by all of the payors pursuant to the order or agreement. The appropriate official must furnish a written statement, under paragraph (c) of this section, to each of the jointly and severally liable payors.

(e) *Payment amount not identified.* If some or all of the payment amount is not identified, as described in § 1.162–21(b)(2)(iii), for paragraphs (a), (b), and (c) of this section, the appropriate

official must file an information return, and furnish the written statement to the payor, as provided by the instructions to Form 1098–F, or any successor form, including instructions as to the amounts (if any) to include on Form 1098–F, only if the government or governmental entity reasonably expects that the aggregate amount required to be paid or incurred pursuant to the order or agreement, relating to the violation of any law, or the investigation or inquiry into the potential violation of any law, will equal or exceed the threshold amount under paragraph (f)(6) of this section.

(f) *Definitions.* The following definitions apply under this section:

(1) *Appropriate official*—(i) *One government or governmental entity.* If the government or governmental entity has not assigned one of its officers or employees to comply with the reporting requirements of paragraph (a), (b), and (c) of this section, the term *appropriate official* means the officer or employee of a government or governmental entity having control of the suit, investigation, or inquiry. If the government or governmental entity has assigned one of its officers or employees to comply with the reporting requirements of paragraph (a), (b), and (c) of this section, such officer or employee is the appropriate official.

(ii) *More than one government or governmental entity*—(A) *In general.* If more than one government or governmental entity is a party to an order or agreement, only the appropriate official of the government or governmental entity listed first on the most recently executed order or agreement is responsible for complying with all reporting requirements under paragraphs (a), (b), and (c) of this section, unless another appropriate official is appointed by agreement under paragraph (f)(1)(ii)(B) of this section.

(B) *By agreement.* The governments or governmental entities that are parties to an order or agreement may agree to appoint one or more other appropriate officials to be responsible for complying with the information reporting requirements of paragraphs (a), (b), and (c) of this section.

(2) *Government.* For purposes of this section, *government* means the government of the United States, a State, the District of Columbia, or a political subdivision (such as a local government unit) of any of the foregoing.

(3) *Governmental entity.* For purposes of this section, *governmental entity* means—

(i) A corporation or other entity serving as an agency or instrumentality of a government (as defined in paragraph (f)(2) of this section), or

(ii) A nongovernmental entity treated as a governmental entity as described in paragraph (f)(4) of this section.

(4) *Nongovernmental entity treated as governmental entity.* For purposes of this section, the definition of nongovernmental entity treated as a governmental entity as set forth in § 1.162–21(e)(3) applies but does not include a nongovernmental entity of a territory of the United States, including American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands, a foreign country, or an Indian tribe.

(5) *Payor.* The payor is the person, as defined in section 7701(a)(1), which, pursuant to an order or agreement, has paid or incurred, or is liable to pay or incur, an amount to, or at the direction of, a government or governmental entity in relation to the violation or potential violation of any law. In general, the payor will be the person to which section 162(f) and § 1.162–21 of the regulations apply.

(6) *Threshold amount.* The *threshold amount* is $50,000.

(g) *Applicability date.* The rules of this section apply only to orders and agreements, pursuant to suits and agreements, which become binding under applicable law on or after January 1, 2022, determined without regard to whether all appeals have been exhausted or the time for filing an appeal has expired.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: January 7, 2021.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40 and 49

[TD 9948]

RIN 1545–BP37

Excise Taxes; Transportation of Persons by Air; Transportation of Property by Air; Aircraft Management Services

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the excise taxes imposed on certain amounts paid for transportation of persons and property by air. Specifically, the final regulations relate to the exemption for amounts paid for certain aircraft management services. The final regulations also amend, revise, redesignate, and remove provisions of existing regulations that are out-of-date or obsolete and generally update the existing regulations to incorporate statutory changes, case law, and other published guidance. The final regulations affect persons that provide air transportation of persons and property, and persons that pay for those services.

DATES:

Effective Date: These regulations are effective January 14, 2021.

Applicability Dates: For dates of applicability, see §§ 40.0–1(e), 49.4261–1(g), 49.4261–2(d), 49.4261–3(e), 49.4261–7(k), 49.4261–9(c), 49.4261–10(i), 49.4262–1(f), 49.4262–2(e), 49.4262–3(e), 49.4281–1(e), 49.4263–1(b), 49.4263–3(b), 49.4271–1(g), and 49.4721–2.

FOR FURTHER INFORMATION CONTACT: Michael H. Beker at (202) 317–6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Facilities and Services Excise Tax Regulations (26 CFR part 49) under sections 4261, 4262, 4263, 4264, 4271, 4281, and 4282 of the Internal Revenue Code (Code). This document also amends the Excise Tax Procedural Regulations (26 CFR part 40).

Sections 4261 and 4271 impose excise taxes on certain amounts paid for transportation of persons or property, respectively, by air, collectively referred to herein as ''air transportation excise tax.'' Section 13822 of Public Law 115–97, 131 Stat. 2054, 2182 (2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA), added an exception to the air transportation excise tax in new section 4261(e)(5). Specifically, section 4261(e)(5)(A) provides that ''[n]o tax shall be imposed by [section 4261] or section 4271 on any amounts paid by an aircraft owner for aircraft management services related to—(i) maintenance and support of the aircraft owner's aircraft, or (ii) flights on the aircraft owner's aircraft.''

Section 4261(e)(5)(B) defines the term ''aircraft management services'' to include: (a) Assisting an aircraft owner with administrative and support services, such as scheduling, flight planning, and weather forecasting; (b)

obtaining insurance; (c) maintenance, storage, and fueling of aircraft; (d) hiring, training, and provision of pilots and crew; (e) establishing and complying with safety standards; and (f) such other services as are necessary to support flights operated by an aircraft owner.

Section 4261(e)(5)(C)(i) provides that the term ''aircraft owner'' includes a person who leases an aircraft other than under a ''disqualified lease.'' Section 4261(e)(5)(C)(ii) defines the term ''disqualified lease'' for purposes of section 4261(e)(5)(C)(i) as ''a lease from a person providing aircraft management services with respect to the aircraft (or a related person (within the meaning of section 465(b)(3)(C)) to the person providing such services), if the lease is for a term of 31 days or less.''

Finally, section 4261(e)(5)(D) provides that in the case of amounts paid to any person which (but for section 4261(e)(5)) are subject to air transportation excise tax, a portion of which consists of amounts described in section 4261(e)(5)(A), section 4261(e)(5) ''shall apply on a pro rata basis only to the portion which consists of amounts described in'' section 4261(e)(5)(A). The Conference Report accompanying the TCJA, H.R. Rep. No. 115–466, at 536 (2017) (Conference Report), provides that in the event that a monthly payment made to an aircraft management company is allocated in part to exempt services and flights on the aircraft owner's aircraft, and in part to flights on aircraft other than that of the aircraft owner, air transportation excise tax must be collected on that portion of the payment attributable to flights on aircraft not owned by the aircraft owner.

On July 31, 2020, a notice of proposed rulemaking (REG–112042–19) was published in the **Federal Register** (85 FR 46032) under sections 4261, 4262, 4263, 4264, 4271, 4281, and 4282 of the Code, and part 40 of the Excise Tax Procedural Regulations (proposed regulations). No public hearing was requested or held. The Department of the Treasury (Treasury Department) and the IRS received three comments in response to the proposed regulations. The comments addressing the proposed regulations are summarized in the Summary of Comments and Explanation of Revisions section of this preamble. All comments were considered and are available at *www.regulations.gov* or upon request. After full consideration of the comments received, this Treasury decision adopts as final regulations the proposed regulations with the modifications described in the Summary of Comments and Explanation of Revisions section of this preamble.

Summary of Comments and Explanation of Revisions

I. Overview

The final regulations retain the basic approach and structure of the proposed regulations, with certain revisions and modifications. This Summary of Comments and Explanation of Revisions discusses these revisions and modifications as well as the comments received in response to the proposed regulations. The final regulations provide guidance under sections 4261, 4262, 4263, 4264, 4271, 4281, and 4282 of the Code related to air transportation excise tax. The final regulations also provide guidance under part 40 of the Excise Tax Procedural Regulations.

Part II of this Summary of Comments and Explanation of Revisions discusses rules related to the exemption from air transportation excise tax for amounts paid for certain aircraft management services provided in section 4261(e)(5) of the Code (aircraft management services exemption). Part III of this Summary of Comments and Explanation of Revisions discusses § 49.4261–1 and other rules of general applicability related to the excise tax on amounts paid for the transportation of persons by air imposed by section 4261, as well as rules in § 49.4261–7(h)(2) related to aircraft charters. See the Explanation of Provisions section of the proposed regulations for a discussion of the rules under 26 CFR part 40 and 26 CFR part 49 that were included in the proposed regulations, for which no comments were received. Those proposed rules are adopted by this Treasury decision—except as discussed in parts II and III of this Summary of Comments and Explanation of Revisions—without change.

II. Aircraft Management Services Exemption Rules

a. Definition of Aircraft Management Services

Proposed § 49.4261–10(b)(1) defined the term ''aircraft management services'' to mean the services listed in section 4261(e)(5)(B), as well as ''other services.'' Proposed § 49.4261–10(b)(1)(ii) defined ''other services'' as any service (including, but not limited to, purchasing fuel, purchasing aircraft parts, and arranging for the fueling of an aircraft owner's aircraft) provided directly or indirectly by an aircraft management services provider to an aircraft owner, that is necessary to keep the aircraft owner's aircraft in an airworthy state or to provide air transportation to the aircraft owner on the aircraft owner's aircraft at a level and quality of service required under the agreement between the aircraft owner and the aircraft management services provider.

A commenter stated that the term ''airworthy'' generally indicates that an aircraft—or one or more of its component parts—meets its type design and is in a condition of safe operations. The commenter noted that some services provided by an aircraft management services provider in maintaining an aircraft do not directly pertain to the airworthiness of an aircraft. These services include, but are not limited to, upgrades in equipment, installation of optional equipment, optional modifications, refurbishment of an aircraft interior, and painting of an aircraft's exterior. The commenter suggested that the final regulations remove the phrase ''that is necessary to keep the aircraft owner's aircraft in an airworthy state'' from the definition of ''other services.''

The Treasury Department and the IRS agree with the commenter that the final regulations should clarify that the definition of aircraft management services is not limited to those services necessary to keep an owner's aircraft in an airworthy state. As a result, the final regulations adopt the change suggested by the commenter and remove the phrase ''that is necessary to keep the aircraft owner's aircraft in an airworthy state'' from final § 49.4261–10(b)(1)(ii).

b. Definition of Aircraft Owner

i. Leases

Proposed § 49.4261–10(b)(3)(i) provided that the term ''aircraft owner'' means an individual or entity that leases or owns (that is, holds title to or substantial incidents of ownership in) an aircraft managed by an aircraft management services provider, commonly referred to as a ''managed aircraft.'' Proposed § 49.4261–10(b)(3)(i) further provided that the term ''aircraft owner'' does not include a lessee of an aircraft under a disqualified lease, as defined in proposed § 49.4261–10(b)(4).

Regarding leases that qualify a person as an aircraft owner under proposed § 49.4261–10(b)(3)(i), a commenter noted that while many aircraft leases are in writing and contain provisions that make it clear that the arrangement constitutes a lease, that is not the case for all aircraft leasing arrangements. The commenter further noted that courts have found that the basic attributes of a lease are ''the right to possess, use, and control the aircraft'' (citing *Petit Jean Air Service, Inc* v. *U.S.,* 74–1 U.S.T.C.

16, 135 (E.D. Ark. 1974)). To this end, the commenter suggested that the final regulations add to the end of § 49.4261–10(b)(3)(i) the sentence ''An arrangement (whether written, oral, or implied) that transfers the right to possess, use, and control an aircraft to an individual or entity qualifies as a lease for the purposes of determining whether that individual or entity meets the definition of aircraft owner.''

The Treasury Department and the IRS note that the suggested ''right to possess, use, and control an aircraft'' language from the commenter is nearly identical to the possession, command, and control test created through existing published guidance. As described in the preamble to the proposed regulations, possession, command, and control is a facts-and-circumstances analytical framework that is used to determine whether a person is providing taxable transportation to another person in cases where each of the parties contribute some, but not all, of the elements necessary for complete air transportation services. The possession, command, and control test has caused confusion and uncertainty in the air transportation excise tax area for decades; in fact, it is partly for that reason—and disagreements between the IRS and taxpayers over the application of the possession, command, and control test to aircraft management services arrangements—that section 4261(e)(5) was added to the Code. *See, e.g.,* Conference Report at 535. As explained in the preamble to the proposed regulations, section 4261(e)(5) directly addresses a situation that, but for section 4261(e)(5), would be analyzed using the possession, command, and control test. The preamble to the proposed regulations further explained that in situations to which the aircraft management services exemption applies, the possession, command, and control test is not relevant.

As a result, the Treasury Department and the IRS decline to introduce into the final regulations a test that is similar to a test that has been the source of confusion, uncertainty, disagreement, and difficulties in administration. Therefore, the final regulations do not adopt the language the commenter proposed to be added to the end of § 49.4261–10(b)(3)(i) and do not provide a special definition of the term ''lease'' solely for purposes of the aircraft management services exemption.

ii. Owner Trusts

A commenter requested clarification regarding whether trustees and beneficiaries of ''owner trusts'' qualify as aircraft owners for purposes of the aircraft management services exemption. The commenter described an owner trust as an ownership structure used for the limited purpose of registering an aircraft in the U.S. with the Federal Aviation Administration (FAA). The structure, which is sanctioned by the FAA, is commonly used by non-U.S. persons to satisfy the U.S. citizenship requirements applicable to registering an aircraft with the FAA. Most owner trusts are established using one of a small number of U.S.-based aviation trust companies—which are not related to the trust beneficiary—as trustee. The trustee holds legal title to the aircraft and satisfies the U.S. citizenship requirement for purposes of registering the aircraft with the FAA, thereby permitting registration in the U.S. of an aircraft that would otherwise be ineligible for such registration.

The commenter stated that an owner trust agreement works in conjunction with an operating agreement that, generally, is separate from, but closely related to, the trust agreement. The operating agreement may contain explicit lease language or may instead use the term ''license to use'' and provides that the beneficiary holds the exclusive right to lease or license and to possess, use, and operate the aircraft (typically requiring a nominal rent or license payment to the trustee, or in some cases, no payment at all). Regardless of how the transfer of control is described in the operating agreement, the result is that the beneficiary holds the exclusive right to lease or license the aircraft, and to possess, use, and operate the aircraft. An operating agreement will usually require that the beneficiary retain the crew and maintain the aircraft per FAA guidance and manufacturer's recommendations. The commenter stated that the relationship created through the operating agreement is consistent with the trustee's status as a holder of only bare legal title, sometimes referred to as ''nominal title,'' to the aircraft.

In addition, the commenter explained that the beneficiary of an owner trust holds many of the attributes of aircraft ownership, other than legal title. The attributes of aircraft ownership that the beneficiary possesses include: The right to any income generated by—and obligation to pay all expenses associated with—the aircraft; the upside benefit or downside risk as to the aircraft's value; bearing the risk of loss; being considered the owner of the aircraft for Federal income tax purposes; and discretion as to when to sell the aircraft. The commenter noted that since both the trustee and the beneficiary of an owner trust are owners of interests in the aircraft, payments for aircraft management services from either party should be eligible for the aircraft management services exemption. The commenter further noted that regardless of whether the operating agreement is written in terms of a lease or a license, the arrangement is not a disqualified lease (as that term was defined in proposed § 49.4261–10(b)(4)).

For purposes of section 4261(e)(5), such an operating agreement between the trustee and the beneficiary of an owner trust is treated as a lease, regardless of whether the document expressly refers to the arrangement as a lease. Therefore, under the terms of the operating agreement, the beneficiary of an owner trust is the lessee of the aircraft held in trust. Both section 4261(e)(5)(C) and proposed § 49.4261–10(b)(3) recognize lessees, other than lessees under a disqualified lease, as an aircraft owner.

Based on the foregoing, the final regulations include a definition of ''owner trust.'' The final regulations also clarify that the beneficiary of an owner trust is an ''aircraft owner'' so long as the lease is not a disqualified lease.

iii. Affiliated Groups, Disregarded Entities, and Other Close Relationships

As discussed in the preamble to the proposed regulations, the proposed regulations applied the principle of statutory interpretation that, as matters of legislative grace, exemptions to tax should be narrowly construed. Therefore, the proposed regulations defined ''aircraft owner'' as an individual or entity that leases (other than under a disqualified lease) or owns (that is, holds title to or substantial incidents of ownership in) an aircraft managed by an aircraft management services provider. The proposed regulations did not include in the definition of ''aircraft owner'' persons that are related to the aircraft owner (for example, another member of the same affiliated group (as defined in section 4282 of the Code)), but are not the aircraft owner itself. As a result, under the proposed regulations, the aircraft management services exemption applied only to payments for aircraft management services that are made by the actual aircraft owner or lessee.

A commenter disagreed with the assertion in the preamble to the proposed regulations that treating payments from parties who are directly related to an aircraft owner as though they were from the aircraft owner, and thus exempt from air transportation excise tax, ''would effectively expand

the exemption [provided in section 4261(e)(5)] in a manner not authorized by Congress.'' The commenter claimed that this assertion is at odds with other Code provisions and implies an unduly narrow and formalistic interpretation of the statute that is inconsistent with the flexible approach otherwise evinced in the proposed regulations. The commenter further claimed that the assertion has no basis in the legislative history, but rather the legislative history implies that at least some related-party payments of aircraft management fees should be excluded from air transportation excise tax under section 4261(e)(5).

The commenter noted that while the statute and legislative history are relatively silent about who or what the term ''aircraft owner'' includes, the legislative history enumerates several examples of what the term *does not* include. Specifically, the legislative history states that the term ''aircraft owner'' does not include ownership of stock in a commercial airline or participation in a fractional aircraft ownership program. The commenter stated that the legislative history expresses Congress's concern about the use of the aircraft management services exemption to circumvent the ordinary application of air transportation excise tax as contemplated in other Code provisions. By negative inference, the commenter reasoned, Congress did not express any similar concerns if the aircraft management services exemption applied to payments made by a party related to the aircraft owner. The commenter asserted that the narrow interpretation of ''aircraft owner'' in the proposed regulations does nothing to further Congress's goal of preventing arrangements designed to circumvent the ordinary application of air transportation excise tax.

The commenter asserted that when an affiliated corporation in a corporate group pays for aircraft management services on behalf of an aircraft owning corporate entity within the group, there is no avoidance of air transportation excise tax. Further, the commenter asserted that there is statutory precedent for ignoring the distinction among corporate entities in the air transportation excise tax area; specifically, the commenter pointed to the affiliated group exemption provided in section 4282 of the Code. Under section 4282(a), if one member of an affiliated group is the owner or lessee of an aircraft, and such aircraft is not available for hire by persons who are not members of such group, air transportation excise tax does not apply to any payment received by one member of the affiliated group from another member of such group for services furnished to such other member in connection with the use of such aircraft. Citing the legislative history to section 4282 (*see* S. Rep. No. 91–706 at 17–18, 1970–1 C.B. 386), the commenter asserted that section 4282 captures Congress's general approach to related-party payments in the area of air transportation excise tax; that is, Congress decided to ignore nominal ownership of an aircraft by one member of an affiliated group and instead looked to the true economic ownership of the aircraft by the group. The commenter asserted that the final regulations should do the same and ignore the formalities of nominal ownership of an aircraft and apply the aircraft management services exemption to payments by any party that is the true economic owner of the aircraft.

The commenter requested that the Treasury Department and the IRS consider expanding the definition of ''aircraft owner'' to include disregarded entities, members of an affiliated group, and family members. The commenter also noted that it is not uncommon for an individual to operate an aircraft but place title to the aircraft in a single member limited liability company (SMLLC) and that such arrangement is, in effect, a constructive lease, but that state law concepts of constructive leases will result in needless and complex controversy.

Another commenter similarly requested that the Treasury Department and the IRS consider expanding the definition of ''aircraft owner'' to include the single member of a SMLLC that holds title to an aircraft. The commenter reasoned that if the member pays an aircraft management services provider for aircraft management services on behalf of the SMLLC, it is economically indistinguishable from a case in which the individual first transfers funds into the SMLLC and then the SMLLC pays the aircraft management services provider. In either situation, the commenter asserted, there is no circumvention of air transportation excise tax; the only difference is who writes the check paying the aircraft management services provider.

The Treasury Department and the IRS continue to have the concerns described in the preamble to the proposed regulations. Specifically, the Treasury Department and the IRS are concerned that extending the aircraft management services exemption to payments made by certain related parties—as suggested by the commenters—would effectively ignore the requirement that payments be made by the ''aircraft owner.'' Such an interpretation would be inconsistent with a plain reading of the statute and would violate a fundamental principle of statutory construction—that effect must be given, if possible, to every word Congress uses in the statute. *See U.S.* v. *Menasche,* 348 U.S. 528, 538–539 (1955).

Further, as described in the preamble to the proposed regulations, a fundamental aspect of administering the Federal excise tax laws is respecting each entity as an entity separate from its owner. *See* § 1.1361–4(a)(8) of the Income Tax Regulations and § 301.7701–2(c)(2)(v) of the Procedure and Administration Regulations. This longstanding treatment of a wholly-owned entity as an entity separate from its owner for Federal excise tax purposes applies even though the entity may not be viewed as separate from its owner for Federal income tax purposes. Consistent with this longstanding treatment, final § 40.0–1(d) of the Excise Tax Procedural Regulations makes it clear that each business unit that is required to have a separate Employer Identification Number is treated as a separate person. The Treasury Department and the IRS decline to create what would effectively be an exception to the way certain entities are treated for Federal excise tax purposes because this would create unnecessary confusion among taxpayers and IRS examiners. For example, it would not be appropriate to respect an entity for fuel excise tax liability and reporting purposes but then disregard the same entity for purposes of the aircraft management services exemption even though a transaction may involve the same aircraft.

Based on the foregoing, the final regulations do not generally incorporate the commenters' request to expand the definition of ''aircraft owner'' to include disregarded entities, members of an affiliated group, or family members of the owner. Instead, the final regulations clarify that amounts paid for aircraft management services by a party related to the aircraft owner (including members of an affiliated group, members of a limited liability company, disregarded entities, and family members) are not amounts paid by the aircraft owner solely by virtue of the relationship between the aircraft owner and the related party. The final regulations further clarify that if one related party leases an aircraft to another related party, amounts paid by the lessee to an aircraft management services provider for aircraft management services related to the leased aircraft qualify for the aircraft management services exemption,

provided the lease is not a disqualified lease and all other requirements of section 4261(e)(5) are satisfied.

v. Principal-Agent

Proposed § 49.4261–10(a)(1) provided, in relevant part, that the aircraft management services exemption does not apply to amounts paid to an aircraft management services provider on behalf of an aircraft owner (other than in a principal-agent scenario in which the aircraft owner is the principal).

A commenter requested that the final regulations clarify what relationships qualify as a ''principal-agent scenario'' for purposes of qualifying payments for the aircraft management services exemption. The commenter noted that all entities, depending on the type of entity formation, have one or more officers, directors, managers, members or partners that may be in a principal-agent relationship with an aircraft owner. Therefore, the commenter suggested that the final regulations clarify that for purposes of § 49.4261–10(a)(1), officers and directors of corporations, managers and members of limited liability companies (LLCs), and partners of a partnership are deemed agents when such corporations, LLCs, or partnerships are the aircraft owner. Alternatively, the commenter suggested that the final regulations clarify that the agency laws of the individual fifty states should be recognized for purposes of determining whether a principal-agent relationship exists between an aircraft owner and another person.

As a general matter, for Federal tax purposes, state agency law applies in determining whether a principal-agent relationship exists. Likewise, in the context of the aircraft management services exemption, state law applies in determining whether the relationship between the aircraft owner and another person is a principal-agent relationship. Therefore, the final regulations adopt the principal-agent language from the proposed regulations as written. The Treasury Department and the IRS will consider providing additional guidance on this issue and invite comments regarding whether a principal-agent rule that relates specifically to the aircraft management services exemption is necessary. Any comments that favor additional guidance should include suggestions for how a more detailed principal-agent rule should be structured. Unless and until the Treasury Department and the IRS provide additional guidance, state agency law applies in determining whether a principal-agent relationship exists between the aircraft owner and another person.

vi. Evidence That Payments Are Made by the Aircraft Owner

Regarding proposed § 49.4261–10(a)(3), a commenter requested that the final regulations clarify what facts or evidence are sufficient to show that the aircraft owner is the party making the payments to the aircraft management services provider so that those payments qualify for the aircraft management services exemption. The commenter suggested that the final regulations provide that ''reasonable documentation'' from the aircraft owner stating that payments for aircraft management services originate from a source covered by the aircraft management services exemption will satisfy the aircraft management services provider's obligation to determine whether a payment comes from a permissible source and constitutes adequate documentation thereof. The commenter believes that including this rule in the final regulations will improve administrability for both aircraft management services providers and the IRS.

The task of verifying the source of every payment received by an aircraft management services provider for services related to an aircraft owner's aircraft is a burdensome one for aircraft management services providers. Verification is important because if a payment is received from someone other than the aircraft owner (as that term is defined in the final regulations), the aircraft management services exemption does not apply and the aircraft management services provider must collect any applicable air transportation tax on the amount paid. If the aircraft management services provider fails to do so, section 4263(c) applies. *See also* § 49.4261–1(b)(2).

The Treasury Department and the IRS recognize that in the context of the aircraft management services exemption, it is important for aircraft management services providers to understand their obligations with regard to verifying that payments are made by aircraft owners and that failure to verify may trigger the application of section 4263(c). However, because section 4263(c) has broad implications for all members of the air transportation industry, issues related to section 4263(c) require additional study and input from a broader cross-section of stakeholders in the air transportation industry. Accordingly, these issues should be addressed in a separate published guidance project.

vii. Substantial Incidents of Ownership

Proposed § 49.4261–10(b)(3)(i) provided, in relevant part, that the term ''aircraft owner'' means an individual or entity that leases or owns (that is, holds title to or substantial incidents of ownership in) an aircraft managed by an aircraft management services provider, commonly referred to as a ''managed aircraft.'' The Treasury Department and IRS did not receive comments specifically relating to the ''substantial incidents of ownership'' language. However, the ''substantial incidents of ownership'' language is problematic because, among other things, it creates an opportunity for abuse by providing a mechanism by which parties can circumvent the disqualified lease rule in section 4261(e)(5)(C). For example, parties that wish to enter into an aircraft lease for 31 days or less could structure the transaction as a transfer of substantial incidents of ownership in the aircraft for a period of 31 days or less. By doing so, the parties could avoid creating a disqualified lease while still availing themselves of the exemption in section 4261(e)(5). Congress clearly did not intend for the aircraft management services exemption to apply in such situations as evidenced by the disqualified lease language in section 4261(e)(5)(C). Because of these concerns, the final regulations clarify that the phrase ''substantial incidents of ownership'' in § 49.4261–10(b)(3)(i) does not apply to an interest with a duration of 31 days or less.

viii. Other Changes Related to the Definition of Aircraft Owner

As stated earlier, proposed § 49.4261–10(b)(3)(i) defined ''aircraft owner'', in relevant part, in terms of ''an individual or entity.'' Final § 49.4261–10(b)(3)(i) replaces the phrase ''individual or entity'' with the word ''person.'' This change improves the precision of the aircraft owner definition because the Code provides a generally applicable definition of ''person'' in section 7701(a)(1). This change also makes § 49.4261–10(b)(3)(i) easier to read.

b. Fractional Ownership Aircraft and Other Arrangements

Proposed § 49.4261–10(b)(3)(ii) provided that a participant in a fractional aircraft ownership program, as defined in section 4043(c)(2) of the Code, does not qualify as an aircraft owner of the program's managed aircraft if the amount paid for such person's participation is exempt from air transportation excise tax by reason of section 4261(j). Proposed § 49.4261–10(b)(3)(ii), referred to herein as the

''other arrangements anti-abuse rule,'' further provided that a participant in a business arrangement that seeks to circumvent the surtax imposed by section 4043 by operating outside of subpart K of 14 CFR part 91, and that allows an aircraft owner the right to use any of a fleet of aircraft (through an aircraft interchange agreement, through holding nominal shares in a fleet of aircraft, or any other similar arrangement), is not an aircraft owner with respect to any of the aircraft owned or leased as part of that business arrangement.

A commenter observed that the other arrangements anti-abuse rule appears to be aimed at persons who create a structure providing access to a fleet of aircraft that fails to meet the definition of ''fractional ownership aircraft program'' in section 4043 in an effort to avoid the fuel surtax imposed by section 4043, while retaining the right to claim the aircraft management services exemption to also avoid paying air transportation excise tax. The commenter further observed that the phrase ''seeking to circumvent the surtax imposed by section 4043'' in the other arrangements anti-abuse rule indicates that for the rule to apply, the primary intent in creating the arrangement must be to avoid the section 4043 surtax. Thus, the commenter noted, if there is a legitimate non-tax business purpose for creating the structure, the other arrangements anti-abuse rule should not apply, and the aircraft management services exemption should apply to amounts paid for aircraft management services relating to the aircraft in the structure. The commenter also observed that the phrase ''right to use any of a fleet of aircraft (through an aircraft interchange agreement, through holding nominal shares in a fleet of aircraft, or any other similar arrangement)'' in the proposed rule appears to apply to structures that are akin to fractional programs, but do not meet the definition of a fractional program in section 4043(c)(2).

Based on the foregoing observations, the commenter disagreed with several aspects of the other arrangements anti-abuse rule. First, the commenter disagreed with the proposed rule as unclear regarding how it would apply to structures that provide access to a fleet of aircraft that exist for reasons unrelated to the applicability of the fuel surtax imposed by section 4043. The commenter further disagreed with the proposed rule for failing to define the point at which a structure becomes enough like a fractional ownership aircraft program for the rule to apply. Finally, the commenter disagreed with the proposed rule because the commenter believes that it can be misinterpreted to include various legitimate structures in which aircraft management services are provided, including (a) instances where a substitute aircraft is provided from the aircraft management services provider's charter fleet (which is addressed in proposed § 49.4261–10(c)); (b) leasing structures where a lessor is providing an insured and maintained aircraft but no pilots (which would not have previously been subject to the tax under the possession, command and control test); and (c) the routine use of interchange agreements between aircraft owners.

The Treasury Department and the IRS share the concerns of the commenter that the proposed other arrangements anti-abuse rule may capture aircraft ownership structures and leasing arrangements that are legitimate and not created for purposes of circumventing the fuel surtax imposed by section 4043. The Treasury Department and the IRS are further concerned that the other arrangements anti-abuse rule would create too much taxpayer uncertainty and confusion, which would be compounded by the similarly worded rule in proposed § 49.4261–10(i) (see later discussion of this rule). As a result, the final regulations in § 49.4261–10(b)(3)(ii) do not include the other arrangements anti-abuse rule. Therefore, the final regulations in § 49.4261–10(b)(3)(ii) merely clarify and confirm that a participant in a fractional ownership aircraft program is not an aircraft owner for purposes of the exemption in section 4261(e)(5) if the amount paid for such person's participation is exempt from the tax imposed by section 4261 by reason of section 4261(j).

c. Definition of Disqualified Lease

Proposed § 49.4261–10(b)(4) provided that the term ''disqualified lease'' has the meaning given to it by section 4261(e)(5)(C)(ii). Proposed § 49.4261–10(b)(4), referred to herein as the ''disqualified lease anti-abuse rule,'' further provided that a disqualified lease also includes any arrangement that seeks to circumvent the rule in section 4261(e)(5)(C)(ii) by providing a lease term that is greater than 31 days but does not provide the lessee with exclusive and uninterrupted access and use of the leased aircraft, as identified by the aircraft's airframe serial number and tail number. In addition, proposed § 49.4261–10(b)(4) provided that the fact that a lease permits the lessee to use the aircraft for for-hire flights, as defined in § 49.4261–10(b)(5), when the lessee is otherwise not using the aircraft does not, because of this fact alone, cause a lease with a term that is greater than 31 days to be a disqualified lease.

A commenter disagreed with the disqualified lease anti-abuse rule as a general matter, because, in the commenter's opinion, it significantly expands the definition of ''disqualified lease'' beyond the definition provided in the statute, ensnaring common non-abusive situations that should not be subject to the rule, and frustrating the intended purpose of the statute. The commenter also disagreed with several specific aspects of the disqualified lease anti-abuse rule. First, the commenter disagreed with the disqualified lease anti-abuse rule for not including language limiting its application to only a lease of an aircraft from a person providing aircraft management services for such aircraft.

Second, the commenter disagreed with the requirement in the disqualified lease anti-abuse rule that the lease should provide the lessee with exclusive and uninterrupted access and use of the leased aircraft as overly broad. The commenter stated that the problem with this aspect of the disqualified lease anti-abuse rule is that many aircraft are leased on a non-exclusive basis for valid business purposes, such as liability protection, state sales and use tax compliance, and FAA regulatory requirements.

Third, the commenter disagreed with the disqualified lease anti-abuse rule as improperly subjecting entity-based co-ownership structures to air transportation excise tax. To illustrate this concern, the commenter offered as an example a situation in which two pilots form a limited liability company to purchase an aircraft. For FAA regulatory compliance reasons, the LLC enters into non-exclusive aircraft dry leases with each of the pilots who will operate the aircraft. Since neither lessee in such an arrangement would have exclusive and uninterrupted use of the aircraft, the proposed disqualified lease anti-abuse rule would cause those otherwise qualified leases to be disqualified leases.

Fourth, the commenter observed that the ''for hire'' language in the disqualified lease anti-abuse rule allows a lessee to use the leased aircraft to provide ''for hire'' flights. The commenter disagreed with this aspect of the rule, stating that an aircraft must typically be leased to an on-demand air taxi operator to conduct such for-hire flights. Therefore, the commenter continued, an aircraft owner may lease its aircraft without a crew on a non-exclusive basis directly to an on-

demand air taxi operator in addition to leasing its aircraft without a crew pursuant to a separate non-exclusive lease to a related party for reasons unrelated to air transportation excise tax; in such a case, the aircraft will be leased to each lessee on a non-exclusive basis. The commenter concluded that, based on the language of the disqualified lease anti-abuse rule, these facts could cause the non-exclusive leases to be disqualified leases.

Finally, the commenter disagreed with the disqualified lease anti-abuse rule because the commenter believes that it is possible that an aircraft owner that provides limited services relating to the aircraft could be deemed an aircraft management services provider based on the broad definitions of the terms ''aircraft management services'' and ''aircraft management services provider.'' The commenter explained that most business aircraft owners provide at least some services, such as insurance, hangarage, or maintenance, when they lease their aircraft for valid business reasons such as liability protection planning, maintenance consistency, insurance requirements, and state sales and use tax compliance.

To illustrate the commenter's concern, the commenter offered the example of an entity that purchases an aircraft and enters into two non-exclusive leases to its parent company and to a sister company with a term greater than 31 days. The lessor may obtain the hangar and the insurance for the aircraft since there is typically one hangar and one insurance policy covering the aircraft even if there is more than one non-exclusive aircraft lessee. Applying the proposed disqualified lease anti-abuse rule to this situation, the commenter concluded that the lessor could be viewed as an aircraft management services provider and the arrangement would be subject to the disqualified lease anti-abuse rule. The commenter further concluded that this scenario would inappropriately broaden the scope of the disqualified lease anti-abuse rule since the statutory language was not meant to apply the disqualified lease provision to lessors that provide only partial or limited services.

The commenter suggested that final § 49.4261–10(b)(4) remove the disqualified lease anti-abuse rule in its entirety so that the regulatory definition of ''disqualified lease'' merely restates the statutory definition of the term.

The Treasury Department and the IRS share the concerns of the commenter, particularly that the disqualified lease anti-abuse rule may capture common, legitimate leasing arrangements. Therefore, the final regulations remove the disqualified lease anti-abuse language from the definition of ''disqualified lease'' in § 49.4261–10(b)(4). As a result, the final version of § 49.4261–10(b)(4) simply defines ''disqualified lease'' by reference to its statutory definition in section 4261(e)(5)(C)(ii).

d. Definition of Private Aviation

Proposed § 49.4261–10(a)(2) limited the aircraft management services exemption to aircraft management services related to aircraft used in private aviation. Proposed § 49.4261–10(b)(6) defined the term ''private aviation'' as the use of an aircraft for civilian flights except scheduled passenger service. A commenter observed that the apparent intent of proposed § 49.4261–10(a)(2), when read in combination with the definition of ''private aviation'' in proposed § 49.4261–10(b)(6), is to prevent the aircraft management services exemption from applying to amounts paid for aircraft management services related to scheduled commercial airline aircraft and flights. The commenter also observed that proposed § 49.4261–10(d) makes clear that the aircraft management services exemption is available for aircraft and flights operated under the charter services rules of part 135 of the FAA regulations (14 CFR part 135). The commenter suggested that the final regulations clarify that ''scheduled passenger service'' refers to flights conducted by airlines that sell tickets on an individual seat basis to the general public. The commenter also suggested that the final regulations further clarify that the term ''private aviation'' includes charter flights operated under part 135 of the FAA regulations.

The Treasury Department and the IRS agree with the commenter that the final regulations should clarify the types of flight operations permitted under the private aviation rule in § 49.4261–10(a)(2). Therefore, the final regulations incorporate the commenter's suggested changes to the definition of private aviation provided in § 49.4261–10(b)(8). Specifically, the final regulations clarify that ''scheduled passenger service'' refers to flights for which tickets are sold on an individual seat basis to the general public. In addition, the definition of private aviation is modified to explicitly include operations conducted under part 135 of the FAA regulations.

e. Section 4261(e)(5)(D)

Section 4261(e)(5)(D) provides that in the case of amounts paid to any person which (but for section 4261(e)(5)) are subject to air transportation excise tax, a portion of which consists of amounts described in section 4261(e)(5)(A), section 4261(e)(5) ''shall apply on a pro rata basis only to the portion which consists of amounts described in'' section 4261(e)(5)(A). The Conference Report provides that in the event that a monthly payment made to an aircraft management company is allocated in part to exempt services and flights on the aircraft owner's aircraft, and in part to flights on aircraft other than that of the aircraft owner, air transportation excise tax must be collected on that portion of the payment attributable to flights on aircraft not owned by the aircraft owner.

Proposed § 49.4261–10(c)(1), which generally tracked the pro rata allocation language in the Conference Report, provided that if an aircraft management services provider provides flight services to an aircraft owner on a substitute aircraft during a calendar quarter, air transportation excise tax applies to that portion of the amounts paid by the aircraft owner to the aircraft management services provider, determined on a pro rata basis, that are related to the flight services provided on the substitute aircraft. Stated differently, the proposed regulations provided that when an aircraft owner is provided flights on a substitute aircraft by an aircraft management services provider (for example, when the aircraft owner's aircraft is unavailable due to maintenance), a portion of the amounts paid by the aircraft owner to the aircraft management services provider is subject to air transportation excise tax.

Proposed § 49.4261–10(c)(2) proposed a method, based on the ratio of flight hours provided on a substitute aircraft compared to the total flight hours provided to the aircraft owner on the aircraft owner's aircraft and on substitute aircraft during a calendar quarter, for calculating the taxable portion of the amount paid to the aircraft management services provider.

A commenter objected to proposed § 49.4261–10(c) as unnecessary; the commenter reasoned that—assuming flights provided on a substitute aircraft are treated as charter flights provided by the aircraft management services provider to the aircraft owner and subject to air transportation excise tax—there is no need for a special calculation to determine the amount paid for such flights. Similarly, again assuming flights provided on a substitute aircraft are treated as charter flights provided by the aircraft management services provider to the aircraft owner and subject to air transportation excise tax, multiple commenters objected to proposed § 49.4261–10(c) because it could result

in air transportation excise tax being applied to the same air transportation twice—once on the amount paid for the charter on the substitute aircraft and then again on a portion of the amount paid for aircraft management services to the aircraft management services provider providing the substitute aircraft.

One commenter offered several comments regarding the allocation methodology in proposed § 49.4261–10(c)(2). First, the commenter disagreed with the proposed allocation methodology because it may result in air transportation excise tax being imposed on amounts paid for non-transportation items. Second, the commenter disagreed with the proposed allocation methodology because it may result in the application of air transportation excise tax to an amount disproportionate to the fair market value of the transportation services actually provided on the substitute aircraft. Third, the commenter disagreed with the proposed allocation methodology because it promotes a loss of revenue to aircraft management services providers. The commenter explained that to avoid having to pay air transportation excise tax on an allocated portion of the amount paid for aircraft management services, the aircraft owner need only hire the replacement aircraft from an operator different than the one that provides aircraft management services to the aircraft owner. Thus, the commenter asserted that the proposed rule incentivizes aircraft owner behavior that will result in lost revenue to the aircraft management services provider. Fourth, the commenter disagreed with the proposed allocation methodology as increasing taxpayer uncertainty because the amount of air transportation excise tax that results from the method will not be known at the time an aircraft management services provider would invoice an aircraft owner for services provided on a substitute aircraft.

A third commenter disagreed with the allocation methodology in proposed § 49.4261–10(c) because the calculation, in the commenter's view, will ordinarily produce nonsensical results since the cost profile of a substitute aircraft will likely be different from the cost profile for the aircraft owner's aircraft. The commenter asserted that averaging the costs of two aircraft with different cost profiles will produce an arbitrary result with no rational relationship to a reasonable, fair market charter rate for flights on the substitute aircraft. The commenter further asserted that the allocation methodology calculation will be further skewed if the aircraft owner-taxpayer owns multiple aircraft with varying flight hours from one quarter to the next, buys or sells aircraft during the quarter, or pays multiple aircraft management services providers rather than a single aircraft management services provider.

All three commenters suggested that the final regulations either completely remove § 49.4261–10(c), as drafted in the proposed regulations, or that the final regulations adopt a different approach than the proposed allocation methodology. All three commenters also suggested that in situations where a substitute aircraft is provided to an aircraft owner, air transportation excise tax should be calculated based on the amount paid by the aircraft owner for the substitute aircraft (that is, in a manner similar to how air transportation excise tax is calculated on amounts paid for charter flights). A commenter also suggested that if an aircraft owner pays less than fair market value for the use of the substitute aircraft, then air transportation excise tax should be calculated on the fair market value rather than the actual amount paid for the substitute aircraft.

In the alternative, if the proposed allocation methodology is incorporated into the final regulations, a commenter suggested that the final regulations provide that when an aircraft owner pays for a substitute aircraft, then the aircraft owner will receive a credit for any air transportation excise tax that it paid in relation to hiring a substitute aircraft against the amount of tax calculated under the allocation methodology. Another commenter suggested that if the proposed allocation methodology is incorporated into the final regulations, then the final regulations provide that an aircraft owner may elect to pay air transportation excise tax on the fair market value of the flight provided on the substitute aircraft rather than pay the air transportation excise tax calculated using the proposed methodology.

The comments prompted the Treasury Department and the IRS to reevaluate the approach taken in the proposed regulations with regard to section 4261(e)(5)(D). Based on this reevaluation, the Treasury Department and the IRS reached two conclusions.

First, section 4261(e)(5)(D) has broader applicability than just the provision of substitute aircraft as evidenced by the plain language of that provision.

Second, the allocation methodology in the proposed regulation is problematic. Specifically, the Treasury Department and the IRS share the concerns expressed by the commenters, particularly with regard to the potential for double taxation and uncertainty under the proposed rule.

For these reasons, the final regulations adopt the general approach suggested by the commenters. Specifically, final § 49.4261–10(c)(1) restates section 4261(e)(5)(D) as a generally applicable rule. Final § 49.4261–10(c)(1) further provides that the tax base for the portion that is subject to the tax imposed by section 4261(a) is the amount paid for such flights or services, provided the amount paid is separable and shown in exact amounts in the records pertaining to the charge. This rule is consistent with commenter suggestions and also reflects the general approach in the air transportation excise tax area that the section 4261(a) tax is imposed on the actual amount paid for taxable transportation. The separability element of the rule is consistent with the rule in § 49.4261–2(c) regarding situations in which a payment covers charges for transportation and nontransportation services. If the portion of the amount paid that is subject to the tax imposed by section 4261(a) is not separable and is not shown in exact amounts in the records pertaining to the charge, the tax base is the fair market value of the flights or services; however, the tax base does not exceed the total amount paid (that is, the sum of the portion that is subject to the tax imposed by section 4261(a) and the portion that consists of amounts described in section 4261(e)(5)(A)). For clarity, the final regulations also include a definition of ''fair market value'' that applies to allocations. The definition of ''fair market value'' is consistent with commenter suggestions.

In addition, final § 49.4261–10(c)(2) treats the provision of a flight on a substitute aircraft to the aircraft owner by an aircraft management services provider as an aircraft charter, with the aircraft owner as the charterer. The final regulations further provide that the allocation rule in final § 49.4261–10(c)(1) applies in determining the tax base.

The final regulations also provide guidance for situations in which a substitute aircraft is used to provide a for-hire flight. In that instance, the final regulations instruct taxpayers and collectors to follow the aircraft charter rules in § 49.4261–7(h)(2).

The final regulations update the first example and add a second example in § 49.4261–10(h) to illustrate these rules.

f. Aircraft Available for Hire

Proposed § 49.4261–10(e)(1) provided that whether an aircraft owner permits

an aircraft management services provider or other person to use its aircraft to provide for-hire flights (for example, when the aircraft is not being used by the aircraft owner or when the aircraft is being moved in deadhead service) does not affect the application of the aircraft management services exemption. Proposed § 49.4261–10(e)(1) further provided that an amount paid for for-hire flights on the aircraft owner's aircraft does not qualify for the aircraft management services exemption. Therefore, under proposed § 49.4261–10(e)(1), an amount paid for a for-hire flight on an aircraft owner's aircraft is subject to air transportation excise tax unless the amount paid is otherwise exempt from air transportation excise tax other than by reason of the aircraft management services exemption.

A commenter expressed concern that the wording of proposed § 49.4261–10(e)(1) may cause confusion and result in the misapplication of air transportation excise tax to amounts paid that should qualify for the aircraft management services exemption. Specifically, the commenter's concern relates to the second and third sentences of proposed § 49.4261–10(e)(1), which explain that amounts paid for for-hire flights are subject to air transportation excise tax. The commenter observed that under section 4261(e)(5), amounts paid by an aircraft owner for flights on the aircraft owner's aircraft are exempt from air transportation excise tax. The commenter further observed that under proposed § 49.4261–10(d), operating an aircraft owner's aircraft under part 135 of the FAA regulations does not affect the application of the aircraft management services exemption. The commenter's concern is that aircraft operations conducted under part 135 of the FAA regulations could arguably be considered for-hire flights; however, proposed § 49.4261–10(e)(1) does not provide a carve-out for part 135 flights paid for by the aircraft owner. Therefore, in order to clarify that amounts paid by an aircraft owner for flights operated under part 135 are not subject to air transportation excise tax, the commenter suggested that the final regulations incorporate a carve-out by modifying the second sentence of proposed § 49.4261–10(e)(1) to read: ''However, an amount paid for for-hire flights on the aircraft owner's aircraft, *except payments made by such aircraft owner,* does not qualify for the section 4261(e)(5) exemption.'' (emphasis added to denote new wording).

The Treasury Department and the IRS agree with the commenter. As a result, final § 49.4261–10(e) incorporates the commenter's suggested change.

g. Coordination With Fuel Tax Provisions

Proposed § 49.4261–10(g) provided that taxable fuel (as defined in section 4083(a)) or any liquid taxable under section 4041(c) that is used as fuel on a flight for which amounts paid are exempt from air transportation excise tax by reason of the aircraft management services exemption is not fuel used in commercial aviation, as that term is defined in section 4083(b). Thus, under the proposed rule, if the aircraft management services exemption applies to amounts paid in relation to a flight, then the higher noncommercial fuel tax rate (as compared to the commercial fuel tax rate) automatically applies to fuel used during such flight.

A commenter stated that proposed § 49.4261–10(g) is inconsistent with the air transportation excise tax-fuel tax statutory scheme and contrary to Congressional intent with regard to that scheme. The commenter asserted that if Congress had intended that all flights qualifying for the aircraft management services exemption be treated as non-commercial flights for fuel tax purposes, Congress could have adopted a corresponding code section to that effect as it did with other exemptions to air transportation excise tax. Specifically, the commenter pointed to the exemptions to air transportation excise tax provided in sections 4261(h) (skydiving), 4261(i) (seaplanes), 4281 (small aircraft on nonestablished lines), and 4282 (affiliated group members), each of which section 4083(b) explicitly excludes from the definition of ''commercial aviation'' for purposes of determining applicable fuel tax rates. By not providing a similar, explicit definitional exclusion in section 4083(b) (or other Code section) for the aircraft management services exemption, the commenter asserted, Congress left the determination of which fuel tax rate—commercial or non-commercial—applies to a particular flight to the application of the general definition of ''commercial aviation'' in section 4083(b). Therefore, the commenter suggested that the final regulations provide that if the aircraft management services exemption applies to amounts paid for a flight, the determination of whether fuel used during the flight is subject to commercial or non-commercial fuel tax rates is made simply through an application of the definition of commercial aviation provided in section 4083(b).

The Treasury Department and the IRS agree with the commenter that proposed § 49.4261–10(g) is inconsistent with the air transportation excise tax-fuel excise tax statutory scheme. As a result, the final regulations do not adopt the rule in proposed § 49.4261–10(g). The rule in proposed § 49.4261–10(e)(2) relating to fuel used in for-hire flights is similarly inconsistent with the air transportation excise tax-fuel excise tax statutory scheme. Therefore, the final regulations also do not adopt the rule proposed in § 49.4261–10(e)(2). Because final § 49.4261–10 does not provide fuel excise tax guidance related to the exemption in section 4261(e)(5), persons affected by the aircraft management services exemption should continue to follow current statutory, regulatory, and administrative guidance related to the rates of tax for aviation fuel.

h. Coordination With Fractional Ownership Aircraft Exemption; Anti-Abuse Rule

Proposed § 49.4261–10(i) provided, in relevant part, that the aircraft management services exemption does not apply to any amount paid for aircraft management services by a participant in any transaction or arrangement, or through other means, that seeks to circumvent the surtax imposed by section 4043. A commenter expressed concern that confusion could result from the phrasing of the first sentence of proposed § 49.4261–10(i) because it is essentially identical to the phrasing of the second sentence of proposed § 49.4261–10(b)(3)(ii) (excluding fractional aircraft ownership programs and similar arrangements from the definition of ''aircraft owner''). The commenter suggested that the first sentence in the final version of § 49.4261–10(i) simply cross-reference § 49.4261–10(b)(3)(ii), rather than repeating the similar language. Specifically, the commenter suggested the following language for the first sentence of final § 49.4261–10(i): ''The aircraft management services exemption does not apply to any amount paid for aircraft management services by a participant in the type of business arrangement described in [§ 49.4261–10(b)(3)(ii)] that does not qualify the participant as an aircraft owner.''

The Treasury Department and the IRS believe that the rule in proposed § 49.4261–10(i) is problematic for the same reasons as the other arrangements anti-abuse rule in proposed § 49.4261–10(b)(3)(ii) (discussed earlier); specifically, it may capture aircraft ownership structures that are legitimate and not created for purposes of circumventing the fuel surtax imposed by section 4043. The Treasury Department and the IRS further believe

that, like the other arrangements anti-abuse rule in proposed § 49.4261–10(b)(3)(ii), the rule in proposed § 49.4261–10(i) would have created taxpayer uncertainty and confusion. Because the final regulations in § 49.4261–10(b)(3)(ii) clarify that a participant in a fractional ownership aircraft program is not an aircraft owner for purposes of the exemption in section 4261(e)(5), an additional coordination rule is redundant. As a result, the final regulations do not adopt proposed § 49.4261–10(i).

i. Adequate Records

Proposed § 49.4261–10(a)(3) stated that in order to qualify for the aircraft management services exemption, an aircraft owner and aircraft management services provider must maintain adequate records to show that the amounts paid by the aircraft owner to the aircraft management services provider relate to aircraft management services for the aircraft owner's aircraft or for flights on the aircraft owner's aircraft.

A commenter requested that the final regulations provide guidance on the types of records required to satisfy this requirement. The Treasury Department and the IRS agree. Accordingly, the final regulations add language to § 49.4261–10(a)(3) stating that such records may include the agreement, if any, between the aircraft owner and the aircraft management services provider, evidence of aircraft ownership, evidence that amounts paid for aircraft management services came from the aircraft owner, the aircraft management services provider's fee schedule, and documents to support any allocations required under the pro rata allocation rule.

j. Examples

Proposed § 49.4261–10(j) included two examples illustrating certain aspects of the rules in proposed § 49.4261–10. Proposed § 49.4261–10(j)(1) (Example 1) illustrated the substitute aircraft allocation methodology in proposed § 49.4261–10(c)(1) and (2). Proposed § 49.4261–10(j)(1)(i) (presenting the facts of Example 1) stated, in relevant part, that:

A commenter stated that it interpreted proposed § 49.4261–10(j)(1)(i) (presenting the facts of Example 1) as saying that if a company hires an aircraft management company to provide only pilot services to the aircraft owner, then—but for the aircraft management services exemption—air transportation excise tax would apply to the amounts paid by the aircraft owner to the aircraft management services provider. Based on its interpretation, the commenter expressed its opinion that the example presents an extreme position with regard to the application of air transportation excise tax to an aircraft owner-aircraft management services provider relationship. The commenter further stated that the second sentence in proposed § 49.4261–10(j)(1)(i) may cause confusion regarding the application of the possession, command, and control test in cases that are not governed by section 4261(e)(5). In addition, the commenter stated that the second sentence in proposed § 49.4261–10(j)(1)(i) is irrelevant to the rest of the example, thereby compounding the other problems that the commenter mentioned. The commenter suggested that the final regulations remove the second sentence from § 49.4261–10(j)(1)(i).

As noted earlier, the final regulations include a revised pro rata allocation rule. The final regulations also revise the first example (including deletion of the second sentence) and add a second example to illustrate the revised pro rata allocation rule. In addition, the final regulations revise the third example (proposed § 49.4261–10(j)(2)) to remove the fuel references in light of the decision not to adopt proposed § 49.4261–10(e)(2) and (g) in the final regulations.

III. Generally Applicable Air Transportation Excise Tax Rules and Aircraft Charter Rules

a. Payment and Collection Obligations

Proposed § 49.4261–1(b)(1) restated, in general terms, statutory provisions and existing regulations related to the duties and obligations of a person that makes a payment subject to the taxes imposed by section 4261 (that is, the taxpayer) and a person that receives such payments (that is, the collector). The duties and obligations include those imposed on the collector to collect the applicable tax from the taxpayer, to report the tax on Form 720, *Quarterly Federal Excise Tax Return,* and to remit the tax to the IRS. The duties and obligations enumerated in the proposed regulations also include the requirement that the collector make semimonthly deposits of the taxes imposed by section 4261.

Proposed § 49.4261–1(b)(2) restated the rule in section 4263(c), which provides that if any tax imposed by section 4261 is not paid at the time payment for transportation is made, then, to the extent the tax is not collected under any other provision of subchapter C of chapter 33 of the Code, the tax must be paid by the carrier providing the initial segment of transportation that begins or ends in the United States.

Regarding proposed § 49.4261–1(b)(1), a commenter expressed concern that current published guidance (primarily in the form of revenue rulings) does not adequately address the duties and obligations of charter brokers with regard to collecting and reporting air transportation excise tax. The commenter described a charter broker as an intermediary that charters aircraft from a certificated air carrier (who actually provides the flight services), and that may act as an agent of the air carrier, an agent of the passengers, or as a principal in the chartering transaction. The commenter stated that the lack of guidance related to charter brokers has created considerable confusion in the charter broker industry. Further, the commenter stated that the need for clear and precise guidance is compounded by the aircraft charter rules provided in proposed § 49.4261–7(h) (discussed later) and section 4263(c), which imposes liability on the air carrier providing the initial segment of transportation that begins or ends in the U.S. in cases where any tax imposed by section 4261 is not paid at the time the payment for transportation is made. Therefore, the commenter requested that the final regulations provide guidance regarding the circumstances in which a charter broker (rather than an air carrier) is obligated to collect air transportation excise tax and file Forms 720. The commenter suggested that such guidance should be consistent with the approaches taken in Rev. Rul. 68–256, 1968–1 C.B. 489; Rev. Rul. 75–296, 1975–2 C.B. 440; and Rev. Rul. 2006–52, 2006–2 C.B. 761.

Regarding proposed § 49.4261–1(b)(2), a commenter stated that the obligation placed on the air carrier to pay the tax imposed by section 4261 if the party responsible for collecting it fails to do so creates confusion and unfair liability exposure for the air carrier. Further, the commenter stated, as an example, that an IRS examiner could assert tax liability on the air carrier for uncollected tax when the air carrier has no means to determine whether another responsible party, such as a charter broker, had collected and paid over the tax. To alleviate these concerns, the commenter suggested that the final regulations provide that if an air carrier documents that it informed the charter broker of its obligation to collect the taxes imposed by section 4261 and file Forms 720 (see the discussion of proposed § 49.4261–7(h) later), then the air carrier will not be liable for uncollected tax under section 4263(c).

The commenter also suggested that the final regulations provide that if the IRS asserts liability on an air carrier under section 4263(c) (irrespective of whether the air carrier can show that it informed the charter broker of its obligations to collect and report) during an examination, then the air carrier should be entitled to obtain information from the IRS on whether the tax was paid by the charter broker or any other party.

The Treasury Department and the IRS understand and share the commenters' concerns related to uncertainty and the possibility of surprise that may result from another party's IRS examination because of the rules in section 4263(c) and proposed § 49.4261–1(b)(2). Because the interactions between section 4263(c) and other air transportation excise tax rules are complex and have broad implications for other members of the air transportation industry, the Treasury Department and the IRS believe that these issues require additional study and input from a broader cross-section of the air transportation industry. Further, the Treasury Department and the IRS believe that section 4263(c) issues should be addressed in a separate published guidance project that could also potentially consider the interplay between section 4263(c) and the existing regulatory rules in § 49.4261–7(h) and § 49.4291–1.

However, because, as mentioned earlier, proposed § 49.4261–1(b)(1) merely restated currently applicable statutory and regulatory rules, the final regulations adopt proposed § 49.4261–1(b)(1) without change. In addition, the final regulations do not adopt the second sentence of proposed § 49.4261–1(b)(2) so that the final regulations simply track the language of section 4263(c), as currently written, without further comment. The Treasury Department and the IRS believe it is necessary to finalize these rules because the existing regulations related to section 4263(c) reflect prior law, which has created widespread confusion among taxpayers and collectors in the air transportation area.

b. Aircraft Charters

Proposed § 49.4261–7(h), which generally restated existing rules in § 49.4261–7(h), provided rules related to the application of the taxes imposed by section 4261 to situations in which a person provides air transportation services on an aircraft that was chartered from—and operated by—another party, commonly referred to as a ''wet lease.'' Proposed § 49.4261–7(h)(2) provided that the charterer of an aircraft who sells transportation to other persons must collect and account for the tax with respect to all amounts paid to the charterer by such other persons. The proposed rule further provided that, in such a case, no tax will be due on the amount paid by the charterer for the charter of the aircraft but that it is the duty of the owner of the aircraft to advise the charterer of the charterer's obligation for collecting, accounting for, and paying over the tax to the IRS. This requirement is intended to ensure the parties communicate with each other regarding air transportation excise tax and prevent misunderstandings about which party is responsible for collecting tax under the arrangement.

Two commenters requested clarification regarding the duty of the ''owner of the aircraft to advise the charterer of the charterer's obligations for collecting, accounting for, and paying over the tax'' to the IRS imposed under the proposed rule. A commenter stated that in the air charter industry, the air carrier does not typically own the aircraft used to provide charter flights. Because the proposed rule imposes on the aircraft owner the duty to advise the charterer of its obligations, the commenter stated that confusion about which party must advise the charterer may result from the phrasing of the proposed rule. The commenter suggested the proposed rule use the phrase ''air carrier'' rather than ''owner of the aircraft.''

A commenter also requested clarification about how and when the duty to advise the charterer of its obligations with regard to air transportation excise tax must be satisfied. Specifically, the commenter asked whether the duty to advise applies separately to each specific charter flight, or whether the duty may be satisfied as part of a long-term underlying agreement between the aircraft owner and the charterer such as a lease agreement for the aircraft owner's aircraft entered into by the aircraft owner and the charterer. The commenter also requested clarification regarding whether the duty to advise the charterer of its obligations with regard to air transportation excise tax creates an obligation on the part of the aircraft owner to collect the tax if the charterer fails to do so.

The Treasury Department and the IRS understand and share the commenters' concern that, because the owner of a chartered aircraft may not be the party that operates the aircraft, the phrasing of the proposed rule may cause confusion. In addition, the Treasury Department and the IRS understand the need for clarification regarding the duty of the aircraft owner to advise the charterer of its collection obligations. However, because these rules are complex and have broad applicability to the air transportation industry, additional study and stakeholder input is required. Accordingly, a separate published guidance project is necessary to address: (a) the possible shifting of the duty to advise the charterer about its obligations for collecting, accounting for, and paying over the tax to the IRS to the air carrier operating the chartered aircraft instead of the owner of the chartered aircraft; (b) whether the duty to advise applies separately to each specific charter flight, or whether the duty may be satisfied as part of a long-term agreement between the aircraft owner and the charterer; and (c) whether the duty to advise the charterer of its obligations with regard to air transportation excise tax creates an obligation on the part of the aircraft owner to collect the tax if the charterer fails to do so.

Because proposed § 49.4261–7(h) merely restated currently applicable rules, the final regulations adopt proposed § 49.4261–7(h) without change. Until additional guidance is issued, § 49.4261–7(h), as finalized, and other existing published guidance apply.

Effect on Other Documents

Revenue Ruling 67–414 (1967–2 C.B. 382), Revenue Ruling 72–309 (1972–1 C.B. 348), and Revenue Ruling 2002–34 (2002–1 C.B. 1150) are obsoleted on January 19, 2021.

Applicability Dates

For dates of applicability, see §§ 40.0–1(e), 49.4261–1(g), 49.4261–2(d), 49.4261–3(e), 49.4261–7(k), 49.4261–9(c), 49.4261–10(i), 49.4262–1(f), 49.4262–2(e), 49.4262–3(e), 49.4281–1(e), 49.4263–1(b), 49.4263–3(b), 49.4271–1(g), and 49.4721–2.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities. Although the rule may affect a substantial number of small entities, the economic impact of the regulations is not likely to be significant. Data are not readily available about the number of

taxpayers affected, but the number is likely to be substantial for both large and small entities because the rule may affect entities that serve as holding companies for aircraft that do not have many revenues or employees. The economic impact of these regulations is not likely to be significant, however, because these final regulations primarily clarify the application of the aircraft management services exception added to the Code by the TCJA. These final regulations will assist taxpayers in understanding the rules to qualify for the exemption under section 4261(e)(5) and make it easier for taxpayers to comply and IRS examiners to administer the exemption. Accordingly, the Secretary of the Treasury's delegate certifies that the rule will not have a significant economic impact on a substantial number of small entities. Notwithstanding this certification, the Treasury Department and the IRS welcome comments on the impact of these regulations on small entities.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, Notices and other guidance cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Drafting Information

The principal author of these regulations is Michael H. Beker, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 40

Excise taxes, Reporting and recordkeeping requirements.

26 CFR Part 49

Excise taxes, Reporting and recordkeeping requirements, Telephone, Transportation.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 40 and 49 are amended as follows:

PART 40—EXCISE TAX PROCEDURAL REGULATIONS

■ **Paragraph 1.** The authority citation for part 40 is amended by removing the entry for § 40.6071(a)–3 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 40.0–1 is amended by redesignating paragraph (d) as paragraph (e), adding a new paragraph (d), and revising newly redesignated paragraph (e) to read as follows:

§ 40.0–1 Introduction.

* * * * *

(d) *Person.* For purposes of this part, each business unit that has, or is required to have, a separate employer identification number is treated as a separate person. Thus, business units (for example, a parent corporation and a subsidiary corporation, a partner and the partner's partnership, or the various members of a consolidated group), each of which has, or is required to have, a different employer identification number, are separate persons.

(e) *Applicability date*—(1) *Paragraphs (a), (b), and (c) of this section.* Paragraphs (a), (b), and (c) of this section apply to returns for periods beginning after March 31, 2013. For rules that apply before that date, *see* 26 CFR part 40, revised as of April 1, 2012.

(2) *Paragraph (d) of this section.* Paragraph (d) of this section applies to returns for periods beginning on or after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 40, revised as of April 1, 2020.

§ 40.6071(a)–3 [Removed]

■ **Par. 3.** Section 40.6071(a)–3 is removed.

PART 49—FACILITIES AND SERVICES EXCISE TAX REGULATIONS

■ **Par. 4.** The authority citation for part 49 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 5.** Section 49.4261–1 is revised to read as follows:

§ 49.4261–1 Imposition of tax; in general.

(a) *In general.* Section 4261 of the Internal Revenue Code (Code) imposes three separate taxes on amounts paid for certain transportation of persons by air. Tax attaches at the time of payment for any transportation taxable under section 4261. The applicability of each section 4261 tax is generally determined on a flight-by-flight basis.

(1) *Percentage tax.* Section 4261(a) imposes a 7.5 percent tax on the amount paid for the taxable transportation of any person. *See* section 4262(a) of the Code and § 49.4262–1(a) for the definition of the term *taxable transportation.*

(2) *Domestic segment tax.* Section 4261(b)(1) imposes a $3 tax (indexed annually for inflation pursuant to section 4261(e)(4)) on the amount paid for each domestic segment of taxable transportation. *See* section 4261(b)(2) for the definition of the term *domestic segment.* The domestic segment tax does not apply to a domestic segment beginning or ending at an airport that is a rural airport for the calendar year in which the segment begins or ends (as the case may be). *See* section 4261(e)(1)(B) for the definition of the term *rural airport.*

(3) *International travel facilities tax.* Section 4261(c) imposes a $12 tax (indexed annually for inflation pursuant to section 4261(e)(4)) on any amount paid (whether within or without the United States) for any transportation by air that begins or ends in the United States. The international travel facilities tax does not apply to any transportation that is entirely taxable under section 4261(a) (determined without regard to sections 4281 and 4282). *See* section 4261(c)(2). A special rule applies to Alaska and Hawaii flights. *See* section 4261(c)(3).

(b) *Payment and collection obligations*—(1) *In general.* The taxes imposed by section 4261 are collected taxes. In general, the person making the payment subject to tax is the *taxpayer. See* section 4261(d). The person receiving the payment is the *collector* (also commonly referred to as the collecting agent). *See* section 4291 of the Code. The collector must collect the applicable tax from the taxpayer, report the tax on Form 720, *Quarterly Federal Excise Tax Return,* and remit the tax to the Internal Revenue Service. *See* sections 4291, 6011, and 7501 of the Code. *See* § 40.6011(a)–1 of this chapter and § 49.4291–1. The collector must also make semimonthly deposits of the taxes imposed by section 4261. *See* section 6302(e) of the Code. *See* §§ 40.0–1(c), 40.6302(c)–1, and 40.6302(c)–3 of this chapter. *See* section 4263(a) and (c) of the Code for special rules relating to the payment and collection of tax.

(2) *Failure to collect tax.* If any tax imposed by section 4261 is not paid at the time payment for transportation is made, then, to the extent the tax is not collected under any other provision of subchapter C of chapter 33 of the Code,

the tax must be paid by the carrier providing the initial segment of transportation that begins or ends in the United States. *See* section 4263(c). *See* section 6672 of the Code for rules relating to the application of the trust fund recovery penalty.

(c) *Type of aircraft.* The taxes imposed by section 4261 generally apply regardless of the type of aircraft on which the transportation is provided, provided all of the other conditions for liability are present and no specific statutory exemption applies. *See* paragraph (f) of this section for a list of statutory exemptions from tax. Amounts paid for the transportation of persons by air cushion vehicles, also known as hovercraft, are not subject to the taxes imposed by section 4261.

(d) *Purpose of transportation.* The purpose of the transportation (for example, business or pleasure) is not a factor in determining taxability under section 4261.

(e) *Routes.* Amounts paid for transportation may be taxable even if the transportation is not between two definite points. Unless otherwise exempt, a payment for continuous transportation that begins and ends at the same point is subject to tax. *See* section 4281 of the Code and § 49.4281–1 for the exemption for small aircraft on nonestablished lines.

(f) *Exemptions from tax; cross-references*—(1) *Aircraft management services.* For the exemption for certain aircraft management services, see section 4261(e)(5) of the Code and § 49.4261–10.

(2) *Hard minerals, oil, and gas.* For the exemption for certain uses related to the exploration, development, or removal of hard minerals, oil, or gas, see section 4261(f)(1).

(3) *Trees and logging operations.* For the exemption for certain uses related to trees and logging operations, see section 4261(f)(2).

(4) *Air ambulances.* For the exemption for air ambulances providing certain emergency medical transportation, see section 4261(g).

(5) *Skydiving.* For the exemption for certain skydiving uses, see section 4261(h).

(6) *Seaplanes.* For the exemption for certain seaplane segments, see section 4261(i).

(7) *Fractionally-owned aircraft.* For the exemption for certain aircraft in fractional ownership aircraft programs, see section 4261(j).

(8) *Small aircraft on nonestablished lines.* For the exemption for certain small aircraft on nonestablished lines, see section 4281 of the Code and § 49.4281–1.

(9) *Affiliated groups.* For the exemption for certain transportation of members of an affiliated group, see section 4282.

(10) *United States and territories.* For exemptions authorized by the Secretary of the Treasury or his delegate for the exclusive use of the United States, see section 4293.

(g) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, see 26 CFR part 49, revised as of April 1, 2020.

■ **Par. 6.** Section 49.4261–2 is amended by:

■ 1. Revising paragraphs (a) and (b).

■ 2. Adding paragraph (d).

The revisions and addition read as follows:

§ 49.4261–2 Application of tax.

(a) *Tax on total amount paid.* The tax imposed by section 4261(a) of the Internal Revenue Code (Code) is measured by the total amount paid for taxable transportation, whether paid in cash or in kind.

(b) *Tax on transportation of each person.* The taxes imposed by section 4261(b) and (c) of the Code are head taxes and, therefore, apply on a per-passenger basis. The taxes apply to each passenger for whom an amount is paid, regardless of whether the payment is made as a single lump sum or is made individually for each passenger. In the case of charter flights for which a fixed amount is paid, the section 4261(b) and (c) taxes are computed by multiplying the applicable rate of tax by the number of passengers transported on the aircraft.

* * * * *

(d) *Applicability date.* Paragraphs (a) and (b) of this section apply to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

■ **Par. 7.** Section 49.4261–3 is amended by:

■ 1. Removing ''§ 49.4262(c)–1'' wherever it appears and adding ''§ 49.4262–3'' in its place.

■ 2. In the first sentence of paragraph (a), removing ''The tax imposed by section 4261(a)'' and adding ''The taxes imposed by section 4261(a) and (b) of the Internal Revenue Code (Code)'' in its place.

■ 3. In the second sentence of paragraph (a), adding ''under section 4261(a) and (b)'' at the end of the sentence.

■ 4. Revising paragraphs (b) and (c).

■ 5. In paragraph (d), removing ''section 4262(b) and § 49.4262(b)–1'' and adding ''section 4262(b) of the Code and § 49.4262–2'' in its place.

■ 6. Adding paragraph (e).

The revisions and additions read as follows:

§ 49.4261–3 Payments made within the United States.

* * * * *

(b) *Other transportation.* In the case of transportation, other than that described in paragraph (a) of this section, for which payment is made in the United States, the taxes imposed by section 4261(a) and (b) apply with respect to the amount paid for that portion of such transportation by air which is directly or indirectly from one port or station in the United States to another port or station in the United States, but only if such portion is not a part of uninterrupted international air transportation within the meaning of section 4262(c)(3) of the Code and § 49.4262–3(c). Transportation that:

(1) Begins in the United States or the 225–mile zone and ends outside such area,

(2) Begins outside the United States or the 225–mile zone and ends inside such area, or

(3) Begins outside the United States and ends outside such area, is taxable only with respect to the portion of the transportation by air which is directly or indirectly from one port or station in the United States to another port or station in the United States, but only if such portion is not a part of ''uninterrupted international air transportation'' within the meaning of section 4262(c)(3) and § 49.4262–3(c). Thus, on a trip by air from Chicago to London, England, with a stopover at New York, for which payment is made in the United States, if the portion from Chicago to New York is not a part of ''uninterrupted international air transportation'' within the meaning of section 4262(c)(3) and § 49.4262–3(c), the taxes would apply to the part of the payment which is applicable to the transportation from Chicago to New York. However, if the portion from Chicago to New York is a part of ''uninterrupted international air transportation'' within the meaning of section 4262(c)(3) and § 49.4262–3(c), the taxes would not apply.

(c) *Method of computing tax on taxable portion.* Where a payment is made for transportation which is partially taxable under paragraph (b) of this section, the tax imposed by section 4261(a) may be computed on that proportion of the total amount paid which the mileage of the taxable portion of the transportation bears to the mileage of the entire trip.

* * * * *

(e) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply

before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4261–4 [Amended]

■ **Par. 8.** Section 49.4261–4 is amended by:

■ 1. In paragraph (a), removing the first ''4261(a)'' and adding ''4261 of the Internal Revenue Code (Code)'' in its place.

■ 2. In paragraph (a), removing ''section 4261(a) (see section 4264(d))'' and adding ''section 4261 (see section 4263(d) of the Code)'' in its place.

■ 3. In paragraph (b), removing ''§ 49.4262(c)–1'' and adding ''§ 49.4262–3'' in its place.

■ 4. In the first sentence of paragraph (d), removing ''§ 49.4262(c)–1'' and adding ''§ 49.4262–3'' in its place.

■ 5. In the first sentence of paragraph (d), removing ''six-hour'' and adding ''12-hour'' in its place.

§ 49.4261–5 [Amended]

■ **Par. 9.** Section 49.4261–5 is amended as follows:

■ 1. In paragraph (a), removing ''4261(b)'' wherever it appears and adding ''4261(a) and (b)'' in its place.

■ 2. In paragraph (c), removing ''§ 49.4262(b)–1'' and adding ''§ 49.4262–2'' in its place.

■ **Par. 10.** Section 49.4261–7 is amended by:

■ 1. In the introductory paragraph, removing ''4263, 4292, 4293, or 4294'' and adding ''4261, 4281, 4282, or 4293 of the Internal Revenue Code,'' in its place.

■ 2. Removing and reserving paragraphs (b), (d), (e), and (g).

■ 3. Revising paragraph (h).

■ 4. In paragraph (i), removing ''paragraph (c) of § 49.4261–2 and paragraph (f)(4) of § 49.4261–8'' and adding ''§§ 49.4261–2(c) and 49.4261–8(f)(4)'' in its place.

■ 5. Adding paragraph (k).

The revision and addition read as follows:

§ 49.4261–7 Examples of payments subject to tax.

* * * * *

(h) *Aircraft charters*—(1) When no charge is made by the charterer of an aircraft to the persons transported, the amount paid by the charterer for the charter of the aircraft is subject to tax.

(2) The charterer of an aircraft who sells transportation to other persons must collect and account for the tax with respect to all amounts paid to the charterer by such other persons. In such case, no tax will be due on the amount paid by the charterer for the charter of the aircraft but it shall be the duty of the owner of the aircraft to advise the charterer of the charterer's obligation for collecting, accounting for, and paying over the tax to the Internal Revenue Service.

* * * * *

(k) *Applicability date.* Paragraph (h) of this section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4261–8 [Amended]

■ **Par. 11.** Section 49.4261–8 is amended as follows:

■ 1. In the introductory paragraph, removing ''4263, 4292, 4293, or 4294'' and adding ''4261, 4281, 4282, or 4293 of the Internal Revenue Code'' in its place.

■ 2. Paragraphs (f)(2), (3), and (5) are removed and reserved.

■ **Par. 12.** Section 49.4261–9 is revised to read as follows:

§ 49.4261–9 Mileage awards.

(a) *Tax imposed.* Any amount paid (and the value of any other benefit provided) to an air carrier (or any related person) for the right to provide mileage awards for or other reductions in the cost of any transportation of persons by air is an amount paid for taxable transportation and is therefore subject to the tax imposed by section 4261(a) of the Internal Revenue Code. *See* section 4261(e)(3)(A).

(b) *[Reserved]*

(c) *Applicability date.* This section applies to amounts paid on and after January 19, 2021.

■ **Par. 13.** Section 49.4261–10 is revised to read as follows:

§ 49.4261–10 Aircraft management services.

(a) *In general*—(1) *Overview.* This section prescribes rules relating to the exemption under section 4261(e)(5) of the Internal Revenue Code (Code) for amounts paid (in cash or in kind) by an aircraft owner to an aircraft management services provider for certain aircraft management services (aircraft management services exemption). Pursuant to section 4261(e)(5), the tax imposed by section 4261 of the Code does not apply to amounts paid by an aircraft owner to an aircraft management services provider for aircraft management services related to maintenance and support of the aircraft owner's aircraft; or related to flights on the aircraft owner's aircraft (flight services). The aircraft management services exemption applies to amounts paid by an aircraft owner to an aircraft management services provider for flight services on the aircraft owner's aircraft, even if the aircraft owner is not on the flight. The aircraft management services exemption does not apply to amounts paid to an aircraft management services provider by another person on behalf of an aircraft owner (other than in a principal-agent scenario in which the aircraft owner is the principal). In addition, amounts paid for aircraft management services by a party related to the aircraft owner are not amounts paid by the aircraft owner solely by virtue of the relationship between the aircraft owner and the related party. However, if an aircraft owner leases an aircraft to another person, including a related party, amounts paid by the lessee to an aircraft management services provider for aircraft management services related to the leased aircraft qualify for the aircraft management services exemption, provided the lease is not a disqualified lease and all other requirements of section 4261(e)(5) are satisfied. For example, amounts paid for aircraft management services by one member of an affiliated group (as that term is defined in section 4282 of the Code) for flights on an aircraft owned by another member of the affiliated group are not amounts paid by the aircraft owner unless the member owning the aircraft leases the aircraft to the member of the affiliated group that pays for the aircraft management services. *See* paragraph (b) of this section for definitions of terms used in this section.

(2) *Private aviation.* The aircraft management services exemption is limited to aircraft management services related to aircraft used in private aviation.

(3) *Adequate records required.* In order to qualify for the aircraft management services exemption, an aircraft owner and aircraft management services provider must maintain adequate records to show that the amounts paid by the aircraft owner to the aircraft management services provider relate to aircraft management services specifically for the aircraft owner's aircraft or for flights on the aircraft owner's aircraft and to support any allocations required under paragraph (c) under of this section. Such records may include the agreement, if any, between the aircraft owner and the aircraft management services provider, evidence of aircraft ownership, evidence that amounts paid for aircraft management services came from the aircraft owner, and the aircraft management services provider's fee schedule.

(b) *Definitions.* This paragraph provides definitions applicable to this section.

(1) *Aircraft management services.* The term *aircraft management services* means—

(i) *Statutory services.* The services listed in section 4261(e)(5)(B)(i)–(v); and

(ii) *Other services.* Any service (including, but not limited to, purchasing fuel, purchasing aircraft parts, and arranging for the fueling of an aircraft owner's aircraft) provided directly or indirectly to an aircraft owner in order to provide air transportation to the aircraft owner on the aircraft owner's aircraft at a level and quality of service required under the agreement between the aircraft owner and the aircraft management services provider.

(2) *Aircraft management services provider.* The term *aircraft management services provider* means a person that provides aircraft management services to an aircraft owner.

(3) *Aircraft owner*—(i) *In general.* Except as otherwise provided in this section, the term *aircraft owner* means a person that owns an aircraft managed by an aircraft management services provider (commonly referred to as a managed aircraft), or a person that leases a managed aircraft (lessee) pursuant to a lease that is not a disqualified lease. A person owns a managed aircraft if the person holds legal title to the aircraft, or if the person holds substantial incidents of ownership in the aircraft for a period of more than 31 days. A lessee includes the beneficiary of an owner trust that holds legal title to the managed aircraft.

(ii) *Persons not included in the definition of aircraft owner.* A lessee of an aircraft under a disqualified lease cannot be an aircraft owner with respect to the aircraft leased pursuant to the disqualified lease. A person that owns stock in a commercial airline does not qualify as an aircraft owner of that commercial airline's aircraft. A participant in a fractional aircraft ownership program, as defined in section 4043(c)(2) of the Code, does not qualify as an aircraft owner of the program's managed aircraft if the amount paid for such person's participation is exempt from the tax imposed by section 4261 reason of section 4261(j).

(4) *Disqualified lease.* The term *disqualified lease* has the meaning given to it by section 4261(e)(5)(C)(ii).

(5) *Fair market value.* The term *fair market value* means the value of comparable flights or services provided with respect to a comparable aircraft as of the date such flights or services are provided. The aircraft management services provider's published fee schedule in effect on the date(s) the flights or services are provided may be used as evidence of fair market value.

(6) *For-hire flight.* The term *for-hire flight* means the use of an aircraft to transport passengers for compensation that is paid in cash or in kind. The term includes, but is not limited to, charter flights, air taxi flights, and sightseeing flights (commonly referred to as flightseeing flights).

(7) *Owner trust.* The term *owner trust* means an arrangement in which legal title of an aircraft is held in the name of the trustee of the trust for the limited purpose of registering the aircraft in the United States with the Federal Aviation Administration pursuant to the registration requirements in 49 U.S.C. 40102(a) and 44102(a), and 14 CFR part 47.

(8) *Private aviation.* The term *private aviation* means the use of an aircraft for civilian flights, except scheduled passenger service for which tickets (or substitutes equivalent to tickets) are sold on a seat-by-seat basis to the general public. The term includes, but is not limited to, civilian flights operated under Part 135 (14 CFR part 135) of the Federal Aviation Regulations prescribed by the Federal Aviation Administration (FARs).

(9) *Substitute aircraft.* The term *substitute aircraft* means an aircraft, other than the aircraft owner's aircraft, that is provided by an aircraft management services provider to the aircraft owner when the aircraft owner's aircraft is not available, regardless of the reason for the unavailability.

(c) *Pro rata allocation*—(1) *In general.* Except as provided in paragraph (c)(2)(iii) of this section, when an amount paid to an aircraft management services provider includes a portion that is subject to the tax imposed by section 4261 and a portion that consists of amounts described in section 4261(e)(5)(A), the exception in section 4261(e)(5) applies on a pro rata basis only to the portion that consists of amounts described in section 4261(e)(5)(A). *See* section 4261(e)(5)(D). In such case, the tax base for the portion that is subject to the tax imposed by section 4261(a) is the amount paid for the flights or services, provided the amount paid is separable and shown in exact amounts in the records pertaining to the charge. If the portion of the amount paid that is subject to the tax imposed by section 4261(a) is not separable, the tax base is the fair market value of the flights or services. However, the tax base determined in the previous sentence may not exceed the total amount paid (that is, the sum of the portion that is subject to the tax imposed by section 4261(a) and the portion that consists of amounts described in section 4261(e)(5)(A)).

(2) *Substitute aircraft*—(i) *Flight treated as a charter.* If an aircraft management services provider provides a flight to an aircraft owner on a substitute aircraft, the flight is treated as a charter flight provided by the aircraft management services provider to the aircraft owner, regardless of whether the aircraft owner is on the flight, and the aircraft owner is treated as the charterer of such flight. If the flight constitutes taxable transportation, as defined in section 4262 of the Code, the tax imposed by section 4261(a) applies, unless the flight is exempt from such tax by reason of an exemption other than the aircraft management services exemption. See section 4261(b) and (c) for other taxes that may apply to flights provided by an aircraft management services provider to an aircraft owner on substitute aircraft.

(ii) *General rule for flights provided on substitute aircraft.* In cases where an aircraft management services provider provides a flight to an aircraft owner on a substitute aircraft and an allocation is required, the rule in paragraph (c)(1) of this section applies in determining the tax base. In all other cases, the tax base and the tax imposed by section 4261(a) thereon must be determined in accordance with the rules of § 49.4261–7(h)(1), unless the flight is otherwise exempt from such tax by reason of an exemption other than the aircraft management services exemption.

(iii) *Special rule for for-hire flights provided on substitute aircraft.* In cases where a substitute aircraft is used to provide a for-hire flight and an amount is paid for the flight by someone other than the aircraft owner, the tax base and the tax imposed by section 4261(a) thereon must be determined in accordance with the rules in § 49.4261–7(h)(2), unless the flight is otherwise exempt from such tax by reason of an exemption other than the aircraft management services exemption.

(d) *Choice of flight rules.* Whether a flight on an aircraft owner's aircraft operates pursuant to the rules under FARs Part 91 (14 CFR part 91) or pursuant to the rules under FARs Part 135 does not affect the application of section 4261(e)(5).

(e) *Aircraft available for hire.* Whether an aircraft owner permits an aircraft management services provider or other person to use its aircraft to provide for-hire flights (for example, when the aircraft is not being used by the aircraft owner or when the aircraft is being moved in deadhead service) does not affect the application of section 4261(e)(5). However, an amount paid for

for-hire flights on the aircraft owner's aircraft, except payments made by the aircraft owner, does not qualify for the aircraft management services exemption under section 4261(e)(5). Therefore, an amount paid by someone other than the aircraft owner for a for-hire flight on the aircraft owner's aircraft is subject to the tax imposed by section 4261 unless the flight is otherwise exempt from such tax by reason of an exemption other than the aircraft management services exemption. *See* § 49.4261–7(h) for rules relating to the application of the tax imposed by section 4261 on amounts paid for certain charter flights.

(f) *Billing methods.* Except as otherwise provided in this section, the method an aircraft management services provider bills, invoices, or otherwise charges an aircraft owner for aircraft management services, whether by specific itemization of costs, flat monthly or hourly fee, or otherwise, does not affect the application of section 4261(e)(5).

(g) *Multiple aircraft management services providers not disqualifying.* Whether an aircraft owner pays amounts to more than one aircraft management services provider for aircraft management services does not affect the application of section 4261(e)(5).

(h) *Examples.* The following examples illustrate the provisions of this section.

(1) *Example 1*—(i) *Facts.* During the first quarter of 2021, an aircraft owner pays a $3,000 monthly management fee to an aircraft management services provider for services related to operating the aircraft owner's aircraft. The aircraft owner used its own aircraft for all but one of the flights the owner took during the period. On the one occasion that the aircraft owner's aircraft was unavailable when the aircraft owner wanted to fly, the aircraft management services provider used a substitute aircraft to transport the aircraft owner. The flight was within the continental United States and the aircraft owner received no compensation for the transportation of other passengers on the flight. The aircraft owner paid $1,000 for the flight on the substitute aircraft. The aircraft management services provider included the $1,000 charge for the substitute aircraft as a separate line item on the monthly management fee invoice.

(ii) *Analysis.* The tax imposed by section 4261(a) applies to services that do not qualify for the section 4261(e)(5) exemption; in this case, the flight provided on the substitute aircraft. The flight provided on the substitute aircraft is treated as a charter flight for purposes of the tax imposed by section 4261(a), and the owner is treated as the charterer of the flight. The amount paid by the aircraft owner for the flight on the substitute aircraft is the section 4261(a) tax base. The monthly invoice from the aircraft management services provider to the aircraft owner included a line item in the amount of $1,000 for the charter flight. Because $1,000 is the actual amount paid for the flight, this amount is the section 4261(a) tax base. The tax imposed by section 4261(b) also applies to the flight on a per-passenger basis. *See* § 49.4261–2(b) for rules regarding the application of the tax imposed by section 4261(b).

(2) *Example 2*—(i) *Facts.* Same facts as in paragraph (h)(1) of this section (Example 1), except the invoice does not show the amount paid for the flight on the substitute aircraft and that amount is not otherwise separable from the monthly management fee. The fair market value of the flight on the substitute aircraft is $1,000.

(ii) *Analysis.* The tax imposed by section 4261(a) applies to the flight provided on the substitute aircraft. The amount paid for the flight on the substitute aircraft is not otherwise separable from the monthly management fee. Because $1,000 is the fair market value of the flight, and such amount does not exceed the $3,000 monthly management fee paid by the aircraft owner, this amount is the section 4261(a) tax base. The tax imposed by section 4261(b) also applies to the flight on a per-passenger basis. *See* § 49.4261–2(b) for rules regarding the application of the tax imposed by section 4261(b).

(3) *Example 3*—(i) *Facts.* An aircraft owner pays a monthly management fee to an aircraft management services provider for aircraft management services related to the aircraft owner's aircraft. When the aircraft is not being used by the owner, the owner sometimes permits a charter company to use the aircraft to provide charter flights. At other times when the aircraft is not being used by the owner, the owner permits a tour operator to use the aircraft for flightseeing tours. All charter and flightseeing flights on the aircraft constitute taxable transportation, as that term is defined in section 4262, and no exemptions (other than section 4261(e)(5)) apply. No charter or flightseeing flights are provided on a substitute aircraft. The aircraft's maximum certificated takeoff weight is 7,000 pounds.

(ii) *Analysis.* Amounts paid by the aircraft owner to the aircraft management services provider for aircraft management services related to the aircraft owner's aircraft are exempt under section 4261(e)(5). Amounts paid by the charterer or passengers for the charter flights are subject to tax under section 4261(a) and (b). *See* § 49.4261–7(h) for rules relating to the application of the tax imposed by section 4261 on amounts paid for charter flights. *See* § 49.4261–2(b) for rules regarding the application of the tax imposed by section 4261(b). Amounts paid by flightseeing customers for flightseeing tours are also subject to tax under section 4261(a) and (b). If a payment for a flightseeing tour includes charges for nontransportation services, the charges for the nontransportation services may be excluded in computing the tax payable provided the payments are separable and provided in exact amounts. *See* § 49.4261–2(c).

(i) *Applicability date.* This section applies to amounts paid on and after January 19, 2021.

§ 49.4262(a)–1 [Redesignated]

■ **Par. 14.** Section 49.4262(a)–1 is redesignated as § 49.4262–1.

■ **Par. 15.** Newly redesignated § 49.4262–1 is amended by:

■ 1. In paragraph (a) introductory text, removing ''section 4262(b) (see § 49.4262(b)–1)'' and adding ''section 4262(b) of the Internal Revenue Code (Code) (see § 49.4262–2)'' in its place.

■ 2. In the first sentence of paragraph (a)(1), removing ''Transportation'' and adding ''Transportation by air'' in its place.

■ 3. In the first sentence of paragraph (a)(1), removing ''(the ''225-mile zone'')'' and adding ''(225-mile zone)'' in its place.

■ 4. Revising paragraph (a)(2).

■ 5. In paragraph (b), removing ''subparagraphs (1) and (5) of this paragraph'' and adding ''paragraph (b)(1) and (5) of this section'' in its place.

■ 6. In paragraph (b), removing ''subject to the tax'' and adding ''subject to the taxes imposed by section 4261(a) and (b)'' in its place.

■ 7. Revising paragraph (b)(2).

■ 8. Removing and reserving paragraph (c).

■ 9. Revising introductory paragraph (d); designating *Example (1)* as paragraph (d)(1) and revising newly designated paragraph (d)(1).

■ 10. In paragraph (d):

■ a. Designating *Example (2)* as paragraph (d)(2) and removing and reserving newly designated paragraph (d)(2).

■ b. Designating *Example (3)* as paragraph (d)(3) and removing ''6 hours'' wherever it appears and adding ''12 hours'' in its place and also removing ''subject to tax'' wherever it appears and adding ''subject to the taxes

imposed by section 4261(a) and (b)'' in its place.

■ c. Designating *Example (4)* as paragraph (d)(4), and removing ''six hours'' wherever it appears and adding ''12 hours'' in its place and also removing ''subject to tax'' wherever it appears and adding ''subject to the taxes imposed by section 4261(a) and (b)'' in its place.

■ 11. Revising paragraph (e).

■ 12. Adding paragraph (f).

The revisions and addition read as follows:

§ 49.4262–1 Taxable transportation.

(a) * * *

(2) In the case of any other transportation by air, that portion of such transportation that is directly or indirectly from one port or station in the United States to another port or station in the United States, but only if such transportation is not part of *uninterrupted international air transportation* within the meaning of section 4262(c)(3) of the Code and § 49.4262–3(c). Transportation from one port or station in the United States occurs whenever a carrier, after leaving any port or station in the United States, makes a regularly scheduled stop at another port or station in the United States irrespective of whether stopovers are permitted or whether passengers disembark.

* * * * *

(b) * * *

(2) New York to Vancouver, Canada, with a stop at Toronto, Canada;

* * * * *

(d) *Examples.* The following examples illustrate the application of section 4262(a)(2) and the taxes imposed by section 4261(a) and (b) of the Code:

(1) *Example (1).* A purchases in New York a ticket for air transportation from New York to Nassau, Bahamas, with a scheduled stopover of 14 hours in Miami. The part of the transportation from New York to Miami is taxable transportation as defined in section 4262(a) because such transportation is from one station in the United States to another station in the United States and the trip is not uninterrupted international air transportation (because the scheduled stopover interval in Miami is greater than 12 hours). Therefore, the amount paid for the transportation from New York to Miami is subject to the taxes imposed by section 4261(a) and (b).

* * * * *

(e) *Examples of transportation that is not taxable transportation.* The following examples illustrate transportation that is not taxable transportation:

(1) New York to Trinidad with no intervening stops;

(2) Minneapolis to Edmonton, Canada, with a stop at Winnipeg, Canada;

(3) Los Angeles to Mexico City, Mexico, with stops at Tijuana and Guadalajara, Mexico;

(4) New York to Whitehorse, Yukon Territory, Canada, by air with a scheduled stopover in Chicago of five hours. Amounts paid for the transportation referred to in examples set forth in paragraphs (e)(1), (2), and (3) of this section are not subject to the tax regardless of where payment is made, since none of the trips:

(i) Begin in the United States or in the 225–mile zone and end in the United States or in the 225–mile zone, nor

(ii) Contain a portion of transportation which is directly or indirectly from one port or station in the United States to another port or station in the United States. The amount paid within the United States for the transportation referred to in the example set forth in paragraph (4) of this section is not subject to tax since the entire trip (including the domestic portion thereof) is *uninterrupted international air transportation* within the meaning of section 4262(c)(3) and § 49.4262–3(c). In the event the transportation is paid for outside the United States, no tax is due since the transportation does not begin and end in the United States.

* * * * *

(f) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4262(b)–1 [Redesignated]

■ **Par. 16.** Section 49.4262(b)–1 is redesignated as § 49.4262–2.

■ **Par. 17.** Newly redesignated § 49.4262–2 is amended as follows:

■ 1. In paragraph (a), ''section 4262(b)'' is removed and ''section 4262(b) of the Internal Revenue Code'' is added in its place.

■ 2. In paragraph (b)(2), *Example (2)* is removed and reserved.

■ 3. Revise paragraph (d).

■ 4. Add paragraph (e).

The revisions and additions read as follows:

§ 49.4262–2 Exclusion of certain travel.

* * * * *

(d) *Example.* The application of paragraph (c) of this section may be illustrated by the following example: A purchases in San Francisco a ticket for transportation by air to Honolulu, Hawaii. The portion of the transportation which is outside the continental United States and is outside Hawaii is excluded from taxable transportation. The tax applies to that part of the payment made by A which is applicable to the portion of the transportation between the airport in San Francisco and the three-mile limit off the coast of California (a distance of 15 miles) and between the three-mile limit off the coast of Hawaii and the airport in Honolulu (a distance of 5 miles). The part of the payment made by A which is applicable to the taxable portion of his transportation and the tax due thereon are computed in accordance with paragraph (c)(1) as follows:

TABLE 1 TO PARAGRAPH (d)

Mileage of entire trip (San Francisco airport to Honolulu airport) (miles)	2,400
Mileage in continental United States (miles)	15
Mileage in Hawaii (miles)	5
	20
Fare from San Francisco to Honolulu	$168.00
Payment for taxable portion (20/2400 × $168)	$1.40
Tax due (7.5% (rate in effect on date of payment) × $1.40)	$0.11

(All distances and fares assumed for purposes of this example. This example addresses only the computation of the tax imposed by section 4261(a). It does not address the computation of any other tax imposed by section 4261 that may apply to these facts.)

(e) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply

before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4262(c)–1 [Redesignated]

■ **Par. 18.** Section 49.4262(c)–1 is redesignated as § 49.4262–3.

■ **Par. 19.** Newly redesignated § 49.4262–3 is amended as follows:

■ 1. In the first sentence of paragraph (a), removing ''includes only the 48 States existing on July 25, 1956 (the date of the enactment of the Act of July 25, 1956 (Pub. L. 796, 84th Cong., 70 Stat. 644)) and the District of Columbia'' and adding ''means the District of Columbia and the States other than Alaska and Hawaii'' in its place.

■ 2. In paragraph (a), the last sentence is removed.

■ 3. In paragraph (c), removing ''six hours'' wherever it appears and adding ''12 hours'' in its place.

■ 4. In paragraph (c), removing ''6 hours'' wherever it appears and add ''12 hours'' in its place.

■ 5. In paragraph (c), removing ''six-hour'' wherever it appears and adding ''12-hour'' in its place.

■ 6. In paragraph (c)(2), removing ''paragraph (a)(2) of § 49.4264(c)–1'' and adding ''§ 49.4263–3(a)(2)'' in its place.

■ 7. Adding paragraphs (d) and (e).

The additions read as follows:

§ 49.4262–3 Definitions.

* * * * *

(d) *Transportation.* For purposes of the regulations in this subpart, the term *transportation* includes layover or waiting time and movement of the aircraft in deadhead service.

(e) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4263–5 [Redesignated]

■ **Par. 20.** Section 49.4263–5 is redesignated as § 49.4281–1.

■ **Par. 21.** Newly redesignated § 49.4281–1 is amended by:

■ 1. Revising paragraphs (a) and (b).

■ 2. In paragraph (c), adding a sentence at the end of the paragraph.

■ 3. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 49.4281–1 Small aircraft on nonestablished lines.

(a) *In general.* Amounts paid for the transportation of persons on a small aircraft of the type sometimes referred to as air taxis shall be exempt from the tax imposed under section 4261 of the Internal Revenue Code provided the aircraft has a maximum certificated takeoff weight of 6,000 pounds or less determined as provided in paragraph (b) of this section. The exemption does not apply, however, when the aircraft is operated on an established line or when the aircraft is a jet aircraft.

(b) *Maximum certificated takeoff weight.* The term *maximum certificated takeoff weight* means the maximum certificated takeoff weight shown in the type certificate or airworthiness certificate issued by the Federal Aviation Administration.

(c) * * * An aircraft is not considered as operated on an established line at any time during which the aircraft is being operated on a flight the sole purpose of which is sightseeing.

(d) *Jet aircraft.* For purposes of this section, the term *jet aircraft* does not include any aircraft which is a rotorcraft (such as a helicopter) or propeller aircraft.

(e) *Applicability date.* This section applies to amounts paid on and January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4264(a)–1 [Redesignated]

■ **Par. 22.** Section 49.4264(a)–1 is redesignated as § 49.4263–1.

■ **Par. 23.** Newly redesignated § 49.4263–1 is revised to read as follows:

§ 49.4263–1 Duty to collect the tax; payments made outside the United States.

(a) *Duty to collect tax.* Where payment upon which tax is imposed by section 4261 of the Internal Revenue Code is made outside the United States for a prepaid order, exchange order, or similar order, the person furnishing the initial transportation pursuant to such order must collect the applicable tax. *See* section 4291 and the regulations under section 4291 for cases where persons receiving payment must collect the tax. *See* section 6672 for rules relating to the application of the trust fund recovery penalty.

(b) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4264(b)–1 [Redesignated]

■ **Par. 24.** Section 49.4264(b)–1 is redesignated as § 49.4263–2.

§ 49.4263–2 [Amended]

■ **Par. 25.** Newly redesignated § 49.4263–2 is amended as follows:

■ 1. In the first sentence of paragraph (a), removing ''4264(b)'' and adding ''4263(b) of the Internal Revenue Code (Code)'' in its place.

■ 2. In the last sentence of paragraph (a), removing ''office of the district director for the district in which the person making the report is located,'' and adding ''Commissioner'' in its place.

■ 3. In paragraph (b), adding ''of the Code'' at the end of the paragraph.

■ 4. In paragraph (c), removing ''*Illustration.*'' and adding ''*Example.*'' in its place.

■ 5. In the last sentence of paragraph (c), removing ''office of the district director of internal revenue for the district in which the carrier is located,'' and adding in its place ''Commissioner''.

§ 49.4264(c)–1 [Redesignated]

■ **Par. 26.** Section 49.4264(c)–1 is redesignated as § 49.4263–3.

■ **Par. 27.** Newly redesignated § 49.4263–3 is amended by:

■ 1. Revising paragraph (a).

■ 2. In paragraph (b), removing the second sentence.

■ 3. In paragraph (b), removing ''4264'' wherever it appears and adding ''4263'' in its place.

■ 4. In paragraph (b), adding ''of the Code'' after ''4291'' in the first sentence.

■ 5. Removing and reserving paragraph (c).

■ 6. Adding paragraph (d).

The revisions and additions read as follows:

§ 49.4263–3 Special rule for the payment of tax.

(a) *In general.* For the rules applicable under section 4263(c) of the Internal Revenue Code, see § 49.4261–1(b)(2).

* * * * *

(d) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4264(d)–1 [Redesignated]

■ **Par. 28.** Section 49.4264(d)–1 is redesignated as § 49.4263–4.

§ 49.4263–4 [Amended]

■ **Par. 29.** Newly redesignated § 49.4263–4 is amended by removing ''4264(d)'' and adding ''4263(d)'' in its place.

§ 49.4264(e)–1 [Redesignated]

■ **Par. 30.** Section 49.4264(e)–1 is redesignated as § 49.4263–5.

§ 49.4264(f)–1 [Redesignated]

■ **Par. 31.** Section 49.4264(f)–1 is redesignated as § 49.4263–6.

§ 49.4263–6 [Amended]

■ **Par. 32.** Newly redesignated § 49.4263–6 is amended by removing and reserving paragraph (b).

■ **Par. 33.** Section 49.4271–1 is amended by revising paragraphs (a) and (b) and adding paragraph (g) to read as follows:

§ 49.4271–1 Tax on transportation of property by air.

(a) *Purpose of this section.* Section 4271 of the Internal Revenue Code (Code) imposes a 6.25 percent tax on amounts paid within or without the United States for the taxable transportation of property (as defined in section 4272 of the Code). This section sets forth rules as to the general applicability of the tax. This section also sets forth rules authorized by section 4272(b)(2) which exempt from tax payments for the transportation of property by air in the course of exportation (including shipment to a possession of the United States) by continuous movement, and in due course so exported.

(b) *Imposition of tax*—(1) The tax imposed by section 4271 applies only to amounts paid to persons engaged in the business of transporting property by air for hire.

(2) The tax imposed by section 4271 does not apply to amounts paid for the transportation of property by air if such transportation is furnished on an aircraft having a maximum certificated takeoff weight (as defined in section 4281(b) of the Code) of 6,000 pounds or less, unless such aircraft is operated on an established line or when such aircraft is a jet aircraft. The tax imposed by section 4271 also does not apply to any payment made by one member of an affiliated group (as defined in section 4282(b) of the Code) to another member of such group for services furnished in connection with the use of an aircraft if such aircraft is owned or leased by a member of the affiliated group and is not available for hire by persons who are not members of such group.

* * * * *

(g) *Applicability date.* This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

■ **Par. 34.** Section 49.4271–2 is added to read as follows:

§ 49.4271–2 Aircraft management services.

For rules regarding the exemption for certain amounts paid by aircraft owners for aircraft management services, see § 49.4261–10. This section applies to amounts paid on and after January 19, 2021. For rules that apply before that date, *see* 26 CFR part 49, revised as of April 1, 2020.

§ 49.4282–1 [Reserved]

■ **Par. 35.** Add and reserve § 49.4282–1.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: January 10, 2021.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2021–00706 Filed 1–14–21; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF EDUCATION

34 CFR Parts 600, 602, 668, 673, 674, 682, and 685

Federal Student Aid Programs (Student Assistance General Provisions, Federal Perkins Loan Program, William D. Ford Federal Direct Loan Program, and Federal-Work Study Programs)

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Updated waivers and modifications of statutory and regulatory provisions; correction.

SUMMARY: On December 11, 2020, the Department of Education published in the **Federal Register** a notice updating waivers and modifications of statutory and regulatory provisions governing the Federal student financial aid programs under the authority of the Higher Education Relief Opportunities for Students Act of 2003 (HEROES Act). This document corrects the date through which certain waivers and modifications extend.

DATES: Effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Barbara Hoblitzell, by telephone: (202) 453–7583 or by email: *Barbara.Hoblitzell@ed.gov,* or Gregory Martin, by telephone: (202) 453–7535 or by email: *Gregory.Martin@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Corrections: In FR document 2020–27042, appearing on page 79856 in the **Federal Register** of December 11, 2020, the following corrections are made:

1. On page 79857, in the third column, in the third paragraph, in the third sentence, remove the word ''further'', and add a new fourth sentence ''On December 4, 2020, the Secretary further extended those benefits through January 31, 2021.''

2. On page 79862, in the first column, in the section titled ''Repayment of a Loan (34 CFR 682.209)'', remove the fifth sentence and add in its place ''Following the President's Memorandum of August 8, 2020, and the Secretary's subsequent announcement on December 4, 2021, the Secretary is further extending until January 31, 2021, in accordance with the prior announcement, the waivers of the regulatory provisions in §§ 682.202 and 682.209 that require that interest be charged on FFEL loans held by the Department from March 13, 2020, through March 27, 2020, and from October 1, 2020 through January 31, 2021.''

3. On page 79862, in the second column, in the section titled ''Obligation to Repay (34 CFR 685.207)'', remove the fifth, sixth, and seventh sentences and add in their place ''The period of this benefit was extended to December 31, 2020 by the President's Memorandum of August 8, 2020. On December 4, 2020, the Secretary further extended the period of this benefit through January 31, 2021. Accordingly, Direct Loans are automatically placed in an administrative forbearance status that is currently scheduled to be in effect from March 13, 2020, through January 31, 2021.''

4. On page 79863, in the first column, in the section titled ''Capitalization of Interest Under the Income-Contingent Repayment Plan (34 CFR 685.209)'', in the second paragraph, remove ''January'' and add in its place ''February''.

5. On page 79863, in the first column, in the section titled ''Capitalization of Interest Under the Income-Contingent Repayment Plan (34 CFR 685.209)'', in the fourth paragraph, remove ''December 31, 2020'' and add in its place ''January 31, 2021''.

6. On page 79863, in the second column, in the section titled ''Section 3513 of the CARES Act'', remove the second paragraph and add in its place ''On August 8, 2020, the President issued a memorandum directing the Secretary to continue to waive interest and payments on such loans until December 31, 2020. On December 4, 2020, the Secretary further extended these benefits through January 31, 2021. Therefore, in accordance with the prior announcement, the Secretary is using her authority under the HEROES Act to modify the terms of the benefits provided under section 3513 of the CARES Act such that they will continue to be provided to borrowers until January 31, 2021.''

Accessible Format: On request to one of the program contact persons listed under **FOR FURTHER INFORMATION**

CONTACT, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at: *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Robert L. King,

Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2020–28105 Filed 1–15–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2020–OESE–0037]

Final Priorities, Requirements, Definitions, And Selection Criteria—Promise Neighborhoods (PN) Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final priorities, requirements, definitions, and selection criteria.

SUMMARY: The Assistant Secretary for the Office of Elementary and Secondary Education announces priorities, requirements, definitions, and selection criteria under the PN program, Assistance Listing Number 84.215N. The Assistant Secretary may use one or more of these priorities, requirements, definitions, and selection criteria for competitions in fiscal year (FY) 2021 and later years. We take this action to make program improvements based on lessons learned over the last decade and to improve program outcomes.

DATES: These priorities, requirements, definitions, and selection criteria are effective February 18, 2021.

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW, Room 4W220, Washington, DC 20202. Telephone: (202) 453–5638. Email: *Adrienne.Hawkins@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The PN program is authorized under the Elementary and Secondary Education Act of 1965, as amended (ESEA). The purpose of the PN program is to significantly improve the academic and developmental outcomes of children living in the most distressed communities of the United States, including ensuring school readiness, high school graduation, and access to a community-based continuum of high-quality services. The program serves neighborhoods with high concentrations of low-income individuals; multiple signs of distress, which may include high rates of poverty, childhood obesity, academic failure, and juvenile delinquency, adjudication, or incarceration; and schools implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA. All strategies in the continuum of solutions must be accessible to children with disabilities and English learners.

Program Authority: 20 U.S.C. 7273–7274.

We published a notice of proposed priorities, requirements, definitions, and selection criteria (NPP) for this program in the **Federal Register** on June 29, 2020 (85 FR 38801). The NPP contained background information and our reasons for proposing the particular priorities, requirements, definitions, and selection criteria.

Except for minor editorial and technical revisions, there are no differences between the proposed priorities, requirements, definitions, and selection criteria and these final priorities, requirements, definitions, and selection criteria.

Public Comment: In response to our invitation in the NPP, eight comments were received, two of which were relevant to the proposed priorities, requirements, definitions, and selection criteria.

Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the NPP.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the proposed priorities, requirements, definitions, and selection criteria follows.

Comment: One commenter noted the importance of child nutrition to successful outcomes and recommended that we include a focus on nutrition education.

Discussion: While we agree with the commenter that there is a need to focus on nutrition education, we do not believe that it is necessary to revise the proposed priorities, requirements, definitions, or selection criteria to address this specific need. Under the program statute, applicants already have flexibility to propose interventions or strategies to address nutrition needs for children, their families, and community members.

Changes: None.

Comment: One commenter asserted that the application requirements are too burdensome for applicants that are small entities. The commenter also contended that, by allowing projects to focus on different issues impacting low-income children, it may be difficult to fairly compare applications in the selection process. The commenter stated that applications should be evaluated to determine whether the proposed project would significantly improve the academic outcomes of the children proposed to be served and whether the proposed project is supported by a needs analysis and evidence-based practices.

Discussion: We appreciate the comment regarding the size of the applying entity and burden level. In recognition of this relationship we have established three priorities to level the playing field for all applicants. Two of the three priorities, Non-Rural and Non-Tribal Communities, and Tribal Communities, can be found elsewhere in this NFP. The Rural Communities priority can be found in the program statute.

Regarding the commenter's concern that applications be fairly considered during the selection process, the peer review process is designed for applications to be evaluated against selection criteria alone; we instruct our peer reviewers not to compare applications. Additionally, applicants should design projects that meet the needs of their respective communities, a key element of a successful PN project. Our peer reviewers rely on the

information provided in each application to determine whether an applicant's plan is appropriate for the context in which the project would operate.

Finally, we appreciate and agree with the comment that funded projects should improve academic outcomes of the students served and this can be achieved, in part, by ensuring that the proposed project is supported by a needs analysis and proposed interventions that are evidence-based. We maintained the requirement included in the NPP that the proposed project be supported by a needs analysis and that proposed interventions, to the extent possible, be evidence-based. We believe this requirement in addition to the evidence-based priority addresses the commenter's concern.

Changes: None.

Comment: None.

Discussion: In reviewing the proposed requirements further, we have decided to clarify that applicants must describe proposed activities to address needs and the extent to which activities are evidence-based. Additionally, an applicant must also describe its, or its partner organization's, if applicable, experience providing these activities, including any data demonstrating effectiveness. These two modifications are intended to strengthen projects and yield higher academic outcomes for students.

Changes: We have clarified the language to require applicants to provide a description of the proposed activities and to ensure that the proposed activities are in alignment with the applicant's identified needs. Also, the applicant must include the extent to which the proposed activities are evidence-based. Furthermore, the applicant must also describe its, or its partner organization's, if applicable, experience providing the proposed activities and any data demonstrating effectiveness in the application.

Final Priorities

Priority 1—Non-Rural and Non-Tribal Communities

To meet this priority, an applicant must propose to implement a PN strategy that serves one or more non-rural or non-Tribal communities.

Priority 2—Tribal Communities

To meet this priority, an applicant must propose to implement a PN strategy that serves one or more Indian Tribes.

Priority 3—Community-Level Opioid Abuse Prevention Efforts

To meet this priority, an applicant must: (1) Demonstrate how it will partner with an organization that conducts high-quality, community-level activities to prevent opioid abuse, such as an organization supported by an Office of National Drug Control Policy, Drug-Free Communities Support Program grant, in PN communities; (2) describe the partner organization's record of success in approaching opioid abuse prevention at the community level; and (3) provide, in its application, a memorandum of understanding between it and the partner organization responsible for managing the effort. The memorandum of understanding must indicate a commitment on the part of the applicant to coordinate implementation and align resources to the greatest extent practicable.

Priority 4—Evidence-Based Activities To Support Academic Achievement

Projects that propose to use evidence-based (as defined in 34 CFR 77.1(c)) activities, strategies, or interventions that support teaching practices that will lead to increased student achievement, graduation rates, and career readiness.

Priority 5—Community-Based Crime Reduction Efforts

To meet this priority, an applicant must: (1) Demonstrate how it will partner with an organization that conducts high-quality activities focused on the re-entry of formerly incarcerated individuals or on community-based crime reduction activities, such as an organization supported by a U.S. Department of Justice (DOJ) Innovations in Community-Based Crime Reduction Program grant, a grant authorized under the Second Chance Act, as reauthorized under the Formerly Incarcerated Reenter Society Transformed Safely Transitioning Every Person (FIRST STEP) Act, or DOJ Office of Justice Programs competitive grants related to juvenile justice and delinquency prevention; (2) describe the partner organization's record of success with supporting the re-entry of formerly incarcerated individuals or community-based crime reduction and how their efforts will be coordinated with the PN activities of this grant; and (3) provide, in its application, a memorandum of understanding between it and a partner organization managing the effort. The memorandum of understanding must indicate a commitment on the part of the applicant to coordinate implementation and align resources to the greatest extent practicable.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Requirements

The Assistant Secretary establishes the following application requirements for this program. We may apply one or more of these requirements in any year in which this program is in effect.

To be considered for an award under this competition, an applicant must provide the following—

(1) In addressing the application requirements in sections 4624(a)(4), (5), and (7) of the ESEA, an applicant must clearly demonstrate needs, including a segmentation analysis, gaps in services, and any available data from within the last 3 years to demonstrate needs. The applicant must also describe proposed activities that address these needs and the extent to which these activities are evidence-based (as defined in 34 CFR 77.1(c)). The applicant must also describe its, or its partner organization's, if applicable, experience providing these activities, including any data demonstrating effectiveness.

(2) In addressing the requirement in section 4624(a)(6) of the ESEA, an applicant must provide a description of the process used to develop the application, which must include the involvement of an LEA(s) (including but not limited to the LEA's or LEAs' involvement in the creation and planning of the application and a signed Memorandum of Understanding) and at least one public elementary or secondary school that is located within

the identified geographic area that the grant will serve.

(3) An applicant must demonstrate that its proposed project—

(a) Is representative of the geographic area proposed to be served; and

(b) Would provide a majority of the solutions from the applicant's proposed pipeline services in the geographic area proposed to be served.

(4) In addressing the requirement in section 4624(a)(9) of the ESEA, an applicant must describe the process it will use to establish and maintain a family navigation system, including an explanation of the process the applicant will use to establish and maintain family and community engagement.

Final Definitions

The Assistant Secretary establishes the following definitions for this program. We may apply one or more of these definitions in any year in which this program is in effect.

Family navigation system means a service delivery model that includes coordinators who teach, mentor, and collaborate with students and their families, as well as community members, to choose interventions, treatments, or solutions provided by the grantee and that best meet the needs of students and their families. Students and their families can select services and supports based on available services and individual needs, as well as advocate for additional services.

Graduation rate means the four-year adjusted cohort graduation rate or extended-year adjusted cohort graduation rate as defined in section 8101(25) and (23) of the ESEA.

Indian Tribe means an Indian Tribe or Tribal Organization as defined in section 4 of the Indian Self-determination Act (25 U.S.C. 450b).

Indicators of need means currently available data that describe—

(a) Education need, which means—

(1) All or a portion of the neighborhood includes or is within the attendance zone of a low-performing school that is a high school, especially one in which the graduation rate is less than 60 percent or a school that can be characterized as low-performing based on another proxy indicator, such as students' on-time progression from grade to grade; and

(2) Other indicators, such as significant achievement gaps between subgroups of students (as identified in section 1111(b)(2)(B)(xi) of the ESEA), within a school or LEA, high teacher and principal turnover, or high student absenteeism; and

(b) Family and community support need, which means—

(1) Percentages of children with preventable chronic health conditions (*e.g.,* asthma, poor nutrition, dental problems, obesity) or avoidable developmental delays;

(2) Immunization rates;

(3) Rates of crime, including violent crime;

(4) Student mobility rates;

(5) Teenage birth rates;

(6) Percentage of children in single parent or no-parent families;

(7) Rates of vacant or substandard homes, including distressed public and assisted housing; or

(8) Percentage of the residents living at or below the Federal poverty threshold.

Regular high school diploma has the meaning set out in section 8101(43) of the ESEA.

Representative of the geographic area proposed to be served means that residents of the geographic area proposed to be served have an active role in decision-making and that at least one-third of the applicant's governing board or advisory board is made up of—

(a) Residents who live in the geographic area proposed to be served, which may include residents who are representative of the ethnic and racial composition of the neighborhood's residents and the languages they speak;

(b) Residents of the city or county in which the neighborhood is located but who live outside the geographic area proposed to be served, and who earn less than 80 percent of the area's median income as published by the U.S. Department of Housing and Urban Development;

(c) Public officials who serve the geographic area proposed to be served (although not more than one-half of the governing board or advisory board may be made up of public officials); or

(d) Some combination of individuals from the three groups listed in paragraphs (a), (b), and (c) of this definition.

Segmentation analysis means the process of grouping and analyzing data from children and families in the geographic area proposed to be served according to indicators of need or other relevant indicators to allow grantees to differentiate and more effectively target interventions based on the needs of different populations in the geographic area.

Student achievement means—

(a) For tested grades and subjects—

(1) A student's score on the State's assessments under the ESEA; and

(2) As appropriate, other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across classrooms and programs; and

(b) For non-tested grades and subjects, alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across classrooms.

Student mobility rate is calculated by dividing the total number of new student entries and withdrawals at a school, from the day after the first official enrollment number is collected through the end of the academic year, by the first official enrollment number of the academic year.

Final Selection Criteria

The Assistant Secretary establishes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria in any year in which this program is in effect.

(a) *Need for project.* In determining the need for the proposed project, the Secretary considers one or more of the following factors—

(1) The magnitude or severity of the problems to be addressed by the proposed project as described by indicators of need and other relevant indicators identified in part by the needs assessment and segmentation analysis; and

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including—

(i) The nature and magnitude of those gaps or weaknesses; and

(ii) A pipeline of solutions addressing the identified gaps and weaknesses, including solutions targeted to early childhood, K–12, family and community supports, and college and career.

(b) *Quality of project design.* In determining the quality of project design for the proposed project, the Secretary considers one or more of the following factors—

(1) The extent to which the applicant describes a plan to create a complete pipeline of services, without time and resource gaps, that is designed to prepare all children in the neighborhood to attain a high-quality education and successfully transition to college and a career;

(2) The extent to which the project will significantly increase the proportion of students in the neighborhood that are served by the

complete continuum of high-quality services; and

(3) The extent to which the proposed family navigation system is high-quality and provides students and their families sufficient services and supports based on available services and individual needs.

This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use these priorities, requirements, definitions, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new regulation that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2021, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. Because these regulations are not a significant regulatory action, the requirements of Executive Order 13771 do not apply.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these final priorities, requirements, definitions, and selection criteria only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. We have determined that these regulations will impose minimal costs on eligible applicants. Program participation is voluntary, and the costs imposed on applicants by these regulations will be limited to paperwork burden related to preparing an application. The potential benefits of implementing the programs—for example, expanding the choices available to parents and students, improving the academic and developmental outcomes of children living in the most distressed communities of the United States—will outweigh any costs incurred by applicants, and the costs of carrying out activities associated with the application will be paid for with program funds. For these reasons, we have determined that the costs of implementation will be minimal for eligible applicants.

Regulatory Flexibility Act Certification

The Secretary certifies that this regulatory action will not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define ''small entities'' as for-profit or nonprofit institutions with total annual revenue below $7,000,000 or, if they are institutions controlled by small governmental jurisdictions (that are comprised of cities, counties, towns, townships, villages, school districts, or special districts), with a population of less than 50,000.

The small entities that this regulatory action will affect are State educational agencies; LEAs, including charter schools that operate as LEAs under State law; institutions of higher education; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations. We believe that the costs imposed on an applicant by the priorities, requirements, definitions, and selection criteria will be limited to paperwork burden related to preparing an application and that the benefits of the priorities, requirements, definitions, and selection criteria will outweigh any costs incurred by the applicant.

Participation in the PN program is voluntary. For this reason, the priorities,

requirements, definitions, and selection criteria will impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for PN program funds, an applicant will evaluate the requirements of preparing an application and any associated costs, and weigh them against the benefits likely to be achieved by receiving a PN program grant. An applicant will probably apply only if it determines that the likely benefits exceed the costs of preparing an application.

We believe that the priorities, requirements, definitions, and selection criteria will not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of this regulatory action. That is, the length of the applications those entities would submit in the absence of this regulatory action and the time needed to prepare an application would likely be the same.

This regulatory action will not have a significant economic impact on a small entity once it receives a grant because it will be able to meet the costs of compliance using the funds provided under this program.

Paperwork Reduction Act of 1995: The proposed priorities, requirements, definitions, and selection criteria contain information collection requirements that are approved by OMB under OMB control number 1894–0006; the proposed priorities, requirements, definitions, and selection criteria do not affect the currently approved data collection.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides early notification of our specific plans and actions for this program.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at: *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Frank T. Brogan,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2021–00902 Filed 1–15–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2020–0372; FRL–10019–21–OAR]

RIN 2060–AU91

Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is finalizing amendments to the Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. We are finalizing specific amendments that would allow owners or operators of storage vessels subject to the Standards of Performance for Volatile Organic Liquid Storage Vessels and equipped with either an external floating roof (EFR) or internal floating roof (IFR) to voluntarily elect to comply with the requirements specified in the National Emission Standards for Storage Vessels (Tanks)—Control Level 2, as an alternative standard, in lieu of the requirements specified in the Standards of Performance for Volatile Organic Liquid Storage Vessels, subject to certain caveats and exceptions for monitoring, recordkeeping, and reporting.

DATES: The final rule is effective on January 19, 2021.

ADDRESSES: The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2020–0372. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically on the *https://www.regulations.gov/* website. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.* The EPA continues to carefully and continuously monitor information from the Center for Disease Control, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Neil Feinberg, Sector Policies and Programs Division (E143–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2214; fax number: (919) 541–0516; and email address: *feinberg.stephen@epa.gov.*

SUPPLEMENTARY INFORMATION: *Preamble acronyms and abbreviations.* We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CFR Code of Federal Regulations
EFR external floating roof
EPA Environmental Protection Agency
ICR Information Collection Request
IFR internal floating roof
kPa kilopascals
m3 cubic meters

NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NSPS new source performance standards
OMB Office of Management and Budget
PRA Paperwork Reduction Act
tpy tons per year
VOC volatile organic compound(s)

Background information. On October 16, 2020, the EPA proposed revisions to the Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. 85 FR 65774. In this action, the EPA is finalizing decisions and revisions for the rule. We summarize the in-scope comments we timely received regarding the proposed rule and provide our responses in this preamble. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review and Administrative Reconsideration
II. Background and Final Amendments
III. Public Comments and Responses
IV. Impacts of the Final Rule
A. What are the air quality impacts?
B. What are the cost impacts?
C. What are the economic impacts?
D. What are the benefits?
V. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially affected by this action are shown in Table 1 of this preamble.

TABLE 1—EXAMPLES OF POTENTIALLY AFFECTED ENTITIES BY CATEGORY

Category	NAICS code [1]	Examples of potentially regulated entities
Industrial	325	Chemical manufacturing facilities.
	324	Petroleum and coal products manufacturing facilities.
	422710	Petroleum bulk stations and terminals.

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. To determine whether your entity is affected by this action, you should carefully examine the applicability criteria found in the final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble, your delegated authority, or your EPA Regional representative listed in 40 CFR 60.4 (General Provisions).

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/volatile-organic-liquid-storage-vessels-including-petroleum-storage.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by March 22, 2021. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that ''[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review.'' This section also provides a mechanism for the EPA to convene a proceeding for reconsideration, ''[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment, (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.'' Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. Environmental Protection Agency, Room 3000, WJC West Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background and Final Amendments

Pursuant to the EPA's authority under CAA section 111, the Agency proposed (49 FR 29698, July 23, 1984) and promulgated (52 FR 11420, April 8, 1987) new source performance standards (NSPS) at 40 CFR part 60, subpart Kb, for Volatile Organic Liquid Storage Vessels, Including Petroleum Liquid Storage Vessels, for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984. To reduce volatile organic compound (VOC) emissions from storage vessels with a capacity of 75

cubic meters (m^3) or more that store organic liquids with a true vapor pressure over 27.6 kilopascals (kPa), and from storage vessels with a capacity of 151 m^3 or more that store organic liquids with a true vapor pressure over 5.2 kPa, NSPS subpart Kb requires the use of either an EFR, an IFR, or a closed vent system and a control device. See 40 CFR 60.110b(a) and 60.112b(a) and (b).[1] NSPS subpart Kb also specifies testing, monitoring, recordkeeping, reporting, and other requirements in 40 CFR 60.113b through 60.116b to ensure compliance with the standards. More specifically, 40 CFR 60.113b requires, among other things, that certain inspections for IFR and EFR occur at least once within certain defined timeframes (such as at least once every year, 5 years, or 10 years). Storage vessels with an EFR consist of an open-top cylindrical steel shell equipped with a deck that floats on the surface of the stored liquid (commonly referred to as a floating roof). Storage vessels with an IFR are fixed roof vessels[2] that also have a deck internal to the tank that floats on the liquid surface within the fixed roof vessel (commonly referred to as an internal floating roof).

The standards in NSPS subpart Kb for storage vessels with an EFR or IFR are a combination of a design, equipment, work practice, and operational standards set pursuant to CAA section 111(h). These standards require, among other things, that a rim seal be installed continuously around the circumference of the vessel (between the inner wall of the vessel and the floating roof) to prevent VOC from escaping to the atmosphere through gaps between the floating roof and the inner wall of the storage vessel. Similarly, NSPS subpart Kb requires deck fittings[3] on the floating roof to be equipped with a gasketed cover or lid that is kept in the closed position at all times (*i.e.,* no visible gap), except when the device (the deck fitting) is in actual use, to prevent VOC emissions from escaping through the deck fittings. In general, NSPS subpart Kb requires owners or operators to conduct visual inspections to check for defects in the floating roof, rim seals, and deck fittings (*e.g.,* holes, tears, or other openings in the rim seal, or covers and lids on deck fittings that no longer close properly) that could expose the liquid surface to the atmosphere and potentially result in VOC emission losses through rim seals and deck fittings.[4]

Since promulgation of NSPS subpart Kb, the EPA promulgated 40 CFR part 63, subpart WW, which is applicable to storage vessels containing organic materials, as part of the generic maximum achievable control technology standards program for setting national emission standards for hazardous air pollutants (NESHAP) under CAA section 112. See 64 FR 34854 (June 29, 1999). NESHAP subpart WW was developed for the purpose of providing consistent EFR and IFR requirements for storage vessels that could be referenced by multiple NESHAP subparts. Like the NSPS subpart Kb standards for floating roof tanks, NESHAP subpart WW is comprised of a combination of design, equipment, work practice, and operational standards. See proposed rule for NESHAP subpart WW (63 FR 55178, 55196 (October 14, 1998)). Both rules specify monitoring, recordkeeping, and reporting requirements for storage vessels equipped with EFR or IFR, and both include numerous requirements for inspections that occur at least once within certain defined timeframes. See 40 CFR 63.1063 for the IFR and EFR inspection requirements of NESHAP subpart WW. The inspections required by NESHAP subpart WW are intended to achieve the same goals as those inspections required by NSPS subpart Kb (*e.g.,* both rules require visual inspections to check for defects in the floating roof, rim seals, and deck fittings). Further, NESHAP subpart WW incorporates technical improvements based on the EPA's experience with implementation of other NESHAP. For storage vessels equipped with either an EFR or IFR, as long as there is visual access (as explained below), NESHAP subpart WW allows that the visual inspection of the floating roof deck, deck fittings, and rim seals may be conducted, while the tank remains in-service, from the top-side of the floating roof (meaning on top of the floating roof, and in the case of an IFR, under the fixed roof and internal to the tank); this is referred to as an in-service top-side of the floating roof visual inspection. In other words, in the case of an IFR, if an owner or operator has physical access to the inside of the tank above the floating roof and a floating roof design which allows inspectors to have visual access to all rim seals and deck fittings of the floating roof (meaning an inspector can see all the components required to be inspected) while the storage vessel is in-service, then NESHAP subpart WW does not require the owner or operator to take the storage vessel out of service to inspect the floating roof, rim seals, and deck fittings in accordance with 40 CFR 63.1063(d)(1).[5] This contrasts with NSPS subpart Kb, which, as explained in the proposed rule, requires that these inspections be conducted when the storage vessel is out-of-service (compare 40 CFR 63.1063(d)(1) with 40 CFR 60.113b(a)(4) and (b)(6)).

Pursuant to the EPA's authority under CAA section 111(h), we proposed amendments to NSPS subpart Kb in a new paragraph (see proposed 85 FR 65782—40 CFR 60.110b(e)(5)) that would allow owners or operators of storage vessels subject to NSPS subpart Kb, and equipped with either an EFR or IFR, the choice to elect to comply with the requirements specified in NESHAP subpart WW as an alternative standard, in lieu of the requirements specified in NSPS subpart Kb. 85 FR 65774 (October 16, 2020). Sources subject to NSPS subpart Kb that are equipped with either an EFR or IFR that elect to utilize the alternative standard would comply with all of the requirements in NESHAP subpart WW instead of the requirements in NSPS subpart Kb, 40 CFR 60.112b through 60.117b, subject to certain caveats and exceptions explained in the proposed rule and below. Among other things, this alternative allows owners or operators of storage vessels subject to NSPS subpart Kb that are equipped with an IFR, and that can meet the visual access requirement of NESHAP subpart WW explained above, to conduct the internal in-service top-side of the floating roof visual inspection pursuant to NESHAP subpart WW, thereby avoiding the need to empty and degas the vessel for the sole purpose of conducting the inspection. Further, we are not changing the underlying monitoring, reporting, or recordkeeping requirements in either NSPS subpart Kb or NESHAP subpart WW (with the

[1] All affected storage vessels storing organic liquids with a true vapor pressure of 76.6 kPa or more must use a closed vent system and a control device. 40 CFR 60.112b(b).

[2] A fixed roof storage vessel consists of a cylindrical steel shell with a permanently affixed roof, which may vary in design from cone or dome-shaped to flat.

[3] Numerous fittings pass through or are attached to floating roof decks to accommodate structural support components or to allow for operational functions. Typical deck fittings include, but are not limited to, the following: Access hatches, gauge floats, gauge-hatch/sample ports, rim vents, deck drains, deck legs, vacuum breakers, and guidepoles. IFR tanks may also have deck seams, fixed-roof support columns, ladders, and/or stub drains.

[4] For details about storage vessel emissions, refer to the Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources, AP–42, Fifth Edition, Chapter 7: Liquid Storage Tanks, dated June 2020, which is available at: *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors.*

[5] "The inspection may be performed entirely from the top side of the floating roof, as long as there is visual access to all deck components specified in paragraph (a) of this section." 40 CFR 63.1063(d)(1).

exception of some conforming and referencing edits to recordkeeping and reporting as discussed in the proposed rule and below), nor are we changing the applicability criteria in NSPS subpart Kb or NESHAP subpart WW. We are requiring that owners or operators that choose to use this optional alternative standard continue to use the same NSPS subpart Kb procedures for all storage vessels when determining applicability of NSPS subpart Kb; thus, owners or operators that choose to use this alternative must continue to comply with the monitoring requirements of 40 CFR 60.116b(a), (c), (e), and (f)(1), and also must keep other records and furnish other reports (as discussed in the proposed rule and below) in addition to all of the requirements specified in 40 CFR 63.1060 through 63.1067 of NESHAP subpart WW. In addition, because NSPS subpart Kb applies to each single storage vessel (see 40 CFR 60.110b for NSPS subpart Kb applicability and definition of affected facility), this alternative standard would be available for each affected facility as defined in NSPS subpart Kb. In other words, an owner or operator with multiple affected facilities can choose to use (or not use) the alternative for each individual affected facility.

After considering the public comments received, the EPA is finalizing the amendments that were proposed with minimal changes as a result of comments. We are clarifying that the notification for switching to or from the alternative standard is only required for the initial inspection after the switch. We are also correcting typographical errors in NSPS subpart Kb that inadvertently referenced the wrong, nonexistent subparts.

III. Public Comments and Responses

This section presents a summary of the relevant public comments received on the proposed amendments and the EPA's responses. The EPA received five relevant public comments on the proposed amendments, some of which contained portions that were out of scope, and one comment that was entirely out of scope. The comments can be obtained online from the Federal Docket Management System at *https://www.regulations.gov/.*

Comment: One commenter stated that the EPA should consider increasing the required frequency of inspections under the alternative standard, and that the EPA did not offer strong evidence of equivalence between the NSPS subpart Kb requirements and the alternative standard.

Response: As discussed in section III.A of the preamble to the proposed rule, EPA determined that the alternative standard is appropriate because it will achieve a reduction in emissions at least equivalent to the reduction in emissions achieved under NSPS subpart Kb, and that the alternative standard is just as stringent as, if not more stringent than, the underlying standard. This determination was based upon the premise that the proposal would not change the underlying compliance schedule(s) for events (inspections) under NSPS subpart Kb or NESHAP subpart WW. The EPA did not solicit comment on, nor did we intend to make changes to, any other provisions of NSPS subpart Kb or NESHAP subpart WW, including the frequency of inspections required by each of those subparts. Further, the EPA referenced and provided background documentation in the docket to support this equivalency determination (see Docket Item No. EPA–HQ–OAR–2020–0372–0004). The commenter did not explain how the EPA's support of the proposed equivalency determination was inadequate or provide any evidence to support the claimed need of increased inspection frequency. While the commenter states that ''empty vessel inspections'' are ''potentially more comprehensive,'' they offer no explanation for this claim and do not dispute the EPA's explanation that ''[c]onducting the in-service top-side-of-the-floating-roof inspection per NESHAP subpart WW affords the inspector the same ability to examine all the listed components for all of the listed defects/inspection failures as if the storage vessel was emptied and degassed.'' 85 FR 65779. Therefore, the EPA does not find it necessary to increase the required frequency of inspections under the alternative standard in order to determine equivalency for the multiple reasons stated in section III.A of the proposal preamble which are not repeated here.

Comment: One commenter suggested that the EPA consider including additional context for the Agency's explanation regarding the emission reduction potential of allowing compliance with the alternative standard.

Response: The EPA has already included a document in the docket titled ''Impacts for Revision of Internal Floating Roof Storage Vessel (Tank) Inspection Requirements Subject to 40 CFR part 60 Subpart Kb'' (Docket Item No. EPA–HQ–OAR–2020–0372–0005) that explains the air quality impacts of the proposal. This document explains emission releases from tank emptying and degassing events and includes national impact estimates of the potential emissions avoided by the proposal in terms of tons per year (tpy) of VOC. This document already includes information that the commenter suggests should be added. Further, the commenter did not provide any explanation as to why it believes the documentation in the docket at proposal provided inadequate context for understanding the predicted emissions reductions associated with the proposed alternative standard. Therefore, the EPA does not find it necessary to conduct any additional analysis of the air quality impacts associated with the alternative standard.

Comment: Several commenters recommended clarifying that the proposed revisions (the alternative standard) can be used by sources subject to other regulations that reference NSPS subpart Kb, such as the National Emission Standard for Benzene Waste Operations and the Gasoline Distribution MACT. The commenters noted that some emission standards that reference NSPS subpart Kb do not have the same design capacity and vapor pressure thresholds for requiring control as NSPS subpart Kb yet still require compliance with NSPS subpart Kb. The commenter suggested that the language of the proposed revisions be changed to be inclusive of storage vessels subject to those referencing standards.

Response: The EPA did not propose to allow the alternative standard for any sources aside from those that meet the applicability criteria in 40 CFR 60.110b and which are equipped with either an IFR or EFR pursuant to 40 CFR 60.112b(a)(1) or (2). If the EPA were to make the alternative standard available to sources that comply with NSPS subpart Kb via a referencing subpart as commenters suggest, then the EPA would first need to conduct a detailed analysis of how each potential referencing subpart references NSPS subpart Kb. The EPA would then need to include conforming regulations in this rulemaking for recordkeeping, reporting, and applicability of general provisions as needed for those referencing subparts. These time-consuming analyses and associated regulatory amendments are outside the scope of this limited rulemaking. Therefore, we are not making changes to the criteria for storage vessels allowed to use the alternative standard at this time. However, the EPA will consider addressing the commenters' suggestion should the Agency decide to propose additional amendments to NSPS subpart

Kb in the future via a different rulemaking process.

Comment: Several commenters recommended clarifying the reporting requirements of the proposed revisions. The commenters stated that the proposed revisions at 40 CFR 60.110b(e)(5)(iv)(B) and (C) require that each affected facility using the alternative standard submit reports under 40 CFR 63.1066 of NESHAP subpart WW; however, it was unclear when these reports need to be submitted. The commenter stated that it was unclear whether these reports should be submitted only with the first inspection using the alternative standard or with every subsequent inspection as well. The commenter stated that if the report was only required for the first inspection, this would be redundant with the reporting requirement in 40 CFR 60.110b(e)(5)(iv)(A). Alternatively, if this requirement were for every inspection, this requirement would conflict with the requirement in 40 CFR 60.110b(e)(5)(iv)(F)(*2*) to submit inspection reports only when inspection failures occur.

Response: The EPA intended to require only the initial notification that occurs after electing to comply with the alternative standard under 40 CFR 60.110b(e)(5)(iv)(A). Therefore, we agree with the commenters' suggestion to remove the proposed provision that would have required inclusion of this notification with subsequent reports and have made the corresponding changes in the final rule language.

Comment: Several commenters suggested clarifying the reporting frequency in the proposed revisions. The commenters stated that maintaining the reporting frequency of NSPS subpart Kb ''could lead to inconsistent and duplicative reporting requirements which . . . EPA has repeatedly acknowledged impose unnecessary burden with no environmental benefit,'' and that the EPA should allow semi-annual reporting frequency. The commenters stated that a semi-annual reporting requirement would be more consistent with reporting requirements established after the promulgation of NSPS subpart Kb in 1987. They also stated that the EPA allows storage vessels subject to both NSPS subpart Kb and a NESHAP to submit compliance reports on a semi-annual basis.

Response: As the EPA explained in section V of the proposed amendments, the Agency did not solicit comment on, nor did we intend to make changes to, any other provisions of NSPS subpart Kb or NESHAP subpart WW aside from incorporating the proposed alternative standard. As such, the EPA is not modifying the reporting schedule for NSPS subpart Kb because such a change would be outside the scope of this limited rulemaking which was intended only to incorporate the proposed alternative standard. It was not the EPA's intent to make changes to the underlying reporting schedules in NSPS subpart Kb. However, the EPA will consider addressing the commenters' suggestion should the Agency decide to propose additional amendments to NSPS subpart Kb in the future via a different rulemaking process.

Comment: Several commenters recommended clarifying the inspection deadlines of the alternative standard. The commenters stated that the EPA should allow inspections to occur at any point within the specified calendar period (*e.g.,* within each calendar year rather than a specific 1-year interval), provided that a minimum amount of time has passed since the last inspection.

Response: As the EPA explained in section V of the proposed amendments, the Agency did not solicit comment on, nor did we intend to make changes to, any other provisions of NSPS subpart Kb or NESHAP subpart WW aside from incorporating the proposed alternative standard. As such, the EPA is not modifying the inspection schedule requirements for NSPS subpart Kb because such a modification would be outside the scope of this limited rulemaking which was intended only to incorporate the proposed alternative standard. It was not the EPA's intent to make changes to the underlying inspection schedules in NSPS subpart Kb. However, the EPA will consider addressing the commenters' suggestion should the Agency decide to propose additional amendments to NSPS subpart Kb in the future via a different rulemaking process.

Comment: One commenter suggested that the EPA make technical corrections to 40 CFR 60.115b(a)(4) and (b) to correct previous inadvertent errors in citations.

Response: The EPA agrees with the commenter and has corrected 40 CFR 60.115b(a)(4) to reference 40 CFR 60.112b(a)(1) and 40 CFR 60.115b(b) to reference 40 CFR 60.112b(a)(2). While this comment and the EPA's associated revisions do not fit squarely within the scope of the proposal to incorporate the alternative standard, and do address a separate provision of NSPS subpart Kb unrelated to the alternative standard, the EPA found it appropriate to make these changes because commenters identified a genuine typographical error. The EPA's revisions here will not alter how sources and/or the Agency have been implementing NSPS subpart Kb in any way. The EPA finds it appropriate and convenient to use this rulemaking to correct the inadvertent typographical error.

IV. Impacts of the Final Rule

A. What are the air quality impacts?

We estimate that nationwide VOC emissions reductions would range from 65.8 tpy to 83.3 tpy as a result of the amendments. As explained at proposal, the alternative standard allows owners or operators to avoid emptying and degassing storage vessels in order to perform certain inspections, thereby reducing emissions caused by degassing vapors which have historically been vented to the atmosphere or sent to control equipment. These emissions reductions were documented in the memorandum, *Impacts for Revision of Internal Floating Roof Storage Vessel (Tank) Inspection Requirements Subject to 40 CFR part 60 Subpart Kb* (see Docket ID No. EPA–HQ–OAR–0372–0005).

B. What are the cost impacts?

We estimate that the amendments will result in a nationwide net cost savings of between $768,000 and $1,091,000 per year (in 2019 dollars). For further information on the cost savings associated with the amendments, see the memorandum, *Impacts for Revision of Internal Floating Roof Storage Vessel (Tank) Inspection Requirements Subject to 40 CFR part 60 Subpart Kb* (see Docket ID No. EPA–HQ–OAR–0372–0005).

C. What are the economic impacts?

As noted earlier, we estimated a nationwide cost savings associated with the amendments. Therefore, we do not expect the actions in this rulemaking to result in business closures, significant price increases or decreases in affected output, or substantial profit loss. For more information, refer to the *Economic Impact Analysis for the Proposed Alternative Standard Available to Floating Roof Storage Vessels (Tanks) Subject to 40 CFR part 60 Subpart Kb,* which is in the docket for this rulemaking.

D. What are the benefits?

The EPA did not monetize the benefits from the estimated emission reductions of VOC associated with this action. However, we expect this action would provide benefits associated with VOC emission reductions.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this rule can be found in the EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 1854.13. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

See section III.A of the preamble for the proposed rule (''What actions are we proposing?'') for a description of the alternative standard. Information about inspection activities related to NSPS subpart Kb is collected to assure compliance with NSPS subpart Kb. Most of the costs associated with the alternative standard are associated with labor hours. The time needed to conduct an in-service top-side-of-the-floating-roof visual inspection pursuant to the requirements in NESHAP subpart WW is expected to be less than the time needed to complete an out-of-service inspection pursuant to NSPS subpart Kb. Therefore, we anticipate a cost savings. This ICR documents the incremental burden imposed by the final amendments only. In summary, there is a decrease in the burden (labor hours) documented in this ICR due a reduction in the number of respondents (storage vessels subject to NSPS subpart Kb) that would be required to empty and degas their storage vessels equipped with an IFR.

Respondents/affected entities: Owners or operators of storage vessels constructed after July 23, 1984, that have capacity greater than or equal to 75 m^3 used to store volatile organic liquids (including petroleum liquids) with a true vapor pressure greater than or equal to 3.5 kPa, and storage vessels constructed after July 23, 1984, that have capacity between 75 and 151 m^3 capacity for which the true vapor pressure of the stored liquid is greater than or equal to 15 kPa.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart Kb, and 40 CFR part 63, subpart WW).

Estimated number of respondents: 385 facilities.

Frequency of response: Variable (storage vessel specific).

Total estimated burden: A reduction of 6,210 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: A savings of $930,000 (per year), includes a savings of $466,000 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The alternative standard is optional; therefore, small entities are not required to comply with the alternative.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA offered consultation with tribal officials during the development of this action; however, the Agency did not receive a request for consultation. The EPA held a webinar with communities on November 10, 2020, which included tribes during the public comment period to inform them of the content of the proposed rule and to encourage them to submit comments on the proposed rule.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order

12898 (59 FR 7629, February 16, 1994). Although the proposed alternative is optional, the alternative standard is at least as stringent as the current applicable requirements.

As discussed above in section V.G, a webinar was held for community groups which included environmental justice communities.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 60

Environmental protection, Air pollution control, Reporting and recordkeeping requirements, Volatile organic compounds.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, the EPA is amending 40 CFR part 60 as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Kb—Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984

■ 2. Section 60.110b is amended by adding paragraph (e)(5) to read as follows:

§ 60.110b Applicability and designation of affected facility.

* * * * *

(e) * * *

(5) *Option to comply with part 63, subpart WW, of this chapter.* Except as specified in paragraphs (e)(5)(i) through (iv) of this section, owners or operators may choose to comply with 40 CFR part 63, subpart WW, to satisfy the requirements of §§ 60.112b through 60.117b for storage vessels either with a design capacity greater than or equal to 151 m^3 containing a VOL that, as stored, has a maximum true vapor pressure equal to or greater than 5.2 kPa but less than 76.6 kPa, or with a design capacity greater than or equal to 75 m^3 but less than 151 m^3 containing a VOL that, as stored, has a maximum true vapor pressure equal to or greater than 27.6 kPa but less than 76.6 kPa.

(i) The general provisions in subpart A of this part apply instead of the general provisions in subpart A of part 63 of this chapter.

(ii) Where terms are defined in both this subpart and 40 CFR part 63, subpart WW, the definitions in this subpart apply.

(iii) Owners or operators who choose to comply with 40 CFR part 63, subpart WW, also must comply with the monitoring requirements of § 60.116b(a), (c), (e), and (f)(1), except as specified in paragraphs (e)(5)(iii)(A) through (C) of this section.

(A) The reference to all records applies only to the records required by § 60.116b(c);

(B) The reference to § 60.116b(b) does not apply; and

(C) The reference to § 60.116b(g) does not apply.

(iv) Owners or operators who choose to comply with 40 CFR part 63, subpart WW, must also keep records and furnish reports as specified in paragraphs (e)(5)(iv)(A) through (F) of this section.

(A) For each affected facility, the owner or operator must notify the Administrator at least 30 days before the first inspection is conducted under 40 CFR part 63, subpart WW. After this notification is submitted to the Administrator, the owner or operator must continue to comply with the alternative standard described in this paragraph (e)(5) until the owner or operator submits another notification to the Administrator indicating the affected facility is using the requirements of §§ 60.112b through 60.117b instead of the alternative standard described in this paragraph (e)(5). The compliance schedule for events does not reset upon switching between compliance with this subpart and 40 CFR part 63, subpart WW.

(B) Keep a record of each affected facility using the alternative standard described in this paragraph (e)(5) when conducting an inspection required by § 63.1063(c)(1) of this chapter.

(C) Keep a record of each affected facility using the alternative standard described in this paragraph (e)(5) when conducting an inspection required by § 63.1063(c)(2) of this chapter.

(D) Copies of all records and reports kept pursuant to § 60.115b(a) and (b) that have not met the 2-year record retention required by the introductory text of § 60.115b must be kept for an additional 2 years after the date of submittal of the inspection notification specified in paragraph (e)(5)(iv)(A) of this section, indicating the affected facility is using the requirements of 40 CFR part 63, subpart WW.

(E) Copies of all records and reports kept pursuant to § 63.1065 of this chapter that have not met the 5-year record retention required by the introductory text of § 63.1065 must be kept for an additional 5 years after the date of submittal of the notification specified in paragraph (e)(5)(iv)(A) of this section, indicating the affected facility is using the requirements of §§ 60.112b through 60.117b.

(F) The following exceptions to the reporting requirements of § 63.1066 of this chapter apply:

(*1*) The notification of initial startup required under § 63.1066(a)(1) and (2) of this chapter must be submitted as an attachment to the notification required by §§ 60.7(a)(3) and 60.115b(a)(1);

(*2*) The reference in § 63.1066(b)(2) of this chapter to periodic reports ''when inspection failures occur'' means to submit inspections results within 60 days of the initial gap measurements required by § 63.1063(c)(2)(i) of this chapter and within 30 days of all other inspections required by § 63.1063(c)(1) and (2) of this chapter.

■ 3. Section 60.115b is amended by revising paragraph (a)(4) and the introductory text of paragraph (b) to read as follows:

§ 60.115b Reporting and recordkeeping requirements.

* * * * *

(a) * * *

(4) After each inspection required by § 60.113b(a)(3) that finds holes or tears in the seal or seal fabric, or defects in the internal floating roof, or other control equipment defects listed in § 60.113b(a)(3)(ii), a report shall be furnished to the Administrator within 30 days of the inspection. The report shall identify the storage vessel and the reason it did not meet the specifications of § 60.112b(a)(1) or § 60.113b(a)(3) and list each repair made.

(b) After installing control equipment in accordance with § 60.112b(a)(2) (external floating roof), the owner or operator shall meet the following requirements.

* * * * *

[FR Doc. 2021–00678 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 410, 414, 415, 423, 424, and 425

[CMS–1734–F, CMS–1734–IFC, CMS–1744–F, CMS–5531–F and CMS–3401–IFC] CN

RIN 0938–AU10, 0938–AU31, 0938–AU32, and 0938–AU33

Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-In Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions From the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule and interim final rule; Correction.

SUMMARY: This document corrects technical errors in the final rule that appeared in the December 28, 2020, **Federal Register** under the same as title above. Hereinafter, the December 28 rule is referred to as the CY 2021 PFS final rule.

DATES: This correction is effective January 19, 2021, and is applicable beginning January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Cynthia Lambert-Lawson, (410) 786–1366, Gaysha Brooks, (410) 786–9649, or Annette Brewer (410) 786–6580.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020–26815 of December 28, 2020, the CY 2021 PFS final rule (85 FR 84472), there were technical errors that are identified and corrected in this correcting document. These corrections are effective and applicable beginning January 1, 2021.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 84545 of the CY 2021 PFS final rule, third column, prior to the first full paragraph, in our discussion of clarifications and proposals related to digitally stored data services/remote physiologic monitoring/treatment management services, we inadvertently deleted, before publication, language summarizing and responding to two sets of public comments. We also inadvertently included language on page 84545 of the CY 2021 PFS final rule, third column, the first partial paragraph at the top of the column.

B. Summary of Errors in the Addenda

On page 85057, in Table B.2. Audiology, second column, second row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85069, in Table B.5. Clinical Social Work, second column, second row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85076, in Table B.8. Diagnostic Radiology, ninth column entry Measure Steward, third row, we inadvertently misidentified the measure steward.

On page 85083, in Table B.10. Endocrinology, second column, third row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85089, in Table B.11. Family Medicine, second column, sixth row, the entry NQF #/eCQM NQF # contains typographical errors.

On page 85110, in Table B.16. Infectious Disease, ninth column entry Measure Steward, fourth row, we inadvertently misidentified the measure steward.

On page 85114, in Table B.17. Internal Medicine, second column, first row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85124, in Table B.19. Mental/Behavioral Health, second column, fifth row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85130, in Table B.21. Neurology, second column, third row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85141, in Table B.24. Obstetrics/Gynecology, third column entry Quality # sixth row, we inadvertently omitted the Quality number.

On page 85146, in Table B.25a. Oncology/Hematology, third column entry Quality #, fifth row, we inadvertently omitted the Quality number.

On page 85157, in Table B.27. Orthopedic Surgery, second column, third row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85171, in Table B.30. Pediatrics, second column, fifth row, the entry NQF #/eCQM NQF # contains typographical errors.

On page 85171, in Table B.30. Pediatrics, ninth column entry Measure Steward, sixth row, we inadvertently misidentified the measure steward.

On page 85173, in Table B.30. Pediatrics, second column, sixth row, the entry NQF #/eCQM NQF # contains typographical errors.

On page 85179, in Table B.32. Physical Therapy/Occupational Therapy, second column, fifth row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85190, in Table B.35. Preventive Medicine, second column, third row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85199, in Table B.38. Skilled Nursing Facility, third column entry Quality #, fifth row, we inadvertently omitted the Quality number.

On page 85203, in Table B.39. Speech Language Pathology, second column, first row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85268, in Table D.26. Preventive Care and Screening: Screening for Depression and Follow-Up Plan, second column, first row, the entry NQF #/eCQM NQF # contains a typographical error.

On page 85333, in Table D.82. Immunizations for Adolescents, second column, first row, the entry NQF #/eCQM NQF # contains a typographical error.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance

or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical errors in the CY 2021 PFS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2021 PFS final rule. As a result, the corrections made through this correcting document are intended to resolve inadvertent errors so that the CY 2021 PFS final rule accurately reflects the policies adopted in the final rule. Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2021 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the final rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2021 PFS final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

IV. Correction of Errors

In FR Doc. 2020–26815 (85 FR 84472), published December 28, 2020, make the following corrections:

A. Correction of Errors in the Preamble

1. On page 84545 of the CY 2021 PFS final rule, third column, the first partial paragraph at the top of the column is corrected by removing the following language:

The medically necessary services associated with all the medical devices for a single patient can be billed by only one practitioner, only once per patient per 30 day period, and only when at least 16 days of data have been collected.

2. On page 84545 of the CY 2021 PFS final rule, third column, prior to the first full paragraph, is corrected by adding the following language:

Comment: Commenters stated that for CPT codes 99457 and 99458, we interpreted ''interactive communication'' to mean ''real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission'' and suggested that the required 20 minutes of time associated with CPT codes 99457 and 99458 should be only synchronous time, real-time between a practitioner and a patient. Commenters stated that these two codes include non-face-to-face time as well as real-time two-way audio interactions.

Response: We agree with commenters that our description of the required 20 minutes of time associated with CPT codes 99457 and 99458 should include care management services, as well as synchronous, real-time interactions. That is, we agree that ''interactive communication'' as we defined it in the CY 2021 PFS proposed rule contributes to the total time, but is not the only activity that should be included in the total time.

After considering comments, we are clarifying for purposes of this final rule, that the 20-minutes of intra-service work associated with CPT codes 99457 and 99458 includes a practitioner's time engaged in ''interactive communication'' as well as time engaged in non-face-to-face care management services during a calendar month.

Comment: Commenters disagreed with our statement that the services associated with CPT codes 99453 and 99454 should be billed only once per patient, per 30-day period, and wrote that CMS should clarify that CPT codes 99453 and 99454 can be billed once per provider, per patient, per 30-day period.

Response: We thank commenters for their insights related to billing CPT codes 99453 and 99454. As we stated in the proposed rule, we believe these two codes should be reported for a patient only once during a 30-day period and only when reasonable and necessary. In response to public commenters, we are clarifying that only one practitioner can bill CPT codes 99453 and 99454 during a 30-day period and only when at least 16 days of data have been collected on at least one medical device as defined in section 201(h) of the FFDCA. CPT language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also note that when a more specific code is available to describe a service, CPT indicates that the more specific code should be billed. We believe that there are additional, more specific codes available for billing that allow remote monitoring (for example, CPT code 95250 for continuous glucose monitoring and CPT codes 99473 and 99474 for self-measured blood pressure monitoring). In summary, we are clarifying that CPT codes 99453 and 99454 should be reported only once during a 30-day period; that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary.

B. Correction of Errors in the Addenda

1. On page 85057, in Table B.2. Audiology, second column, second row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

2. On page 85069, in Table B.5. Clinical Social Work, second column, second row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

3. On page 85076, in Table B.8. Diagnostic Radiology, ninth column, third row, the Measure Steward entry ''American College of Radiology/American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance'' is corrected to read ''American College of Radiology/National Committee for Quality Assurance''.

4. On page 85083, in Table B.10. Endocrinology, second column, third row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

5. On page 85089, in Table B.11. Family Medicine, second column, sixth row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e'', and in the second column, sixth row, the NQF #/eCQM NQF # entry ''1407/N/A'' is corrected to read ''N/A/N/A''.

6. On page 85110, in Table B.16. Infectious Disease, the ninth column, fourth row, the Measure Steward entry ''Health Resources and Services Administration'' is corrected to read ''National Committee for Quality Assurance''.

7. On page 85114, in Table B.17. Internal Medicine, second column, first row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

8. On page 85124, in Table B.19. Mental/Behavioral Health, second column, fifth row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

9. On page 85130, in Table B.21. Neurology, second column, third row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

10. On page 85141, in Table B.24. Obstetrics/Gynecology, third column, fifth row, the blank Quality # entry is corrected to read ''111''.

11. On page 85146, in Table B.25a. Oncology/Hematology, third column, fifth row, the blank Quality # entry is corrected to read ''110''.

12. On page 85157, in Table B.27. Orthopedic Surgery, second column, third row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

13. On page 85171, in Table B.30. Pediatrics, second column, fifth row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

14. On page 85171, in Table B.30. Pediatrics, ninth column, sixth row, the Measure Steward entry ''Health Resources and Services Administration'' is corrected to read ''National Committee for Quality Assurance''.

15. On page 85173, in Table B.30. Pediatrics, second column, sixth row, the NQF #/eCQM NQF # entry ''1407/N/A'' is corrected to read ''N/A/N/A''.

16. On page 85179, in Table B.32. Physical Therapy/Occupational Therapy, second column, fifth row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

17. On page 85190, in Table B.35. Preventive Medicine, second column, third row, the NQF #/eCQM NQF # ''entry 0418/0418e'' is corrected to read ''N/A/0418e''.

18. On page 85199, in Table B.38. Skilled Nursing Facility, third column, fifth row, the blank Quality # entry is corrected to read ''110''.

19. On page 85203, in Table B.39. Speech Language Pathology, second column, first row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

20. On page 85268, in Table D.26. Preventive Care and Screening: Screening for Depression and Follow-Up Plan, second column, first row, the NQF #/eCQM NQF # entry ''0418/0418e'' is corrected to read ''N/A/0418e''.

21. On page 85333, in Table D.82. Immunizations for Adolescents, second column, first row, the NQF #/eCQM NQF # entry ''1407/N/A'' is corrected to read ''N/A/N/A''.

Dated: January 11, 2021.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021–00805 Filed 1–14–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 67

[Docket No. USCG–2020–0215]

RIN 1625–AC26

Certificate of Documentation—5 Year Renewal Fees

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is issuing a final rule extending the validity of a recreational vessel endorsement on a Certificate of Documentation (COD) from 1 to 5 years. Congress passed and the President signed the Frank LoBiondo Coast Guard Authorization Act of 2018, which requires the Coast Guard to issue recreational vessel CODs for 5 years. By updating the Code of Federal Regulations to reflect this change, the Coast Guard anticipates this final rule to harmonize with the requirements of the 2018 Act that decreased the burden on recreational vessel owners by requiring COD renewals every 5 years rather than annually.

DATES: This final rule is effective February 18, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0215 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Mr. Ronald Teague, Department of Homeland Security, U.S. Coast Guard, National Vessel Documentation Center, 792 T J Jackson Drive, Falling Waters, WV 25419; telephone 304 271–2506; email *ronald.s.teague@uscg.mil.*

SUPPLEMENTARY INFORMATION:

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I. Abbreviations

2018 Act Frank LoBiondo Coast Guard Authorization Act of 2018 (Pub. L. 115–282, 132 Stat. 4192)
BLS Bureau of Labor Statistics
CFR Code of Federal Regulations
COD Certificate of Documentation
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
NVDC U.S. Coast Guard National Vessel Documentation Center
OMB Office of Management and Budget
§ Section
SME Subject matter expert
U.S.C. United States Code

II. Basis and Purpose, and Regulatory History

The legal basis for this final rule is found in Section 512 of the Frank LoBiondo Coast Guard Authorization Act of 2018 (2018 Act) (Pub. L. 115–282, 132 Stat. 4192) (the 2018 Act), which the President signed on December 4, 2018. The 2018 Act directed the Coast Guard to do the following: (1) Make Certificates of Documentation (CODs) for recreational vessels of at least five

net tons [1] effective for 5 years; and (2) require owners of recreational vessel of at least five net tons to notify the Coast Guard of each change in the information on which the issuance of the COD is based. Vessel owners must report each change of information that occurs before expiration of the certificate not later than 30 days after such change. This rulemaking is issued under authority found in Title 46 of the United States Code (U.S.C.) 2103.

The Coast Guard finds that good cause exists under the Administrative Procedure Act, 5 U.S.C. 553, to dispense with notice and comment procedures. Prior notice and opportunity to comment on this rule are unnecessary under 5 U.S.C. 553(b)(3)(B) because Section 512 of the 2018 Act provides the Coast Guard no discretion in adopting the specific time frames for renewal of recreational vessel CODs. The 2018 Act does not allow for alternatives. It does not permit the Coast Guard to decide upon a different time frame for renewal, choose to adopt a different renewal period, or respond to public comments by modifying the substance of the rule. Soliciting public comment on the correct time period for COD renewal for a recreational vessel, or on the decision to update the regulations to comport with the statutory mandate, is unnecessary and would in fact be futile.[2] It should be noted that the Coast Guard has already implemented the requirements of Section 512 of the 2018 Act and is presently issuing multi-year CODs to recreational vessels of at least 5 net tons.

III. Background

Section 512 of the 2018 Act directs how the Coast Guard must administer its certificate of documentation program, and this rule conforms sections in Title 46 of the Code of Federal Regulations (CFR) part 67 to reflect what is now the law. As described above, the Coast Guard finds that good cause exists to forego notice and comment rulemaking because the statute provides the Coast Guard with no discretion to exercise in response to comments. Accordingly, the Coast Guard did not issue a notice of proposed rulemaking. This final rule only amends the regulations so that they are in agreement with the requirements already in the law.

The purpose of this final rule is to meet the Congressional mandate contained in Section 512 of the 2018 Act, in which Congress requires the Coast Guard to issue recreational endorsements on CODs with a validity of 5 years. Additionally, the 2018 Act directs the Coast Guard to establish phased user fees for 5-, 4-, 3-, 2-, and 1-year recreational endorsements. After the phase-in period is complete, on December 31, 2021, applicants will only be able to apply for a 5-year recreational endorsement.

In accordance with 46 U.S.C. 12105(e)(2)(C), the cost of the user fee will be calculated by multiplying 5 years by the recently established $26 annual fee, for a total of $130.[3] The 5-year fee is consistent with statute and will ensure that the Coast Guard collects the appropriate user fees, consistent with the cost to provide the service. The new fee for a 5-year recreational endorsement will be in addition to the fee collected for initial and exchanges of CODs.

Lastly, this final rule repeats the requirement in the 2018 Act for vessel owners to notify the Coast Guard of each change in the information on which the issuance of the COD for the vessel is based, before the expiration of the COD and no later than 30 days after the change. The COD will terminate upon the expiration of the 30-day period if the owner has not notified the Coast Guard of changes within the 30-day timeframe.

IV. Discussion of the Rule

On March 3, 2015, the Coast Guard published a request for comments, specifically seeking input on increasing the validity period for renewing CODs, methods for doing so, and possibly updating the fee for services (80 FR 11361). We received 2,844 comments in response to our notice, largely in support of a multiyear registration option. However, our request for comments was superseded by section 311 of the Coast Guard Authorization Act of 2015 (Pub. L. 114–120), and again by the Frank LoBiondo Coast Guard Authorization Act of 2018 (Pub. L. 115–282), which specifically directed the Coast Guard to change the validity period of CODs for recreational vessels to a 5-year option only, after a 3-year phase-in period during which vessel owners could choose 1, 2, 3, 4, or 5 years.

There are no maritime safety or security reasons to change the recreational vessel COD validity from 1 year to 5. However, Congress determined that a change in the validity was in the best interest of recreational vessel owners, and the Coast Guard is required to recoup the costs of providing a service.[4] To ensure the appropriate user fees are collected for 5-year CODs, the Coast Guard will collect fees consistent with the annual cost multiplied by 5, as required by section 512 of the 2018 Act.

Currently, 46 CFR 67.163(a) states that all endorsements on a COD, including commercial vessel CODs, are valid for 1 year. In this final rule, the Coast Guard is amending this section to reflect what is already stated in the 2018 Act: That only commercial vessel CODs are valid for one 1 year, and that recreational endorsements are valid for 5 years. Additionally, the amendment clarifies that a vessel with both recreational and commercial endorsements must renew annually. The Coast Guard is also amending § 67.163(b) to reflect the appropriate renewal application, as the currently listed form no longer exists. Lastly, as the 2018 Act requires, the Coast Guard is adding paragraph (c) to § 67.163 to establish the 5-year renewal requirement and inform recreational vessel owners that they have the option to renew recreational endorsements for durations of 1, 2, 3, 4, or 5 years during the phase-in period. The ability for the owner to select validity is only in effect from January 1, 2019, to December 31, 2021.

The Coast Guard is amending § 67.317 to reflect that recreational endorsements must be renewed every 5 years. The Coast Guard is also amending § 67.319 to reflect that an owner of a vessel that has a change of information on which the issuance of the COD of the vessel is based must notify the Coast Guard of the change of information within 30 days, as is required by section 512 of the 2018 Act. Furthermore, the Coast Guard is amending this section to reflect that the vessel's COD will be terminated if the owner fails to notify the Coast Guard within 30 days of any changes on which the issuance of the COD is based. The Coast Guard is also amending § 67.515 to remove the word ''annual'' in describing endorsement renewals.

Finally, the Coast Guard is amending table 1 to § 67.550 to reflect the appropriate fee for a 5-year recreational endorsement, and the fees associated with the owner choosing to have a certificate issued or renewed for 1, 2, 3,

[1] 46 U.S.C. 12103 provides, in pertinent part, ''Except as otherwise provided, a certificate of documentation for a vessel may be issued under this chapter only if the vessel is—. . .(2) at least 5 net tons as measured under part J of this subtitle; . . .''

[2] *See Metzenbaum* v. *Federal Energy Regulatory Commission,* 675 F. 2d 1282, 1291 (D.C. Cir. 1982) (finding notice and comment unnecessary for nondiscretionary acts where notice and comment ''might even have been contrary to the public interest, given the expense that would have been involved in a futile gesture.'') (internal quotation marks omitted).

[3] *See* 79 FR 47015, 47106 (Aug. 12, 2014).

[4] 46 U.S.C. 2110.

4, or 5 years from January 1, 2019, to December 31, 2021.

V. Regulatory Analyses

We developed this final rule to reflect current law, in accordance with numerous statutes and Executive orders related to rulemaking. Below, we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. DHS considers this rule to be an Executive Order 13771 deregulatory action. *See* the OMB Memorandum titled ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017). Details on the estimated cost savings of this final rule can be found in the rule's regulatory analysis (RA) that follows.

Following guidance in OMB Circular A–4, we assess the impacts of this rule against a no-action baseline as well as a pre-statutory baseline. The no-action baseline is an assessment against what the world would be like if the rule is not adopted. The pre-statutory baseline is an assessment against what the world would be like if the relevant statute had not been adopted.

This final rule will codify requirements in the 2018 Act that established a new schedule for the renewal of CODs for owners of recreational vessels of at least 5 net tons. Since the final rule does not add any new requirements beyond what is already required and implemented under the 2018 Act, under a no-action baseline, its total impacts on costs, cost savings, and benefits is zero.

We also present impacts of the final rule based on a pre-statutory baseline. In other words, in the analysis that follows, we present the impacts of the 2018 Act by comparing the requirements of this rule to a baseline prior to implementation of the 2018 Act.

Summary of Impacts (Pre-Statutory Baseline)

Prior to the 2018 Act, CODs were effective for one year. The 2018 Act, codified by this rule, creates savings due to a reduction in the time necessary for the submission and approval of COD renewals. We anticipate that approximately 165,309 recreational vessel owners will be affected annually. In addition, the Government will be affected because the number of annual renewals the Coast Guard processes will decline. We estimate that the industry for recreational vessel owners of vessels of at least 5 net tons will see a savings of $696,727 annualized over 10 years, and the Coast Guard will reduce spending on administrating COD renewals by an annualized amount of approximately $997,345. Both cost savings are in $2018, discounted at 7 percent. We estimate the annualized cost savings to industry and the Government combined to be approximately $1.7 million, discounted at 7 percent.

Table 1 presents a summary of the economic impacts. We provide a detailed description of the estimates in the next section of this analysis.

TABLE 1—SUMMARY OF THE ECONOMIC IMPACT
[Pre-statutory baseline]

Description	Affected population	Cost	Cost savings	Benefits
Require owners of recreational vessels of at least 5 net tons to renew CODs every 5 years, thereby making CODs effective for a 5-year term instead of a 1-year term.	Estimated average annual population over a 10-year period of analysis of owners of recreational vessels affected by the 2018 Act (and codified by this regulation) is 165,309 vessels.	The 2018 Act will not impose any cost burden on industry.	The affected industry will see a 10-year annualized savings of $696,727. In addition, the government will see a 10-year annualized savings of $997,345; both estimates are discounted at 7 percent.	The restructuring of CODs from an annual renewal to a 5-year renewal period will reduce the industry's annual time burden for submitting COD applications. In addition, the Government will benefit due to a reduction in the amount of applications processed annually.
Vessel owners are currently required to update changes that impact information attested to on the COD. Since the 2018 Act requires renewal every 5 years instead of annually, a provision within this final rule is clarifying that owners need to amend any changes to CODs within 30 days of said changes occurring.	Recreational vessel owners impacted by the 2018 Act would be affected by the provision in § 67.319 of this final rule.	No cost. This is clarifying a requirement to keep COD information current and will not impose any cost burden.	There are no savings associated with this provision.	There are no benefits associated with this provision, other than clarifying when changes to COD information must be addressed.
The fee schedule in Table 1 in § 67.550 provides owners with information about the applicable fees for obtaining the CODs for their vessels.	The affected population is those owners under 46 CFR part 67, subpart Y.	No cost. This clarifies information about the fees associated with CODs.	No savings. This is clarification only.	There are no benefits associated with the updated table. It is updating the cost schedule to account for the change to a 5-year renewal.

The 2018 Act requires owners of recreational vessels of at least 5 net tons to renew their CODs every 5 years. Owners were to begin phase-in starting January 1 of 2019.

Population

We estimate that there are an average of 162,647 recreational vessels in

service in a given year that have a COD. The certification and documentation of recreational vessels comes with rights as well as responsibilities that entitle vessel owners the protection under the U.S. flag.

There are two reasons for documenting a recreational vessel. The first reason is voluntary, for qualified recreational vessels that are at least 5 net tons, thereby granting them protection under the U.S. flag. The second reason is to satisfy mortgage lender requirements.

Documenting recreational vessels occurs according to five criteria:

(1) As a result of the initial documentation of a newly produced vessel (not documented);

(2) As a result of the initial documentation of a newly acquired existing vessel, not previously documented;

(3) As an exchange of the vessel from one party to another;

(4) As a reinstatement or replacement of a vessel; or

(5) As a return to documentation of a vessel.

The data used to formulate the affected population is provided by the Coast Guard's National Vessel Documentation Center (NVDC), which is the approving authority for the issuance of CODs. The NVDC provides CODs according to the criteria presented above. The information we present in this analysis uses NVDC data for the affected population over a 5-year period, from 2013 to 2017.[5] Based on this data, we estimate the average existing number of owners obtaining CODs in a given year to be 162,309, of which 7,402 (or 4.6 percent) are initial CODs. We assume this is the number of CODs that would have been renewed annually in the absence of the 2018 Act.

To estimate the number of CODs for new vessels entering into use each year, we use the NVDC data to estimate the number of new owners requesting initial CODs as a percent of total CODs. We base our estimate on 4.6 percent, as this represents the average increase of CODs (7,402 [average number of initial CODs] divided by 162,309 [average total number of CODs]).

The number of new vessels entering into use will vary slightly every year. However, based on historical data, we can expect their average annual rate to converge to a steady figure. Assuming this subset (new vessel CODs) of initial CODs is, on average, consistent with the average increase of the total COD population (4.6 percent annually), we can then assume that, on an annual basis, 338 new vessels owners will request CODs each year (7,402 average initial CODs multiplied by 4.6 percent). We then add 338 to 162,309 to obtain 162,647, the average total population of CODs. We use this total population estimate to derive the number of CODs that will not need to renew as a result of the 2018 Act (which is codified by this regulation). As is presented in the cost savings section below, this annual estimate varies per year according to the five different annual certification criteria and the 3-year phase-in period.

Cost Savings

Industry Assessment

As a result of the 2018 Act, the Coast Guard will no longer require owners of recreational vessels to renew their CODs annually. Therefore, the 2018 Act will not impose any cost; only cost savings will be realized by the affected population.

As of January 1, 2019, owners have been able to select a renewal period of multiple years, up to a limit of 5 years. This cost savings assessment outlines the Coast Guard's anticipated industry adaptation of moving to a 5-year renewal period.

The 2018 Act provides that vessel owners will have 3 years (starting January 1, 2019 and ending December 31, 2021) to select a timeframe for COD renewal that does not exceed 5 years. Hence, vessel owners can choose any timeframe from 1 to 5 years during this 3-year period. Beginning January 1, 2022, all recreational CODs will be renewed with a validity period of 5 years. Therefore, in order to formulate the best approximation of how owners will select their renewal periods during the phase-in period, we make the assumption that equal portions of the affected population selected a renewal period of 1 to 5 years in 2019.

Since the Coast Guard is unable to determine individual preferences regarding how owners will choose a renewal term during the phase-in period, our methodology anticipates cost savings throughout a 10-year period of analysis (2019–2028).[6] We begin by acknowledging that all active CODs had to be renewed in 2019. Therefore, when renewing or receiving an initial COD in 2019, all made a decision as to when they would renew their next COD. Accordingly, for the first year of the 10-year assessment period, 2019, no one within the affected population received any savings.[7] Therefore, savings begin in 2020.

[5] Information pertaining to the historical data can be found in the Appendix, under the supporting documents in the docket, where indicated in the **ADDRESSES** portion of the preamble. The data for 2013 to 2017 is as follows: 171,293; 160,669; 156,552; 155,221; 167,810.

[6] The Coast Guard has collected 2019 data about the behavior of owners towards selecting a new renewal period. However, the data was too incomplete to formulate an accurate representation of the affected population's choices in that year. In addition, because 2019 is the only year for which the Coast Guard has information, this data does not provide enough information (statistically) to develop a trend analysis to project actual changes in behavior. Therefore, we have elected to proceed with analyzing this regulatory assessment by equally dividing the affected population over a 5-year period, resulting in 80% of the annual population not renewing their CODs in a given year.

[7] Further information can be found in the Appendix, under supporting documents in the docket, where indicated in the **ADDRESSES** portion of the preamble.

To conduct this assessment, we create five subcategories (divided equally) of the affected population, and assign each category a specific year for renewal. Any owner who selects a timeframe for renewal greater than 2 years, or beyond 2021 (60 percent of the affected population), will have their follow-on renewals occurring every 5 years after their initial renewal choice. However, we assume that those who select a timeframe of 1 or 2 years (which we refer to as groups A and B), will not necessarily renew their CODs in 5 years. Since groups A and B have chosen the option of renewing in 1 or 2 years, which falls within the phase-in period, they will be given another opportunity to select a renewal period of 1 to 5 years at the time of their renewal.[8] Since groups A and B will, again, have the option of selecting a renewal period of 1 to 5 years, we again partition, within each group, equal portions of owners selecting 1 to 5 years renewal. Once an individual in group A and B selects a renewal period that goes beyond 2021, their follow-up renewal will occur on a 5-year renewal cycle. In Table 2 we present a summary outline as to how we estimate the number of non-renewals occurring during a 10-year period of analysis. Further details about how we estimated the number of renewals and avoided renewals can be found in the Appendix, under supporting documents in the docket, where indicated in the **ADDRESSES** portion of the preamble.

TABLE 2—SUMMARY OF POTENTIAL NON-RENEWING COD POPULATION OVER 10-YEAR PERIOD OF ANALYSIS [9]

[Pre-statutory baseline]

	Potential non-renewing population									
	Phase-in period			5-year renewal period						
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
COD applications under the baseline (A)	162,647	162,647	162,647	162,647	162,647	162,647	162,647	162,647	162,647	162,647
COD applications under the 2018 Act (B)	162,647	32,867	39,441	47,329	47,329	47,329	14,800	8,226	47,667	47,667
Avoided COD applications (A–B)	0	129,780	123,206	115,317	115,317	115,317	147,846	154,421	114,978	114,979

Note: Values may not add due to rounding.

The summary in Table 2 provides an approach as to how industry may react to the changes in the renewal process. In addition, it provides the affected population, which serves as a basis for cost savings throughout the 10-year period of analysis.

All savings realized will be administrative, from the perspective of vessel owners and the Government. Because the 2018 Act changed annual renewals to a 5-year renewal period, owners will spend less time submitting paperwork for renewing their CODs. In addition to the savings that owners will receive, the industry as a whole will see a reduction in paperwork (see Paperwork Reduction Act in section V. D of the preamble to this final rule).

In order to obtain a wage rate for our calculations, to determine the amount of savings incurred by this rulemaking, we first identify the individual(s) who submit the renewal form (CG–1280) to the Coast Guard. Using the 2018 wage rate data from the Bureau of Labor Statistics (BLS) website, we obtain the employee wage that most resembles the persons tasked with renewing CODs as Transportation Employment, Storage and Distribution Managers (OES code 11–3071). The mean hourly wage rate associated with this profession, as reported by BLS, is $49.45 per hour.[10] In order to account for employee benefits, we apply a load factor to the mean hourly wage rate. We calculate the load factor from BLS's Employer Cost for Employee Compensation survey and apply it to the mean hourly wage rate to obtain a fully loaded wage rate, which more accurately represents the employers' cost per hour for employees' work.[11] The load factor we used for this economic assessment is 1.52.[12] The loaded mean hourly wage rate we used to assess the savings estimates is calculated at $75.16 ($49.45 multiplied by 1.52).

From the Supporting Statement for Vessels Documentation collection of information (OMB Control No. 1625–0027), we obtain the amount of time (or time burden) necessary for filling out the renewal documentation as 5 minutes. Applicants may submit the renewal form CG 1280 through regular postal service or through the internet. For the proportion of those submitting form CG–1280 through the internet, annual renewal is about 28 percent [13] of the affected population, while the remaining 72 percent continue utilizing the postal service for their submissions. We estimate that the cost of submitting a renewal form via postal service is 0.55 cents (the cost of a first-class postage stamp), while those who submit the form through the internet incur no additional mailing costs. There are no associated savings with submitting the form online, as we assume that for those choosing that method, internet service is an established part of business operations.

[8] Because we are unable to determine how or why owners make their financial decisions, we assume that groups A and B are not inclined to make a long-term commitment (beyond year 2021) due to projected or un-projected future financial plans. Therefore, we assume that short-term financial decisions will direct them to select a shorter term of 1 or 2 years. For the years following 2021, we assume renewals will be conducted every 5 years. For this illustrative analysis, we break down the renewals in equal annual portions over the five-year period. However, the Coast Guard recognizes that renewal numbers could vary over the 5-year period for several reasons, including the possibility the owners could get rid of their vessels prior to the renewal term.

[9] An expanded population matrix appears in the appendix, which can be found in the supporting documents in the docket, where indicated under the **ADDRESSES** portion of this preamble.

[10] Information about the wage rates for Transportation, Storage and Distribution Managers (11–3071) can be found at *https://www.bls.gov/oes/2018/may/oes113071.htm.*

[11] A loaded wage rate is what a company pays per hour to employ a person, not the hourly wage the employee receives. The loaded wage rate includes the cost of benefits (health insurance, vacation, etc.).

[12] From the BLS, Employer Cost for Employee Compensation survey. The load factor for wages is calculated by dividing total compensation by wages and salaries. For this report, we used the Transportation and Materials Moving Occupations, Private Industry report (Series IDs, CMU2010000520000D and CMU2020000520000D for Total Compensation and Wages and Salaries, respectively, not seasonally adjusted) for all workers using the multi-screen data search. Using 2018 4th quarter data, we divide $29.53/$19.42 to obtain a load factor of 1.52. See *https://data.bls.gov/cgi-bin/dsrv?cm.*

[13] The NVDC provided their assessment on renewal submissions that will be received via internet.

TABLE 3—SUMMARY OF VALUES USED TO FORMULATE SAVINGS

[Pre-statutory baseline]

	Burden hours	HR equivalent
From collection of information	5 Min	0.08
YR–2018	Hourly Wage	$49.45
	Load Rate	1.52
	Total Wage Rate	$75.16
	Submission Cost	** $0.55
	Percent of Submission	100%
	Letter Carrier	72%
	Via Internet	28%

** This cost is only associated with submission of the renewal documentation via letter carrier.

We estimate the savings of this 10-year assessment by combining the information found in Tables 2 and 3. From Table 2, we anticipate how industry will react to changes in the certification renewal process. Therefore, the calculations for determining savings are as follows: Since the number of affected population throughout the 10-year assessment is not uniform, we utilize a sample year to explain how we obtain savings. From table 2, we use the year 2024 as an example. We estimate the number of the affected population for 2024 not renewing their CODs to be about 115,317. The amount of cost savings associated with not having to fill out the request for certification, per person, is estimated at $6.01 ($75.16 loaded wage rate multiplied by 0.08 time burden associated with filling out documentation). Multiplying the affected population in 2024 by the potential savings of $6.01 due to the reduction in time burden results in administrative savings for that year of $693,061. We then account for the cost of submitting the application, at $0.55 for 72 percent of the population in that year, adding an additional cost savings of about $45,666 (72 percent of 115,317 [the affected population in 2024] equals 83,029 multiplied by $0.55 [the cost of a first-class stamp]). The resulting total cost savings for year 2024 is approximately $738,723 (non-discounted). Table 4 provides a 10-year summary of cost savings that industry will realize.

TABLE 4—SUMMARY OF 10-YEAR ASSESSMENT OF INDUSTRY COST SAVINGS, IN $2018

[Pre-statutory baseline]

Year	Cost savings non-discounted	Cost savings discounted 3%	Cost savings discounted 7%
2019	No savings in first year		
2020	$831,371	$783,647	$726,151
2021	789,251	722,277	644,264
2022	738,721	656,344	563,566
2023	738,723	637,229	526,700
2024	738,723	618,669	492,243
2025	947,104	770,082	589,809
2026	989,211	780,892	575,730
2027	736,549	564,504	400,634
2028	736,558	548,069	374,429
Total	7,246,212	6,081,712	4,893,526
Annualized	.....	712,962	696,727

Note: Values may not add due to rounding.

Summarizing Table 4, we note that industry will not incur any cost savings during the first year of our assessment, since the entire affected population had to renew in 2019 and, in that year, make a determination regarding their next renewal date.[14] However, after the first year, industry will begin to realize savings due to the extended renewal period provided by the 2018 Act. We estimate that the total 10-year savings is $4.9 million, and the annualized savings is $0.697 million, both discounted at 7 percent.

Government Assessment

The 2018 Act also affects the Federal government by reducing the amount of renewal applications it will process in a given year. The anticipated reduction in the administration of renewal applications is correlated to the anticipated reduction in the number of the affected population renewing their CODs in a given year. The Government's reduction in approved certification will follow the data found in Table 2.

The COD approval is a two-phase process, in which the Government initiates, as a courtesy, the renewal process, and then, in the processing phase, issues the CODs to vessel owners. The first phase, initiating a request for vessel owners to renew their annual CODs, is accomplished by sending CG–1280 Vessel Renewal Notification Application for Renewal mailers to vessel owners approximately 45 days prior to the expiration date of their current CODs. The first step of this phase is to determine who is eligible for renewal and to remind current COD holders that their COD is expiring

[14] In 2019, all CODs were still affected by pre-mandated regulations, which means all CODs were renewed. For more information on the distribution of the population, please see the Appendix in the docket.

within 45 days. Once that is accomplished, all material relating to renewal notices, to include metered mail, is processed and sent to vessel owners. In the second step, the Government receives the application packet from owners, which is reviewed and approved prior to issuance of the COD.

The Government employees assigned the duties of initiating renewal notices are classified as GS–5 and GS–7-employees. Subject matter experts (SMEs) estimate the individual cost of sending a renewal notice at approximately $3.05.[15] To estimate the annual reduction in cost to the Government, we multiply the individual cost of annual notifications by the number of vessel owners not submitting annual renewals in a given year. Table 5 shows the estimated cost savings, per year, that the Government will realize from a reduction in the annual number of notifications sent out to owners of recreational vessels.

TABLE 5—ESTIMATED GOVERNMENT SAVINGS FOR INITIATING COD RENEWALS IN $2018

[Pre-statutory baseline]

Year	Estimated reduction in applications	Government savings non-discounted
2019	0	0
2020	129,780	$395,829
2021	123,205	375,775
2022	115,317	351,717
2023	115,317	351,718

TABLE 5—ESTIMATED GOVERNMENT SAVINGS FOR INITIATING COD RENEWALS IN $2018—Continued

[Pre-statutory baseline]

Year	Estimated reduction in applications	Government savings non-discounted
2024	115,317	351,718
2025	147,846	450,932
2026	154,419	470,979
2027	114,978	350,683
2028	114,979	350,687
Total ..	.....	3,450,039

Note: Values may not add due to rounding.

The second phase of the process involves the Government receiving the renewal applications from vessel owners, processing those applications, and then issuing the CODs. The Government employees responsible for reviewing the applications and granting CODs are also classified as GS–5 and GS–7 employees. According to data provided by the SME, it takes a GS–5 9 minutes to process a renewal application, at a cost of $5.40 per renewal.[16] Additionally, it takes a GS–7 approximately 1 minute to approve a COD, at a cost of $0.72 per renewal request.[17] The individual cost of finalizing the renewal process, to include mailing the certificates, is estimated at $6.12 per renewal.[18] The savings that the Government will realize from approving and issuing CODs will be the number of owners not submitting COD renewals in a given year. Table 6 shows the estimated savings, annually, that the Government will realize from a reduction in processing renewal applications.

TABLE 6—ESTIMATED GOVERNMENT SAVING FOR PROCESSING AND GRANTING COD RENEWALS IN $2018

[Pre-statutory baseline]

Year	Estimated reduction in applications received	Cost savings non-discounted
2019	0	0
2020	129,780	$794,254
2021	123,205	754,015
2022	115,317	705,740
2023	115,317	705,743
2024	115,317	705,743
2025	147,846	904,820
2026	154,419	945,047
2027	114,978	703,665
2028	114,979	703,674
Total ..	.....	6,922,700

Note: Values may not add due to rounding.

We estimate the 10-year combined (initial phase and processing phase) cost savings that the Government will realize at $10,372,739 (non-discounted). We estimate the total discounted cost savings at $7,004,938, and annualized cost savings of $997,345, both discounted at 7 percent. Table 7 shows the total estimated Government cost savings over the 10-year period of analysis.

TABLE 7—ESTIMATED TOTAL GOVERNMENT COST SAVING, IN $2018

[Pre-statutory baseline]

Year	Non-discounted cost savings	3%	7%
2019	No savings first year		
2020	$1,190,083	$1,121,766	$1,039,464
2021	1,129,790	1,033,917	922,245
2022	1,057,457	939,536	806,729
2023	1,057,461	912,175	753,955
2024	1,057,461	885,606	704,631
2025	1,355,752	1,102,350	844,294
2026	1,416,026	1,117,824	824,140
2027	1,054,348	808,070	573,496
2028	1,054,361	784,543.93	535,984
Total	10,372,739	8,705,792	7,004,938
Annualized	.....	1,020,584	997,345

Note: Values may not add due to rounding.

[15] The NVDC provided the information pertaining to government expenditure from a draft study they commissioned through an independent third party. At the time of publishing this assessment, the document has not been made available to the public.

[16] The NVDC provided the information pertaining to government expenditure from a draft study they commissioned from an independent third party. At the time of publishing this assessment, the document has not been made available to the public.

[17] Ibid.

[18] The estimated cost was obtained by combining the administrative cost of a Clerk 1, $5.40 ($.60 wage per minute multiplied by 9 minutes of administrative time), and a Clerk 2, $.72 ($.72 wage rate per minute multiplied by 1 minute of administrative time). Total administrative cost burden is $6.12 ($5.40 plus $.72) per applicant.

The total 10-year combined (industry and Government) cost savings is estimated at $17,618,951, non-discounted, with an annualized savings of $1,694,073, discounted at 7 percent. Table 8 provides the total annual estimated cost savings that the Act will provide to the affected stakeholders.

TABLE 8—TOTAL COST SAVINGS IN $2018

[Pre-statutory baseline]

Year	Vessel owners not submitting renewals	Cost savings	3%	7%
2019	No savings in first year			
2020	129,780	$2,021,453	$1,905,414	$1,765,616
2021	123,205	1,919,041	1,756,194	1,566,509
2022	115,317	1,796,178	1,595,881	1,370,295
2023	115,317	1,796,184	1,549,404	1,280,655
2024	115,317	1,796,184	1,504,276	1,196,874
2025	147,846	2,302,856	1,872,433	1,434,103
2026	154,419	2,405,237	1,898,716	1,399,870
2027	114,978	1,790,897	1,372,574	974,129
2028	114,979	1,790,920	1,332,612	910,413
Total		17,618,951	14,787,504	11,898,463
Annualized			1,733,546	1,694,073

Note: Values may not add due to rounding.

In addition to estimating the normal savings for this rule, we use the perpetual period of analysis for observing the long-term affect this assessment will have on the affected population. Therefore, we estimate the total annualized cost savings of the 2018 Act at $1.49 million in 2016 dollars, using a 7-percent discount rate.

Final Rule Regulatory Impacts

As previously stated, under a no-action baseline, this final rule produces no impact on the regulated industry. The rule is merely harmonizing current practices implemented by the 2018 Authorization Act with 46 CFR part 67. The impacts presented above are measured against a pre-statutory baseline and represent the result of the 2018 Act, which this rule codifies.

Alternatives

The Coast Guard did not examine any alternatives for this final rule as this rule is mandated by Congress under the Coast Guard Authorization Act of 2018. The 2018 Act requires that Coast Guard issue recreational Certificates of Documentation with a validity of 5 years, thereby reducing the amount of annual reporting burden vessel owners incur each year. The Coast Guard is promulgating this rule to comply with statute and may not adopt a different renewal period or pursue any other alternatives.

B. Small Entities

The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. This rule is not preceded by a notice of proposed rulemaking and is, therefore, exempt from the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act does not apply when notice and comment rulemaking is not required.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this rule. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This final rule codifies the 2018 Act, which results in a change to an existing collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Vessel Documentation.

OMB Control Number: 1625–0027.

Summary of the Collection of Information: This final rule, by harmonizing with the 2018 Act, modifies the existing Certification of Documentation (COD) reporting and recordkeeping requirements in § 67.163(c), which will amend current reporting. The current regulation requires owners of recreational vessels of at least 5 net tons to renew their CODs annually. This final rule will codify current industry practice as of January 1, 2019 and will require

recreational vessel owners to convert from an annual renewal period to a 5-year renewal period.

Need for Information: The information is being collected for two reasons: (1) The documenting of a U.S. vessel comes with rights as well as responsibilities, which entitle the vessel owners protection under the U.S. flag; (2) vessel documentation is a requirement in satisfying mortgage lender requirements.

Proposed Use of Information: The collection of this information is maintained by the Coast Guard as a matter of record for identifying vessels that will be entitled to protection under U.S. flag. In addition, the certification of a vessel is an obligation to be performed by the vessel owners as part of a financial agreement they have entered into with a mortgage company.

Description of the Respondents: The respondents are the owners of recreational vessels of at least 5 net tons that choose to document their vessels or are required to document their vessels due to financial obligations, which a financial institution may require when a borrower takes out a loan for the purchase of a vessel.

Number of Respondents: The total number of respondents affected is estimated at 162,309, plus an estimated average of 338 new vessels obtaining CODs each year.

Frequency of Response: The final rule codifies the 2018 Act that converts the annual renewal of CODs to a 5-year renewal, reducing the frequency of responses in any given year. From January 1, 2019 to December 31, 2021, owners are allowed to choose their 1 to 5-year renewal period. As of January 1, 2022, owners will only be allowed to apply for 5-year CODs. However, during the first year (2019), 100 percent (162,647) of the affected population sought COD renewals for their vessels. From 2020 on, we take the anticipated annual 9-year average to estimate the potential reduction in frequency of responses required from this information collection request. Hence, we estimate the average number of responses annually will be reduced from 189,614 to 63,930.

Burden of Response: This final rule codifies the 2018 Act and, as a result, will reduce the burden of renewing annual CODs to a 5-year renewal period. Therefore, reduction in time for submitting renewal application forms will decrease by approximately 10,061 hours.

Estimate of Total Annual Burden: The annual reduction in burden is estimated as follows:

(a) *Annual reduction in burden resulting from converting annual reporting requirement for recreational vessel of at least 5 net tons to a 5-year renewal period:* The final rule codifies the 2018 Act that will reduce the number of CODs requested and approved annually. We estimate that it takes 5 min (0.08 equivalent hours) to send in a vessel documentation renewal. We estimate the total average annual burden or hour reduction for those vessel owners who will not be required to renew their documentation to be 10,054 hours (125,684 * 0.08 hours).

(b) *The total reduction in annual burden hours due to the conversion from an annual renewal to a 5-year renewal period:* This final rule will result in an estimated average annual reduction in total burden hours in the collection of information from 11,373 to 1,319.

As required by 44 U.S.C. 3507(d), we will submit a copy of this final rule to OMB for its review of the collection of information. You are not required to respond to a collection of information unless it displays a currently valid OMB control number.

E. Federalism

A rule has implications for federalism under Executive Order 13132 (Federalism) if it has a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under Executive Order 13132 and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. Our analysis follows.

As explained in Sections II and III above, this rulemaking is needed to conform the regulations to the existing law as amended by the 2018 Act. The 2018 Act requires the Coast Guard to issue CODs for recreational vessels with a period of validity of 5 years, following a phase-in period. The 2018 Act prescribes how the cost of the renewal of such a recreational endorsement must be calculated in both the phase-in period and thereafter. It also requires vessel owners to notify the Coast Guard of each change in the information on which the issuance of the COD for the vessel is based, before the expiration of the COD and no later than 30 days after the change. The 2018 Act also requires that a COD will terminate upon the expiration of the 30-day period if the owner has not notified the Coast Guard of changes within the 30-day timeframe.

Documentation under chapter 121 of title 46, United States Code, including under 46 U.S.C. 12105 as amended by the 2018 Act (see amendments described in the preceding paragraph), is the means by which the Federal government allows a vessel to operate in certain trades, establishes vessel nationality, and enables a vessel to be subject to preferred mortgages. It is well settled that States may not regulate in categories reserved by Congress for regulation by the Coast Guard. It also is well settled that all the categories regulated under 46 U.S.C. 2103, 3103, 3306, 3703, 4102, 4502, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels), as well as any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. *See* the Supreme Court's decision in *United States* v. *Locke* and *Intertanko* v. *Locke,* 529 U.S. 89, 120 S.Ct. 1135 (2000). This rule implements changes made by Congress to the comprehensive federal vessel documentation requirements of 46 U.S.C. ch. 121, over which Congress clearly has granted the Coast Guard, via delegation from the Secretary, exclusive authority. Therefore, because the States may not regulate within this category, this rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. The Coast Guard values the input of State and local governments in such matters.

F. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Although this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have

taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. This rule is categorically excluded under paragraph L57 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev 1. Paragraph L56 pertains to documentation of vessels. This rule involves extending the validity of a recreational vessel endorsement on a Certificate of Documentation.

List of Subjects in 46 CFR Part 67

Reporting and recordkeeping requirements, Vessels.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR part 67 as follows:

PART 67—DOCUMENTATION OF VESSELS

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 4 U.S.C. 664; 31 U.S.C. 9701; 42 U.S.C. 9118; 46 U.S.C. 2103, 2104, 2107, 12102, 12103, 12104, 12105, 12106, 12113, 12133, 12139; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 67.163 by:

■ a. Revising paragraph (a) introductory text;

■ b. Revising paragraph (b); and

■ c. Adding paragraph (c).

The revisions and addition read as follows:

§ 67.163 Renewal of endorsement.

(a) *Requirement for renewal of endorsement.* Endorsements on Certificates of Documentation are valid for 1 year, except for Recreational Endorsements on Certificates of Documentation, which are valid for 5 years. However, a Certificate of Documentation with a Recreational Endorsement and a Commercial Endorsement will only be valid for 1 year. Prior to the expiration of an endorsement, the owner of a vessel, which is not exempt from the requirement for documentation under paragraph (c) of § 67.9, must apply for renewal of the endorsement(s) by complying with paragraph (b) of this section. The owner of a vessel exempt from the requirement for documentation under paragraph (c) of § 67.9 must either:

* * * * *

(b) *Renewal application.* The owner of a vessel must apply for renewal of each endorsement by executing an original Vessel Renewal Notification, Application for Renewal (CG–1280) certifying that the information contained in the Certificate of Documentation and any endorsement(s) thereon remains accurate, and that the Certificate has not been lost, mutilated, or wrongfully withheld. The completed CG–1280 must be sent to the Director, National Vessel Documentation Center.

(c) *Requirement for renewal of recreational endorsements.* A certificate of documentation for a recreational vessel and the renewal of such a certificate shall be effective for a 5-year period. During the period beginning January 1, 2019, and ending December 31, 2021, the owner of a recreational vessel may choose a period of effectiveness of 1, 2, 3, 4, or 5 years for such a certificate of documentation for such vessel or the renewal thereof.

§ 67.317 [Amended]

■ 3. In § 67.317 amend paragraph (a) by adding, after the introductory phrase, ''Except as provided in paragraph (b) of this section,'' the text ''and except for recreational endorsements, which must be renewed every 5 years,''.

■ 4. Revise § 67.319 to read as follows:

§ 67.319 Requirement to report change in vessel status and surrender Certificate of Documentation.

(a) The owner of a vessel must notify the Coast Guard of each change in the information on which the issuance of the Certificate of Documentation for the vessel is based that occurs before the expiration of the certificate under this subsection, by no later than 30 days after such change.

(b) The Certificate of Documentation for a vessel is terminated upon the expiration of the 30-day period if the owner has not notified the Coast Guard of such change before the end of the period.

§ 67.515 [Amended]

■ 5. In § 67.515, remove the word ''annual''.

■ 6. Revise § 67.550 to read as follows:

§ 67.550 Fee table.

The fees charged under subpart Y are as set forth in Table 1 to 67.550.

TABLE 1 TO 67.550—FEES

Activity	Reference	Fee
Applications:		
Initial Certificate of Documentation	Subpart K	$133.00
Exchange of Certificate of Documentation	do	84.00
Return of vessel to documentation	do	84.00
Replacement of lost or mutilated Certificate of Documentation	do	50.00
Approval of exchange of Certificate of Documentation requiring mortgagee consent	do	24.00
Trade endorsement(s):		
Coastwise endorsement	Subpart B	29.00
Coastwise Boaters endorsement	46 CFR part 68	29.00
Fishery endorsement	do	12.00
Registry endorsement	do	none
Recreational endorsement	do	
Recreational vessel endorsements (5-year)		130.00
Through December 31, 2021:		
4-year recreational vessel endorsement		104.00
3-year recreational vessel endorsement		78.00
2-year recreational vessel endorsement		52.00
1-year recreational vessel endorsement		26.00
Note 1: When multiple trade endorsements are requested on the same application, the single highest applicable endorsement fee will be charged, resulting in a maximum endorsement fee of $29.00. This does not apply to recreational endorsements.		
Evidence of deletion from documentation	Subpart L	15.00
Renewal fee	do	26.00
Commercial vessel endorsements (annual)	do	26.00
Recreational vessel endorsements (5-year)		130.00
Through December 31, 2021:		
4-year recreational vessel endorsement		104.00
3-year recreational vessel endorsement		78.00
2-year recreational vessel endorsement		52.00
1-year recreational vessel endorsement		26.00
Late renewal fee	do	[1] 5.00
Waivers:		
Original build evidence	Subpart F	15.00
Bill of sale eligible for filing and recording	Subpart E	15.00
Miscellaneous applications:		
Wrecked vessel determination	Subpart J	555.00
New vessel determination	Subpart M	166.00
Rebuild determination—preliminary or final	do	450.00
Filing and recording:		
Bills of sale and instruments in nature of bills of sale	Subpart P	[2] 8.00
Mortgages and related instruments	Subpart Q	[2] 4.00
Notice of claim of lien and related instruments	Subpart R	[2] 8.00
Certificate of compliance:		
Certificate of compliance	46 CFR part 68	55.00
Miscellaneous:		
Abstract of Title	Subpart T	25.00
Certificate of ownership	do	125.00
Attachment for each additional vessel with same ownership and encumbrance data	do	10.00
Copy of instrument or document	(3)	(3)

[1] Late renewal fee is in addition to the cost of the endorsement sought.
[2] Per page.
[3] Fees will be calculated in accordance with 6 CFR part 5, subpart A.

Dated: January 8, 2021.

R.V. Timme,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2021–00526 Filed 1–15–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 210112–0008]

RIN 0648–BK08

International Fisheries; Pacific Tuna Fisheries; Fishing Restrictions for Tropical Tuna in the Eastern Pacific Ocean for 2021

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim final rule; request for comments.

SUMMARY: NMFS is issuing regulations under the Tuna Conventions Act to implement Resolution C–20–05 (*Conservation of Tuna in the Eastern Pacific Ocean During 2021*), which was adopted by the Inter-American Tropical Tuna Commission (IATTC or Commission) on December 22, 2020. All of the provisions of Resolution C–20–05 are identical in content to the previous resolution on tropical tuna management that expired at the end of 2020. This interim final rule implements the C–20–05 fishing management measures for tropical tuna (*i.e.,* bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), and skipjack tuna (*Katsuwonus pelamis*)) in the eastern Pacific Ocean (EPO). The fishing restrictions in this interim final rule are applicable in 2021 only and apply to purse seine vessels of class sizes 4–6 (carrying capacity of 182 metric tons (mt) or greater) and longline vessels greater than 24 meters (m) in overall length that fish for tropical tuna in the EPO. This interim final rule is necessary for the conservation of tropical tuna stocks in the EPO and for the United States to satisfy its obligations as a member of the IATTC.

DATES: This interim final rule is effective January 19, 2021. Comments on the interim final rule must be submitted in writing by February 18, 2021.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0122, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0122*, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Rachael Wadsworth, NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2020–0122'' in the comments.

Instructions: Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

ADDRESSES: Copies of supporting documents that were prepared for this interim final rule, including the regulatory impact review (RIR) are available via the Federal e-Rulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2020–0122, or contact Rachael Wadsworth, NMFS WCR SFD, NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or *WCR.HMS@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Rachael Wadsworth, NMFS, at (206) 561–3457.

SUPPLEMENTARY INFORMATION:

Background on the IATTC

The United States is a member of the IATTC, which was established under the 1949 Convention for the Establishment of an Inter-American Tropical Tuna Commission. In 2003, the IATTC adopted the Convention for the Strengthening of the IATTC Established by the 1949 Convention between the United States of America and the Republic of Costa Rica (Antigua Convention). The Antigua Convention entered into force in 2010. The United States acceded to the Antigua Convention on February 24, 2016. The full text of the Antigua Convention is available at: *https://www.iattc.org/PDFFiles/IATTC-Instruments/_English/IATTC_Antigua_Convention%20Jun%202003.pdf.*

The IATTC consists of 21 member nations and 5 cooperating non-member nations and facilitates scientific research into, as well as the conservation and management of, tuna and tuna-like species in the IATTC Convention Area. The IATTC Convention Area is defined as waters of the EPO within the area bounded by the west coast of the Americas and by 50° N latitude, 150° W longitude, and 50° S latitude. The IATTC maintains a scientific research and fishery monitoring program and regularly assesses the status of tuna, sharks, and billfish stocks in the IATTC Convention Area to determine appropriate catch limits and other measures deemed necessary to promote sustainable fisheries and prevent the overexploitation of these stocks.

International Obligations of the United States Under the Antigua Convention

As a Party to the Antigua Convention and a member of the IATTC, the United States is legally bound to implement decisions of the IATTC. The Tuna Conventions Act (16 U.S.C. 951 *et seq.*) directs the Secretary of Commerce, in consultation with the Secretary of State and, with respect to enforcement measures, the U.S. Coast Guard, to promulgate such regulations as may be necessary to carry out the United States' obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. The authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS.

IATTC Resolution on Tropical Tuna Conservation

On November 30–December 4, 2020, the IATTC met virtually for the 95th IATTC meeting and was unable to reach consensus on management measures for tropical tuna in the EPO, which is unusual. This meeting, which is typically held in person during the summer months, had been delayed due to travel restrictions. The failure of the Commission to reach consensus at its meeting created an urgent situation because the tropical tuna management measures were set to expire at the end of the 2020 calendar year, and no measures would have been in place for the start of the 2021 fishing season. The IATTC ultimately adopted Resolution

C–20–05 (*Resolution on Conservation and Management Measures of Tropical Tunas in 2021*) by consensus at its 96th Extraordinary Meeting on December 22, 2020.

Applicable to 2021 only, the provisions of Resolution C–20–05 are identical in content to those contained in the previous IATTC Resolution (C–17–02; *Multiannual Program for the Conservation of Tuna in the Eastern Pacific Ocean During 2018–2020*) on tropical tuna management that were in place from 2018–2020. The provisions include a 72-day fishing closure period for purse seiners, provisions for exemptions from that closure period due to force majeure, a time/area closure in the EPO for 31 days for purse seiners, catch limits of bigeye tuna caught in the EPO for longline vessels greater than 24 m in overall length, catch limit transfer requirements for bigeye tuna, a requirement that all tropical tuna be retained and landed (with some exceptions), and restrictions on the use and design of fish aggregating devices (FADs).

As described further under the Classification section, due to the unforeseen circumstances of the delayed IATTC meeting, the late-adoption of Resolution C–20–05, and given that NMFS must implement regulations quickly to ensure conservation of tropical tuna stocks in the EPO and to comply with its international obligations, NMFS is implementing these regulations through an interim final rule without providing the public with advance notice in a proposed rule or the opportunity for comment. This interim final rule will be effective immediately upon publication. NMFS will, however, accept and consider public comments submitted on this interim final rule.

Final Regulations—Tuna Conservation Measures for 2021

This interim final rule is implemented under the Tuna Conventions Act of 1950 (16 U.S.C. 951 *et seq.*), as amended on November 5, 2015, by title II of Public Law 114–81. This interim final rule implements the provisions of Resolution C–20–05 and applies to U.S. commercial fishing vessels using purse seine and longline gear to catch tropical tuna in the IATTC Convention Area. Resolution C–20–05 continues for 2021 provisions that were included in the previous IATTC Resolution C–17–02 that were applicable to 2018–2020. Those provisions were implemented into regulation in a final rule published on April 11, 2018 (83 FR 15503). This interim final rule continues those regulations for 2021.

First, this rule maintains a 750 mt catch limit on bigeye tuna caught by longline vessels greater than 24 m in overall length in the IATTC Convention Area (50 CFR 300.25(a)(2)). Second, the rule maintains the prohibition on purse seine vessels of class size 4 to 6 (*i.e.,* vessels with a carrying capacity greater than 182 mt) from fishing for tropical tuna in the IATTC Convention Area for a period of 72 days (50 CFR 300.25(e)(1)). Specifically, vessels will continue to be prohibited from fishing in the EPO for 72 days during one of the following two periods: (1) From July 29 to October 8; or (2) from November 9 to January 19 of the following year (50 CFR 300.25(e)(1)(i) and (ii)). Third, the rule maintains a closure period (*i.e.,* Corralito closure) for the purse seine fishery for tropical tuna within the area of 96° and 110° W and between 4° N and 3° S from 0000 hours on October 9, 2021, to 2400 hours on November 8, 2021 (50 CFR 300.25(e)(5)). The three regulations described in this paragraph are amended by this interim final rule solely to specify that they apply in calendar year 2021.

This interim final rule also continues for 2021 several other regulations that were applicable in 2018–2020 but that do not need to be amended by this rulemaking because their regulatory text does not specify the calendar years to which they apply. Therefore, this interim final rule continues the effectiveness of those regulations in 2021 without amendment. Those regulations are included below:

- Provisions related to transferring longline catch limits for bigeye tuna between IATTC members (50 CFR 300.25(a)(5)).
- Provisions related to selection of a 72-day closure period (50 CFR 300.25(e)(2) and (3)).
- Provisions related to exemptions from the 72-day closure period requirement due to force majeure (50 CFR 300.25(e)(4)).
- Requirements related to stowing gear during time/area closure periods (50 CFR 300.25(e)(6)).
- A requirement for all tropical tuna to be retained on board and landed (with certain exceptions) (50 CFR 300.27(a)).
- A number of restrictions related to FADs for purse seine vessels in the IATTC Convention Area (50 CFR 300.22(a)(3); 50 CFR 300.28).

The definitions of ''Active FAD'' and ''Force majeure'' included in 50 CFR 300.21 and the prohibitions against failing to comply with gear-stowing restrictions, time/area closure restrictions, and FAD-related restrictions described in 50 CFR 300.24 also continue to apply.

Classification

The NMFS Assistant Administrator has determined that this interim final rule is consistent with the Tuna Conventions Act of 1950 and other applicable laws. This interim final rule has been determined to be not significant for purposes of Executive Order 12866.

This interim final rule does not contain a change to a collection of information requirement for the purposes of the Paperwork Reduction Act of 1995. The existing collection of information requirement would continue to apply under the following OMB Control Numbers 0648–0214 (Pacific Islands Region Logbook Family of Forms) and 0648–0148 (West Coast Region Pacific Tuna Fisheries Logbook and Fish Aggregating Device Form).

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number. All currently approved NOAA collections of information may be viewed at: *https://www.reginfo.gov/public/do/PRAMain*.

Good Cause for Immediate Adoption

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. Under section 553(d) of the APA, an agency must delay the effective date of regulations for 30 days after publication, unless the agency finds good cause to make the regulations effective sooner.

The Assistant Administrator for Fisheries determined that good cause exists to issue this interim final rule without advance notice in a proposed rule or the opportunity for public comment and to make the rule effective immediately without providing a 30-day delay after publication. NMFS is obligated to implement these measures immediately to conserve tropical tuna stocks in the EPO and to comply with the international obligations of the United States under a binding resolution adopted by the IATTC under

the Antigua Convention, which constitute good cause. Given the IATTC's delay in convening its 2020 annual meeting (typically held in June or July), its failure to adopt a binding Resolution at a meeting held November 30–December 4, 2020, and its adoption of a binding Resolution in late December (less than 2 weeks before the existing regulations were set to expire), it would be impracticable and contrary to the public interest in conserving tropical tuna stocks in the EPO and in ensuring U.S. compliance with international obligations to proceed with further notice and comment or to delay the effective date for 30 days before implementing the rollover conservation measures contained in this rule.

Commercial purse seine and longline vessels are expected to begin fishing for tropical tuna in the EPO on January 1, 2021, under the fishing restrictions that apply in the same year. If this rule were delayed pending publication of a proposed rule and consideration of additional public comments, there is potential for U.S. purse seine and longline vessels to be out of compliance with IATTC management measures, and for the United States to be out of compliance with our international obligations. Owners and operators of U.S. purse seine and longline vessels operating in the EPO are familiar with this Resolution because it is identical to the resolution in place for the past 3 years that was implemented through notice and comment rulemaking. In addition, many of the affected individuals attended the 96th Extraordinary Meeting of the IATTC on December 22, 2020, where the Resolution was adopted. Industry representatives were also consulted in advance of the December meeting through a U.S. Delegation call and were involved in briefings and discussions with the U.S. Department of State and NOAA officials on the periphery of the December IATTC meeting. As soon as the rule is published, NMFS will send a notice of this rule to owners of vessels that are affected by this rule.

Ensuring conservation of tropical tuna stocks in the EPO and remaining in compliance with binding international obligations of the United States by expedient domestic implementation of Resolution C–20–05 through issuing this final rule now, rather than risking violation of our obligations or the health of tuna stocks, is in the public's interest and further supports the good cause for waiving the requirement to publish a notice of proposed rulemaking for public comment and for making the rule effective immediately upon publication. The IATTC will meet again in the upcoming months to discuss tropical tuna measures for 2022 and beyond.

NMFS encourages the public to participate in this rulemaking by submitting comments containing relevant information, data, or views. This interim final rule may be amended based on comments received.

Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA), 5 U.S.C. 603 and 604, requires an agency to prepare an initial and a final regulatory flexibility analysis whenever an agency is required by 5 U.S.C. 553 or any other law to publish a general notice of proposed rulemaking. Because NMFS found good cause under 5 U.S.C. 553(b)(3)(B) to forgo publication of a notice of proposed rulemaking, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 are not required for this rulemaking.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: January 12, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300, subpart C is amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for 50 CFR part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 2. Amend § 300.25 by revising paragraphs (a)(2), (e)(1), and (e)(5) as follows:

§ 300.25 Fisheries management.

(a) * * *

(2) For calendar year 2021, there is a limit of 750 metric tons of bigeye tuna that may be caught by longline gear in the Convention Area by U.S. commercial fishing vessels that are over 24 meters in overall length. The catch limit within a calendar year is subject to increase if the United States receives a transfer of catch limit from another IATTC member or cooperating non-member, per paragraph (a)(5) of this section.

* * * * *

(e) * * * (1) *72-day closure.* A commercial purse seine fishing vessel of the United States that is of class size 4–6 (more than 182 metric tons carrying capacity) may not be used to fish with purse seine gear in the Convention Area for 72 days in calendar year 2021 during one of the following two periods:

(i) From 0000 hours Coordinated Universal Time (UTC) July 29 to 2400 hours UTC October 8, or

(ii) From 0000 hours UTC November 9 to 2400 hours UTC January 19 of the following year.

* * * * *

(5) *31-day area closure.* A fishing vessel of the United States of class size 4–6 (more than 182 metric tons carrying capacity) may not be used from 0000 hours on October 9, 2021, to 2400 hours on November 8, 2021, to fish with purse seine gear within the area bounded at the east and west by 96° and 110° W longitude and bounded at the north and south by 4° N and 3° S latitude.

* * * * *

[FR Doc. 2021–00975 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 11
Tuesday, January 19, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 109, 120, and 123

[Docket Number SBA–2020–0057]

RIN 3245–AH60

Ensuring Equal Treatment for Faith-Based Organizations in SBA's Loan and Disaster Assistance Programs

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (''SBA'' or ''Agency'') is proposing to remove five regulatory provisions that run afoul of the Free Exercise Clause of the First Amendment. All five provisions make certain faith-based organizations ineligible to participate in certain SBA business loan and disaster assistance programs because of their religious status. Because the provisions exclude a class of potential participants based solely on their religious status, the provisions violate the Free Exercise Clause of the First Amendment. SBA now proposes to remove the provisions to ensure in its business loan and disaster assistance programs the equal treatment for faith-based organizations that the Constitution requires.

DATES: Comments must be received on or before February 18, 2021.

ADDRESSES: You may submit comments, identified by RIN 3245–AH60, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or Hand Delivery/Courier:* Valerie Mills, Executive Operations Officer, Office of General Counsel, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

SBA will post all comments on *https://www.regulations.gov.* If you wish to submit confidential business information (''CBI''), as defined in the User Notice at *https://www.regulations.gov,* please submit the information to Valerie Mills, Executive Operations Officer, Office of General Counsel, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416, or send an email to *Valerie.Mills@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Valerie Mills, Executive Operations Officer, Office of General Counsel, (202) 619–0539, *Valerie.Mills@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

Consistent with its April 3, 2020, letter to Congress pursuant to 28 U.S.C. 530D (''530D letter''), SBA is proposing to remove from the Code of Federal Regulations (''CFR'') five provisions that run afoul of the Free Exercise Clause of the First Amendment. The provisions that SBA proposes to remove consist of the two provisions with which SBA's 530D letter was concerned and three other, substantially similar provisions. All five provisions make certain faith-based organizations ineligible to participate in certain SBA business loan and disaster assistance programs because of their religious status. Because the provisions exclude a class of potential participants solely based on their religious status, the provisions violate the Free Exercise Clause of the First Amendment, as construed in *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 137 S. Ct. 2012 (2017), and *Espinoza* v. *Montana Department of Revenue,* 140 S. Ct. 2246 (2020). After consulting with the Department of Justice, in its 530D letter, SBA already has announced its decision not to enforce, apply, or administer two of the provisions, as well as its intention to propose amendments to conform those provisions to the Constitution. SBA now proposes such amendments, as well as amendments to three substantially similar provisions, to ensure in its business loan and disaster assistance programs the equal treatment for faith-based organizations that the Constitution requires.

A. The Subject Programs

Intermediary Lending Pilot Program (''ILP''). The Intermediary Lending Pilot (''ILP'') program was established as a pilot program authorized by the Small Business Jobs Act of 2010, Public Law 111–240 (2010), to provide loans of up to $1,000,000 to nonprofit intermediaries for the purpose of providing loans to small businesses. The program authorized SBA to select up to 20 nonprofit intermediaries each year to receive loans of up to $1,000,000, subject to the availability of funds. Selected ILP intermediaries, in turn, use the funds to make loans of up to $200,000 to eligible startup, newly established, or growing small businesses. ILP Intermediaries continue to relend a portion of the payments received on small business loans made under the program until they have fully repaid their loans to SBA.

Business Loan Programs. SBA provides financial assistance to small businesses under three business loan programs: its general business loan program authorized by section 7(a) of the Small Business Act, 15 U.S.C. 636(a) (''7(a) loans''), its microloan program authorized by section 7(m) of the Small Business Act, 15 U.S.C. 636(m) (''microloans''), and its development company program authorized by title V of the Small Business Investment Act, 15 U.S.C. 695–697f (''504 loans''). 7(a) loans provide financing to eligible small businesses for general business purposes and are guaranteed loans by which SBA guarantees a portion of a loan made by a lender. Through its microloans, SBA makes loans to non-profit intermediaries that in turn make short-term loans with a maximum amount of $50,000 to eligible small businesses for general business purposes, including the purchase of furniture, fixtures, supplies, materials, equipment, and for working capital. SBA also makes technical assistance grants to intermediaries for use in providing management assistance and counseling to microloan borrowers and prospective microloan borrowers. Projects involving 504 loans require long-term, fixed-asset financing for small businesses. A 504 project has three main partners: A Third Party Lender provides 50 percent or more of the financing; a Certified Development Company (CDC) provides up to 40 percent of the financing through a 504

debenture (guaranteed 100% by SBA); and an applicant (Borrower) injects at least 10 percent of the financing.

Economic Injury Disaster Loan Program (''EIDL''). The Economic Injury Disaster Loan (''EIDL'') program provides economic relief to eligible small businesses and private nonprofit organizations that experience substantial economic injury as a direct result of a declared disaster. Substantial economic injury is such that a business concern is unable to meet its obligations as they mature or to pay its ordinary and necessary operating expenses. EIDL loan proceeds may be used only for working capital necessary to carry on the business concern until resumption of normal operations and for expenditures necessary to alleviate the specific economic injury, but not to exceed that which the business concern could have provided had the injury not occurred.

Military Reservist Economic Injury Disaster Loan Program (''MREIDL''). The Military Reservist Economic Injury Disaster Loan (''MREIDL'') program provides loan funds to eligible small businesses to meet their ordinary and necessary operating expenses that they could have met, but are unable to meet, because an essential employee was called up to active service for a period of more than 30 consecutive days in his or her role as a military reservist. The loans provide the amount of working capital that eligible small businesses need to pay their necessary obligations as they mature until operations return to normal after the essential employee is released from active service. Loans can be provided for a maximum amount of $2,000,000 and a maximum term of 30 years.

Immediate Disaster Assistance Program (''IDAP''). The Immediate Disaster Assistance Program (''IDAP'') is a guaranteed disaster loan program for small businesses that have suffered physical damage or economic injury due to a declared disaster. An IDAP loan is an interim loan in an amount not to exceed $25,000 made by an IDAP lender to meet the immediate business needs of an IDAP borrower while approval of long-term financing from a disaster loan is pending with SBA. Currently, there is no funding available for IDAP loans.

B. Religious-Status-Based Exclusions in the Subject Programs and Conflict With Recent Supreme Court Decisions Construing the Free Exercise Clause

Current regulatory provisions governing the ILP, Business Loan programs, EIDL, MREIDL, and IDAP all render ineligible to participate businesses that are ''[p]rincipally engaged in''—or businesses whose ''principal activity'' is—''teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting.'' 13 CFR 109.400(b)(11), 120.110(k), 123.301(g), 123.502(n), 123.702(b)(6). Notably, these exclusions of otherwise-eligible participants are based not on any religious use of business loan funds or disaster assistance, but rather are based on the religious activities in which they generally engage, precluding them from even secular uses of business loan funds and disaster assistance. In short, they categorically disqualify otherwise-eligible faith-based organizations from receiving business loan funds and disaster assistance solely on account of their religious status.

In two recent decisions, the Supreme Court has made clear that such religious-status-based exclusions from a public benefit violate the Free Exercise Clause of the First Amendment.

In *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 137 S. Ct. 2012 (2017), the Court examined a state's ''policy of categorically disqualifying churches and other religious organizations from receiving grants under its playground resurfacing program.'' *Id.* at 2017. The Court held that the policy violated the Free Exercise Clause. It explained that ''[t]he Free Exercise Clause 'protect[s] religious observers against unequal treatment' and subjects to the strictest scrutiny laws that target the religious for 'special disabilities' based on their 'religious status.' '' *Id.* at 2019 (quoting *Church of Lukumi Babulu Aye, Inc.* v. *Hialeah,* 508 U.S. 520, 533, 542 (1993)). The Court noted that it repeatedly had applied this ''basic principle'' to ''confirm[ ] that denying a generally available benefit solely on account of religious identity imposes a penalty on the free exercise of religion that can be justified only by a state interest 'of the highest order.' '' *Id.* (quoting *McDaniel* v. *Paty,* 435 U.S. 618, 628 (1978) (plurality opinion)). The state policy failed this stringent test. The Court concluded that, ''[i]n the face of the clear infringement on free exercise before us,'' the State's proffered interest—a ''policy preference for skating as far as possible from religious establishment concerns,'' even where the Establishment Clause did not prohibit the funding at issue—''cannot qualify as compelling.'' *Id.* at 2024.

Three years later, in *Espinoza* v. *Montana Department of Revenue,* 140 S. Ct. 2246 (2020), the Court examined a state-court decision that had applied a state constitutional provision to invalidate a tax-credit scholarships program solely on the ground that some scholarship recipients had sought to use their scholarships at religious schools. The question presented was ''whether the Free Exercise Clause precluded'' the state court ''from applying [the state constitutional] provision to bar religious schools from the scholarship program.'' *Id.* at 2254. The Court answered that question in the affirmative. The Court began by reiterating the basic principle that ''[t]he Free Exercise Clause . . . 'protects religious observers against unequal treatment' and against 'laws that impose special disabilities on the basis of religious status,''' *id.* (quoting *Trinity Lutheran,* 137 S. Ct. at 2019), and by noting *Trinity Lutheran's* '' 'unremarkable' conclusion that disqualifying otherwise eligible recipients from a public benefit 'solely because of their religious character' imposes 'a penalty on the free exercise of religion that triggers the most exacting scrutiny,' '' *id.* at 2255 (quoting *Trinity Lutheran,* 137 S. Ct. at 2021). The Court then observed that, as construed by the state court, the state constitutional provision ''bars religious schools from public benefits solely because of the religious character of the schools'' and ''also bars parents who wish to send their children to a religious school from those same benefits, again solely because of the religious character of the school.'' *Id.* at 2255. The Court was unpersuaded by the State's assertion that the status-based exclusion aimed to prevent religious uses of funds. ''Status-based discrimination,'' the Court concluded, ''remains status based even if one of its goals or effects is preventing religious organizations from putting aid to religious uses.'' *Id.* at 2256. Accordingly, the Court held ''that strict scrutiny applies under *Trinity Lutheran* because [the state constitutional] provision discriminates based on religious status,'' *id.* at 2257, and that, like the state policy it examined in *Trinity Lutheran,* the state constitutional provision under review failed that test, *id.* at 2260–63.

Like the state policy that the Court declared unconstitutional in *Trinity Lutheran* and the state constitutional provision that the Court declared unconstitutional in *Espinoza,* the five subject provisions deny a public benefit solely on account of religious status. Each categorically renders ineligible to participate in an SBA business loan or disaster assistance program all businesses that are ''[p]rincipally engaged in''—or businesses whose ''principal activity'' is—''teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting.'' 13 CFR 109.400(b)(11), 120.110(k), 123.301(g),

123.502(n), 123.702(b)(6). Notably, none of these exclusions concerns religious uses of business loan or disaster assistance funds. Instead, each prohibits an otherwise-eligible applicant from receiving such funds solely on account of its religious activities, even if it uses the funds for secular purposes. And any interest in prohibiting religious uses of funds cannot justify such a sweeping, status-based exclusion. As the Court held in *Espinoza,* ''[s]tatus-based discrimination remains status based even if one of its goals or effects is preventing religious organizations from putting aid to religious uses.'' 140 S. Ct. at 2256. Moreover, SBA cannot identify any other possible interest underlying the subject provisions, much less one that would pass muster under the '' 'strictest scrutiny,' '' *id.* at 2257 (quoting *Trinity Lutheran,* 137 S. Ct. at 2019), that the Court applies to such religious-status-based exclusions.

In addition, the five subject regulatory provisions cannot be justified under *Locke* v. *Davey,* 540 U.S. 712 (2004), because they are not restrictions on religious uses of business loans or disaster assistance. Rather, they exclude certain recipients from even secular uses of business loans and disaster assistance based solely on their religious status.

Therefore, the five subject provisions—13 CFR 109.400(b)(11), 120.110(k), 123.301(g), 123.502(n), and 123.702(b)(6)—are inconsistent with the Free Exercise Clause of the First Amendment, as construed by the Supreme Court in *Trinity Lutheran* and *Espinoza.*

C. SBA's 530D Letter and Subsequent Review of SBA Regulations

In light of the Supreme Court's decision in *Trinity Lutheran,* and after consultation with the U.S. Department of Justice, SBA determined that the religious-status-based exclusions in its Business Loan and EIDL programs—13 CFR 120.110(k) and 123.301(g)—are unconstitutional. In a letter submitted on April 3, 2020, pursuant to 28 U.S.C. 530D, SBA informed Congress of its determination. SBA explained that the provisions ''impermissibly exclude a class of potential recipients based solely on their religious identity, just like the State policy that was struck down in *Trinity Lutheran*''*;* that they ''categorically exclude religious organizations simply because they are religious''; and that ''[t]hese status-based prohibitions also cannot be justified under *Locke* v. *Davey,* 540 U.S. 712 (2004)'' because they ''are not limited to religious uses of business loans or economic disaster assistance, but rather exclude certain recipients from even secular uses based on their religious character.'' SBA notified Congress that it would ''refrain from enforcing, applying, or administering'' the subject provisions, and that it intended to ''propose amendments to 13 CFR 120.110 and 123.301 that will conform these provisions to the Constitution.''

Since submitting its 530D letter, SBA has reviewed its other regulations and identified three other substantially similar provisions—13 CFR 109.400(b)(11), 123.502(n), and 123.702(b)(6)—that suffer from the same constitutional defect identified in the 530D letter. Accordingly, SBA now proposes to remove all five of the invalid provisions to conform its regulations to the requirements of the Free Exercise Clause.

D. President Trump's Executive Order 13798 and the Attorney General's Memorandum on Religious Liberty

SBA's proposal not only follows from recent Supreme Court precedent and will ensure compliance with the Constitution, but also accords with Executive Branch policy. On May 4, 2017, President Trump issued Executive Order 13798, Presidential Executive Order Promoting Free Speech and Religious Liberty, 82 FR 21675 (May 9, 2017). Executive Order 13798 states that ''Federal law protects the freedom of Americans and their organizations to exercise religion and participate fully in civic life without undue interference by the Federal Government'' and further provides that the executive branch will honor and enforce those protections. It also directed the Attorney General to ''issue guidance interpreting religious liberty protections in Federal law.'' 82 FR at 21675. Pursuant to this instruction, the Attorney General, on October 6, 2017, issued the Memorandum for All Executive Departments and Agencies, ''Federal Law Protections for Religious Liberty,'' 82 FR 49668 (Oct. 26, 2017) (the ''Attorney General's Memorandum on Religious Liberty'').

Consistent with *Trinity Lutheran,* the Attorney General's Memorandum on Religious Liberty emphasized that individuals and organizations do not forfeit religious-liberty protections by receiving government grants or otherwise interacting with Federal, state, or local governments, and that ''government may not exclude religious organizations as such from secular aid programs . . . when the aid is not being used for explicitly religious activities such as worship or proselytization.'' 82 FR at 49669.

II. Section by Section Analysis

A. Section 109.400—Eligible Small Business Concerns

SBA is proposing to amend 13 CFR 109.400 to remove paragraphs (b)(11) and (b)(12) and redesignate the following paragraphs accordingly. 13 CFR 109.400(b) currently enumerates a list of ''types of businesses'' that ''are not eligible to receive a loan from an ILP Intermediary under'' the ILP. Included in this list is 13 CFR 109.400(b)(11), ''[b]usinesses principally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting[.]'' This exclusion based on religious status violates the Free Exercise Clause of the First Amendment to the Constitution. Therefore, SBA proposes to remove it but leave intact the other exclusions listed in 13 CFR 109.400(b).

B. Section 120.110—What businesses are ineligible for SBA business loans?

SBA is proposing to amend 13 CFR 120.110 to remove paragraphs (k) and (l) and redesignate the following paragraphs accordingly. 13 CFR 120.110 currently enumerates a list of ''types of businesses'' that ''are ineligible for SBA business loans.'' Included in this list is 13 CFR 120.110(k), ''[b]usinesses principally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting[.]'' This exclusion based on religious status violates the Free Exercise Clause of the First Amendment to the Constitution. Therefore, SBA proposes to remove it but leave intact the other exclusions listed in 13 CFR 120.110.

C. Section 123.301—When would my business not be eligible to apply for an Economic Injury Disaster Loan?

SBA is proposing to amend 13 CFR 123.301 to remove paragraph (g) and redesignate the following paragraph accordingly. 13 CFR 123.301 currently enumerates a list of types of businesses that ''are not eligible for an economic [injury] disaster loan.'' Included in this list is 13 CFR 123.301(g), businesses that are ''[p]rincipally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting[.]'' This exclusion based on religious status violates the Free Exercise Clause of the First Amendment to the Constitution. Therefore, SBA proposes to remove it but leave intact the other exclusions listed in 13 CFR 123.301.

D. Section 123.502—Under what circumstances is your business ineligible to be considered for a Military Reservist Economic Injury Disaster loan?

SBA is proposing to amend 13 CFR 123.502 to remove paragraph (n) and redesignate the following paragraph accordingly. 13 CFR 123.502 currently enumerates a list of types of businesses that are ''ineligible for a Military Reservist EIDL.'' Included in this list is 13 CFR 123.502(n), listing businesses whose ''[p]rincipal activity is teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting[.]'' This exclusion based on religious status violates the Free Exercise Clause of the First Amendment to the Constitution. Therefore, SBA proposes to remove it but leave intact the other exclusions listed in 13 CFR 123.502.

E. Section 123.702—What are the eligibility requirements for an IDAP loan?

SBA is proposing to amend 13 CFR 123.702 to remove paragraph (b)(6) and redesignate the following paragraphs accordingly. 13 CFR 123.702(b) currently enumerates a list of types of businesses that are ''not eligible for an IDAP loan.'' Included in this list is 13 CFR 123.702(b)(6), businesses that are ''[p]rincipally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting[.]'' This exclusion based on religious status violates the Free Exercise Clause of the First Amendment to the Constitution. Therefore, SBA proposes to remove it but leave intact the other exclusions listed in 13 CFR 123.702(b).

III. Compliance With Executive Orders 12866, 13771, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

A. Executive Order 12866

Under Executive Order 12866, the Office of Information and Regulatory Affairs (OIRA) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a regulation that may (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as an ''economically significant'' regulation); (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in Executive Order 12866.

OIRA has determined that this proposed rule is a significant, but not economically significant, regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

The proposed rule removes paragraphs that excluded from SBA's loan and disaster assistance programs types of businesses that were ''principally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs . . . .''

Executive Order 12866 requires assessment of available alternatives. An alternative to the proposed rule's elimination of invalid provisions is to take no action regarding the invalid exclusions. This alternative is untenable as it would leave in place provisions that are invalid under the Free Exercise Clause. The other alternative to the proposed rule's elimination of the invalid provisions is to create new restrictions barring religious uses of business loans and disaster assistance. This alternative is unnecessary under the First Amendment; [1] would create unnecessary regulation as current regulations already specify—in secular terms—the permissible uses of funds; [2] and would thus be inconsistent with the Administration's deregulatory agenda, *see* Executive Order 13771, Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs, 82 FR 9,339 (Feb. 3, 2017).

In accordance with Executive Order 12866, SBA has assessed the potential costs and benefits of this regulatory action. SBA estimates that no quantifiable effects exist from this proposed rule relative to a baseline that represents the state of SBA's programs in the absence of this action. Because these exclusions are not enforceable (and, indeed, SBA has informed Congress of its determination not to enforce 13 CFR 120.110(k) and 123.301(g)), SBA expects the removal of these exclusions to impose no additional costs or significant benefits.

In terms of benefits, SBA recognizes a nonquantifiable benefit to religious liberty that comes from removing exclusions of faith-based organizations, in conflict with the Free Exercise Clause. SBA also recognizes a nonquantifiable benefit to participants in SBA's loan and disaster assistance programs that comes from increased clarity in the regulatory requirements that apply to faith-based organizations operating in these programs. Benefits may also accrue from the increased capacity of faith-based social-service providers to provide services, both because these providers will be able to allocate resources with less uncertainty and because more faith-based organizations may participate. The SBA does not expect the proposed rule to materially alter the budgetary impact of its loan programs or the rights and obligations of recipients.

B. Executive Order 13771

This proposed rule is not expected to be an Executive Order 13771 regulatory action.

C. Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

D. Executive Order 13132

This proposed rule does not have federalism implications as defined in Executive Order 13132. It would not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. As such it does not warrant the preparation of a Federalism Assessment.

E. Paperwork Reduction Act, 44 U.S.C., Ch. 35

For the purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this rule will not

[1] *See Religious Restrictions on Capital Financing for Historically Black Colleges and Universities,* 43 Op. O.L.C.—**7–15 (Aug. 15, 2019) (slip op.) (analyzing a loan program substantially similar to SBA's business loan programs and concluding that the Establishment Clause did not require any use-of-funds restrictions); *Authority of FEMA to Provide Disaster Assistance to Seattle Hebrew Academy,* 26 Op. O.L.C. 114, 122–32 (2002) (analyzing a disaster assistance program substantially similar to SBA's disaster assistance programs and concluding that the Establishment Clause permitted the provision of disaster assistance to a religious school).

[2] *See* 13 CFR 109.430, 120.120, 120.130, 120.131, 123.303, 123.508, 123.509, and 123.704.

impose any new reporting or record keeping requirements.

F. Regulatory Flexibility Act, 5 U.S.C. 601–612

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (''RFA'') generally requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' that will ''describe the impact of the proposed rule on small entities.'' 5 U.S.C. 603(a). But the RFA allows the head of an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

The RFA defines ''small entity'' to include small businesses, small organizations, and small governmental jurisdictions. 5 U.S.C. 601(6). This proposed rule concerns participation in SBA's business loan and disaster assistance programs by certain faith-based organizations. As such, the rule relates to small organizations.

Small organizations that are the subject of this proposed rule include entities in NAICS Code 813110—Religious Organizations. According to the Census Bureau's Statistics of U.S. Businesses (SUSB), in 2012, approximately 182,000 organizations in this NAICS code met the definition for SBA's Small Business Size Standards, as updated in 2019.[3] The number of those organizations that meet the general requirements for eligibility to participate in SBA's business loan and disaster assistance programs is likely much smaller.

Considering that the proposed rule imposes no costs while ensuring that SBA's regulations conform with requirements of the Free Exercise Clause, SBA estimates that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. SBA does not believe that the impact will be significant within any size groupings because this proposed rule eliminates invalid provisions in its business loan and disaster assistance programs. Accordingly, the Administrator of the SBA hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. SBA invites comment from members of the public who believe there will be a significant impact on any small entities, including small businesses.

[3] According to the SUSB, 183,411 establishments were under NAICS Code 813110 in 2012, the last year for which this data set is available. Of the total number of establishments, 181,298 have annual receipts under $7.5 million. SBA uses a revenue standard for determining small businesses in NAICS 813110. In the 2019 SBA Table of Size Standards, that revenue standard was $8 million and below. SUSB information is arranged in dollar ranges of receipt size, with the next category ranging from above $7.5 million to $9,999,999, which is in excess of SBA's small business standard. 660 establishments were in that category.

List of Subjects

13 CFR Part 109

Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 120

Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 123

Disaster assistance, Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA proposes to amend 13 CFR parts 109, 120, and 123 as follows:

PART 109—INTERMEDIATE LENDING PILOT PROGRAM

■ 1. The authority citation for 13 CFR part 109 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), (b)(7), and 636(l).

§ 109.400 [Amended]

■ 2. Amend § 109.400 by removing paragraph (b)(11) and redesignating paragraphs (b)(13) through (23) as paragraphs (b)(11) through (21), respectively.

PART 120—BUSINESS LOANS

■ 3. The authority citation for 13 CFR part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b) (6), (b) (7), (b) (14), (h), and note, 636(a), (h) and (m), and note, 650, 657t, and note, 657u, and note, 687(f), 696(3) and (7), and note, and 697(a) and (e), and note.

§ 120.110 [Amended]

■ 4. Amend § 120.110 by removing paragraph (k) and redesignating paragraphs (m) through (s) as paragraphs (k) through (q), respectively.

PART 123—DISASTER LOAN PROGRAM

■ 5. The authority citation for 13 CFR part 123 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(b), 636(d), and 657n.

§ 123.301 [Amended]

■ 6. Amend § 123.301 by:

■ a. Adding the word ''or'' to the end of paragraph (f); and

■ b. Removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

§ 123.502 [Amended]

■ 7. Amend § 123.502 by:

■ a. Adding the word ''or'' to the end of paragraph (m); and

■ b. Removing paragraph (n) and redesignating paragraph (o) as paragraph (n).

§ 123.702 [Amended]

■ 8. Amend § 123.702 by removing paragraph (b)(6) and redesignating paragraphs (b)(7) through (25) as paragraphs (b)(6) through (24), respectively.

Signed in Washington, DC.

Jovita Carranza,

Administrator.

[FR Doc. 2021–00446 Filed 1–14–21; 11:15 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1173; Project Identifier MCAI–2020–00299–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters. This proposed AD was prompted by a reassessment of the flight control system. This proposed AD would require modification of the cyclic stick, as specified in a European Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 5, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
• *Fax:* 202–493–2251.
• *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material proposed for IBR in this proposed AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1173.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1173; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kristin Bradley, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2020–1173; Product Identifier MCAI–2020–00299–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposal.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Kristi Bradley, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *kristin.bradley@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2018–0063, dated March 22, 2018 (EASA AD 2018–0063), to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD), formerly Eurocopter Deutschland GmbH (ECD), Eurocopter España S.A., Model EC135 P1, EC135 P2, EC135 P2+, EC135 P3, EC135 T1, EC135 T2, EC135 T2+, EC135 T3, EC635 P2+, EC635 P3, EC635 T1, EC635 T2+ and EC635 T3 helicopters, all variants, all serial numbers (S/Ns) up to 1263 inclusive and S/N 1265, if equipped with autopilot, and S/N 2001 up to 2024 inclusive, except S/N 2006, 2008, 2013, 2017, 2019, 2020 and 2022.

This proposed AD was prompted by a reassessment of the flight control system, which revealed that uncommanded disengagement of the main rotor trim actuators during flight with the autopilot engaged and hands-off controls could result in high roll and pitch rates, which would require pilot intervention within a reaction time below that required by current airworthiness standards. The FAA is proposing to require installing a cyclic stick weight compensation modification to correct this unsafe condition, which if not corrected, may lead to subsequent loss of control of the helicopter. See the EASA AD for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0063 describes procedures for modifying the helicopter by retrofitting the cyclic stick weight compensation.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

These products have been approved by the aviation authority of another country, and are approved for operation in the United States. Pursuant to the bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the EASA AD referenced above. The FAA is proposing this AD after evaluating all the relevant information and determining the unsafe condition described previously is likely to exist or develop in other products of the same type designs.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0063, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding

FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2018–0063 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2018–0063 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2018–0063 that is required for compliance with EASA AD 2018–0063 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1173 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

The EASA AD applies to certain serial-numbered EC635-series helicopters with an autopilot installed, whereas this proposed AD does not apply to the Model EC635-series helicopters because these models are not FAA type-certificated. The EASA AD requires a calendar compliance time, whereas this proposed AD would require using hours time-in-service.

Costs of Compliance

The FAA estimates that this proposed AD affects 331 helicopters of U.S. registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this proposed AD.

Modifying the cyclic stick weight compensator would take about 8 work-hours and parts would cost about $1,300 for an estimated cost of about $1,980 per modification and $655,380 for the U.S. fleet.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus Helicopters Deutschland GmbH: Docket No. FAA–2020–1173; Project Identifier MCAI–2020–00299–R.

(a) Comments Due Date

The FAA must receive comments by March 5, 2021.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters, certificated in any category, with autopilot installed, having serial numbers (S/Ns) up to 1263 inclusive, 1265, and 2001 up to 2024 inclusive, but excluding S/N 2006, 2008, 2013, 2017, 2019, 2020, and 2022.

Note 1 to paragraph (c): Helicopters with an EC135P3H or EC135T3H designation are Model EC135P3 or EC135T3 helicopters, respectively.

(d) Subject

Joint Aircraft System Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Reason

This AD was prompted by a reassessment of the flight control system, which revealed that uncommanded disengagement of the main rotor trim actuators during flight with the autopilot engaged and hands-off controls could result in high roll and pitch rates requiring pilot intervention within a reaction time below that required by current airworthiness standards. The FAA is issuing this AD to require installing a cyclic stick weight compensation modification to correct this unsafe condition, which if not corrected, could result in subsequent loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2018–0063, dated March 22, 2018 (EASA AD 2018–0063).

(h) Exceptions to EASA AD 2018–0063

(1) Where EASA AD 2018–0063 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2018–0063 requires modifying the helicopter within 7 months, this AD requires modifying the helicopter within 200 hours time-in-service.

(3) Although the service information referenced in EASA AD 2018–0063 specifies to discard certain parts, this AD requires removing those parts from service instead.

(4) The ''Remarks'' section of EASA AD 2018–0063 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0063 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs):

(1) The Manager, Strategic Policy Rotorcraft Section, FAA, has the authority to approve AMOCs for this AD, if requested

using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. Send your proposal to: Manager, Strategic Policy Rotorcraft Section, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For EASA AD 2018–0063, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1173.

(2) For more information about this AD, contact Kristi Bradley, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *kristin.bradley@faa.gov.*

Issued on January 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–00581 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1156; Airspace Docket No. 20–ANE–7]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Monhegan Island, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for Monhegan Island Heliport, Monhegan Island, ME, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before March 5, 2021.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2020–1156; Airspace Docket No. 20–ANE–7, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace in Monhegan Island, ME, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–1156 and Airspace Docket No. 20–ANE–7) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–1156; Airspace Docket No. 20–ANE–7.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays

at the office of the Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, Room 350, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR), part 71, to establish Class E airspace extending upward from 700 feet above the surface at Monhegan Island Heliport, Monhegan Island, ME, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at Monhegan Island Heliport.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'', prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE ME E5 Monhegan Island, ME [New]

Monhegan Island Heliport, ME
(Lat. 43°45′16.41″ N, long. 69°18′52.78″ W)

That airspace extending upward from 700 feet above the surface of the earth within a 6-mile radius of Monhegan Island Heliport.

Issued in College Park, Georgia, on January 5, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–00593 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1195; Airspace Docket No. 20–ANE–11]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Framingham, MA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface for MSP GHQ Heliport, Framingham, MA, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this heliport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before March 5, 2021.

ADDRESSES: Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2020–1195; Airspace Docket No. 20–ANE–11, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace at MSP GHQ Heliport in Framingham, MA, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–1195 and Airspace Docket No. 20–ANE–11) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–1195; Airspace Docket No. 20–ANE–11.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace extending upward from 700 feet above the surface at MSP GHQ Heliport (Massachusetts State Police HQ), Framingham, MA, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for IFR operations at this heliport.

Class E airspace designations are published in Paragraph 6005, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'', prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Framingham, MA [New]

MSP GHQ Heliport, MA
(Lat. 42°17′48″ N, long. 71°24′57″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of MSP GHQ Heliport.

Issued in College Park, Georgia, on January 7, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–00498 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1146; Airspace Docket No. 20–AEA–10]

RIN 2120–AA66

Proposed Establishment, Amendment, and Revocation of Air Traffic Service (ATS) Routes; Northeast United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend 11 VOR Federal airways, remove 10 VOR Federal airways; amend four low altitude RNAV routes (T-routes), establish seven T-routes; amend one high altitude RNAV route (Q-route), and establish one Q-route. This action would support the Northeast Corridor Atlantic Coast Route Project and the VOR Minimum Operational Network (VOR MON) Program to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems.

DATES: Comments must be received on or before March 5, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527 or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1146; Airspace Docket No. 20–AEA–10 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the airway route structure in the northeastern United States to maintain the efficient flow of air traffic.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2020–1146; Airspace Docket No. 20–AEA–10) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–1146; Airspace Docket No. 20–AEA–10''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend 11 VOR Federal airways; remove 10 VOR Federal airways; amend four low altitude RNAV routes (T-routes); establish seven T-routes; amend one high altitude RNAV route (Q-route); and establish one Q-route. The proposed VOR Federal airway changes are described below.

The names listed in the VOR Federal airway descriptions are the names of the

VOR or VORTAC navigation facilities that form the route. This NPRM proposes changes to some VOR Federal airways having segments in Canadian airspace, and the extension of some Canadian RNAV routes into U.S. airspace. The FAA developed these proposed changes in cooperation with NAV CANADA (Canada's civil air navigation services provider).

The following section describes proposed VOR Federal airway changes.

V–2: V–2 extends, in two parts, between Seattle, WA, and Nodine, MN; and between Buffalo, NY, and Gardner, MA. The FAA proposes to remove the sections between Buffalo and Gardner. As amended, the route would extend between Seattle, WA, and Nodine, MN. Additional changes to other portions of the airway have been proposed in a separate NPRM.

V–3: V–3 extends between Key West, FL, and Quebec, PQ, Canada. The FAA proposes to remove the segments between the intersection of the Boston, MA, 014°, and the Pease, NH, 185° radials, and Houlton, ME. As amended, V–3 would consist of two parts: Between Key West, FL, and Boston, MA; and between Presque Isle, ME, and Quebec, Canada. The airspace within Restricted areas R–2916, R–2934, R–2935, and within Canada is excluded.

V–14: V–14 extends, in two parts, between Chisum, NM, and Flag City, OH; and between Buffalo, NY, and Norwich, CT. This action proposes to remove the sections between Buffalo and Norwich. As amended, V–14 would extend between Chisum, NM, and Flag City, OH. Additional changes to other portions of the airway have been proposed in a separate NPRM.

V–29: V–29 extends between Snow Hill, MD, and Massena, NY. This action would remove the sections between Watertown, NY, and Massena, NY. As amended, V–29 would extend between Snow Hill, MD, and Syracuse, NY.

V–39: V–39 extends between Sandhills, SC, and Mont Joli, PQ, Canada. This action would remove the sections between Chester, MA, and Augusta, ME. As amended, V–39 would consist of two parts: Between Sandhills, SC, and the intersection of the Barnes, MA, 265°, and the Chester, MA, 223° radials; and between Augusta, ME, and Mont Joli, PQ, Canada, excluding the portion within Canada.

V–93: V–93 consists of two parts: Extending between Patuxent River, MD, and the intersection of the Wilkes-Barre, PA, 037°, and the Sparta, NJ, 300° radials; and between the intersection of the Sparta, NJ, 018°, and the Kingston, NY, 270° radials, and Bangor, ME. This action would remove the sections between Chester, MA, and Bangor, ME. The amended route would extend between Patuxent River, MD, and the intersection of the Barnes, MA, 265°, and the Chester, MA, 223° radials.

V–106: V–106 consists of two parts: Between Johnstown, PA, and the intersection of the Wilkes-Barre, PA, 037°, and the Sparta, NJ, 300° radials; and between Barnes, MA, and Kennebunk, ME. This proposal would remove the sections between Barnes, MA, and Kennebunk, ME. The amended route would extend between Johnstown, PA, and the intersection of the Wilkes-Barre, PA, 037°, and the Sparta, NJ, 300° radials.

V–145: V–145 extends between Utica, NY, and the intersection of the Watertown, NY, 005°, and the Ottawa, ON, Canada 185° radials. The FAA proposes to remove the entire route.

V–196: V–196 extends between Utica, NY, and the intersection of the Saranac Lake, NY, 058°, and the Burlington, VT, 296° radials. The FAA proposes to remove the entire route.

V–203: V–203 extends between the intersection of the Chester, MA, 266°, and the Albany, NY, 134° radials, and Massena, NY. The FAA proposes to remove the entire route.

V–229: V–229 extends between Patuxent, MD, and Burlington, VT. This proposal would remove the segments between Hartford, CT, and Burlington, VT. As amended, V–229 would extend between Patuxent, MD, and Hartford, CT.

V–249: V–249 extends between Robbinsville, NJ, and Utica, NY. This action would remove the segments between DeLancey, NY, and Utica, NY. The amended route would extend between Robbinsville, NJ, and DeLancey, NY.

V–273: V–273 extends between the intersection of the Huguenot, NY, 134°, and the Solberg, NJ, 044° radials, and Syracuse, NY. The FAA proposes to remove the segments between Hancock, NY, and Syracuse, NY. As amended, the route would extend between the intersection of the above noted Huguenot and Solberg radials, and Hancock, NY.

V–282: V–282 extends between Saranac Lake, NY, and the intersection of the Saranac Lake, NY, 008° and the Massena, NY, 080° radials. The FAA proposes to remove the entire route.

V–318: V–318 extends between the intersection of the Beauce, PQ, Canada, 103°, and the Quebec, PQ Canada, 047° radials, through United States airspace, to St. John, NB, Canada. The FAA proposes to remove the entire route.

V–322: V–322 extends between Concord, NH, and the intersection of the Concord, NH, 022°, and the Augusta, ME, 265° radials. The FAA proposes to remove the entire route.

V–352: V–352 extends between the intersection of the Beauce, PQ, Canada 085° and the Bangor, ME, 336° radials, and Houlton, ME. The FAA proposes to remove the entire route.

V–428: V–428 extends between Georgetown, NY, and Utica, NY. The FAA proposes to remove the entire route.

V–471: V–471 extends between Bangor, ME, and the intersection of the Houlton, ME, 085° radial, and the United States Canadian border. This proposal would remove the segments between Millinocket, ME, and the above border intersection. As amended, the route would extend between Bangor, ME, and Millinocket, ME.

V–490: V–490 extends Utica, NY, and Manchester, NH. The FAA proposes to remove the entire route.

V–542: V–542 currently extends between Elmira, NY, and Lebanon, NH. A separate rulemaking action proposes to remove the route segments between Rockdale, NY, and Lebanon, NH. This NPRM proposes to remove the entire remaining route.

The following section describes proposed changes to U.S. low altitude RNAV routes.

T–295: T–295 extends between the LOUIE, MD, waypoint (WP), and the Bangor, ME, VORTAC. This action proposes to extend the route northeastward from Bangor, ME, to Presque Isle, ME. The Keene, NH (EEN) VORTAC is replaced by the KEYNN, NH, WP, which is located 60 feet north of the Keene VORTAC. The amended route would extend between LOUIE, MD, and Presque Isle, ME.

T–314: T–314 is a proposed new route that would extend between the Barnes, MA, VORTAC, and the Kennebunk, ME, VOR/DME.

T–315: T–315 is a proposed new route that would extend between the Hartford, CT, VOR/DME and the Burlington, VT, VOR/DME.

T–316: T–316 is a proposed new route that would extend between the LAMMS, NY, WP, and the MANCH, NH, WP.

T–391: T–391 extends between the TUMPS, NY, Fix, and the SSENA, NY, WP. This action proposes to remove the TUMPS Fix and extend the route southeast from the Syracuse, NY, VORTAC, to the Hancock, NY, VOR/DME. As amended, the route would extend between Hancock, NY, and SSENA, NY.

The following section describes proposed changes to Canadian low altitude RNAV routes.

T–608: T–608 is an existing Canadian route that was extended into U.S. airspace in 2014 (79 FR 57758, September 26, 2014). It currently extends between the HOCKE, MI, WP, through Canadian airspace, and ends at the WOZEE, NY, WP. This proposal would extend the route from the WOZEE WP eastward into U.S. airspace to the YANTC, CT, WP. The amended T–608 would overlie VOR Federal airway V–2 between the WOZEE, NY, WP and the Gardner, MA (GDM), VORTAC; and it would overlie V–14 between the Albany, NY (ALB), VORTAC and the YANTC, CT, WP. The YANTC, CT, WP replaces the Norwich, CT (ORW), VOR/DME. The LAMMS, NY, WP replaces the Utica, NY (UCA), VORTAC. As amended, T–608 would extend from the HOCKE, MI, WP, through Canadian airspace, to the WOZEE, NY, WP; and from the WOZEE WP, to the YANCT WP. The order of points listed in the route description is changed to read from ''west to east'' to comply with formatting requirements.

T–634: T–634 is an existing Canadian route that the FAA proposes to extend into U.S. airspace. The route currently ends at the VIBRU, Canada, WP (adjacent to the U.S./Canadian border). The VIBRU WP will be moved 0.55NM to the south of its current position to align it with the U.S./Canada border. It will be re-labled as ''VIBRU, NY.'' The FAA proposes to extend T–634 into U.S. airspace between the Syracuse, NY, VORTAC, and the VIBRU, NY, WP. The extended portion of the route would replace VOR Federal airway V–145 as described above.

T–662: T–662 is a Canadian route that would be extended into U.S. airspace between the DEPRI, ME, WP, and the HULTN, ME, WP. The HULTN WP would replace the Houlton, ME (HUL) VOR/DME. It is located 60 feet east of the Houlton VOR/DME. T–662 would extend across Maine from the DEPIR WP to the KATAH, ME, WP, to the HULTN, ME, WP. T–662 would replace VOR Federal airway V–352 as described above.

T–698: T–698 is a Canadian route that would be extended to cross the State of Maine from the EBGIX, ME, WP, to the HULTN, ME, WP, to the ACTON, ME, WP. The EBGIX WP is being moved 1.16NM east to coincide with the U.S./Canada border in western Maine. The ACTON WP is a new point to be added on the U.S./Canada border to the southeast of the Houlton, ME (HUL) VOR/DME.

T–705: T–705 is an existing Canadian route that was extended into U.S. airspace, between the U.S./Canadian border, and the Utica, NY, VORTAC, in 2018 (83 FR 31855, July 10, 2018). This proposal would extend T–705 further southward to the DANZI, NY, WP (near the Delancey, NY, VOR/DME). The Utica, NY, VORTAC, and the Saranac Lake, NY, VOR/DME would be removed from the route. The new LAMMS, NY, WP would replace the Utica VORTAC, and the new SRACK, NY, WP would replace the Saranac Lake VOR/DME in the route description. The MUTNA, Canada, WP would be moved 0.79NM southward to align with the U.S./Canada border. It would be re-labled as ''MUTNA, NY.'' As amended, the U.S. portion of T–705 would extend between the DANZI, NY, WP and MUTNA, NY, WP at the U.S./Canadian border.

T–781: T–781 is a Canadian route that was extended into U.S. airspace in 2014 (79 FR 57758, September 26, 2014). Currently, the U.S. portion of the route extends from the Flint, MI, VORTAC, eastward to the AXOBU, Canada, WP (in the vicinity of the U.S./Canadian border near Port Huron, MI). T–781 then continues eastward across Canada and terminates at the PINTE, Canada Fix (on the U.S./Canadian border). The PINTE Fix would be moved 0.07 NM east to the U.S./Canada border and would be converted to a WP. This proposal would extend T–781 eastward from the PINTE, ME, WP to terminate at the HULTN, ME WP. As amended, the U.S. portion of T–781 would extend between the Flint, MI, VORTAC, and the AXOBU, Canada, Fix; and between the PINTE, ME, WP, and the HULTN, ME, WP.

The following section describes proposed changes to Canadian high altitude RNAV routes.

Q–806: Q–806 is a Canadian route that was extended into U.S. airspace in 2014 (79 FR 57758, September 26, 2014). The U.S. portion currently extends from the MEKSO, Canada, WP, eastward through the Millinocket, ME, VOR/DME, to the CANME, ME, WP, and the VOGET, Canada, WP. Canada is realigning Q–806 by shifting the route segment from the MEKSO, Canada, WP, southward to the VINDI, Canada, WP. The VINDI WP would be moved 0.13NM eastward to align with the U.S./Canada border and listed as ''VINDI, ME.'' Consequently, this proposal would remove the route segment between the MEKSO WP and the Millinocket, ME, VOR/DME, and add the segment between the VINDI, ME, WP, and the Millinocket VOR/DME. The VIGDU, Canada, WP would be moved 0.50NM westward to align with the U.S./Canada border and listed as ''VIGDU, ME.'' The VIGDU, ME, WP added east of the CANME, ME, WP. As amended, the U.S. portion of Q–806 would extend from the VINDI, ME, WP, eastward to the Millinocket, ME, VOR/DME, to the CANME, ME, WP, to the VIGDU, ME, WP.

Q–864: Q–864 is an existing Canadian route that the FAA proposes to extend into U.S. airspace across northern Maine. The route currently ends at the EBGIX, Canada, WP (at the U.S./Canadian border in western Maine). This action would extend the route eastward from EBGIX, across the State of Maine, running north of the Millinocket, ME, VOR/DME, to the TUGUB, Canada, WP (located southeast of the Houlton, ME, VOR/DME) where it would rejoin the remainder of Q–864 into Canada. The EBGIX WP would be moved 1.16NM eastward to align with the U.S./Canadian border, and the TUGUB WP would be moved 1.23NM west to align with the U.S./Canada border. The amended Q–864 would extend between the EBGIX, ME, WP, and the TUGUB, ME, WP.

The proposed full descriptions of the above route changes are found in ''The Proposed Amendment'' section of this NPRM.

Domestic VOR Federal airways are published in paragraph 6010(a); United States area navigation routes are published in paragraph 6011; and Canadian area navigation routes are published in paragraphs 2007, and 6013; respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways and area navigation routes listed in this document would be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial

number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

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V–2 [Amended]

From Seattle, WA; Ellensburg, WA; Moses Lake, WA; Spokane, WA; Mulan Pass, ID; Missoula, MT; Helena, MT; INT Helena 119° and Livingston, MT, 322° radials; Livingston; Billings, MT; Miles City, MT; 24 miles, 90 miles 55 MSL, Dickinson, ND; 10 miles, 60 miles 38 MSL, Bismarck, ND; 14 miles, 62 miles 34 MSL, Jamestown, ND; Fargo, ND; Alexandria, MN; Gopher, MN; to Nodine, MN.

V–3 [Amended]

From Key West, FL; INT Key West 083° and Dolphin, FL, 191°radials; Dolphin; Ft. Lauderdale, FL; Palm Beach, FL; Treasure, FL; Melbourne, FL; Ormond Beach, FL; Brunswick, GA; INT Brunswick 014° and Savannah, GA, 177° radials; Savannah; INT Savannah 028° and Vance, SC, 203° radials; Vance; Florence, SC; Sandhills, SC; Raleigh-Durham, NC; INT Raleigh-Durham 016° and Flat Rock, VA, 214° radials; Flat Rock; Gordonsville, VA; INT Gordonsville 331° and Martinsburg, WV, 216° radials; Martinsburg; Westminster, MD; INT Westminster 048° and Modena, PA, 258° radials; Modena; Solberg, NJ; INT Solberg 044° and Carmel, NY, 243° radials; Carmel; Hartford, CT; INT Hartford 084° and Boston, MA, 224° radials; to Boston. From Presque Isle, ME; to Quebec, PQ, Canada. The airspace within R–2916, R–2934, R–2935, and within Canada is excluded.

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V–14 [Amended]

From Chisum, NM; Lubbock, TX; Childress, TX; Hobart, OK; Will Rogers, OK; INT Will Rogers 052° and Tulsa, OK, 246° radials; Tulsa; Neosho, MO; Springfield, MO; Vichy, MO; INT Vichy 067° and St. Louis, MO, 225° radials; St. Louis; Vandalia, IL; Terre Haute, IN; Brickyard, IN; Muncie, IN; to Flag City, OH.

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V–29 [Amended]

From Snow Hill, MD; Salisbury, MD; Smyrna, DE; DUPONT, DE; Modena, PA; Pottstown, PA; East Texas, PA; Wilkes-Barre, PA; Binghamton, NY; INT Binghamton 005° and Syracuse, NY, 169° radials; to Syracuse.

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V–39 [Amended]

From Sandhills, NC, South Boston, VA; Gordonsville, VA; INT Gordonsville 331° and Martinsburg, WV, 216° radials; Martinsburg; Lancaster, PA; East Texas, PA; Sparta, NJ; Carmel, NY; INT Carmel 045° and Bridgeport, CT, 343° radials; INT Bridgeport 343° and Chester, MA, 223° radials; to INT Barnes, MA 265° and Chester 223° radials; From Augusta, ME; Millinocket, ME; Presque Isle, ME; Mont Joli, PQ, Canada, excluding the portion within Canada.

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V–93 [Amended]

From Patuxent River, MD, INT Patuxent 013° and Baltimore, MD, 122° radials; Baltimore; INT Baltimore 004° and Lancaster, PA, 214° radials; Lancaster; Wilkes-Barre, PA; to INT Wilkes-Barre 037° and Sparta, NJ 300° radials. From INT Sparta 018° and Kingston, NY, 270° radials; Kingston; Pawling, NY; to INT Barnes, MA 265° and Chester 223° radials.

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V–106 [Amended]

From Johnstown, PA; INT Johnstown 068° and Selinsgrove, PA, 259° radials; Selinsgrove; INT Selinsgrove 067° and Wilkes-Barre, PA, 237° radials; Wilkes-Barre; to INT Wilkes-Barre 037° and Sparta, NJ 300° radials.

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V–145 [Removed]

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V–196 [Removed]

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V–203 [Removed]

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V–229 [Amended]

From Patuxent, MD; INT Patuxent 036° and Atlantic City, NJ, 236° radials; Atlantic City; INT Atlantic City 055° and Colts Neck, NJ, 181° radials; INT Colts Neck 181° and Kennedy, NY, 209° radials; Kennedy; INT Kennedy 040° and Calverton, NY, 261° radials; INT Calverton 261° and Kennedy 053° radials; INT Kennedy 053° and Bridgeport, CT, 200° radials; Bridgeport; to Hartford, CT; The airspace within R–5002B is excluded during times of use. The airspace below 2,000 feet MSL outside the United States is excluded.

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V–249 [Amended]

From Robbinsville, NJ; INT Robbinsville 320° and Solberg, NJ, 161° radials; Solberg; Sparta, NJ; INT Sparta 018° and Delancey, NY, 119° radials; to DeLancey.

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V–273 [Amended]

From INT Huguenot, NY, 134° and Solberg, NJ, 044° radials; Huguenot; INT Huguenot 303° and Hancock, NY, 148° radials; to Hancock;

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V–282 [Removed]

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V–318 [Removed]

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V–322 [Removed]

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V–352 [Removed]

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V–428 [Removed]

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V–471 [Amended]

From Bangor, ME; to Millinocket, ME.

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V–490 [Removed]

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V–542 [Removed]

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Paragraph 6011 United States Area Navigation Routes

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T–295 LOUIE, MD to Presque Isle, ME (PQI) [Amended]

LOUIE, MD	WP	(Lat. 38°36′44.33″ N, long. 076°18′04.37″ W)
BAABS, MD	WP	(Lat. 39°19′51.39″ N, long. 076°24′40.87″ W)
Lancaster, PA (LRP)	VOR/DME	(Lat. 40°07′11.91″ N, long. 076°17′28.66″ W)
Wilkes-Barre, PA (LVZ)	VORTAC	(Lat. 41°16′22.08″ N, long. 075°41′22.08″ W)
LAAYK, PA	WP	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
SAGES, NY	WP	(Lat. 42°02′46.33″ N, long. 074°19′10.33″ W)

SASHA, MA	WP	(Lat. 42°07′58.70″ N, long. 073°08′55.39″ W)
KEYNN, NH	WP	(Lat. 42°47′39.99″ N, long. 072°17′30.35″ W)
Concord, NH (CON)	VOR/DME	(Lat. 43°13′11.23″ N, long. 071°34′31.63″ W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25′32.42″ N, long. 070°36′48.69″ W)
BRNNS, ME	WP	(Lat. 43°54′08.64″ N, long. 069°56′42.81″ W)
Bangor, ME (BGR)	VORTAC	(Lat. 44°50′30.46″ N, long. 068°52′26.28″ W)
LAUDS, ME	FIX	(Lat. 45°25′10.13″ N, long. 068°12′26.96″ W)
HULTN, ME	WP	(Lat. 46°02′22.29″ N, long. 067°50′02.06″ W)
Presque Isle, ME (PQI)	VOR/DME	(Lat. 46°46′27.07″ N, long. 068°05′40.37″ W)

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T–314 BARNES, MA (BAF) to KENNEBUNK, ME (ENE) [New]

Barnes, MA (BAF)	VORTAC	(Lat. 42°09′43.05″ N, long. 072°42′58.32″ W)
FAIDS, MA	FIX	(Lat. 42°17′00.75″ N, long. 072°30′33.91″ W)
PUDGY, MA	FIX	(Lat. 42°19′38.52″ N, long. 072°26′04.25″ W)
LAPEL, MA	FIX	(Lat. 42°27′40.92″ N, long. 072°12′15.79″ W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32′45.31″ N, long. 072°03′29.48″ W)
JOHNZ, NH	FIX	(Lat. 42°43′22.87″ N, long. 071°40′55.80″ W)
MANCH, NH	WP	(Lat. 42°52′12.03″ N, long. 071°22′06.54″ W)
KHRIS, NH	FIX	(Lat. 42°57′01.09″ N, long. 071°15′35.56″ W)
RAYMY, NH	FIX	(Lat. 43°03′36.89″ N, long. 071°06′42.16″ W)
YUKES, ME	FIX	(Lat. 43°16′47.89″ N, long. 070°48′47.74″ W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25′32.42″ N, long. 070°36′48.69″ W)

T–315 HARTFORD, CT (HFD) to BURLINGTON, VT (BTV) [New]

Hartford, CT (HFD)	VOR/DME	(Lat. 41°38′27.98″ N, long. 072°32′50.70″ W)
DVANY, CT	WP	(Lat. 41°51′44.56″ N, long. 072°18′11.25″ W)
DARTH, CT	WP	(Lat. 41°56′55.86″ N, long. 072°16′20.80″ W)
WITNY, MA	WP	(Lat. 42°02′57.82″ N, long. 072°14′11.96″ W)
SPENO, MA	WP	(Lat. 42°16′48.55″ N, long. 072°09′14.70″ W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32′45.31″ N, long. 072°03′29.48″ W)
KEYNN, NH	WP	(Lat. 42°47′39.99″ N, long. 072°17′30.35″ W)
JAMMA, VT	WP	(Lat. 43°16′11.87″ N, long. 072°35′10.63″ W)
EBERT, VT	FIX	(Lat. 43°32′58.08″ N, long. 072°45′42.45″ W)
MUDDI, VT	WP	(Lat. 43°44′39.85″ N, long. 072°51′26.92″ W)
Burlington, VT (BTV)	VOR/DME	(Lat. 44°23′49.58″ N, long. 073°10′57.48″ W)

T–316 LAMMS, NY to MANCH, NH [New]

LAMMS, NY	WP	(Lat. 43°01′35.30″ N, long. 075°09′51.50″ W)
ROOMS, NY	WP	(Lat. 43°01′09.84″ N, long. 074°35′03.27″ W)
PAYGE, NY	WP	(Lat. 43°00′50.48″ N, long. 074°15′12.76″ W)
GALWA, NY	FIX	(Lat. 43°00′34.00″ N, long. 074°00′34.51″ W)
ETZUN, NY	FIX	(Lat. 42°59′55.04″ N, long. 073°31′03.83″ W)
Cambridge, NY (CAM)	VOR/DME	(Lat. 42°59′39.44″ N, long. 073°20′38.47″ W)
DORIS, VT	WP	(Lat. 42°58′42.88″ N, long. 073°03′51.57″ W)
BRATS, VT	FIX	(Lat. 42°57′19.89″ N, long. 072°40′27.73″ W)
STRUM, NH	WP	(Lat. 42°55′51.18″ N, long. 072°16′48.88″ W)
DUBIN, NH	FIX	(Lat. 42°54′43.15″ N, long. 071°59′35.41″ W)
MUGGY, NH	WP	(Lat. 42°53′44.91″ N, long. 071°45′17.41″ W)
BASUU, NH	FIX	(Lat. 42°53′17.86″ N, long. 071°38′48.69″ W)
MANCH, NH	WP	(Lat. 42°52′12.03″ N, long. 071°22′06.54″ W)

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T–391 HANCOCK, NY (HNK) to SSENA, NY [Amended]

Hancock, NY (HNK)	VOR/DME	(Lat. 42°03′47.01″ N, long. 075°18′58.62″ W)
OXFOR, NY	FIX	(Lat. 42°22′03.81″ N, long. 075°31′44.03″ W)
PITCH, NY	FIX	(Lat. 42°40′36.94″ N, long. 075°44′49.58″ W)
GTOWN, NY	WP	(Lat. 42°47′20.81″ N, long. 075°49′36.52″ W)
POMPY, NY	FIX	(Lat. 42°55′48.00″ N, long. 075°58′10.10″ W)
FATUP, NY	FIX	(Lat. 43°01′31.89″ N, long. 076°03′59.74″ W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09′37.87″ N, long. 076°12′16.41″ W)
PAGER, NY	FIX	(Lat. 43°25′25.64″ N, long. 076°09′30.34″ W)
BRUIN, NY	FIX	(Lat. 43°39′59.04″ N, long. 076°06′55.97″ W)
Watertown, NY (ART)	VORTAC	(Lat. 43°57′07.67″ N, long. 076°03′52.66″ W)
WILRD, NY	FIX	(Lat. 44°15′43.61″ N, long. 075°47′03.12″ W)
LETUS, NY	FIX	(Lat. 44°37′22.34″ N, long. 075°27′11.44″ W)
SSENA, NY	WP	(Lat. 44°54′51.43″ N, long. 074°43′21.31″ W)

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Paragraph 2007 Canadian Area Navigation Routes

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Q–806 VINDI, ME to VIGDU, ME [Amended]

VINDI, ME	WP	(Lat. 45°40′16.23″ N, long. 070°31′10.90″ W)
MILLINOCKET, ME (MLT)	VOR/DME	(Lat. 45°35′12.15″ N, long. 068°30′55.67″ W)
CANME, ME	WP	(Lat. 45°29′16.29″ N, long. 067°37′16.80″ W)
VIGDU, ME	WP	(Lat. 45°28′25.25″ N, long. 067°29′43.86″ W)

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Q–864 EBGIX, ME to TUGUB, ME [New]

EBGIX, ME	WP	(Lat. 45°43′32.67″ N, long. 070°23′50.92″ W)
TUGUB, ME	WP	(Lat. 45°58′42.08″ N, long. 067°46′52.21″ W)

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Paragraph 6013 Canadian Area Navigation Routes

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T–608 HOCKE, MI to YANTC, CT [Amended]

HOCKE, MI	WP	(Lat. 43°15′43.38″ N, long. 082°42′38.27″ W)
KATNO, Canada	WP	(Lat. 43°10′34.00″ N, long. 082°19′32.00″ W)
UKNIX, NY	WP	(Lat. 42°56′44.51″ N, long. 078°55′05.60″ W)
WOZEE, NY	WP	(Lat. 42°56′01.65″ N, long. 078°44′19.64″ W)
CLUNG, NY	WP	(Lat. 43°03′17.17″ N, long. 078°00′13.38″ W)
MONCK, NY	WP	(Lat. 43°04′33.36″ N, long. 077°53′36.67″ W)
Rochester, NY (ROC)	VOR/DME	(Lat. 43°07′04.65″ N, long. 077°40′22.06″ W)
LORTH, NY	FIX	(Lat. 43°07′47.93″ N, long. 077°19′05.32″ W)
MAGEN, NY	WP	(Lat. 43°08′03.28″ N, long. 077°11′00.84″ W)
KONDO, NY	WP	(Lat. 43°08′48.99″ N, long. 076°45′01.72″ W)
WIFFY, NY	WP	(Lat. 43°09′07.96″ N, long. 076°33′00.08″ W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09′37.87″ N, long. 076°12′16.41″ W)
STODA, NY	WP	(Lat. 43°07′00.20″ N, long. 075°51′21.23″ W)
VASTS, NY	FIX	(Lat. 43°04′34.62″ N, long. 075°32′29.89″ W)
LAMMS, NY	WP	(Lat. 43°01′35.30″ N, long. 075°09′51.50″ W)
NORSE, NY	WP	(Lat. 42°57′37.88″ N, long. 074°50′03.72″ W)
MARIA, NY	WP	(Lat. 42°50′02.76″ N, long. 074°13′00.50″ W)
Albany, NY (ALB)	VORTAC	(Lat. 42°44′50.20″ N, long. 073°48′11.47″ W)
WARUV, NY	WP	(Lat. 42°45′52.14″ N, long. 073°34′41.41″ W)
GRAVE, NY	WP	(Lat. 42°46′47.34″ N, long. 073°22′20.91″ W)
GRISY, MA	WP	(Lat. 42°41′46.40″ N, long. 072°53′30.14″ W)
WARIC, MA	WP	(Lat. 42°37′42.00″ N, long. 072°30′37.72″ W)
HURLY, MA	FIX	(Lat. 42°35′19.49″ N, long. 072°17′30.40″ W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32′45.31″ N, long. 072°03′29.48″ W)
GRAYM, MA	WP	(Lat. 42°06′04.27″ N, long. 072°01′53.49″ W)
BLATT, CT	WP	(Lat. 41°49′37.10″ N, long. 072°00′54.94″ W)
MOGUL, CT	WP	(Lat. 41°43′22.76″ N, long. 072°00′32.87″ W)
YANTC, CT	WP	(Lat. 41°33′22.81″ N, long. 071°59′56.95″ W)

Excluding the airspace within Canada.

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T–634 Syracuse, NY (SYR) to VIBRU, NY [New]

Syracuse, NY (SYR)	VORTAC	(Lat. 43°09′37.87″ N, long. 076°12′16.41″ W)
PAGER, NY	WP	(Lat. 43°25′25.64″ N, long. 076°09′30.34″ W)
BRUIN, NY	WP	(Lat. 43°39′59.04″ N, long. 076°06′55.97″ W)
Watertown, NY (ART)	VORTAC	(Lat. 43°57′07.67″ N, long. 076°03′52.66″ W)
VIBRU, NY	WP	(Lat. 44°20′21.30″ N, long. 076°01′19.96″ W)

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T–662 DEPRI, ME to HULTN, ME [New]

DEPRI, ME	WP	(Lat. 45°57′13.32″ N, long. 070°15′23.83″ W)
KATAH, ME	WP	(Lat. 46°05′00.00″ N, long. 069°00′00.00″ W)
HULTN, ME	WP	(Lat. 46°02′22.29″ N, long. 067°50′02.06″ W)

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T–698 EBGIX, ME to ACTON ME [New]

EBGIX, ME	WP	(Lat. 45°43′32.67″ N, long. 070°23′50.92″ W)
HULTN, ME	WP	(Lat. 46°02′22.29″ N, long. 067°50′02.06″ W)
ACTON, ME	WP	(Lat. 46°02′33.81″ N, long. 067°46′51.65″ W)

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T–705 DANZI, NY to MUTNA, NY [Amended]

DANZI, NY	WP	(Lat. 42°10′41.86″ N, long. 074°57′24.19″ W)
CODDI, NY	FIX	(Lat. 42°22′52.15″ N, long. 075°00′21.84″ W)
MILID, NY	FIX	(Lat. 42°30′25.88″ N, long. 075°02′12.28″ W)
LAMMS, NY	WP	(Lat. 43°01′35.30″ N, long. 075°09′51.50″ W)
USICI, NY	WP	(Lat. 43°11′23.04″ N, long. 075°03′06.15″ W)
GACKE, NY	WP	(Lat. 43°19′11.10″ N, long. 074°57′40.88″ W)
BECKS, NY	WP	(Lat. 43°32′56.63″ N, long. 074°48′03.47″ W)
SMAIR, NY	WP	(Lat. 44°03′32.47″ N, long. 074°26′20.99″ W)
FOSYU, NY	WP	(Lat. 44°12′25.39″ N, long. 074°19′58.15″ W)
SRACK, NY	WP	(Lat. 44°23′05.00″ N, long. 074°12′16.11″ W)
UUBER, NY	WP	(Lat. 44°28′00.25″ N, long. 074°01′10.54″ W)
RIGID, NY	WP	(Lat. 44°35′19.53″ N, long. 073°44′34.07″ W)
PBERG, NY	WP	(Lat. 44°42′06.25″ N, long. 073°31′22.18″ W)
LATTS, NY	WP	(Lat. 44°51′29.78″ N, long. 073°32′29.26″ W)
MUTNA, NY	WP	(Lat. 45°00′20.84″ N, long. 073°33′27.65″ W)

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T–781 Flint, MI (FNT) to HULTN ME [Amended]

Flint, MI (FNT)	VORTAC	(Lat. 42°58′00.38″ N, long. 083°44′49.08″ W)
KATTY, MI	WP	(Lat. 42°57′50.59″ N, long. 083°30′50.76″ W)
HANKY, MI	WP	(Lat. 42°57′43.51″ N, long. 083°21′59.93″ W)
ADRIE, MI	WP	(Lat. 42°57′29.80″ N, long. 083°06′49.84″ W)
MARGN MI	WP	(Lat. 42°56′59.18″ N, long. 082°38′49.14″ W)
BLUEZ, MI	WP	(Lat. 42°56′49.98″ N, long. 082°31′36.44″ W)
AXOBU, Canada	WP	(Lat. 42°56′39.51″ N, long. 082°23′42.31″ W)
PINTE, ME	FIX	(Lat. 46°26′44.89″ N, long. 070°03′01.26″ W)

HULTN ME	WP	(Lat. 46°02′22.29″ N, long. 067°50′02.06″ W)

Excluding the airspace within Canada.

* * * * *

Issued in Washington, DC, on January 5, 2021.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–00655 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

14 CFR Parts 241 and 298

[Docket No. DOT–OST–2018–0132]

RIN 2105–AE45

Updates to the Origin—Destination Survey of Airline Passengers

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Department is proposing to update the method of collecting and processing aviation traffic data in the Origin-Destination Survey of Airline Passenger Traffic (O&D Survey), as well as to expand the number of reporting air carriers, the sample size collected, and the scope of the data reported. These changes would align the current O&D Survey with modern industry business and accounting practices, enable cost savings, reduce burden through automation, and provide enhanced utility for users of the data. In addition, DOT is proposing to change the timing of the release of the Form 41, Schedule T–100(f) ''Foreign Air Carrier Traffic Data by Nonstop Segment and On-flight Market'' from a 6-month delay to a 3-month delay to match that of Form 41, Schedule T–100 ''Air Carrier Traffic and Capacity Data by Non-Stop Segment and On-Flight Market.''

DATES: Submit comments on or before March 19, 2021, 11:59 p.m. Eastern Time. The Department will consider late comments to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit all comments by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: At the beginning of your comments, include the agency name, docket name, and docket number (DOT–OST–2018–0132) or Regulation Identifier Number (RIN) for this rulemaking (2105–AE45). All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Physical access to the Docket is available at the Hand Delivery address noted above.

Electronic Access and Filing: You can view this document by going to the Federal eRulemaking Portal: *http://www.regulations.gov* and search for docket DOT–OST–2018–0132. The website is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the website. An electronic copy of this document is available for download from the Office of the Federal Register's home page at: *http://www.archives.gov/federal-register* and the U.S. Government Publishing Office's web page at: *https://www.gpo.gov/fdsys/.*

FOR FURTHER INFORMATION CONTACT: Mark Raggio, Office of Aviation Analysis, 1200 New Jersey Ave. SE, Room W86–470, Washington, DC 20590–0001, 202–366–1271 (phone) or *Mark.Raggio@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Authority

Section 429(b)(1) of Title 49, U.S.C., requires the Department to collect and disseminate information on the origin and destination of airline passengers including, at a minimum, information on: (1) The origin and destination of passengers in interstate air transportation, and (2) the number of passengers traveling by air between any two points in interstate air transportation. In addition, 49 U.S.C. 40101(a)(7) states that the Secretary shall respond to the needs of the public, including the airline industry, all levels of government, and airports, by disseminating information to foster a national air transportation system capable of meeting the present and future needs of U.S. commerce. In fulfillment of these responsibilities, DOT collects data submitted under:

- *14 CFR part 217:* Reporting Traffic Statistics by Foreign Air Carriers in Civilian Scheduled, Charter, and Nonscheduled Services, whereby foreign air carriers that are authorized by DOT to provide scheduled passenger services to or from the U.S. must file Form 41 Schedule T–100(f), accumulated in accordance with the data elements prescribed in § 217.5.
- *14 CFR part 241:* Uniform System of Accounts and Reports for Large Certificated Air Carriers, under which all large certificated air carriers must report their traffic movements by filing Form 41 Schedule T–100, Financials Information, and O&D fare information.
- *14 CFR part 298:* Exemptions for Air Taxi and Commuter Air Carriers, whereby air taxi operators and commuter air carriers, which are provided certain exemptions from some of the economic regulatory provisions of Subtitle VII of Title 49 of the United States Code, are required to submit simplified Financials and T–100 traffic.

In this rulemaking, the Department proposes to update its method of collecting and processing O&D fare information under part 241 to: (1) Allow full automation of the reporting of the O&D Survey by aligning it with current airline passenger accounting practices; and (2) enhance the accuracy and usefulness of DOT's collection of aviation traffic data.

B. Background on the O&D Survey

Currently, the O&D Survey, as outlined in 14 CFR part 241, Sec. 19–7, collects airline tickets from select air carriers,[1] ''O&D Survey Reporting Carriers,'' each quarter. The O&D Survey Reporting Carriers combine the information from tickets with the same itinerary and price into a summary record reported every 3 months. Under 49 U.S.C. 329(b)(1), the Department is obligated to collect and disseminate this information. There are many private and public stakeholders that depend on this data to make decisions on aviation business and policy. For example, this data is used by the industry to plan air services, develop commercial aviation

[1] 49 U.S.C. 40102(a)(2).

infrastructure, measure the economic impact of passenger flows, and create business plans for start-up airlines. The O&D Survey is also a primary source of information used to quantify and evaluate the effectiveness of Federal aviation policy and programs as well as to develop and implement new policies and infrastructure initiatives.

When the current rules for collection of the O&D Survey were established in the 1960s, the O&D Survey provided the best reasonably obtainable measure of passenger aviation activity. The mainframe technologies of the era dictated many aspects of the O&D survey business process and the elements selected for collection. A key driver of the process was that data storage was expensive in that era which resulted in a minimum of data elements being included. This meant more robust descriptive data, such as the time of arrival and departure, were not included in the collection. Because mainframes were centralized computing resources, the O&D Survey process was designed to route paper tickets to a centralized facility for processing and loading into the systems. In the intervening years, changes in airline business models and accounting practices enabled by technology improvements were not reflected in DOT's collection methodology, leading to a misalignment between the rules for reporting the information and current accounting practices that generally requires human intervention to reconcile differences and prevents O&D Survey Reporting Carriers from fully automating the system of data collection. The primary design issue that prevents current improvements is the regulatory requirement that the operating carrier that first touches the ticket is the carrier that has responsibility to report the ticket, known as the ''first reporting carrier rule.'' In the 1960s, this rule was selected because the most efficient process was physically to detach the ticket coupons as they were flown for each flight and send all the coupons to the centralized processing facility to be matched and combined with the relevant revenue information. Because the carrier that issued the ticket, which had all the necessary information on hand, often did not first touch the ticket, the carrier with the least amount of information was by rule responsible for reporting the ticket. Modern and decentralized E-ticket systems eliminate the need for a physical coupon matching process and enables more efficient reporting rules and access to more relevant data.

DOT has worked with representatives of the aviation industry trade association Airlines for America (A4A) to determine the best way to improve the methodology, collection, and utility of the O&D Survey. DOT is proposing this rule to reform and simplify the O&D Survey, principally by reorienting the reporting requirements so that air carriers report primarily information for tickets that they issue.

II. The Need To Modernize Current Data Collection Requirements

The data collected in the O&D Survey provides DOT with the information to help foster an air transportation system capable of meeting the present and future needs of commerce in the United States. However, the current O&D Survey methodology was designed based on accounting processes long abandoned by airlines, including manual accounting systems that often had handwritten records. As a result, the Survey's data collection methodology does not reflect today's decentralized and integrated industry-wide practices and technologies, and, in some cases, it is not capable of accurately documenting consumer behavior. For example, in today's environment, it is far more efficient for the carrier that issues the ticket to be responsible for reporting the ticket because it is the issuing carrier that has all the information about the ticket. Current process requires the operating carrier that flies the first coupon of the ticket to report and this is often not the issuing carrier. Because current reporting does not contain information about the length of stay at each intermediate point in a ticket, the system must impute the intended destination of round trip tickets. With the advent of large-scale connecting services, this has made the determination of intended destination less accurate. Though the Survey remains a unique and foundational pillar of industry economic analysis, its limitations create high levels of uncertainty in certain situations, such as identifying the true origin and destination of some passengers; the month of travel; and the portion of the total amount paid that is the revenue retained by the air carrier, as opposed to taxes and fees remitted to other government entities. By aligning the O&D Survey with current industry technology and integrated business process, this proposal would vastly simplify the reporting of appropriate data elements and increase the utility of the Survey to its users.

A. Changes in Airline and Consumer Behavior Since 1978

The way the airline industry markets and delivers air transportation services to the public changed significantly following the Airline Deregulation Act of 1978.[2] The 1978 Act enabled airlines to set their own fares, flight frequencies, and route structure. The current rules for the collection of ticket information were specifically designed to measure the relatively static air travel industry of the 1960s, when fares and flight frequencies were set by the Federal Civil Aeronautics Board and tended to be from a single point to a single point. The current O&D Survey data collection rules do not reflect the increasingly dynamic and complex business practices that have emerged since deregulation, including the development of hub-and-spoke systems, frequent flier programs, revenue management systems, internet distribution of tickets, and other industry-transforming innovations. For example, under the post-deregulation hub-and-spoke model developed by legacy air carriers, it became increasingly common to fly initially to a single, large ''hub airport'' where some passengers would change planes to complete their journey, while others remained on the same plane during intervening stop(s), known as a ''direct'' passenger flight. In the case of the ''direct'' passenger, the carriers would use a single ticket that identifies the origin and ultimate destination, but not the intermediate stop(s). Furthermore, in combination with these changes, new airline loyalty programs altered passenger ticket purchasing behavior; travelers in these programs were increasingly incentivized to take longer, indirect routes, often through an airline's large hub airport, that would allow them to accumulate more mileage-based loyalty points, exacerbating reporting issues, such as identification of the intended destination of travel, with the O&D Survey. The industry innovations forged after deregulation changed the fundamentals of airline competition, but the process used and the data DOT collects did not modernize concomitant with these changes.

B. Reevaluation of O&D Survey Burden and Data Quality

Considering these developments, DOT initiated a retrospective analysis of its aviation traffic reporting rules. The Department recognizes that there are concerns with the quality of the current O&D Survey, and that it is expensive

[2] Public Law 95–504.

and burdensome to collect, validate, and use. Collaborative discussion with A4A representatives revealed that there is a substantial hidden cost of compliance in reporting aviation statistics due to the difficulty in identifying and investigating problems that are often only revealed during post-submission quality control processing. The carriers are also often in the position of having to interpret how to stay in compliance with outdated rules that require them to deviate from their current accounting practices. For these reasons, the Department believes that the O&D Survey no longer meets the guidance outlined in OMB Circular A–130 [3] or the data collection standards of the Information Quality Act.[4] In addition, DOT identified instances in the reporting regulations that contribute to deficiencies in data quality. These deficiencies are often not observable until after the data from all the carrier submissions is combined during post-processing analysis. Moreover, ambiguity in the current regulation may lead O&D Survey Reporting Carriers to interpret reporting instructions differently, contributing to the degradation of the O&D Survey data quality and increasing the air carrier's reporting burden as they must review the suspected data and resubmit once the problem is found.

Furthermore, DOT determined that the collection and dissemination of the O&D Survey remains justified under the regulatory philosophy stated in Executive Order (E.O.) 12866, sec. 1(a) which is that ''the Federal Government should . . . promulgate regulations as required . . .'' It was also determined that, given its role and statutory duties, DOT is best positioned to collect uniform, accurate, and complete data on the Nation's civil aeronautics sector as well as ensure widespread dissemination of the collected data. Diverse public and private stakeholders, including air carriers, investors, and aircraft manufacturers, rely on this data to inform business decisions, infrastructure improvements, and aviation regulations or public policies. For example, the airline industry continues to use the O&D Survey to plan air services, develop commercial aviation infrastructure, measure the economic impact of passenger flows, and create business plans for start-up airlines. The data is also a primary source of information used to measure and evaluate the effectiveness of Federal aviation policy and programs, including by: (1) Improving international air services by seeking market liberalization, (2) ensuring the benefits of a deregulated, competitive domestic airline industry, and (3) developing policies to improve air service and access to the national air transportation system for small and rural communities. Furthermore, the Federal Aviation Administration (FAA) requires airports to use accurate aviation data for qualifying, planning, allocating, and monitoring of Airport Improvement Program (AIP) funds and to justify the need for Passenger Facility Charges (PFCs). The outdated and cumbersome O&D Survey methodologies impose excessive burdens on O&D Survey Reporting Carriers and diminish the data's utility to its users due to quality, objectivity, and completeness issues, and therefore requires modernization. In addition, ensuring universal participation across air carriers and collection of the best reasonably obtainable measurements of economic activity in the aviation sector requires updating the O&D Survey methodologies.

C. Meeting Reporting and Data Quality Demands

This proposed rule would modernize the O&D Survey to reflect current airline passenger behavior and revenue accounting practices, which allow air carriers to track the sale and the usage of every ticket sold, including through partner carriers. In doing so, the proposed rule would ensure that the O&D Survey meets the requirements and objectives of the Information Quality Act,[5] E.O. 12866, E.O. 13771, and OMB Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002.[6]

III. Development of the Proposed Rule

A. Prior Related Rulemakings

The Department initiated a retrospective analysis of its passenger traffic statistics on July 15, 1998, when DOT published an advance notice of proposed rulemaking (ANPRM),[7] requesting comment on a variety of issues related to aviation economic data collection.

On February 17, 2005, DOT published a notice of proposed rulemaking (NPRM) [8] as part of DOT's effort to revise the rules governing the nature, scope, source, and means for collecting and processing aviation traffic data as well as modernize the collection, processing, and dissemination of this data. While there was considerable support for these changes among stakeholders, the comments from the airlines indicated that the burdens of reporting the data would be unacceptably high relative to the current collection. The 2005 proposal to collect all relevant data on the ticket was overly broad and too costly to implement. The Department withdrew the proposal on June 1, 2011, stating that the proposed approach did not adequately address some issues, including measures that could both enhance the utility, integrity, and accuracy of the data and reduce the cost of reporting. The current proposal, by comparison, is more narrowly tailored to address specific well-known quality problems that have been identified by both producers and users of the data over a long period of time, maintains the same data structure of the current reporting allowing for reuse of as much of the existing infrastructure as possible, removes elements that are no longer required, adds new useful elements, and improves reporting rules.

B. Summary of Modifications Suggested by the Industry

This proposed rule renews DOT's effort to revise its aviation statistical reporting process. In an October 5, 2015, letter to DOT, A4A recommended changes to the reporting regulation that would increase the utility and accuracy of the data while simplifying reporting. Representatives of A4A notified DOT that their members favored updating the rule governing the collection of the O&D Survey under prescribed circumstances. A4A identified changes to reporting that would increase the utility of the data and, at the same time, simplify reporting. These proposed changes were reflective of numerous interactions related to the data collection between government and industry over many years. The series of ideas that stemmed from this collaboration are listed below.

Methodology Changes

(1) Change the responsibility of reporting tickets from the First Reporting Carrier Rule to the Issuing Carrier; [9]

[3] Circular A–130 requires DOT to take affirmative steps to ensure data quality objectivity and utility of Federal statistics before disseminating them and notes that public and private resources are allocated inefficiently when uncertainty is introduced due to inexact or incorrect data.

[4] Public Law 106–554 Section 515 charges Federal agencies with a responsibility to produce the best reasonably obtainable scientific and economic information available to measure the impact of their regulatory responsibilities.

[5] Public Law 106–554, sec. 515.

[6] 72 FR 33362 (June 15, 2007).

[7] 63 FR 28128.

[8] 70 FR 8140.

[9] The current regulation places the reporting responsibility on the first O&D Survey Reporting Carrier in the sequence of travel for a ticket. The

(2) Classify all Certificated air carriers and commuter air carriers holding out scheduled passenger service as O&D Survey Reporting Carriers by removing the exemptions from reporting given to U.S.-based air carriers and commuter air carriers with a business model that limits them to flying aircraft with fewer than 60 seats;

(3) Refrain from requiring foreign air carriers to report O&D Survey data, other than foreign air carriers granted anti-trust immunity under 49 U.S.C. 41308 and 41309; instead, the responsibility to report tickets issued by a foreign air carrier (that does not submit data under 49 U.S.C. 41308 and 41309) should remain with the O&D Survey Reporting Carrier that appears first in the travel sequence of the ticket;

(4) Change the period of reporting from quarterly to monthly;

(5) Increase the sample size to 40% of airline tickets so that the sample size is statistically valid for measuring travel to small and rural communities; and

(6) Shorten time lag for the release of T–100(f) data from the current 6 months to 3 months, consistent with the release of T–100 Domestic data. Historically this time lag has existed because of technological and business practice limitations.

New Data Items To Be Collected

(1) ''Dwell Time,'' an indication of the hours that the passenger spends at an airport between their arriving and departure flights;

(2) ''Via Airport,'' an entry for airlines to report hidden airports or ''via'' airports where a passenger lands, but does not necessarily deplane;

(3) ''Total Tax,'' a value of the total taxes and government-imposed fees collected for each ticket, to distinguish this value from the Total Amount of the fare collected;

(4) ''Travel Year and Month,'' to include a field detailing the year and month the passenger travels for each segment of travel;

(5) ''Exchanged Ticket Indicator,'' alerting data users that a reported fare may not comport with the reported itinerary; and

(6) ''Reporting Record Identifier,'' facilitating easier record identification by the O&D Survey Reporting Carrier when correcting tickets reported with errors.

Data Items the Department Proposed No Longer Be Collected

(1) The fare class the passenger uses on each of the flights;

(2) The cabin class the passenger uses on each of the flights; and

(3) The date of ticket purchase.

In November 2015, the Airline Tariff Publishing Company (ATPCO), the leading distributor of airline fares and airline fare information for the industry notified DOT that it had the ability to report the proposed restructured O&D Survey as envisioned by A4A and DOT and that ATPCO could offer that capability as a third-party service to airlines.

C. Goals and Objectives of This Regulatory Action

The Department established the following objectives for this rulemaking: (1) Reduce the long-term reporting burden on the O&D Survey Reporting Carriers; (2) make the O&D Survey more relevant and useful to airlines, aviation policy makers, researchers, and stakeholders; (3) obtain more accurate ticket data from a broader group of air carriers and markets; (4) reduce the time it takes to disseminate the O&D Survey and the T–100(f); and (5) increase the statistical correlation between the O&D Survey and the T–100/T100(f) for data validation purposes. Taken together, this proposed rule would alleviate unnecessary regulatory burdens placed on the American people and businesses.

IV. Proposed Changes to the Collection of Data

The Department proposes the following modifications to its collection of scheduled passenger aviation data:

D. Altering the Reporting Framework

The general process for reporting O&D data is to collect the ticket information once there is an indication that the ticket has been flown, combine all the ticket coupons to determine all the points flown and the sequence of travel on the ticket, and integrate the flown information with revenue information related to the price the consumer paid for the ticket.

1. Selection of Tickets to Report

a. Making the Ticket the Basic Unit of Reporting

This proposed rule would give O&D Survey Reporting Carriers the responsibility for reporting a ticket when it is the Issuing Carrier for that ticket, relieving air carriers of the responsibility to report any ticket issued by another O&D Survey Reporting Carrier. Under the proposed rule, Issuing Carriers would know when a coupon from one of their tickets is used for transportation by any other air carrier on the ticket, triggering a Reporting Event. Moving the responsibility to report to the Issuing Carrier would simplify the reporting process by establishing one identifiable air carrier that has all the information on a ticket and is responsible for reporting the ticket. These types of tickets will account for the majority of reported tickets. Tickets issued by an O&D Survey Reporting Carrier would be referred to as ''Category One Tickets.''

In addition to Category One tickets, tickets may be issued by air carriers who would not fall under the new definition of O&D Survey Reporting Carriers; however, those tickets may still present information that should be recorded. The proposed rule would continue to require each O&D Survey Reporting Carrier to report these encountered tickets issued by Non-O&D Survey Reporting Carriers. These tickets would be referred to as ''Category Two Tickets.'' Category Two Tickets would require a process for recognizing a Reporting Event that is different than that for Category One Tickets. The proposed Category Two reporting process would be like the existing process, but the expected volume of Category Two Tickets will be significantly less under this proposed rule due to the expansion of the pool of O&D Survey Reporting Carriers and the Category One reporting rule, which will have primacy.[10]

The Department recognizes that it could eliminate Category Two Tickets, and therefore the associated burden of reporting these tickets, by requiring all foreign air carriers providing scheduled service to the United States to submit O&D Survey data. The Department, therefore, seeks comment on whether to require all foreign air carriers providing scheduled service to the United States submit O&D Survey data.

b. Increasing Sample Size to 40 Percent

This proposed rule would increase the number of passenger tickets air carriers are required to report, which would create a statistically valid sample for meaningful analysis of smaller markets that is not available under the current O&D Data collection. The current sample size of 10 percent is only sufficient for analyzing large markets and the national air transportation

proposed regulation will place the reporting responsibility on the carrier that issued the ticket. It is the carrier that issues the ticket that will have the most information about the ticket.

[10] For evaluating Category 2 tickets, foreign air carriers that have been granted Antitrust Immunity under 49 U.S.C. 41308 and 41309 will be responsible for reporting Eligible Tickets they issue and U.S. air carriers will no longer have to report these.

system at a broad level. Studies indicate that a 40 percent sample is sufficient to allow proper evaluation of small aviation markets, and so the Department is proposing to increase the number of passenger tickets are required to report to 40 percent.[11] The ability to measure small markets is important to air carriers and to policy makers in order to monitor the effectiveness of Federal dollars spent in programs such as the Essential Air Service (EAS) and the Small Community Air Service Development Program (SCASDP), that are designed to ensure that small and rural communities have access to the national air transportation system. The 40 percent sample, in combination with expanding the universe of O&D Survey Reporting Carriers, would substantially improve the ability to measure smaller markets accurately.

c. Providing an Unbiased Sample Selection

The proposed rule would designate the final, right-most digit of the standard ticket document number as the basis for the new, random sample size. Analyses by DOT suggest that the final digit of a ticket number does not pertain directly to any particular type of passenger or journey, and every digit (0–9) has an equal probability of appearing. This method ensures that the random sampling of 40 percent of Eligible Tickets for the O&D Survey would be truly unbiased and random, protecting the validity and integrity of the data.

Any O&D Survey Reporting Carrier that does not assign ticket numbers to passenger journeys or does not assign ticket numbers such that the final, right-most digit is not randomly assigned would be required to develop an alternative method of creating a valid 40 percent sample. Those O&D Survey Reporting Carriers would need to submit their alternative sample methods to DOT for approval within 90 days of the date that the O&D Survey Reporting Carrier recognizes that it must make use of the alternative sample selection method to comply with the proposed reporting regulation for determining an Eligible Ticket.

2. Removing the Requirement for Summarization

Under the proposed rule, O&D Survey Reporting Carriers would report individual tickets as separate records, rather than aggregating tickets with identical characteristics into a single reporting record. Currently, the number of tickets in each grouping is tracked and reported as a passenger count. This process was initially instituted because the cost of data transmission and storage exceeded the cost of processing the records into summarized records. However, due to significant advances in data transmission and storage technology, any such savings are now minimal. The process of grouping and summarizing similar tickets into one summary reporting record creates an additional, unnecessary step for the O&D Survey Reporting Carriers, and is inconsistent with modern revenue accounting practices. Combining the tickets also increased the difficulty of correcting the occasional, inevitable mistakes that arise in reporting to the O&D Survey because the individual records that cause the problem are not identifiable in the summary record that is provided.

E. Modification to O&D Survey Reporting Carriers

The proposed rule would simplify the identification of the air carriers responsible for reporting a ticket, correcting the current onerous and burdensome process. It would also all but eliminate the need for an air carrier that may not have information on a ticket in its internal systems to obtain the information from other sources outside its normal business process.

1. U.S. Air Carriers [12] as O&D Survey Reporting Carriers

The proposed rule would require that all U.S. air carriers that hold either a certificate of public convenience and necessity for scheduled passenger air transportation pursuant to 49 U.S.C. 41102 or that hold a Commuter Air Carrier Authorization pursuant to 14 CFR part 298 and that hold out a schedule and issue tickets for scheduled passenger air transportation be considered O&D Survey Reporting Carriers for the O&D Survey. This proposed rule would require all O&D Survey Reporting Carrier to submit O&D Survey data to capture travel in markets served by all types of air carriers. However, by making the reporting regulation compatible with industry accounting structures, DOT expects this reporting would add minimal additional burden to affected air carriers. Carriers would only report tickets that satisfy the reporting criteria. In most cases, air carriers operating as contract lift providers (*i.e.,* code-share branded regional partners) would not have to report tickets. If necessary, DOT would work with outside third-party vendors, such as ATPCO, to make data collection and reporting services available to all O&D Survey Reporting Carriers. The Department seeks comment on whether any further accommodation is necessary for these smaller air carriers.

2. Foreign Air Carriers That Are Not O&D Survey Reporting Carriers

Under the proposed rule, foreign air carriers would not report passenger O&D data under 14 CFR part 241, Sec. 19–8, which is consistent with current reporting requirements. However, foreign air carriers would still need to report data as required by a grant of antitrust immunity under 49 U.S.C. 41308 and 41309, which represent a separate set of reporting regulations. O&D Survey Reporting Carriers will determine if a foreign air carrier that reports under 49 U.S.C. 41308 and 41309 issued a ticket, and if so, the O&D Survey Reporting Carrier will not be responsible for reporting the ticket.

3. O&D Survey Reporting Carriers List

The proposed rule would require that DOT post the O&D Survey Reporting Carriers List one month in advance of its monthly effective date to ensure that O&D Survey Reporting Carriers are aware of all updates and give the O&D Survey Reporting Carriers time to update their internal processes to comply with reporting requirements.[13] For example, an update to the list posted January 31st would be effective for reporting beginning in March. The O&D Survey Reporting Carriers List would be updated as soon as administratively possible when an O&D Survey Reporting Carrier becomes qualified or is disqualified as an O&D Survey Reporting Carrier.

F. Increasing the Frequency of Reporting

The proposed rule would require O&D Survey Reporting Carriers to report data monthly instead of the current quarterly reporting period. Information would have to be reported to the Department no later than 45 days after the last day of a reporting month. This would make the data available to stakeholders on an

[11] Statistical analyses by Michael Wittman (Michael D. Wittman, *A Note on the Use of U.S. DB1B Passenger Ticket Data for Estimating Airfares in Thin Airline Markets or Small Airports,* Massachusetts Institute of Technology), and Eric Amel (Eric Amel, *Report on the Results of Different Sampling Rates on the Reliability of the US DOT O&D Survey,* Compass Lexecon, May 18, 2015) are available in the Docket.

[12] 49 U.S.C. 40102(a)(2).

[13] Domestic air carriers may change their business model from one of only providing contract lift, not holding out scheduled air service and not issuing tickets, to selling their own services. When this occurs, the carrier will need to be added to the O&D Survey Reporting List. The same may happen in reverse requiring a carrier to be removed from the list. This same process applies to foreign air carriers immunized under 49 U.S.C. 41308 and 41309. They may also be added or removed from the list depending on their immunity status.

expedited basis compared to the existing quarterly reporting and enables users to validate it against other data disseminated monthly, such as the T–100.

G. Expanding Data Elements Collected

Through discussions with A4A, the Department determined the expanded data elements selected below are already collected and maintained by industry and therefore are minimally burdensome to collect. The Department may expand or change the regulatory language to include further definition of the requirements for submission, subject to the comments received for the final rulemaking.

1. Reporting Scheduled Year and Month of Travel

The proposed rule would require the O&D Survey Reporting Carriers to report the scheduled year and month of departure of each flight coupon. Providing this level of granularity would increase the utility of the O&D Survey by enabling users to, for example, better compare economic activity in the aviation sector against other measures of economic activity in the economy that are reported monthly, or with other aviation traffic data collected by DOT. Including month of travel also would make it easier to validate the submissions against other data sources, such as the T100 and T–100(f). Data in the O&D Survey currently cannot properly support a direct comparison to 3 months of T–100/T–100(f) data because the current survey reporting includes data with travel dates outside of the three months of the quarterly O&D reporting window that cannot be identified in the collected data; therefore, the data cannot be accurately segmented on specific time periods for comparison with the T–100 or T–100(f).

2. Reporting All Airports in the Itinerary Including Via Airports

The proposed rule would require reporting of Eligible Tickets to include all airports wherein the passenger is scheduled to travel, even when the passenger does not deplane. Whereas most tickets document travel that consists of flight coupons with one aircraft take-off and one aircraft landing, sometimes the passenger is on a flight that lands at an airport but the passenger remains on board. This airport is not expressly identified in the ticket, and is generally referred to as a ''via'' airport. The current rules of the O&D Survey do not allow for the reporting of ''via'' airports. Collecting this information would enable data users to understand better how passengers travel through various airline networks, and would provide the necessary information for relating T100/T100(f) segment data directly to O&D Survey information.

Identifying the ''via'' airports, currently hidden in an itinerary, requires knowledge of the flight number, because each flight number has its own unique routing, as well as the date of the scheduled travel, because schedules change within monthly boundaries and some flight number schedules change by day-of-week (*e.g.,* differing weekday and weekend flight itineraries). The Department is not proposing to require the reporting of flight number and flight date. Instead, DOT proposes that the O&D Survey Reporting Carriers report the ''via'' airport in a ''Via Airport'' field because the O&D Survey Reporting Carrier knows the flight number and flight date while the Department does not.

3. Reporting Dwell Time

The proposed rule would assist DOT in creating a more accurate record of the passenger's intended destination (*i.e.,* true O&D) by requiring O&D Survey Reporting Carriers to report the number of hours elapsed between the passenger's arrival at an airport on a flight and the passenger's departure from the next airport in the tickets travel sequence. The standard measure of continuity of a journey in the industry is time between flights at an airport, or ''dwell time.'' Reporting ''dwell time'' would enable users to make an accurate determination of when a passenger has reached a destination versus when the passenger is simply waiting for a connecting flight to the intended destination. For example, when a passenger stays only an hour or two at an airport, the airline assumes that this airport is not an intended destination but, instead, the passenger was only at that airport to travel onward to an intended destination.

As the O&D Survey Reporting Carrier knows the flight dates and flight times on an individual ticket, the Department proposes that the O&D Survey Reporting Carriers report in one hour increments the number of hours elapsed between a passenger's arrival and the passenger's departure from an Airport, rounding up to the nearest whole hour. This measure of time would be reported as a new element, ''Dwell Time.''

4. Reporting an Exchanged Ticket Indicator

The proposed rule adds a new element, the ''Exchanged Ticket Indicator,'' to notify O&D Survey data users that a ticket may warrant further examination. The proposed rule would continue to require that tickets issued in exchange for unused coupons of a previously issued ticket be reported. For Exchanged Tickets, the user of the data would be alerted that the value reported as the Total Amount may include a form of payment from unused coupons of a previously issued ticket.

5. Reporting a Frequent Flyer Program Ticket

The Department seeks comment on whether O&D Survey Reporting Carriers should report whether a ticket was purchased in part or in whole by redemption through a Frequent Flyer Program (FFP). The user of the data would be alerted that the value reported as the Total Amount may include a form of payment by redemption of FFP miles or points.

6. Reporting Total Amount and Tax Amount

The rule proposes adding a data element for the ''Tax Amount'' to understand the effect of government policy on aviation and allow data users the ability to separate taxes paid from the total fare. The rule also proposes to rename the currently reported element ''Total Dollar Value'' to ''Total Amount.''

a. Total Amount

The proposed rule would keep the reporting element ''Total Dollar Value'' but change the name of the reporting element to the industry standard term ''Total Amount'' and clarify the instructions for populating the data element. For all Eligible Tickets, the O&D Survey Reporting Carrier would report the Total Amount paid for the ticket that was mandatory for the passenger to board the aircraft. The Department proposes that the Total Amount would include all mandatory carrier-imposed charges and government-imposed fees and taxes. Carrier-imposed charges, which are variously described as fuel surcharges, ticketing, check-in, seat, or other fees or charges that are mandatory, that a passenger must pay to board the aircraft would be included. In addition, the amount of non-airline imposed taxes and fees for the ticket would be included. The Total Amount would not include charges for optional or ancillary services such as baggage fees, premium seat fees, or ticket change fees. For example, if a consumer can choose a no-cost seat or seating category, but chooses to purchase a particular seat or seating category, that fee should not be included. However, if a passenger has a

choice of seats or seating categories, but there is a cost associated with all the options and the consumer must pay a fee regardless of which option is chosen, the fee is mandatory and that fee should be included in the total cost of the ticket. Regarding mandatory ticket purchase fees, if the passenger must pay a fee the amount of which depends on the outlet from which the ticket is purchased (*e.g.,* one fee for online purchases, a slightly higher (or lower) fee for telephone purchases, and a slightly lower (or higher) fee for purchases at the ticket counter), payment of one of those fees is mandatory, and the fee paid by the passenger should be reported. However, if there is an outlet for which there is no ticket fee (*e.g.,* online purchases) and the only additional purchase fees are for tickets purchased via the airline's disfavored outlets, such as telephone or in-person sales, then the fee is not mandatory and would not need to be included in the ''Total Amount'' reported to the Department.

The Department seeks comment on whether an ''optional'' ticket purchase fee collected from most tickets sold by a carrier should be included in the Total Amount of the ticket. For example, if there is a disfavored outlet, such as in-person sales, for which there is no ticket fee, but a ticket fee is collected from tickets sold from the outlet a majority of passengers use (*e.g.,* online purchases), should this fee be included in the Total Amount of the ticket? If yes, what should the threshold be—greater than 50 percent of tickets sold?

When reporting Category Two Tickets, the O&D Survey Reporting Carrier may not have access to the accounting system of the Issuing Carrier. However, because ticket information is routinely shared between air carriers and foreign air carriers when transporting shared passengers, it can be expected that the O&D Survey Reporting Carrier would report as accurately as possible the Total Amount based on the information shared by the Issuing Carrier.

b. Tax Amount

The proposed rule would create a new reporting element, ''Tax Amount.'' Along with informing tax policy, this change would allow users of the data to determine the actual passenger revenue retained by an airline. For Category One Tickets, the O&D Survey Reporting Carrier would report the aggregate of fees and taxes imposed by external entities (*e.g.,* airport operating authorities and government jurisdictions) and paid by the passenger as the Tax Amount, and would exclude all carrier-imposed fees.

When reporting Category Two Tickets, the O&D Survey Reporting Carrier may not have access to the accounting system of the Issuing Carrier. However, since ticket information is routinely shared between air carriers and foreign air carriers in the normal course of business when transporting interline passengers, it can be expected that the O&D Survey Reporting Carrier would report as accurately as possible the Tax Amount based on the information shared by the Issuing Carrier.

An alternative approach would be to require that the O&D Survey Reporting Carrier report all taxes and non-carrier fees separately, instead of the current proposal to aggregate the taxes and fees into one lump sum. The Department seeks comment regarding the utility to users and additional burden to O&D Survey Reporting Carriers of reporting individual tax and fee amounts instead of reporting the aggregate amount of taxes and fees.

c. Currency and Fractions of a Dollar

The rule proposes all amounts would be reported in United States Dollars (USD), rounded to two decimal places. The rule does not propose to impose a uniform methodology for the conversion of foreign currency to USD. O&D Survey Reporting Carriers would, however, be expected to use a currency conversion methodology that is generally accepted within the industry.

7. Record Identification Number

The rule proposes the creation of a unique Record Identification Number (Record ID) generated by the O&D Survey Reporting Carrier for each Eligible Ticket submitted to the O&D Survey. This would allow the Department to communicate precisely to the O&D Survey Reporting Carrier any records that may have missing or incomplete data elements, or are otherwise flagged for review. The Department seeks comment on how to standardize the format of the Record ID by incorporating helpful elements, such as the month and year of travel, plate code of the O&D Survey Reporting Carrier, ticket number, or origin/destination, while at the same time preserving the number as a unique record identifier.

8. Removal of Fare Basis Code

The Department seeks comment on whether to cease reporting the Fare Basis Code as currently collected, the usefulness of such a data element, and how this data element could be revised to minimize the burden on O&D Survey Reporting Carriers. Currently, O&D Survey Reporting Carriers must map their fare types to a standard set of government-defined definitions that do not always match well with their business model-specific products, resulting in inconsistent fare basis codes being assigned across carriers. Ceasing to report Fare Basis Codes would also decrease the burden on the O&D Survey Reporting Carriers. Alternatively, the O&D Survey could collect fare class or a replacement data element instead, such as cabin class of ticket purchased. The Department believes that such a data element would prove useful to a variety of industry stakeholders, and would also allow users of the data to segment average fares.

V. Proposed Changes to Dissemination of Data

A. Changes to Dissemination of O&D Survey Data

By collecting data on a monthly basis, instead of quarterly, this proposed rule would allow DOT the ability to disseminate the O&D Survey statistics more frequently. The Department, however, must balance the value of providing timely information to stakeholders with the need to protect the business confidentiality of the air carriers. Currently, O&D Survey data is typically released 90 days from the end of the reporting quarter. The Department proposes withholding the O&D Survey monthly data for a minimum of 60 days from the end of the Reporting Year and Month. DOT seeks comment on the appropriate amount of time to withhold data from dissemination that would still protect the competitive interests of the air carriers.

Another data dissemination issue is the restrictions placed on the release of domestic carrier-submitted itineraries with foreign origin and destination points in the O&D Survey to non-U.S. citizens. Currently, because data covering the operations of foreign air carriers that is similar to the information collected in the O&D Survey is not available, international itinerary data in the Passenger Origin-Destination Survey is not generally disclosed because of the potential damaging competitive impact on U.S. carriers and the adverse effect upon the public interest that would result from unilateral disclosure of data related to foreign markets (14 CFR part 241, Sec. 19–7(d)). The disclosure policy identifies exceptions for government interests and for air carriers contributing data to the O&D Survey. The international travel data is available to persons upon a showing that the

release of the data will serve specifically identified needs of U.S. users which are consistent with U.S. interests (14 CFR part 241, Sec. 19–7(d)).

The Department is not contemplating a change to its policy regarding the release of international travel data; however, DOT proposes adding the descriptor ''citizens and non-citizens'' to the other persons offered an opportunity to receive the data based on specifically identified needs and consistency with U.S. interests. The Department seeks comment on the advisability of this clarification of language, and whether to grant non-citizens access to the O&D Survey data under these circumstances. Finally, DOT seeks comment on whether to replace the phrase ''specifically identified need'' with a defined list of permissible, specifically identified needs that would be codified in the regulation, and, if so, what that defined list should include.

All itineraries that contain a foreign point and involve a U.S. O&D Survey Reporting Carrier in the itinerary, regardless of whether a domestic or foreign air carrier reports it, would continue to be made available under the disclosure policy discussed above.

B. Changes to Dissemination of T–100/T–100(f)

The Department is considering shortening the time that it withholds public release of the T–100(f). Such a change would not only expedite public access to O&D Survey data, but it would also make the T–100(f) release more consistent with T–100 domestic data by having each released on the same schedule. This would simplify the process of using DOT's aviation data products by making it easier to harmonize domestic and international planning tasks. Considering the increased utility of the data in the O&D Survey, DOT is requesting comment on shortening the time that T–100(f) is withheld from the current 6 months to 3 months.

VI. Complete List of Elements To Report

Below is the proposed list of all elements that would be reported in the O&D Survey. Elements marked with an asterisk (*) indicate new or significantly changed elements. Elements for each submitted report would be submitted only once with each report; elements for each submitted ticket would be submitted once for each ticket; and elements submitted for each airport in the ticket sequence of travel would be submitted once for each airport in the sequence of travel.

A. Elements for Each Submitted Report

- *O&D Survey Reporting Carrier Identifier:* The two-character International Air Transport Association (IATA) identifier of the air carrier that reports the ticket.
- *Reporting Year:* Year in which a coupon in a ticket is used for air transportation for the first time.
- *Reporting Month:** Month in which a coupon in a ticket is used for air transportation for the first time.

B. Elements for Each Submitted Ticket

- *Record Identification Number:** A unique number assigned by the O&D Survey Reporting Carrier to each Eligible Ticket submitted to the O&D Survey, allowing DOT to precisely communicate to the O&D Survey Reporting Carrier any records that may have missing or incomplete data elements, or are otherwise flagged for review.
- *Issuing Carrier:** The two character IATA/DOT identifier of the air carrier or foreign air carrier that issued the ticket.
- *Total Amount:* The gross total of funds collected on a ticket by the Issuing Carrier for the transportation of a passenger, inclusive of taxes and fees imposed by non-carrier entities or air carriers, and exclusive of ancillary fees not required to board the plane charged by the air carrier.
- *Tax Amount:* The* portion of the Total Amount that is imposed by and remitted to a non-air carrier entity, such as a government. This value may also include airport-imposed taxes or fees assessed by privately operated airports.
- *Exchanged Ticket Indicator:** A record indicator when at least one form of payment for the ticket is one or more Coupons of a previously issued ticket.

C. Elements for Each Airport in the Ticket Sequence of Travel

- *Airport:* The IATA/DOT airport code of the station in the ticket's sequence of travel that represents the point of embarkation for the flight segment indicated by Operating Carrier, Marketing Carrier, Scheduled Flight Year, Scheduled Flight Month. The elements Dwell Time, and Via Airport would apply to this Airport.
- *Operating Carrier:* The IATA/DOT designator code for the air carrier or foreign air carrier whose aircraft are used to operate from the subject airport.
- *Marketing Carrier:* The IATA/DOT designator code for the air carrier or foreign air carrier which marketed the seat on the aircraft that is scheduled to depart that appears on the flight segment for the subject airport. In the case of a Franchise (contract lift) or Marketing Codeshare, the Operating Carrier would be different than the Marketing Carrier.
- *Scheduled Flight Year:** Departure year in which the flight is scheduled to depart the subject Airport.
- *Scheduled Flight Month:** Departure Month in which the flight is scheduled to depart the subject Airport.
- *Dwell Time:** A value that describes the time reported in one hour increments between the time a passenger arrived at the subject airport and departed from the subject airport. When an itinerary shows that the passenger arrives at an airport that is different from the departure airport (*i.e.,* there is a surface segment in the itinerary), the Dwell Time would still report the elapsed time between arrival and departure by air.
- *Via Airport(s):** Any points of scheduled stopover or connection at airports as part of a ''direct'' or ''through'' flight.

VII. Implementation and Compliance Date

The Department proposes that the compliance date for these improvements to the O&D Survey would be no earlier than one year from the publication of the final rule. The Department envisions the submission of 12 months of data under Sec. 19–8 for testing and validation as sufficient to resolve any problems that may arise in the submission and processing of data. DOT seeks comment on what a reasonable compliance date would be based on the scope of the proposal in this NPRM.

Carriers would continue to report under Sec. 19–7 until such a time that it is determined by DOT that testing and validation of data submitted under Sec. 19–8 is complete and suitable to replace data collected under Sec. 19–7 as the statistics of record. The Department seeks comment on this reporting requirement.

VIII. Regulatory Analysis and Notices

A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs), and DOT Regulatory Policies and Procedures (49 CFR Part 5)

This rulemaking is not considered a significant regulatory action under section 3(f) of E.O. 12866,[14] as supplemented by E.O. 13563,[15] which define a significant regulatory action as one that is likely to result in a rule that may have an annual effect on the

[14] 58 FR 51735; September 30, 1993.

[15] 76 FR 3821; January 21, 2011.

economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The impact on the economy would be less than $100 million; it would create no conflicts with actions taken by other agencies; it would not alter budgetary impacts of entitlements, grants, fees, or loans; nor would it raise any unusual legal or policy issues.

This proposed regulatory action would modify an existing regulation and is expected to result in cost savings to producers and users of the data as well as to the Federal government. The proposed action is also expected to result in benefits to users of the data, including the O&D Survey Reporting Carriers themselves.

1. Cost Savings

The net costs of the proposed rule were determined by comparing the costs of the existing system to the projected costs with the proposed modification. The Department's analysis identified three primary categories of potential cost reductions:

- Cost reductions to data producers: The reduction in the costs of producing information for government reporting, due to technological simplification of data processing and submission.
- Cost reductions to the government: The reduction in costs to edit, manipulate, and validate the O&D data for release.
- Cost reductions to the public/users of the data: The reduction in time that users must spend applying specialized analytical skills to manipulate and adjust the data to account for current deficiencies in the Origin and Destination Survey.

Cost reductions to data producers include costs for accounting and auditing clerks, computer systems analysts, and computer programming analysts that are part of the ongoing production of data by the air carriers. Labor rates were taken based on Bureau of Labor Statistic's Standard Occupational Classification (SOC) and hours were estimated based on industry input for current operations. Average cost per airline based on the labor rates and estimated hours was then calculated, and this was multiplied by the expected number of carriers that will report over a 10-year timeframe. The ''as is'' costs were then compared to the ''to be'' costs that would be achieved under the proposed rule. The ''to be'' costs include the transition costs from the current system to the new system as well as an ongoing cost estimate for the processing of the data by a third-party fee-for-service provider. ATPCO, the leading distributor of airline fares and airline fare information, notified DOT that it can create software to assemble the O&D Survey report for any air carrier that exchanges ticket information using their services. ATPCO is a non-profit industry consortium that provides tariff services and other ticket-related services to air carriers and foreign air carriers ''at-cost.'' ATPCO's shared software would relieve air carriers from the cost of maintaining separate systems, each of which carries attendant secondary expenses for training and technical maintenance. This option would not only simplify the information technology operations, but also amortize the cost of creating and maintaining the software. Therefore, upfront costs resulting from this proposed action are expected to include the expenses related to developing, installing, and maintaining an automated reporting system. These upfront costs have been accounted for as ongoing payments to a third-party provider.

Cost reductions to the government include systems investment costs and ongoing production costs. Labor rates were taken based on Bureau of Labor Statistic's Standard Occupational Classification (SOC) and hours were based on estimates provided by the Bureau of Transportation Statistics (BTS), the agency responsible for the current processing. The ''as is'' comparison assumed the use of existing infrastructure while the ''to be'' assumed a 2-year development and implementation window as well as ongoing production costs.

Cost reductions to the public/users estimated for the ''as is'' total hours users of the data spend on computer systems analysts to further prepare the data and the number of hours an analyst may take to perform final data quality procedures that must be done to ensure clean data for final analysis outputs. The comparison ''to be'' calculation includes an estimated investment cost for creating processes for the new data prior to its release to public/users.

All costs were estimated over 10 years and discounted at a 7 percent rate.

SUMMARY OF COST SAVINGS

Stakeholder	Costs under the current regulation	Costs under the proposed regulation	Cost savings
Regulated Entities (Data Producers)	$8,355,747	$7,458,801	$896,946
Government	18,127,583	10,912,800	7,214,783
Public (Data Users)	2,452,586	196,613	2,255,973
Total Cost Savings (10 years @7% Discount Rate)			*10,367,702*
Annualized Cost Savings			*1,476,128*

This analysis finds that the proposed modification would result in annualized cost savings of approximately $1.5 million at a 7 percent discount rate.

2. Implementation and Transition Costs

To comply with the proposed revised O&D Survey, a certain investment is likely necessary by data producers. The proposed modification would simplify the design of the O&D Survey sufficiently, allowing for third-party providers to create fee-for-service software that would produce the Survey reporting records for all air carriers.

3. Benefits to Users of the Data

Users of the data include both air carriers and industry-related entities, such as airports, manufacturers, researchers, and investors, who often cite the O&D Survey as one of the most critical datasets used to formulate short- and long-term business plans and forecast industry trends. Improving the quality of the O&D Survey data would also yield several other unquantified benefits to users of the data, including:

- Reporting the Dwell Time between flights would help reduce the

difficulties and potential errors associated with determining when a passenger has reached a destination (''Trip Break'') and when the passenger is simply waiting for a connecting flight to the intended destination.

• Reporting all the cities in the itinerary would better align O&D Survey data with the T–100, removing much of the uncertainty in market validation analysis. This would allow the T–100 to facilitate validation of O&D Survey data submissions.

• Reporting a larger sample size to capture small and rural markets with the statistically significant equivalence of larger markets would reduce the need to make much less accurate manual statistical adjustments as well as increase the accuracy of data available for the analysis of small markets.

• Differentiating the amount of tax collected from the amount of total fare collected would remove uncertainty in determining the actual passenger revenue retained by the airlines.

• Reporting the month and year of travel would enable determinations of market trends that are not discernable inside the quarterly data reports and would allow direct cross-validation to other datasets such as the T–100.

4. Cost-Benefit Analysis Summary

Major provisions of this regulatory action	Benefit	10-Year costs (discounted at 7%)
Change sample size to 40%	Would enable more effective oversight of Congressional programs designed to help small communities and provide more accurate market information for a wide variety of research and industry uses.	The estimated total reduction in cost over 10 years discounted at 7% for all the major provisions would provide a reduction of $10,367,702 from the cost of continuing the current methodology.*
Report each ticket as a single record.	Would simplify reporting and improves quality assurance.	
Designate all certificated air carriers and commuter air carriers holding out scheduled passenger service as O&D Survey Reporting Carriers and require them to report the tickets that they sell.	Would simplify the reporting procedures to enable full automation of reporting, which enhances efficiency and accuracy; and eliminate loopholes in collection secure integrity of the sample of tickets.	
Move to monthly reporting	Would create more useful and timely economic information; and align the reporting process with the corresponding industry accounting process.	
Report the month/year of travel	Would create more useful, timely economic information; and align reporting process with the corresponding industry accounting process.	
Report all airports in the itinerary.	Would provide clarity and completeness in passenger movements.	
Report Dwell Time as the number of hours between each arrival and next departure in the itinerary.	Would allow accurate determination of the passenger's intended destination based on industry standard practice.	
Report an Exchanged Ticket Indicator.	Would alert data users that the fare on a specific ticket may require further investigation.	
Elimination of Fare Basis Code reporting.	Would remove sensitive business information that is burdensome to report.	
Report taxes paid on the ticket	Would inform tax policy and allow data users to separate taxes paid from the total fare.	
Report a Record Identification Number.	Would enable communication between a O&D Survey Reporting Carrier and DOT regarding data quality.	

* The industry requests to align the regulation with current accounting practices, which means that the system is to be restructured, so all new provisions can be included in a one-time programming cost.

This proposed rule is expected to be an E.O. 13771 deregulatory action.[16] As is described above in the discussion of the benefit-cost analysis that was conducted for the proposed rule, this action is expected to result in annualized cost savings (to producers and users of the data and the Federal Government) of approximately $1.5 million per year, while also yielding additional unquantified benefits to users of the data through improved data quality and utility.

B. The Unfunded Mandates Reform Act of 1995.

The Unfunded Mandates Reform Act of 1995 [17] requires Federal agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. The proposed changes we are considering making to the aviation data collections would not result in expenditures by State, local, or tribal governments.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act [18] requires an agency to assess the impacts of proposed and final rules on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. The Department has evaluated the effects of this action on small entities and anticipates that the action will not have a significant economic impact on a substantial number of small entities.

[16] 82 FR 9339; Feb. 3, 2017.

[17] 2 U.S.C. 1531–1538.

[18] 5 U.S.C. 601 *et seq.*

The small entities which will begin reporting the data collected under this proposed rule routinely collect this data as a normal course of business, as a necessity to common industry accounting practices. The Department hereby certifies that this action would not have a significant economic impact on a substantial number of small entities.

D. E.O. 13132 (Federalism)

E.O. 13132 [19] requires agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have a substantial, direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The Department has analyzed this action in accordance with the principles and criteria contained in E.O. 13132. This rule does not include any provision that substantially directly affect the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. It imposes no direct compliance costs on State and local governments nor does it preempt State law. States are already preempted from regulating in this area by the Airline Deregulation Act.[20] Therefore, the consultation and funding requirements of E.O. 13132 do not apply.

E. E.O. 13175 (Consultation and Coordination With Indian Tribal Governments)

The proposed changes to the O&D Survey would not have tribal implications, impose substantial direct compliance costs on Indian tribal governments, or preempt tribal law. Therefore, this NPRM is exempt from the consultation requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' [21] If tribal implications are identified during the comment period, the Department will undertake appropriate consultations with the affected Indian tribal officials.

F. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) [22] requires that the Department consider the impact of paperwork and other information collection burdens imposed on the public and obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations.

This action contains the following proposed amendments to the existing information collection requirements previously approved under OMB Control Number 2105–AE45. As required by the PRA, DOT has submitted these proposed information collection amendments to OMB for its review.

Summary: Origin-Destination Survey of Airline Passenger Traffic (O&D Survey), which collects information on the origin and destination of passengers including, at a minimum, information on: (1) The origin and destination of passengers in interstate air transportation, and (2) the number of passengers traveling by air between any two points in interstate air transportation. Modifications to the existing requirements would include making the air carrier that issues the ticket primarily the carrier responsible for submitting the ticket, reporting each ticket as a single record, expanding the O&D Survey Reporting Carrier threshold, changing the period of reporting to monthly, increasing the sample size to 40 percent, reducing the lag time for release of T–100(f), adding dwell time, adding a Via Airport data element, adding a Total Tax element, adding Travel Year and Travel Month as recorded elements, adding an Exchange Ticket Indicator, adding a Reporting Record Identifier, and removing the requirement to record the Fare Basis Code.

Use: The Department is obligated by statute to collect and disseminate this information. There are many private and public stakeholders that depend on this data to make decisions on aviation business and policy. For example, this data is used by the industry to plan air services, develop commercial aviation infrastructure, measure the economic impact of passenger flows, and create business plans for start-up airlines. The O&D Survey is also a primary source of information used to quantify and evaluate the effectiveness of Federal aviation policy and programs as well as develop and implement new policies and infrastructure initiatives.

Respondents (including number of): All certificated air carriers and commuter air carriers holding out scheduled passenger service. The Department currently estimates approximately 27 air carriers will qualify to submit data to the O&D Survey as envisioned by this rulemaking.

Frequency: Monthly.

Annual Burden Estimate: The Department is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of collecting information on those who are to respond, including by using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may send comments on the information collection requirement by March 19, 2021, 11:59 p.m. Eastern Time, and should direct them to the address listed in the **ADDRESSES** section at the beginning of this preamble. Comments should also be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for OST, New Executive Building, Room 10202, 725 17th Street NW, Washington, DC 20053.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*) and has preliminarily determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). The purpose of this rulemaking is to update the method of collecting and processing aviation traffic data as well as expanding the number of reporting air carriers, the sample size collected, and the scope of the data reported in the O&D Survey. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

H. Regulation Identifier Number

2105–AE45.

[19] 64 FR 43255; August 10, 1999.

[20] 49 U.S.C. 41713.

[21] 65 FR 67249; November 9, 2000.

[22] 44 U.S.C. 3501, *et seq.*

List of Subjects

14 CFR Part 241

Air carriers, Reporting and recordkeeping requirements, Uniform system of accounts.

14 CFR Part 298

Air taxis, Reporting and recordkeeping requirements.

Issued in Washington, DC.

Elaine L. Chao,

Secretary of Transportation.

Proposed Rule

Accordingly, the Department proposes to amend 14 CFR parts 241 and 298 as follows:

PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR LARGE CERTIFICATED AIR CARRIERS

■ 1. The authority citation for part 241 continues to read as follows:

Authority: 49 U.S.C. 329, 41101, 41708, and 41709.

Sec. 19–7 [Removed]

■ 2. Remove Sec. 19–7.

■ 3. Add Sec. 19–8 to read as follows:

Sec. 19–8 Passenger Origin—Destination Survey applicability.

(a) All U.S. certificated and commuter air carriers conducting scheduled passenger services (except helicopter carriers) shall participate in a Passenger Origin-Destination (O&D) Survey covering domestic and international air carrier operations, as prescribed by the Department's Bureau of Transportation Statistics (BTS), Office of Airline Information (OAI).

(b) A statistically valid sample of flight coupons shall be selected for reporting purposes. The sample shall consist of a selection of all Tickets involving a Reporting Carrier that meet the reporting criteria as defined in the Instructions, or further defined in Directives, except those participating O&D carriers with nonstandard ticketing procedures, or other special operating characteristics, may propose alternative procedures. Such departures from standard O&D Survey practices shall not be authorized unless approved in writing by the Director, Office of Airline Information under the procedures in Sec. 1–2. The data to be recorded and reported, as stipulated in the Instructions and Directives, shall include at a minimum the following data elements: Reporting Carrier, Reporting Month, Reporting Year, Record Identification Number, Issuing Carrier, Total Amount, Tax Amount, Exchanged Ticket Indicator, Airport, Operating Carrier, Marketing Carrier, Scheduled Flight Year, Scheduled Flight Month, Dwell Time and Via Airport(s).

(c) Any Ticket that is submitted that involves a O&D Survey Reporting Carrier providing service in whole or in part under this part or 49 U.S.C. 41308 or 41309 and any data covering the operations of foreign air carriers that are similar to the information collected in the Passenger Origin-Destination Survey are generally not available to the Department, the U.S. carriers, or U.S. interests. Therefore, because of the damaging competitive impact on U.S. carriers and the adverse effect upon the public interest that would result from unilateral disclosure of the U.S. survey data, the Department will not disclose the international data in the Passenger Origin-Destination Survey except:

(1) To an air carrier directly participating in and contributing input data to the Survey or to a legal or consulting firm designated by an air carrier to use on its behalf O&D data in connection with a specific assignment by such carrier;

(2) To parties to any proceeding before the Department to the extent that such data are relevant and material to the issues in the proceeding upon a determination to this effect by the Administrative Law Judge or by the Department's decision-maker. Any data to which access is granted pursuant to this section may be introduced into evidence subject to the normal rules of admissibility of evidence.

(3) To agencies and other components of the U.S. Government.

(4) To other persons upon a showing that the release of the data will serve specifically identified needs of U.S. users which are consistent with U.S. interests.

(5) To foreign governments and foreign users as provided in formal reciprocal arrangements between the foreign and U.S. Governments for the exchange of comparable O&D data.

(6) Or as otherwise determined by the Department as consistent with its regulatory functions and responsibilities.

(d) Each O&D Survey Reporting Carrier shall maintain its prescribed reportable records in a manner and at such locations as will permit ready accessibility for examination by representatives of DOT. The record retention requirements are prescribed in part 249 of this chapter.

PART 298—EXEMPTIONS FOR AIR TAXI AND COMMUTER AIR CARRIER OPERATIONS

■ 4. The authority citation for part 298 continues to read as follows:

Authority: 49 U.S.C. 329 and chapters 401, 411, and 417.

■ 5. In § 298.60, revise paragraph (a) to read as follows:

§ 298.60 General reporting instructions.

(a) Each commuter air carrier and each small certificated air carrier shall file the applicable schedules of Form 298–C, ''Report of Financial and Operating Statistics for Small Aircraft Operators'', Schedule T–100, ''U.S. Air Carrier Traffic and Capacity Data by Nonstop Segment and On-Flight Market'', and the ''Passenger Origin—Destination Survey'' prescribed in part 241, Sec. 19–8, of this subchapter.

* * * * *

[FR Doc. 2020–29229 Filed 1–15–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 232, 239, and 249

[Release Nos. 33–10911; 34–90773; File No. S7–24–20]

RIN 3235–AM78

Rule 144 Holding Period and Form 144 Filings

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is proposing to amend Rule 144 to revise the holding period determination for securities acquired upon the conversion or exchange of certain market-adjustable securities of issuers that do not have securities listed on a national securities exchange. Under the proposed amendments, the holding period for those securities would not begin until the securities are acquired upon the conversion or exchange of the market-adjustable security. The Commission is also proposing to mandate electronic filing of Form 144 with respect to securities issued by issuers subject to Exchange Act reporting requirements, to amend the filing deadline for Form 144 to coincide with the filing deadline for Form 4, and to streamline the filing process in cases where both Form 4 and Form 144 are required to report the same transaction. Finally, the Commission is proposing to eliminate

the requirement to file a Form 144 for resales of securities of issuers that are not subject to Exchange Act reporting.

DATES: Comments should be received on or before March 22, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/submitcomments.htm*).

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–24–20. We will post all submitted comments, requests, other submissions and other materials on our internet website (*http://www.sec.gov/rules/proposed.shtml*). Typically, comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Due to pandemic conditions, however, access to the Commission's public reference room is not permitted at this time. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information. You should submit only information that you wish to make available publicly.

Studies, memoranda or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: John Fieldsend or Sean Harrison, at (202) 551–3430, in the Office of Rulemaking, Division of Corporation Finance, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are proposing amendments to:

Commission reference		CFR citation (17 CFR)
Regulation S–T [17 CFR 232.10 through 232.903]	Rule 101	§ 232.101.
Securities Act of 1933 (''Securities Act'') [15 U.S.C. 77a *et seq.*]	Rule 144(b)(3)	§ 230.144(b)(3).
	Rule 144(d)(3)(ii)	§ 230.144(d)(3)(ii).
	Rule 144(h)	§ 230.144(h).
	Form 144	§ 239.144.
Securities Exchange Act of 1934 (''Exchange Act'') [15 U.S.C. 78a *et seq.*]	Form 4	§ 249.104.
	Form 5	§ 249.105.

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I. Discussion of the Proposed Amendments

A. Overview of the Proposed Amendments

We are proposing to amend Rule 144, Form 144, Form 4, Form 5 and Rule 101 of Regulation S–T. We propose to amend Rule 144(d)(3)(ii) to revise the holding period determination for securities acquired upon the conversion or exchange of certain market-adjustable securities of an issuer that does not have a class of securities listed, or approved to be listed, on a national securities exchange registered pursuant to Section 6 [1] of the Exchange Act (''unlisted issuer'') so that the holding period would not begin until the conversion or exchange. As used in this release, a ''market-adjustable security'' is a convertible or exchangeable security that provides for a conversion rate, conversion price, or other terms that, in each case, would have the effect of offsetting, in whole or in part, declines in value of the underlying securities that may occur prior to conversion or exchange.

We are proposing this amendment to mitigate the risk of unregistered distributions in connection with sales of market-adjustable securities. As

[1] 15 U.S.C. 78f.

discussed below, the application of the ''tacking'' provisions of Rule 144 to market-adjustable securities undermines one of the key premises of Rule 144, which is that holding securities at risk for an appropriate period of time prior to resale can demonstrate that the seller did not purchase the securities with a view to distribution [2] and, therefore, is not an underwriter for the purpose of Securities Act Section 4(a)(1).[3] Amending the Rule 144 holding period for the securities received on conversion or exchange of market-adjustable securities so that it will not commence until the time the underlying securities are acquired would help maintain the effectiveness of this key aspect of the Rule 144 safe harbor.

We are also proposing amendments to update and simplify the Form 144 filing requirements by mandating the electronic filing of all Form 144 notices related to the resale of securities of issuers that are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, and eliminating the filing requirement for Form 144 notices related to the resale of securities of issuers that are not subject to Exchange Act reporting. Additionally, we are proposing to eliminate two unnecessary data fields and intend to create an online fillable document for entering the information required by Form 144. In connection with these amendments, we are planning to streamline filing procedures for individuals who are subject to notice filing requirements under Rule 144 and reporting requirements under Section 16 [4] of the Exchange Act. These amendments would also change the filing deadline for Form 144 to coincide with the filing deadline for Form 4. In addition, we are proposing to amend Forms 4 and 5 to add a check box to permit filers to indicate that a sale or purchase reported on the form was made pursuant to a transaction that satisfied 17 CFR 240.10b5–1(c) (''Rule 10b5–1(c)'').

We welcome feedback and encourage interested parties to submit comments on any or all aspects of the proposed rule amendments. When commenting, it would be most helpful if you include the reasoning behind your position or recommendation.

B. Proposed Amendment to Rule 144(d)(3)(ii)

1. Background

a. Rule 144 Safe Harbor

Securities Act Section 5 requires registration of all offers and sales of securities in interstate commerce or by use of the United States mails, unless an exemption from the registration requirement is available.[5] Securities Act Section 4(a)(1) provides an exemption for ''transactions by any person other than an issuer, underwriter, or dealer.'' Securities Act Section 2(a)(11) defines an ''underwriter'' to mean any person who has purchased from an issuer with a view to, or offers or sells for an issuer in connection with, the distribution of any security or participates or has a direct or indirect participation in any such undertaking.[6]

In 1972,[7] the Commission adopted Rule 144 to provide a non-exclusive safe harbor from the statutory definition of ''underwriter'' to assist security holders in determining whether the Section 4(a)(1) exemption is available for their resale of restricted or control securities.[8] Rule 144 sets forth objective criteria on which security holders seeking to resell such securities may rely to be assured they would not be deemed to be engaged in a distribution and, therefore, not be considered an underwriter under Section 2(a)(11). A selling security holder that seeks to rely on the safe harbor for the resale of securities must satisfy the following conditions: [9]

- There must be adequate current public information available about the issuer if the selling security holder is an affiliate of the issuer; [10]
- The selling security holder must have held the securities for a specified holding period if the securities being sold are restricted securities; [11]
- The resale must be within specified sales volume limitations if the selling security holder is an affiliate of the issuer; [12]
- The resale must comply with the manner of sale requirements if the selling security holder is an affiliate of the issuer; [13] and
- The selling security holder must file a Form 144 if the selling security holder is an affiliate of the issuer and the amount of securities being sold exceeds specified thresholds.[14]

b. Rule 144 Holding Period Condition and Tacking

One of the conditions of Rule 144 for restricted securities is that a selling security holder must have held the securities for a specified period of time prior to resale. This condition helps to ensure that a holder who claims an exemption under Section 4(a)(1) has assumed the full economic risks of investment and, therefore, is not acting as a conduit, directly or indirectly, on behalf of the issuer for the sale of unregistered securities to the public.[15] Under Rule 144(d)(1)(i), restricted securities acquired from an issuer that has been subject to Exchange Act reporting for at least 90 days before the sale (a ''reporting issuer'') must be held for a minimum of six months. If the issuer is not subject to Exchange Act reporting, or has not been for a period of at least 90 days immediately before the sale (a ''non-reporting issuer''), the restricted securities must be held for a minimum of one year pursuant to Rule 144(d)(1)(ii).

As originally adopted, Rule 144 required a two-year holding period before a security holder could make

[2] The term ''underwriter'' is broadly defined to mean any person who has purchased from an issuer with a view to, or offers or sells for an issuer in connection with, the distribution of any security, or participates, or has a direct or indirect participation in any such undertaking, or participates or has a participation in the direct or indirect underwriting of any such undertaking. *See* Securities Act Section 2(a)(11) [15 U.S.C. 77b(a)(11)]. The interpretation of this definition traditionally has focused on the words ''with a view to'' in the phrase ''purchased from an issuer with a view to . . . distribution.'' For simplicity, in this release we often only refer to the ''with a view to'' prong of the underwriter definition.

[3] 15 U.S.C. 77d(a)(1).

[4] 15 U.S.C. 78p.

[5] 15 U.S.C. 77e.

[6] As used in Section 2(a)(11), the term ''issuer'' includes any person directly or indirectly controlling or controlled by the issuer, or any person under direct or indirect common control with the issuer. An affiliate of an issuer is a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such issuer. *See* 17 CFR 230.405 and 17 CFR 230.144(a)(1).

[7] *See Definition of Terms ''Underwriter'' and ''Brokers' Transactions,''* Release No. 33–5223 (Jan. 11, 1972) [37 FR 591 (Jan. 14, 1972)] (''1972 Adopting Release'').

[8] Restricted securities are securities acquired pursuant to one of the transactions listed in Securities Act Rule 144(a)(3), such as securities issued in a private placement. Although not defined in Rule 144, the term ''control securities'' commonly refers to securities held by an affiliate of the issuer, regardless of how the affiliate acquired the securities. *See* Rule 144(b)(2).

[9] In general, these are the conditions that a selling security holder must satisfy when seeking to rely on the safe harbor for the resale of securities. However, a person seeking to rely on the safe harbor when reselling securities of certain types of companies must satisfy different conditions. *See* 17 CFR 230.144(i).

[10] *See* 17 CFR 230.144(c). A sale by a non-affiliate also must satisfy the current public information condition if the non-affiliate is selling securities of a reporting issuer and has held the securities for less than one year.

[11] *See* 17 CFR 230.144(d).

[12] *See* 17 CFR 230.144(e).

[13] *See* 17 CFR 230.144(f) and (g).

[14] *See* Rule 144(h).

[15] *See* 1972 Adopting Release, *supra* note 7, at 594 (noting that the holding period condition in Rule 144 was designed to assure that the registration provisions of the Securities Act are not circumvented by persons acting, directly or indirectly, as conduits for an issuer in connection with resales of restricted securities and that to accomplish this, the rule provides that such persons be subject to the full economic risks of investment during the holding period).

limited sales of restricted securities.[16] Later changes to the rule established a separate three-year holding period for unlimited sales of restricted securities by non-affiliates of the issuer.[17] In 1997, the Commission shortened the holding periods for restricted securities to one-year and two-year periods, respectively.[18] In 2007, the Commission adopted the current holding periods of six months for reporting issuers and one year for non-reporting issuers based on its observations of Rule 144's application since 1997 and its desire that the holding period be no longer than necessary nor impose any unnecessary costs or restrictions on capital formation.[19] By reducing the holding periods for restricted securities, the Commission intended to help companies to raise capital more easily and less expensively.[20]

Rule 144 contains ''tacking'' provisions in specified situations that allow holders to count other holding periods—either of prior owners of the securities or of different securities owned by the holders—to satisfy their holding period requirement. One situation where Rule 144 permits tacking of the holding period involves convertible securities. Rule 144(d)(3)(ii) allows securities acquired solely in exchange for other securities of the same issuer to be deemed to have been acquired at the same time as the securities surrendered for conversion or exchange. A variation of this provision has existed since 1972,[21] and the current version of this provision was adopted in 2007.[22]

c. Market-Adjustable Securities Transactions

A typical convertible security, for example a convertible bond, a convertible promissory note, or convertible preferred stock, can be converted into a different security, such as shares of the issuer's common stock, under specified terms and conditions.[23] In a conventional convertible security transaction, the conversion formula is generally fixed, such that the convertible security converts into common stock based on a conversion price that is fixed at the time the convertible security is sold and remains at that fixed price through its conversion. Convertible securities may contain mechanical adjustments to the number of underlying shares and the conversion price upon the occurrence of events such as splits, dividends, or other distributions on the underlying securities. They also may contain anti-dilution provisions designed to protect the holder's economic interest if the issuer subsequently issues shares of the underlying securities at a price below their current market value or below the holder's original purchase price. The terms of market-adjustable securities, however, go beyond these typical adjustments and anti-dilution provisions to adjust for, and protect the holder against, general decreases in market value of the underlying securities.[24]

While the holder of a typical convertible security is at substantial economic risk upon conversion with respect to the underlying security if the underlying security fails to appreciate or declines in value, this is not the case in market-adjustable securities transactions where the conversion or exchange price and/or the amount of securities received on conversion are not fixed at the time of the initial transaction. In these transactions, holders have the right to convert the securities into the underlying securities (often shares of common stock) at a conversion price that yields a substantial discount to the market price of the underlying securities at the time of conversion or exchange. If the securities are converted or exchanged after the Rule 144 holding period is satisfied, the underlying securities may be sold quickly into the public market at prices above the price at which they were acquired. Accordingly, initial purchasers or subsequent holders have an incentive to purchase the market-adjustable securities with a view to distribution of the underlying securities following conversion to capture the difference between the built-in discount and the market value of the underlying securities. As noted above, when a holder purchases with a view to distribution, it is acting as an underwriter and is unable to rely on the Section 4(a)(1) exemption from registration.

A holding period is essential to assure that purchasers have assumed the economic risks of investment, and therefore, are not acting as conduits for sale to the public of unregistered securities, directly or indirectly, on behalf of an issuer.[25] The discounted conversion or exchange features in market-adjustable securities typically provide holders with protection against investment losses that would occur due to declines in the market value of the underlying securities prior to conversion or exchange. As a result, these holders are not exposed to the market risk associated with holding the underlying security prior to conversion or exchange;[26] they are only exposed to that market risk during the time that they hold the underlying security after the conversion or exchange.[27] In these circumstances, holders that convert and promptly resell the underlying security in order to secure a profit on the sale based on the built-in discount have not assumed the economic risks of investment of the underlying security. Therefore, under Rule 144's current

[16] *See id.*

[17] *See Resales of Securities,* Release No. 33–6032 (Mar. 5, 1979) [44 FR 15610 (Mar. 14, 1979)] and *Resales of Securities,* Release No. 33–6286 (Feb. 6, 1981) [46 FR 12195 (Feb. 13, 1981)] (''1981 Adopting Release'').

[18] *See Revision of Holding Period Requirements in Rules 144 and 145,* Release No. 33–7390 (Feb. 20, 1997) [62 FR 9242 (Feb. 28, 1997)]. In that adopting release, the Commission stated that it was shortening the holding to reduce the cost of capital, lower the illiquidity discount given by companies raising capital in private placements, and increase the usefulness of the Rule 144 safe harbor. *See id.* at 9242. Additionally, the Commission stated that it did not believe that the shorter holding periods would diminish investor protection because the holding periods were still sufficiently long to ensure that resales under Rule 144 would not facilitate indirect public distributions of unregistered securities by issuers or affiliates.

[19] *See Revisions to Rules 144 and 145,* Release No. 33–8869 (Dec. 6, 2007) [72 FR 71546 (Dec. 17, 2007)] (''2007 Adopting Release''). In the 2007 Adopting Release, the Commission eliminated the bifurcated holding periods for affiliates and non-affiliates, and added different holding periods for reporting and non-reporting issuers because non-reporting issuers are not obliged to file periodic reports with updated financial information that are publicly available on EDGAR.

[20] *See id.*

[21] *See* 1972 Adopting Release, *supra* note 7, at 597.

[22] *See* 2007 Adopting Release, *supra* note 19, at 71555.

[23] *See infra* Section II.B.1; *see also, Convertible Securities,* U.S. Sec. & Exchange Commission (last visited Dec. 18, 2020), available at *https://www.sec.gov/fast-answers/answersconvertibleshtm.html.*

[24] For example, the conversion or exchange rate of the overlying convertible securities into the underlying equity securities may be discounted from a weighted average price of the publicly traded class of securities, typically, common stock, calculated for a period leading up to the date of conversion or exchange. Therefore, the conversion price provides a discount from the recent market price that can be realized at the time sales of the underlying equity securities begin.

[25] *See* 1972 Adopting Release, *supra* note 7.

[26] Prior to conversion or exchange, a holder of market-adjustable securities is at risk of bankruptcy of the issuer. However, this risk is borne for a briefer duration currently than when Rule 144 was originally adopted because of the shortened holding periods.

[27] This period of time can be very limited because the discounted equity securities acquisition, through conversion or exchange, and the market-priced sales can occur almost simultaneously. For example, when the applicable holding period ends, the holder may demand that the issuer issue the required number of underlying securities at the discounted conversion or exchange price and concurrently sell those securities at market prices. The underlying securities are received from the issuer in time to settle the sales at market prices made earlier.

formulation, holders are able to purchase market-adjustable securities with a view to distribution while still satisfying the holding period requirements and tacking period provisions of Rule 144.

Permitting the holding period of the underlying securities to be ''tacked'' onto the holding period of the convertible or exchangeable security allows the initial holders of market-adjustable securities to structure transactions without significant economic risk prior to conversion. The structure of these transactions incentivizes purchases with a view to distribution because, by selling the underlying securities into the market promptly after conversion, holders of market-adjustable securities can capture the value of the built-in discount to the then-current market value. This is inconsistent with the purpose of Rule 144 to provide a safe harbor for transactions that are not distributions of securities. These unregistered transactions pose the risk that distributions of securities will reach the public markets without the same level of disclosure and liability protections that registration provides to investors.

2. Proposed Amendment

We are proposing to amend Rule 144(d)(3)(ii) to provide that the holding period for the securities acquired upon conversion or exchange of certain market-adjustable securities issued by unlisted issuers would not begin until conversion or exchange.[28] The proposed amendment would be limited to unlisted issuers because national securities exchanges registered pursuant to Section 6 of the Exchange Act have certain listing requirements, such as requiring shareholder approval of an issuance of 20 percent or more of a company's common stock. Because market-adjustable securities have the potential to result in highly dilutive issuances of large amounts of the issuer's securities, these required approvals are not likely to be granted in the situations the amendment is intended to address.[29]

We have also observed that issuers that are able to satisfy the listing criteria of these exchanges have generally not been engaging in these transactions. The proposed amendment is intended to avoid the potential under the current Rule 144 safe harbor for holders to acquire market-adjustable securities with a view to an unregistered distribution of the underlying securities acquired upon their conversion or exchange, resulting in significant resales of the underlying securities without investors having the benefit of registration.[30]

The proposed amendment would not affect the use of Rule 144 for most convertible or variable-rate securities transactions. The proposed amendment would apply only to market-adjustable securities transactions where:

- The newly acquired securities were acquired from an issuer that, at the time of the conversion or exchange, does not have a class of securities listed, or approved for listing, on a national securities exchange registered pursuant to Section 6 of the Exchange Act; and
- The convertible or exchangeable security contains terms, such as conversion rate or price adjustments, that offset, in whole or in part, declines in the market value of the underlying securities occurring prior to conversion or exchange, other than terms that adjust for stock splits, dividends, or other issuer-initiated changes in its capitalization.

We believe the proposed amendment would reduce the potential for unregistered distributions because after the conversion or exchange of the overlying convertible securities, the underlying securities would need to be held for the applicable Rule 144 holding period before they would be eligible for resale under the Rule 144 safe harbor. A holder who has held the underlying securities for the entire six months or one year, as applicable, during which period market adjustments are no longer available, is generally appropriately excluded from the definition of an underwriter.

While we believe the proposed amendment would mitigate the risk of unregistered distributions in connection with market-adjustable securities transactions, we also emphasize that the Rule 144 safe harbor is not available to any person with respect to any transaction or series of transactions that is part of a plan or scheme to evade the registration requirements of the Securities Act, as currently stated in the Preliminary Note to Rule 144. We propose to move this statement to new paragraph (b)(3) of Rule 144 so that the statement is explicitly included in the rule text.[31]

Request for Comment

1. Should we amend Rule 144(d)(3)(ii) as proposed?

2. Should the rule only apply if the issuer is an ''unlisted issuer'' at the time of conversion or exchange, as proposed? Or should the determination of whether an issuer is unlisted be made at the time the holder buys the market-adjustable security, the time of the resale of any of the underlying equity securities, or some other time? Should the determination be made both at the time of the purchase of the market-adjustable security and at the time of the conversion or exchange, or some other combination of times?

3. Is the description of market-adjustable securities in proposed Rule 144(d)(3)(ii) sufficient to achieve the purpose of the proposal? If not, how should we modify the description?

4. Should we define the securities that would be subject to the proposed rules more narrowly or more broadly? If so, how? We do not intend for adjustments for recapitalizations, stock or cash dividends, or other anti-dilution adjustments that apply to issuer-initiated actions, to be considered the type of adjustments that would cause a security to be considered a market-adjustable security. However, are there specific additional factors or clarification that we should provide in the rule to indicate when a transaction may be considered a market-adjustable securities transaction?

5. As an alternative to the proposed amendment to Rule 144(d)(3)(ii), should we amend Rule 144(d)(1)(i) to increase from six months to one year (or some other period) the holding period that would apply to the market-adjustable securities that are issued by reporting, unlisted issuers? Should we amend Rule 144(d)(1)(i) to increase the holding period to one year (or some other period) for these market-adjustable

[28] Nothing in this proposed amendment is intended to impact the availability of the Securities Act Section 3(a)(9), 15 U.S.C. 77c(a)(9), exemption from registration for such conversions or exchanges as long as the requirements of Section 3(a)(9) are otherwise met.

[29] *See, e.g.,* Section 312.03(c) of the New York Stock Exchange LLC Listed Company Manual (requiring shareholder approval of any issuance of securities in any transaction or related transactions relating to 20 percent or more of a listed company's stock before the issuance) and Nasdaq Stock Market LLC Listing Rule 5635(d) (requiring shareholder approval prior to an issuance or potential issuance by a company of common stock (or securities convertible into or exercisable for common stock), which alone or together with sales by officers, directors, or certain other shareholders equals 20 percent or more of the common stock or 20 percent or more of the voting power outstanding before the issuance at a price that is less than the certain, minimum price).

[30] In addition to lacking the disclosure and liability protections that registration provides, market-adjustable securities may result in extreme dilution to holders of the underlying securities, especially when the conversions or exchanges occur in tranches at subsequently lower market prices.

[31] In addition to this amendment, due to current **Federal Register** formatting requirements we are also proposing a technical change to move the rest of Rule 144's Preliminary Note to a note that immediately follows the rule. Neither new Rule 144(b)(3) nor this technical change would alter the substance of the Preliminary Note.

securities in addition to amending Rule 144(d)(3)(ii) as proposed?

6. Are there alternative approaches that we should consider that would better mitigate the risk of unregistered distributions of securities acquired upon the conversion or exchange of market-adjustable securities?

7. Should market-adjustable securities of both listed and unlisted issuers be covered by the amendment to Rule 144(d)(3)(ii) rather than only those of unlisted issuers, as proposed? Do an exchange's listing criteria provide sufficient safeguards against the type of transaction that the proposal seeks to address? If not, are there alternatives that we should consider?

8. Should the proposed amendment to Rule 144(d)(3)(ii) only apply to issuers that do not have a class of *equity* security listed on an exchange, rather than to issuers that do not have any class of security listed on an exchange, as proposed?

9. Are there any additional amendments or changes to the proposed amendments that we should consider that would help achieve the purposes of the proposal?

C. Proposed Amendment to the Form 144 Filing Requirements

1. Background

Form 144 is a notice form that must be filed with the Commission by an affiliate of an issuer who intends to resell restricted or control securities [32] of that issuer in reliance upon Securities Act Rule 144.[33] Under Securities Act Rule 144(h), an affiliate who intends to resell securities of the issuer during any three-month period in a transaction that exceeds either 5,000 shares or has an aggregate sales price of more than $50,000 must file a Form 144 concurrently with either the placing of an order with a broker to execute the sale or the execution of a sale directly with a market maker.

Rule 101(b) of Regulation S–T permits Form 144 to be filed electronically or in paper if the issuer of the securities is subject to Exchange Act reporting requirements. If the issuer of the securities is not subject to Exchange Act reporting requirements, Rule 101(c)(6) of Regulation S–T requires Form 144 to be filed in paper.[34] During the 2019 calendar year, the Commission received over 31,000 Form 144 filings. Based on an analysis of these filings, Commission staff estimates that approximately 99 percent related to the resale of securities of issuers subject to Exchange Act reporting requirements. Although most of these Form 144 filings can be made electronically, during the 2019 calendar year, only 221 Form 144 filings were made electronically and the vast majority were filed in paper.[35]

2. Proposed Amendments

a. Mandatory Electronic Filing of Form 144

Since the Commission's implementation of the Electronic Data Gathering, Analysis, and Retrieval system (''EDGAR''), we have sought to make the system more comprehensive by subjecting more filings to our mandated electronic filing requirements. The mandated electronic submission of documents required to be filed with the Commission has enabled investors, market participants, and other EDGAR users to access more quickly the information contained in registration statements, periodic reports, and other filings made with the Commission. We are proposing rule amendments that would mandate the electronic filing of Form 144 and eliminate the paper filing option. Specifically, we propose to amend Rules 101(a) and 101(b) of Regulation S–T to mandate the electronic filing of all Form 144 filings for the sale of securities of Exchange Act reporting companies.

Mandating the electronic filing of Form 144 would facilitate more efficient storage and retrieval of the transaction information and facilitate analysis of this information. In addition, as described in more detail below, Form 144 filers would benefit from the planned EDGAR changes to make the form an online fillable document that would make electronic filing easier. Under the proposed amendments, affiliates of an issuer that is subject to Exchange Act reporting who resell or expect to resell securities in reliance upon Rule 144 in an amount exceeding the Form 144 filing thresholds would be required to file a Form 144 electronically on EDGAR.[36] Any Form 144 filer who has not previously made an electronic filing on EDGAR would need to apply for EDGAR access in accordance with the EDGAR Filer Manual in order to file documents on EDGAR. We are also proposing to provide a six-month transition period after the effective date of the amendments to Regulation S–T to give Form 144 paper filers who would be first-time electronic filers sufficient time to apply for codes to make filings on EDGAR.

In addition, we propose to amend Rule 144(h)(1) to delete the requirement that an affiliate send one copy of the Form 144 notice to the principal exchange, if any, on which the restricted securities are admitted to trading. This provision was designed for Form 144 filings made in paper and will no longer be needed if we mandate the electronic filing of Form 144.[37]

We are also proposing minor changes to Form 144 to update the form and eliminate certain personally identifiable information (''PII'') and immaterial information fields that are unnecessary. Specifically, we propose to delete the fields requiring the home address of the person for whose account the securities are to be sold and the IRS identification number of the issuer of the securities.[38]

[32] *See* Rule 144(h).

[33] *See* Rule 144(a)(1) (defining ''affiliate of the issuer as a person who directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the issuer).

[34] In April 2020, in recognition of several logistical difficulties related to the submission of Form 144 in paper pursuant to Rules 101(b)(4) or 101(c)(6) of Regulation S–T, as well as ongoing health and safety concerns related to COVID–19, the Division of Corporation Finance provided temporary no-action relief that specified that it would not recommend enforcement action to the Commission if Forms 144 for the period from and including April 10, 2020 to June 30, 2020 were submitted as a complete PDF attachment and emailed to the Commission in lieu of filing the form in paper. Subsequently, on June 25, 2020, the Division of Corporation Finance updated this no-action relief by indefinitely extending it from the period beginning on April 10, 2020. *See Division of Corporation Finance Statement Regarding Requirements for Form 144 Paper Filings in Light of COVID–19 Concerns,* U.S. Sec. & Exchange Comm'n (June 25, 2020), available at *https://www.sec.gov/corpfin/announcement/form-144-paper-filings-email-option-update.*

[35] The paper filings of Form 144 are retained in the Commission's public reference room for a period of 90 days. Investors or other interested parties wishing to access and review a Form 144 filed in paper must do so in person at our public reference room or subscribe to a third party information service that records and distributes the information electronically after a paper Form 144 is filed. Due to pandemic conditions, prospective data users cannot, at this time, access the Commission's public reference room. Therefore, access to paper filings is limited to those records which have been obtained and incorporated by vendor databases.

[36] An affiliate, however, would be able to file the form in paper pursuant to a temporary hardship exemption under 17 CFR 232.201 (Rule 201 of Regulation S–T) if the affiliate experiences unanticipated technical difficulties preventing the timely preparation and submission of the electronic filing.

[37] Many exchanges have rules or guidance that specify that it is not necessary for a company listed on the exchange to provide it with physical copies of any documents that the company has filed on EDGAR. *See, e.g., New York Stock Exchange Listed Company Regulation Guidance Memo,* N.Y. Stock Exch. (Feb. 20, 2018), available at *https://www.nyse.com/publicdocs/nyse/regulation/nyse/2018_Listed_Company_Regulation_Guidance_Memo.pdf.*

[38] For purposes of Form 144, we have determined that we can achieve our regulatory objectives without the PII. Furthermore, the IRS identification number of the issuer is redundant as this information is required to be disclosed on the cover

We intend to provide an online fillable document on EDGAR for entering information required by Form 144 and to streamline the electronic filing process for those filing both a Form 144 and a Form 4 to report the same sale of equity securities, as discussed in more detail below. In connection with these changes, we are also proposing to amend the Form 144 filing deadline to coincide with the Form 4 filing deadline.[39] Specifically, we propose to amend Securities Act Rule 144(h)(2) to revise the filing deadline to require that a Form 144 be filed before the end of the second business day following the day on which the sale of securities has been executed or the deemed date of execution[40] rather than have it due concurrently with either the placing of an order with a broker to execute the sale or the execution of a sale directly with a market maker, as currently required.

The proposed amendment to the Form 144 filing deadline would facilitate this new filing process. This filing deadline would apply to all Forms 144, regardless of whether a Form 4 also needs to be filed for the same transaction.[41] The proposal therefore would provide all Form 144 filers more time to file the form, yet would generally result in the Form 144 becoming publicly available earlier than under the existing filing deadline because the Form 144 would be filed electronically rather than mailed to the Commission in paper at the time the sale is executed. The proposed filing deadline, however, would not preclude filers from filing a Form 144 concurrently with either the placing of an order to execute a sale with a broker, or the execution of a sale directly with a market maker.

Finally, we observe that the Commission considered Rule 144 to be in the nature of an experiment at the time of its adoption in 1972.[42] The Commission has used Form 144 filings to monitor the operation of the rule and as an enforcement tool to assist in the detection of abuses.[43] Since the Commission initially adopted the Rule 144 requirements, the Commission has amended the rule to eliminate certain Form 144 filing requirements.[44] While, at this time, we are not proposing the elimination of the current Form 144 filing requirement for sales of securities by affiliates of issuers that are subject to Exchange Act reporting, we are soliciting comment on the continued utility of Form 144 filings.

Request for Comment

10. Do investors or other market participants have an interest in the information provided by Form 144? Does Form 144 provide important information that would not otherwise be publicly available? Do investors or other market participants obtain benefits from this information? If so, please describe the benefits.

11. How do market participants and the public currently access Form 144 information? Should we mandate the electronic filing of Form 144 for affiliates' sales of securities of issuers that are subject to Exchange Act reporting and that exceed the thresholds in Rule 144(h), as proposed? Would electronic filing of Form 144 make those forms more readily accessible to the public? Would electronic filing result in cost savings? Given that the majority of Form 144 filings are made in paper, has the inability to access the paper Forms 144 filed during the pandemic had any effect on the usefulness of this information to market participants and the public?

12. Should we, as proposed, amend Rule 144(h)(1) to eliminate the requirement that an affiliate send one copy of the Form 144 notice to the principal exchange, if any, on which the restricted securities are admitted to trading?

13. Should we amend Form 144 to update the form and eliminate certain information, as proposed? Is there any other information in Form 144 that we should remove because it is unnecessary to further the purposes of Rule 144? Is there any other information that should be included in the form?

14. Should we instead continue to permit a Form 144 filer to have the option of filing in paper or electronically?

15. In the alternative, should we eliminate the Form 144 filing requirement altogether?

16. Is the proposed six-month transition period appropriate? Would a shorter or longer transition period be more appropriate (*e.g.,* three months, nine months)?

17. Is it common for Form 144 filers to use a filing agent or a third party such as a broker to prepare and submit the Form 144 filing? If so, would the proposed amendments create any difficulties in the filing process or add costs to the process?

18. Should we amend the Form 144 filing deadline to coincide with the Form 4 filing deadline, as proposed? If not, should we change the deadline in some other way?

19. If we mandate the electronic filing of Form 144 without amending the filing due date, the Form 144 disclosures would be available to investors and other EDGAR users more quickly than if we amend the Form 144 filing deadline to coincide with the Form 4 filing deadline. Should we maintain the existing Form 144 filing deadline that requires the form to be transmitted for filing concurrently with either the placing with a broker of an order to execute a sale of securities in reliance on the rule or execution of the sale directly with a market maker? Is there a benefit to having the Form 144 filed at an earlier date than a Form 4 that reports the same sale? If so, how does that benefit compare to the efficiencies that a filer subject to both the Form 144 and Form 4 requirements could realize from being able to file both forms simultaneously?

b. Eliminating Form 144 Filing Requirement for Investors Selling Securities of Non-Reporting Issuers

As noted above, the Commission staff estimates that approximately one percent of the Form 144 filings made during the 2019 calendar year related to the resale of securities of issuers that are not subject to Exchange Act reporting.[45] The proposed amendments discussed above that would mandate the electronic filing of a Form 144 notice for the securities of an Exchange Act

page of registration statements and periodic reports and would be available through these forms.

[39] We are proposing to amend the filing deadline for Form 144 to facilitate the simultaneous filing of Form 144 and Form 4. *See infra* Section II.B.2.c.

[40] Consistent with the exception to the Form 4 two-business day filing deadline provided in Exchange Act Rule 16a–3(g)(2)(i) [17 CFR 240.16a–3(g)(2)(i)], the proposed amendments provide that if the transaction is pursuant to a contract, instruction or written plan that satisfies the affirmative defense conditions of Exchange Act Rule 10b5–1(c), and the affiliate does not select the date of execution, the date on which the executing broker, dealer notifies the security holder of the execution of the transaction is deemed the date of execution for a transaction.

[41] To better reflect the proposed change to the Form 144 filing deadline, we also propose to revise the title of Form 144 to read: ''Notice of sale or proposed sale of securities pursuant to Rule 144 under the Securities Act of 1933.'' We are also proposing a conforming amendment to Instruction 3(d) to Form 144 to clarify that the filer should provide the total sales proceeds for completed sales rather than the aggregate market value for sales that have not yet been completed.

[42] *See* 1972 Adopting Release, *supra* note 7, at 595.

[43] *See Resales of Securities,* Release No. 33–6252 (Oct. 24, 1980) [45 FR 72685 (Nov. 3, 1980)] at 72686.

[44] *See, e.g.,* 1981 Adopting Release, *supra* note 17, at 12197 (amending Rule 144 to relieve non-affiliates from the Form 144 filing requirement and explaining that the ''costs and burdens of the requirement outweigh its usefulness, at least in this area'').

[45] *See infra* Section I.C.1.

reporting issuer would reduce a large majority of the paper Form 144 filings that the Commission receives. Although one of the primary goals of EDGAR is to facilitate the dissemination of financial and business information contained in Commission filings,[46] given the limited number of paper Form 144 filings related to non-reporting issuers that we receive, we believe that the benefits of having this information filed electronically would not justify the burdens on filers. For this reason, we are proposing to amend Rule 144 and Rule 101(c)(6) of Regulation S–T to require affiliates relying on Rule 144 to file a notice of sale on Form 144 only when the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act.

Form 144 provides the Commission, among other things, with information concerning the issuer, the person on whose behalf the securities are to be sold, the broker who will execute the sale order, the securities to be sold, the approximate date of sale, and other securities of the same issuer sold during the past three months. The form, however, is not the sole source of information available to the Commission regarding resale transactions under the rule. For example, brokers are generally required to make and maintain records, for a period of time, of all purchases and sales of securities[47] and to furnish promptly legible, true, complete, and current copies of those records upon request by a representative of the Commission.[48] In addition, brokers that execute a sale under Rule 144 must conduct a reasonable inquiry to determine that the person for whose account the securities are sold is not an underwriter or that the transaction is not part of a distribution of securities of the issuer.[49]

Although the Form 144 filing requirement would be eliminated for resales of securities by affiliates of issuers that are not subject to Exchange Act reporting, the proposed amendments to eliminate the Form 144 filing requirement would not change any of the other conditions of the Rule 144 safe harbor.

Request for Comment

20. Should we eliminate the Form 144 filing requirement for affiliates' sales of securities of non-reporting companies, as proposed? Does Form 144 provide important information concerning the resale of securities of non-reporting issuers that would not otherwise be publicly available to investors or other users of this information? Do investors or market participants currently rely on Form 144 for this information or do they rely on other publicly available sources? If so, which other public sources are relied upon?

21. Do investors have an interest in the information provided by Form 144 regarding the resale of securities of non-reporting issuers? Do investors or market participants obtain benefits from this information? If so, please describe the benefits.

22. We have received comments indicating that the information contained in Form 144 could be used to satisfy some of the public information requirements in Rule 144(c)(2),[50] in particular the information specified in Rule 15c2–11(b)(5)(i)(N) and (b)(5)(i)(P).[51] For the purpose of Rule 144(c)(2), is the Rule 15c2–11 information specified in paragraphs (b)(5)(i)(N) and (b)(5)(i)(P) publicly available from other sources? If so, which sources?

23. Rule 15c2–11 does not require that the information specified in paragraphs (b)(5)(i)(N) and (b)(5)(i)(P) of Rule 15c2–11 be publicly available but requires, in certain circumstances, that a broker-dealer make it available upon request of a person expressing an interest in a proposed transaction in the issuer's security. Rule 144(c)(2) requires the information specified in these paragraphs to be publicly available. Should we amend Rule 144(c)(2) to require the information in these paragraphs to be available upon request in accordance with the provisions of Rule 15c2–11(b)(5)(ii) instead of publicly available?

24. How do the costs of electronically filing a Form 144 notice related to the resale of securities of a non-reporting issuer compare with the benefits of having the form available on EDGAR?

c. Filing Options for Form 4 and Form 144

Section 16 of the Exchange Act applies to every person who is the beneficial owner of more than 10 percent of any class of equity security registered under Section 12 of the Exchange Act[52] and each officer and director (collectively, ''reporting persons'' or ''insiders'') of the issuer of the security. Upon becoming a reporting person, or upon the Section 12 registration of that class of securities, Section 16(a) requires a reporting person to file an initial report with the Commission disclosing the amount of his or her beneficial ownership of all equity securities of the issuer. To keep this information current, Section 16(a) also requires insiders to report changes in such ownership. Under Rule 16a–3 of the Exchange Act,[53] insiders are required to report most changes in beneficial ownership, including purchases and sales of securities, on Form 4.

As discussed above, Rule 144 requires an affiliate of an issuer to file a Form 144 concurrently with either the placing with a broker of an order to execute a sale of securities in reliance upon Rule 144 or the execution directly with a market maker of such a sale. Some of the disclosures required by Form 144 duplicate the disclosure requirements of Form 4. For example, both Form 144 and Form 4 require disclosure concerning the title of the class of securities being sold, the number of shares subject to sale, the aggregate market value of those shares, and the date of sale.

Many affiliates of an issuer under Rule 144 are also insiders of that issuer under Section 16 of the Exchange Act. Affiliates selling securities under Rule 144 often are required to file a Form 4 within two business days after they file a Form 144 to report information regarding the same sale of securities.[54]

[46] *See Electronic Filing, Processing and Information Dissemination System,* Release No. 33–6519 (Mar. 22, 1984) [49 FR 12707 (Mar. 30, 1984)].

[47] *See* 17 CFR 240.17a-3 and 17 CFR 240.17a-4.

[48] *See* 17 CFR 240.17a-4(j).

[49] *See* 17 CFR 230.144(g)(4) (Rule 144(g)(4)).

[50] *See* letter from OTC Markets Group Inc. (dated Sept. 24, 2019), available at *https://www.sec.gov/comments/s7-08-19/s70819-6193364-192517.pdf,* which was submitted in response to the *Concept Release on Harmonization of Securities Offerings Exemptions,* Release No. 33–10649 (Jun. 18, 2019) [84 FR 30460 (Jun. 26, 2019)] (recommending ''pre-publication'' of Form 144 so that the information contained in it is publicly available for the purposes of rule 144(c)(2)). *See also* U.S. Sec. & Exch. Comm'n, Report on the 39th Annual Small Business Forum 31 (2020) (recommending ''pre-publication'' of Form 144), available at *https://www.sec.gov/files/2020-oasb-forum-report-final_0.pdf.*

[51] *See* 17 CFR 240.15c2–11. Rule 15c2–11(b)(5)(i)(N) requires information about whether the broker or dealer or any associated person of the broker or dealer is affiliated, directly or indirectly, with the issuer. Rule 15c2–11(b)(5)(i)(P) requires information about whether the quotation is being submitted or published, directly or indirectly, by or on behalf of the issuer or a company insider and, if so, the name of such person and the basis for any exemption under the Federal securities laws for any sales of such securities on behalf of such person. In the recently adopted amendments to Rule 15c2–11, the prior references to Rule 15c2–11(a)(5)(xiv) and (a)(5)(xvi) were changed to (b)(5)(i)(N) and (b)(5)(i)(P). *See Publication or Submission of Quotations Without Specified Information,* Release No. 33–10842 (Sept. 16, 2020) [85 FR 68124 (Oct. 27, 2020)].

[52] 15 U.S.C. 78*l.*

[53] 17 CFR 240.16a–3.

[54] The Sarbanes-Oxley Act of 2002 [Public Law 107–204, 116 Stat. 745] amended Section 16(a) to require insiders to file Form 4 before the end of the second business day following the day on which the subject transaction has been executed or at such other time as the Commission shall establish if the

In June 2007, the Commission issued a release proposing amendments to update Securities Act Rules 144 and 145.[55] In that release, the Commission discussed possible approaches to, and requested comment about, amending Form 144 and Form 4 in order to reduce duplicative requirements and coordinate the filing requirements of these two forms. The Commission ultimately did not adopt any amendments to the forms to reduce duplicative requirements.[56] The Commission also has received a rulemaking petition requesting that the Commission revise its rules and regulations so that Form 144 be combined into Form 4 for persons that need to file both forms.[57]

If we adopt the proposed amendments to Form 144 discussed above, we intend to modify EDGAR to provide filers with the option to file a Form 144 and a Form 4 through a single user interface. The system would use the information entered into the fields to create separate Form 4 and Form 144 filings. After the information is entered, a filer would have the opportunity to correct errors and verify the accuracy of the information before choosing to file one or both forms on EDGAR. Once the information is filed on EDGAR, the system would provide the filer with separate accession numbers for the Form 4 and Form 144 and also a return copy for both the Form 4 and Form 144 shortly after filing. We believe these changes would make the filing of these forms more efficient for filers subject to both reporting requirements. This filing option, however, would not be available for a Form 4 filing that is made on behalf of multiple insiders.[58]

In addition, we would make Form 144 available online as a fillable document that could be used by filers that do not have a corresponding Form 4 reporting obligation, as well as those who need to report the same sale on Form 4 and Form 144 but choose to enter the information separately for each form. An online fillable form would enable the convenient input of information, and support the electronic assembly of such information and transmission to EDGAR, without requiring a Form 144 filer to purchase or maintain additional software or technology. The fillable form would be similar to other fillable forms that are currently available to file Forms D,[59] 3, 4, and 5.

Request for Comment

25. If the Commission adopts the proposed rules, should we enable the filing of a Form 4 and Form 144 on EDGAR through a single user interface? Would this option make the filing of these documents more efficient for filers?

26. Are there alternative methods that we should consider that could reduce the duplicative requirements of Form 144 and Form 4?

d. Rule 10b5–1(c) Transaction Indication in Forms 4 and 5

Form 144 requires a selling security holder to represent, as of the date that the form is signed, that he or she does not know any material adverse information in regard to the current and prospective operations of the issuer of the securities to be sold which has not been publicly disclosed. In 2007, we amended Form 144 to allow filers who satisfy Rule 10b5–1(c) by adopting a written trading plan or providing trading instructions to make that representation as of the date they adopted the plan or gave instructions, rather than the date they signed the Form 144.[60]

Exchange Act Rule 16a–3(g) provides that a reporting person must report specified changes in beneficial ownership on Form 4 before the end of the second business day following the date of execution for the transaction. In addition, Rule 16a–3(f) provides that every person who at any time during an issuer's fiscal year was subject to Section 16 of the Exchange Act must file a Form 5 within 45 days after the issuer's fiscal year end to disclose certain beneficial ownership transactions and holdings not reported previously on Forms 3,[61] 4, or 5. For transactions executed pursuant to a contract, instruction, or written plan for the purchase or sale of equity securities that satisfies the affirmative defense conditions of Rule 10b5–1(c)[62] and for which the reporting person does not select the date of execution, the date on which the executing broker, dealer, or plan administrator notifies the reporting person of execution of the transaction is deemed the date of execution, so long as the notification date is not later than the third business day following the trade date.[63]

We propose to permit a Form 4 filer, at the filer's option, to indicate through a check box on the form that a sale or purchase reported on the form was made pursuant to Rule 10b5–1(c).We believe that the check box option would provide Form 4 filers with an efficient method to provide this disclosure. Consistent with current practice, filers could provide additional information, such as the date of a Rule 10b5–1 plan, in the ''Explanation of Responses'' portion of the form along with other relevant information about the transactions reported on the Form 4. We propose to add a similar checkbox to Form 5.[64]

2-day period is not feasible. On August 27, 2002, the Commission adopted rule and form amendments to implement this filing deadline. *See Ownership Reports and Trading by Officers, Directors and Principal Security Holders,* Release No. 34–46421 (Aug. 27, 2002) [67 FR 56462 (Sept. 3, 2002)].

[55] 17 CFR 230.145. *See Revisions to Rule 144 and Rule 145,* Release No. 33–8813 (June 22, 2007) [72 FR 36822 (July 5, 2007)].

[56] In the 2007 Adopting Release, the Commission stated that it expected to issue a separate release in the future to provide affiliates that are subject to both the Form 4 and Form 144 filing requirements with greater flexibility in satisfying their requirements. *See* 2007 Adopting Release, *supra* note 19, at 72 FR 71554 and 71555.

[57] *See Request for rulemaking to combine Form 144 into Form 4,* File No. 4–671 (Dec. 13, 2013) (requesting that the Commission amend its rules to combine Form 144 with Form 4), *https://www.sec.gov/rules/petitions/2013/petn4-671.pdf.* The proposal, if adopted, would achieve the objectives sought by the petitioner.

[58] Form 4 permits multiple insiders to file on a single form if they all have an interest in the transaction(s) being reported. Form 144, however, does not have a similar feature.

[59] 17 CFR 239.500.

[60] *See* 2007 Adopting Release, *supra* note 19. Exchange Act Rule 10b5–1 defines when a purchase or sale of a security constitutes trading ''on the basis of'' material nonpublic information in insider trading cases brought under Section 10(b) of the Exchange Act [15 U.S.C. 78j] and Rule 10b–5. Specifically, a purchase or sale of a security of an issuer is ''on the basis of'' material nonpublic information about that security or issuer if the person making the purchase or sale was aware of the material nonpublic information when the person made the purchase or sale. Rule 10b5–1(c) establishes affirmative defenses that permit a person to trade in circumstances where it is clear that the information was not a factor in the decision to trade.

[61] 17 CFR 249.103.

[62] Reporting persons sometimes provide additional disclosure in the ''Explanation of Responses'' portion of Form 4 indicating that a transaction satisfies the affirmative defenses conditions of Rule 10b5–1(c). For example, a reporting person may state that a transaction was made pursuant to a written trading plan and indicate the date the plan was adopted.

[63] *See* 17 CFR 240.16a–3(g)(2) (Exchange Act Rule 16a-3(g)(2)) and 17 CFR 240.16a–3(g)(4) (Exchange Act Rule 16a–3(g)(4)). If the notification date is later than the third business day following the trade date, the date of execution is deemed to be the third business day following the trade date.

[64] Under the proposal, the check boxes on Forms 4 and 5 would permit filers to indicate whether a transaction was made pursuant to a binding contract, instruction, or written trading plan for the purchase or sale of equity securities of the issuer that satisfies the conditions of Rule 10b5–1(c). This is broader than the representation on Form 144, which refers only to written trading plans and trading instructions, because the purpose of the proposed amendment is to simplify reporting for filers who provide Rule 10b5–1(c) transaction information in the ''Explanation of Responses'' portion of Forms 4 and 5, and some filers provide this information with respect to transactions made pursuant to binding contracts.

Request for Comment

27. Should we add a check box to Forms 4 and 5 to provide filers the option of disclosing that their sales or purchases were made pursuant to Rule 10b5–1(c)?

28. Should we instead require Form 4 and Form 5 to indicate via a check box whether any of their reported transactions were made pursuant to Rule 10b5–1(c) rather than provide it as an option for the filer?

29. Would a Rule 10b5–1(c) check box on Forms 4 and 5 provide useful information to investors and market participants?

II. Economic Analysis

A. Introduction

The Commission is proposing amendments to Rule 144, Form 144, Form 4, Form 5, and Regulation S–T. We are mindful of the costs imposed by and the benefits obtained from our rules and the proposed amendments.[65] The discussion below addresses the potential economic effects of the proposed amendments. These effects include the likely benefits and costs of the proposed amendments and reasonable alternatives thereto, as well as the potential effects on efficiency, competition, and capital formation. We attempt to quantify these economic effects whenever possible; however, due to data limitations, in many cases we are unable to do so. When we are unable to provide a quantitative assessment, we provide a qualitative discussion of the economic effects instead.

Due to the differing nature of the proposed amendments' baselines, affected parties, and anticipated economic effects, we provide separate analyses of the proposed changes. We first discuss the economic effects of the proposed amendments to the holding period for securities acquired upon conversion or exchange of certain market-adjustable securities issued by unlisted issuers, and then separately discuss the proposed amendments to Form 144, Form 4, Form 5, and Regulation S–T.

B. Proposed Amendments to Holding Period for Market-Adjustable Securities

1. Broad Economic Considerations

The size of the market for all U.S.-issued convertible securities has historically been slightly less than half the size of the seasoned equity market and just less than one-tenth the size of the regular bond market.[66] Despite this difference in size, it is generally understood that the market for convertible securities is an important and highly innovative market that can provide solutions to investment inefficiencies or barriers to capital formation that would otherwise occur if issuers were restricted to offerings of only non-hybrid securities.[67] Studies have suggested that because convertible securities can mitigate certain agency problems, forms of adverse selection, overinvestment, and misallocation of risk, they enable firms to make investments in business opportunities that would otherwise be infeasible for those firms.[68] Empirical evidence on the impact of these investments on longer-term firm value and shareholder wealth, however, is ambiguous on whether such investments represent efficient allocations of external financing.[69] Interpreting the value of convertible bond financing from market outcomes like short-term stock returns or long-term stock price performance is further complicated by the increase in arbitrage hedge fund activity and arbitrage-related short-selling.[70] Therefore, while there are a number of reasons why convertible securities can uniquely facilitate investments of economic value, it is difficult to generalize about their impact on shareholder wealth.

Market-adjustable securities[71] are an innovation in the market for convertible securities dating back to the 1990s.[72] By allowing the holder of the market-adjustable security to convert at discount to the market price (or a reference price based on recent market prices), the issuer can avoid the adverse selection problems it would face by offering equity or fixed-rate convertible securities instead. In practice, however, it does not appear that many issuers have taken advantage of this aspect of market-adjustable securities, and their use has been concentrated in the subpopulation of issuers who are unable to issue additional equity or fixed-rate convertibles, such as financially distressed firms, other low- or no-revenue firms, and those approaching bankruptcy.[73]

The main economic characteristic of market-adjustable securities is that they may provide protection to the holder against declines in market value from the time of purchase of the overlying security until the time of conversion or exchange.[74] Although the risk to investors from purchasing such a security is significantly lower than the risk associated with a convertible security with a fixed conversion rate, risks associated with the investment during the pre-conversion period still exist.[75]

We are proposing to amend Rule 144(d)(3)(ii) to provide that the holding period for certain securities acquired

[65] Section 2(b) of the Securities Act, 15 U.S.C. 77b(b), and Section 3(f) of the Exchange Act, 15 U.S.C. 78c(f), require us, when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation. In addition, Section 23(a)(2) of the Exchange Act, 15 U.S.C. 78w(a)(2), requires us to consider the effects on competition of any rules that the Commission adopts under the Exchange Act and prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

[66] Marie Dutordoir *et al., What We Do and Do Not Know About Convertible Bond Financing,* 24 J. CORP. FIN. 3 (2014) (''Dutordoir'').

[67] *Id.; see also* Craig Lewis and Patrick Verwijmeren, *Convertible Security Design and Contract Innovation,* 17 J. CORP. FIN. 809 (2011).

[68] *See* Dutordoir, *supra* note 66; *see also* Sudha Krishnaswami & Devrim Yaman, *The Role of Convertible Bonds in Alleviating Contracting Costs,* 78 Q. REV. ECON. FIN. 942 *(2008);* Craig Lewis *et al., Agency Problems, Information Asymmetries, and Convertible Debt Security Design,* J. FIN. INTERMEDIATION (1998).

[69] *See* Felix Ziedler *et al., Risk Dynamics Surrounding the Issuance of Convertible Bonds,* 18 J. CORP. FIN. 273 (2012); Dutordoir, *supra* note 66; Craig Lewis *et al., The Long-Run Performance of Firms that Issue Convertible Debt: An Empirical Analysis of Operating Characteristics and Analysts Forecasts,* 7 J. CORP. FIN. 447 (2001).

[70] *See* Eric Duca *et al., Why are Convertible Bond Announcements Associated with Increasingly Negative Issuer Stock Returns? An Arbitrage-Based Explanation,* 36 J. BANKING & FIN. 2884 (2012); *see also* Stephen Brown *et al., Convertibles and Hedge Funds as Distributors of Equity Exposure,* 25 REV. FIN. STUD. 3077 (2012), and Darwin Choi *et al., Convertible Bond Arbitrage, Liquidity Externalities, and Stock Prices,* 91 J. FIN. ECON. 227 (2009)

[71] In the empirical literature cited in the Economic Analysis section, the term ''floating priced convertibles'' is often used to denote the ''market-adjustable securities'' referred to in this release. Other terms, such as ''floating rate convertibles'' or ''future-priced convertibles,'' also may be used in the literature referring to the same securities.

[72] *See* Dutordoir, *supra* note 66.

[73] *See* Austin Dwyer *et al., An Investigation of Death Spiral Convertible Bonds,* (Tenn. State Univ., Working Paper, 2018) (''Dwyer *et al.*''); Zachary T. Knepper, *Future-Priced Convertible Securities and the Outlook for Death Spiral Securities-Fraud Litigation,* 26 WHITTIER L. REV. 359 (2004); Pierre Hillion & Theo Vermaelen, *Death Spiral Convertibles,* 71 J. Fin. Econ. 381 (2004) (''Hillion & Vermaelen'') (examining 467 floating-priced convertibles issued over the 1994–1998 period and finding, among other things, that such convertibles are issued by younger, smaller, riskier issuers, for which adverse selection problems are potentially large.)

[74] One common method that may provide such protection is the inclusion of a floating conversion rate. When the amount of securities to be received upon conversion of a convertible security is conditioned on the stock price performance of the issuer prior to conversion, the conversion ratio is known as a floating conversion rate.

[75] For example, investors are exposed to risk during the pre-conversion period if the company becomes bankrupt and its stock price declines to zero value.

upon conversion or exchange of market-adjustable securities issued by unlisted issuers would not begin until the conversion or exchange occurs. The proposed amendment would expose the holder of the market-adjustable security to the economic risk of the underlying securities during the proposed corresponding holding period following the conversion or exchange.

We expect that exposing these investments to risk during the post-conversion or post-exchange period would limit market-adjustable security holders' ability to immediately resell converted or exchanged market-adjustable securities, which might otherwise constitute a public distribution of securities without the investor protections afforded by registration. However, the proposed holding period would reduce the liquidity of these investments, and thus could prevent some unlisted issuers from obtaining financing or increasing the costs of doing so, particularly since market-adjustable securities may constitute a ''last resort'' form of financing for issuers.[76] To the extent that such firms have presented attractive arbitrage opportunities, it is foreseeable that demand-side investors would hold significant bargaining power in the design of the securities' specific terms and could require additional compensation for limitations imposed upon that power or on final contract terms in future exchanges.

Overall, we believe that the net impact of the proposed amendments may depend on the relative significance of these two competing consequences.

2. Economic Baseline

The economic baseline for the proposed amendment includes unlisted issuers that issue, or may seek to issue, market-adjustable securities.[77] We estimate that as of the end of 2019, there were approximately 2,760 unlisted reporting issuers.[78] We find that during 2019, 106 of these issuers submitted a combined 207 disclosures regarding convertible securities issued that included a floating conversion rate feature.[79] Of the identified floating conversion rate issues, roughly 80 percent involved convertible debt and 20 percent involved convertible preferred stock. Issuers of these securities are predominantly non-accelerated filers[80] and smaller reporting companies (''SRCs'')[81] concentrated in pharmaceutical, biotechnology, and business technology industries.[82] Approximately 25 percent of these convertible issuers had no revenue in their most recent fiscal year, but had average net income and market capitalization of approximately −$5.3 million and $18.8 million, respectively. For the remaining 75 percent of issuers, average revenue, net income, and market capitalization values were $7.2 million, −$12.0 million, and $12.3 million for the most recent fiscal year reported in 2019. We are unable to assess such characteristics for the population of unlisted, non-reporting issuers given current limitations to data availability.

Of Form 144 filings submitted in calendar year 2019, approximately two percent pertained to transactions in reporting, unlisted issuances and only one percent to intended sales of non-reporting, unlisted issuances.

3. Benefits and Costs to Proposed Amendment to Rule 144(d)(3)(ii)

As observed, use of the current tacking provisions essentially eliminates the holding period that would otherwise apply to the underlying securities after conversion or exchange, enabling holders of the overlying securities to convert and then immediately sell the underlying securities received upon conversion or exchange to the open market.[83] Investments in such securities carry little risk given the floating conversion rate and the ability of holders to sell the stock to the open market immediately upon conversion.

The proposed amendment to Rule 144(d)(3)(ii) would require the holding period of the underlying securities to begin upon conversion or exchange of the overlying securities by the holder. Upon conversion or exchange, the amount or value of the underlying securities received by the holder would have been determined. The proposed restriction from selling the underlying securities in the open market during the holding period would put the value of the underlying securities and the holder's investment at risk because, upon conversion or exchange, any subsequent decline in the stock price of the underlying securities during the holding period would result in a decrease in the value of the investment to the holder.

The proposed amendment to Rule 144(d)(3)(ii) would likely have a number of benefits. We believe this proposed amendment would curb the occurrence of situations where purchasers of such instruments have a view to an unregistered public distribution. Restricting the underlying securities from being sold to the broader market during the proposed holding period would introduce greater risk to the holder of the market-adjustable securities. During the holding period, any decline in the price of the underlying securities would decrease the value of the investment. We expect that this proposed amendment would discourage parties from engaging in such transactions because they would no longer be able to immediately distribute the underlying securities on an unregistered basis to capture the discount feature of these instruments. Instead, such parties would now be exposed to economic risk for the requisite holding period following

[76] *See* Ming Dong *et al., Why Do Firms Issue Convertible Bonds?* 7 CRITICAL FIN. REV. 111 (2018) (''Dong *et al.*''). *See also* Hillion & Vermaelen, *supra* note 73; Helgi Walker *et al., Aggressive SEC Enforcement Actions Could Limit Small Business Recovery Resources,* NATIONAL LAW JOURNAL (Aug. 20, 2020, 1:08 p.m.), available at *https://www.gibsondunn.com/wp-content/uploads/2020/08/Walker-Goldsmith-Seibald-Richman-Aggressive-SEC-Enforcement-Actions-Could-Limit-Small-Business-Recovery-Resources-NLJ-08-20-2020.pdf.*

[77] *See* Section I.B.2

[78] This estimate is based upon staff review of all filers who submitted a 10–K, 20–F, 40–F, or an amendment thereto within calendar year 2019. Unlisted reporting issuers are identified by unique CIKs as those without a class of securities registered pursuant to Section 12(b) of the Exchange Act. Because of limitations in available data, we were unable to construct a reliable estimate of the number of unlisted, non-reporting issuers who may also be affected by the proposed amendments. We request information on such issuers in the Request for Comment. *See infra* Section II.B.6.

[79] This number is based on a search of Forms 8–K (17 CFR 249.308) filed by unlisted issuers that indicate the issuance of a convertible security that appears to have a floating conversion rate. If there are other issued securities by unlisted issuers that meet the definition of a market-adjustable security, the number reported represents a lower bound of the prevalence of such securities in the market.

[80] Although Rule 12b–2 defines the terms ''accelerated filer'' and ''large accelerated filer,'' it does not define the term ''non-accelerated filer.'' If an issuer does not meet the definition of accelerated filer or large accelerated filer, it is considered a non-accelerated filer. *See Accelerated Filer and Large Accelerated Filer Definitions,* Release No. 34–88365 (Mar. 12, 2020) [85 FR 17178 (Mar. 26, 2020)] (Accelerated Filer Adopting Release), *https://www.sec.gov/rules/final/2020/34-88365.pdf*

[81] ''Smaller reporting company'' is defined in 17 CFR 229.10(f) as an issuer that is not an investment company, an asset-backed issuer (as defined in 17 CFR 229.1101), or a majority-owned subsidiary of a parent that is not a smaller reporting company and that: (i) Had a public float of less than $250 million; or (ii) had annual revenues of less than $100 million and either no public float, or a public float of less than $700 million.

[82] In calendar year 2019, all 106 identified unlisted reporting issuers of floating-rate convertibles self-identified as either a non-accelerated filer, a smaller reporting company, or both. Insofar as recently adopted amendments to the definitions of accelerated filer and smaller reporting company will effect cost savings for issuers newly eligible as non-accelerated filers or smaller reporting companies, the ability to reinvest such savings in business operations may to some degree offset the potential increased costs of financing to issuers affected by the proposed amendment to Rule 144(d)(1)(ii).

[83] *See supra* Section I.B.1.

conversion. To the extent that this would lead to fewer instances of significant, unregistered but public distributions of the underlying securities, it would enhance investor protection.

However, we anticipate that the proposed amendment to Rule 144(d)(3)(ii) may also impose costs on some market participants including, but not limited to, an increase in the cost of financing and a decrease in total access to financing for unlisted issuers. The proposed post-conversion holding period would reduce the liquidity of these investments. As a consequence, investors are likely to demand additional compensation for providing capital through market-adjustable securities to these issuers. Academic literature links the issuance of convertibles with a floating conversion rate, such as market-adjustable securities, to smaller, potentially higher growth issuers with elevated likelihoods of bankruptcy and less diversified sources of potential revenue that are in need of immediate financing.[84] The same literature also suggests that such issuers have limited options to raise capital due to their characteristics and issue market-adjustable securities, as a ''last resort'' form of financing. To the extent that these issuers have limited options to raise capital, the proposed amendment may also trigger changes to the design of these contracts in order to provide additional compensation to investors for the increase in risk. For example, investors may demand a steeper upfront discount when investing in these securities.

The net effect of the proposed amendment on the affected issuers' other existing shareholders is unclear.[85] The proposed amendment could affect existing shareholders of affected issuers if it changes the propensity of such issuers to issue unregistered market-adjustable securities or if it changes the terms of those securities. Conversion of these unregistered securities may dilute the holdings of existing shareholders, which may lead to a significant decline in the value of existing shareholders' holdings. If the proposed amendment changes the propensity of issuers to issue unregistered market-adjustable securities, it could also affect the likelihood of such effects on existing shareholders.

Similarly, if as a result of the proposed amendment, potential buyers of unregistered market-adjustable securities demand a higher conversion rate, the proposed amendment may increase the potential dilutive effects of conversion. If shareholders are unaware of the existence of these contracts and plan of distribution, such as for non-reporting issuers, or if shareholders are aware but not able to infer the consequences of these contracts, they may experience the negative effects of these unregistered distributions. Because of uncertainty surrounding how the proposed amendment would affect the issuance of unregistered market-adjustable securities across issuer types and the terms of such securities, the net effect of the proposed amendment on the affected issuers' other existing shareholders is unclear. Below we request comment on the effects of the proposal on non-converting, existing shareholders.

4. Effects on Efficiency, Competition, and Capital Formation

As discussed above, the proposed amendment is likely to have an effect on capital formation. To the extent that the sales of underlying securities into the broader market following a conversion of market-adjustable securities constitute a distribution of securities, the proposed amendment is likely to reduce the number of instances in which existing shareholders and new investors would not have the disclosure and liability protections that registration provides. In addition, investors in the underlying securities may be more willing to increase their investments in the issuer because they are less concerned about potential dilution of their holdings and therefore capital formation may be improved.[86] However, if the costs to the issuers of these market-adjustable securities increase, issuers continuing to sell such securities may raise less capital. Other issuers may be required to seek other options for raising capital.

Because total effects on efficiency and competition would aggregate across issuers, industries, and markets that the proposed changes may impact differentially, we anticipate that the unique impact of the amendment to the holding period requirements would not be readily observable or reliably quantified. We invite commenters to submit data or studies that would facilitate estimating such effects.

5. Reasonable Alternatives

We could propose to amend the holding period for only a subset of unlisted issuers, either reporting or non-reporting. Such an alternative would create an asymmetry within the subset of unlisted issuers with regard to the required holding period, and accordingly provide a disincentive for transactions in market-adjustable securities that in effect may result in an unregistered distribution of securities for only a subset of unlisted issuers. Under such alternative, it is possible that currently observed unregistered distributions would continue to take place in the subset of unlisted issuers that would not be affected by the proposed amendments.

We could, in addition to amending the start of the holding period, propose to increase the holding period for market-adjustable securities that are issued by reporting unlisted issuers from six months to one year to align with the holding period for such securities issued by non-reporting unlisted issuers. Such alternative would reduce the liquidity of these investments to the holder, and accordingly increase the issuers' financing costs. To the extent that market-adjustable securities are issued by reporting unlisted issuers to replicate the distribution of securities, it is possible that increasing the holding period could provide disincentives for potentially abusive practices.

6. Request for Comment

30. What are the economic effects of the proposed amendments to Rule 144(d)(3)(ii)? To the extent possible, please provide any data, studies, or other evidence that would allow us to quantify or better qualitatively assess the costs and benefits of the proposed amendments to affected parties. In particular, have we assessed all of the costs and benefits to market participants who would be affected by the change in tacking provisions?

31. We seek information on the prevalence of market-adjustable securities issued by non-reporting unlisted issuers. Please provide any data, studies, or other evidence that would allow us to quantify this component of the industry baseline.

32. What is the impact of the proposed rule on efficiency, competition, and capital formation?

C. Proposed Amendments to Form 144, Form 4, and Regulation S–T

1. Broad Economic Considerations

Existing Commission rules require the filing in paper of Form 144 for securities of issuers not subject to Exchange Act reporting requirements, and allow for either paper or electronic filing of Form 144 for securities of issuers subject to

[84] *See* Hillion & Vermaelen, *supra* note 73; Dwyer *et al., supra* note 73; Dong *et al., supra* note 76.

[85] *See supra* note 66 and accompanying text.

[86] *See supra* at note 30; *see also supra* Section II.B.3.

Exchange Act reporting requirements.[87] By requiring the electronic filing of all Forms 144, the proposed amendments seek to lower the cost of access to Form 144 information and to enable investors, market participants and other EDGAR users to access that information more quickly.[88] The proposed amendments are expected to enable those filers that currently are permitted to file Form 144 either in paper or electronically to benefit from the technology and efficiency associated with electronic filing, thereby potentially lowering the cost and burden of existing compliance requirements. As discussed in more detail below, while some filers may incur an initial cost to transition to electronic filing, we expect that the proposed amendments to file Form 144 electronically on EDGAR would result in cost savings on an ongoing basis and over the long term. Because we are additionally proposing a six-month transition period, filers for whom the initial costs of transition might otherwise be highest might reduce their transition costs by availing themselves of the additional time to adopt requisite technological changes to their submissions processes.

Additionally, the proposed amendments would eliminate the filing requirement for affiliates of issuers not subject to Exchange Act reporting requirements, thus eliminating certain compliance costs for those affiliates.

Finally, we are proposing to allow Form 4 and Form 5 filers, at their discretion, to include a check box to indicate that a sale or purchase of securities was made pursuant to Rule 10b5–1(c). Because this would be discretionary, we expect that filers will elect to do so when the anticipated benefits of doing so exceed the related costs and that this additional information may provide benefits to Form 144 data users.

The discussion below addresses the potential economic effects of the proposed amendments, including their likely costs and benefits as well as the likely effects of the proposed amendments on efficiency, competition, and capital formation, relative to the economic baseline, which comprises the filing practices in existence today.

2. Economic Baseline

Existing Commission rules permit Form 144 to be submitted either electronically via EDGAR or in paper form only for forms reporting proposed sales of reporting issuers. Regulation S–T does not provide for the electronic filing of Form 144 to report proposed sales of securities of issuers not subject to Exchange Act reporting requirements. Recently, in response to COVID–19 conditions, Commission staff announced a no-action position that temporarily affords Form 144 filers a third option to submit paper Form 144s via email.[89] In the period following this announcement, the Commission received approximately 13,400 Form 144 submissions: 52.9 percent in paper form, 46.5 percent electronically via email, and 0.6 percent electronically on EDGAR.[90] Thus, while when given the option, many paper filers have elected to submit their forms electronically via email, very few filers have opted to file Form 144 electronically on EDGAR.

Figures 1 and 2 provide examples to illustrate the lag time between when Form 144 is received by the Commission and when that information becomes available in a commercial database. As seen in Figure 1, in one commercial database, pre-COVID–19, most Form 144 filings became available in commercial databases six days after being received by the Commission. We further observe that in 2020, while the six-day lag time for availability of the majority of the filings remains true for the year on aggregate, after the additional ability to file via email was introduced, the majority of Form 144 filings have been processed and posted in that commercial database in fewer than five days (Figure 2). Overall, the number of records available via that commercial database is considerably lower in 2020 than in 2019, which may reflect increased difficulty and delays in integrating the paper form submissions into such databases under COVID–19 conditions. Thus, while access to data from paper submissions has been significantly reduced by the pandemic, we observe in Figure 2 that for transactions disclosed via a Form 144 submitted electronically via email or EDGAR, data vendors and those who access Form 144 filing data from such sources now appear to receive that information with a shorter delay.

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[87] *See supra* Section I.C.1.

[88] *See id.; see also* 1972 Adopting Release, *supra* note 7, at 595.

[89] *See supra* note 34.

[90] Staff analysis is based on all Form 144 filings received by the Commission between April 13 and August 31, 2020. The average number of filings received during this same window of time in the four preceding years was approximately 11,800 Form 144s.

Figure 1.[91]

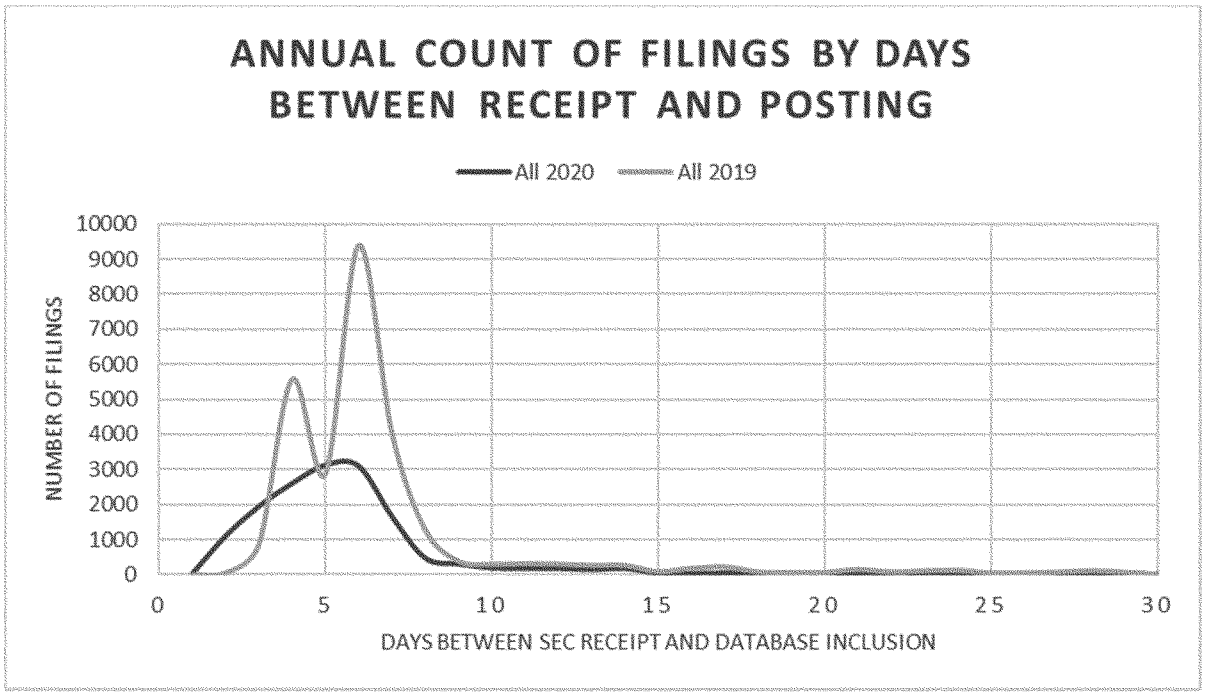
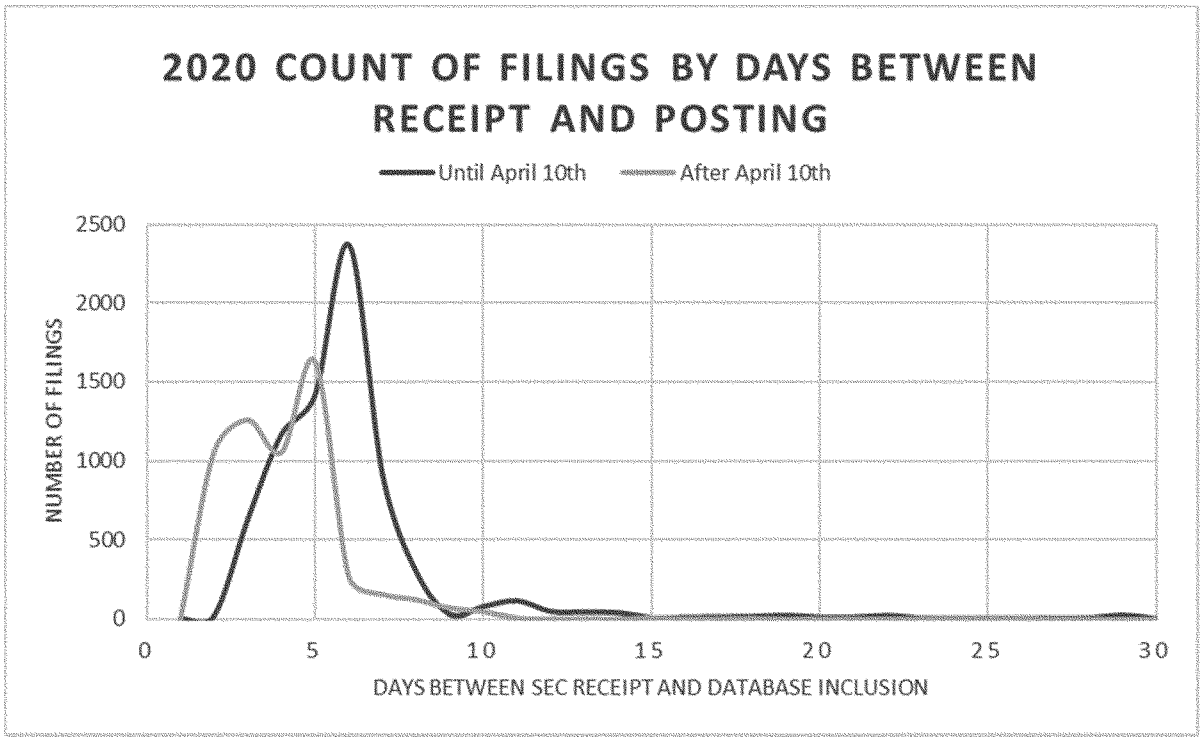


Figure 2.[92]



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a. Affected Parties [91] [92]

The main parties that would be affected by the proposed amendments are current and future filers of Form 144, specifically affiliates of an issuer subject to Exchange Act reporting requirements.[93] It is our understanding that the majority of affected filers currently prepare and file these forms individually or with the assistance of a broker or personal counsel.[94] Filings of Forms 144 from holders of securities of an issuer not subject to Exchange Act reporting requirements currently make up approximately one percent of all Form 144 filings.[95] As the majority of Form 144 filings are paper filings, most filers would have to modify their processes for submitting their Form 144 filings if the Commission adopts the proposed amendments. Based on past filings, we estimate that approximately 12,250 filers would be required to switch from paper filings to electronic filings and 313 filers would no longer be subject to filing Form 144.[96]

Additionally, the proposed change to electronic filing may affect the manner by which members of the public obtain these filings. Currently, the public can access these filings using EDGAR on the Commission's website or, for paper filings (under normal operating conditions), by visiting the Commission's public reference room in person, or, for either format, by subscribing to a third-party information vendor (such as private information aggregators that distribute the information obtained from EDGAR or the Commission's public reference room and records).[97] While the proposed amendments would not change the general public's ultimate access to the Form 144 information from affiliates selling securities of an issuer subject to Exchange Act reporting requirements, the public would no longer have access to similar information from the relatively small subpopulation of affiliates filing Form 144 to report sales (or potential sales) of securities of issuers not subject to Exchange Act reporting requirements.

b. EDGAR

From 2016 to 2019, an average of 30,000 Form 144 filings were made each year, of which an average of approximately 250 were submitted electronically via EDGAR. As EDGAR submissions thus constitute less than one percent of all Form 144 submissions per year, the proposed amendments could be anticipated to significantly increase the volume of Form 144 filings made electronically on EDGAR.[98]

3. Benefits and Costs of Proposed Amendments to Form 144, Form 4, and Regulation S–T

The proposed amendments would change some of the Commission's current practices related to making Form 144 information available to the public. First, holders of securities of an issuer subject to Exchange Act reporting requirements would be required to file Form 144 electronically. In contrast, holders of securities of an issuer not subject to Exchange Act reporting requirements would no longer be required to file Form 144. Second, the deadline for filing a Form 144 would be revised to coincide with the filing deadline of Form 4, which reports changes in beneficial ownership (purchases and sales of securities and derivatives and exercise of options) rather than have it due concurrently with either the placing of an order with a broker to execute the sale or the execution of a sale directly with a market maker, as currently required. As Form 4 is required to be submitted within two business days of a change in beneficial ownership, this could result in a delay of the reporting of an affiliate's sale of restricted or control securities on Form 144 by two business days.

This proposed change in the Form 144 filing deadline could result in the information on Form 144 sales being made available later than under the current rule. However, because currently most Form 144 filings are made in paper form and thus as a practical matter are generally accessible to most of the public only after a delay of a number of days (*e.g.,* after being uploaded into electronic databases for purchase as in Figure 1), it is likely that any delay due to changing the deadline of Form 144 to align with Form 4 submissions would be offset by the proposed change to require electronic filing. Under the proposal, the public would be able to access the filing electronically via EDGAR upon submission rather than needing to wait for electronic access via a commercial database.[99]

After initial transition costs, the proposed amendments are expected to benefit all Form 144 filers. Filers are expected to realize direct benefits in the form of reduced time required to file forms electronically, compared to a paper filing, and avoided copying and mailing expenses. Filers who make multiple submissions of Form 144 per year or longer submissions likely would benefit most. Electronic filing using EDGAR and the revised filing deadline are expected to make the filing process more efficient by making it easier and less costly for filers to assure timely receipt of the filing (*e.g.,* filers would have no reason to pay for premium services such as delivery confirmation).[100] We anticipate that the proposed amendments will also provide benefits to users of the Form 144 disclosures by significantly reducing both time and costs currently associated with obtaining the data contained in paper form submissions.[101]

The proposal would also modify the data format in which Form 144 would be electronically submitted. Form 144 would be available on EDGAR as a fillable document, similar to other fillable forms that filers can use such as Forms D, 3, 4, and 5.[102] An online fillable form would enable the convenient input of information and support the electronic assembly of such

[91] Based on Form 144 filings accessed via Thomson Reuters Insiders Data with the field ''SEC Receipt'' dated between January 1, 2019 and August 31, 2020.

[92] Based on Form 144 filings accessed via Thomson Reuters Insiders Data with the field ''SEC Receipt'' dated between January 1, 2020 and August 31, 2020.

[93] *See supra* Section I.C.1.

[94] *See* letter from Jesse Brill (dated Dec. 18, 2013), available at *https://www.sec.gov/rules/petitions/2013/petn4-671.pdf.*

[95] *See supra* Section I.C.2.b.

[96] These estimates assume that filers of Form 144 submissions in our data are not also affiliates of other issuers. Because we lack data on the holdings of filers in securities of issuers other than those disclosed in the Form 144, we are unable to identify any filers that are such affiliates.

[97] Paper filings submitted via email based on the staff's no-action position are available at *https://www.sec.gov/corpfin/form-144-email. See supra* note 34.

[98] A rate of change based on the current one percent EDGAR submission rate may slightly overestimate the changes in volume to the extent that the proposed removal of a filing requirement for securities not subject to Exchange Act reporting requirements may simultaneously decrease total submissions. Further, based on the observed EDGAR filing behavior of affiliates who use an issuer's existing access to EDGAR, the number of new Form IDs required to be processed could be reduced, but would not otherwise affect the increase in submission volume.

[99] Data users who continue to choose to access these filings via a commercial database rather than accessing EDGAR might also be able to access them more quickly than at present, depending on the interplay of the two-business-day-delay and the change from paper to electronic filing. We note that, as seen in Figure 2, electronic databases appear to incorporate email filings more quickly than paper submissions, which may indicate that electronic filings would also be processed more quickly.

[100] The proposed amendments also benefit filers by avoiding uncertainty about how to comply with paper filing obligations in events similar to the current COVID–19 pandemic.

[101] We estimate, for example, that annual subscription costs for access to Form 144 data from a third party vendor would approach $2,600 per person.

[102] *See supra* Section I.C.2.c.

information and transmission to EDGAR, without requiring a Form 144 filer to purchase or maintain additional software or technology, thus minimizing the compliance costs. This modification of the data format of Form 144 would also benefit data users by standardizing the inputted data into a structured, machine-readable custom XML format and thus making it easier to extract and process that data.

The fillable form would be similar to other fillable forms that are currently available to file Forms D, 3, 4, and 5.

We expect that filers who use EDGAR for purposes of complying with filing obligations under existing rules would not incur additional EDGAR access costs due to the proposed rules. If filers with EDGAR experience require time or specialized training to switch Form 144 from paper to EDGAR, then they may incur an additional initial transition cost. Given the experience of such filers with EDGAR filing, as well as the six-month transition period proposed, we expect such cost would be minimal.

The proposed amendments also would result in the direct costs of transitioning to filing electronically using EDGAR for the large subset of filers who do not currently file electronically on EDGAR. Currently, 52.9 percent of filers file paper forms and 46.5 percent file via email.[103] In particular, such filers would need to prepare a Form ID as required by Rule 10(b) of Regulation S–T and submit the Form ID following the processes detailed in Volume I of the EDGAR Filer Manual.[104] Once a Form ID has been successfully completed and processed, EDGAR establishes a Central Index Key (''CIK'') number, which permits each authorized user to create an EDGAR access code, enabling the filer to use EDGAR. We estimate that approximately 25 percent of Form 144 filers have already prepared a Form ID and obtained a CIK number through other EDGAR filing obligations.[105] Therefore, we estimate that at most 75 percent of Form 144 filers would need to file a Form ID as a result of the proposed amendments.[106] For purposes of the PRA, we estimate that respondents require 0.15 hours to complete the Form ID and that 100 percent of the burden of preparation for Form ID is carried by the respondent. For purposes of the Paperwork Reduction Act of 1995 (''PRA'')[107] discussed below, we estimate that the proposed amendments would result in an incremental increase of at 1,378 annual burden hours for Form ID.[108] We believe that such direct costs would be justified by the anticipated benefits from eliminating paper filing of Form 144.

The remaining costs of transitioning to EDGAR, which would apply to all Form 144 filers that do not currently file using EDGAR, would be mitigated by the ease of filing Form 144. The revised Form 144 would be an online fillable form with a similar user interface to Form 4, and for simultaneous filings of Forms 4 and 144, the same user interface could be used to file both forms.[109] Because current EDGAR filers represent such a small proportion of those who submit Form 144, our ability to generalize electronic filing behavior from this group to the full population of filers may be of limited reliability.[110] However to the extent that behavior may be similar, we estimate that up to one-third of affiliates submitting a Form 144 who do not currently access EDGAR may be able use an issuer's existing connection to EDGAR or rely upon other support by issuers in meeting their Form 144 electronic filing obligations. These filers likely will incur lower costs as a result of the proposed amendments than filers who cannot or will not use an issuer's existing connection to EDGAR. We lack the data to quantify the difference in costs.

In addition, we estimate that the proposed amendment to eliminate the requirement to file a Form 144 to report the resale of securities of issuers that are not subject to Exchange Act reporting requirements would result in a one percent reduction of current filings of Form 144.[111]

For Form 144 filers, we do not expect that the proposed custom XML format would impose any incremental costs, because filers would be able to enter their disclosures directly into the online fillable form. We expect that completing this XML-based fillable form would not require any more time than any other fillable form and would generally require the same time as completing the paper form. Some filers may choose to file directly in custom XML format (pursuant to the Commission's custom XML schema) integrated into their software because it enables greater automation of reporting. Other filers without XML experience or software could simply use the online fillable form and would not be required to license any XML-based filing preparation software or establish any XML-based filing processes.

The proposed amendments could reduce revenue for market information aggregators who currently aggregate the information from Form 144 fillings into databases and provide access to such databases to various users of this data for a fee.[112] The online filing of Form 144 may make it more cost-effective for some data users to extract the data themselves. The reduction in revenue could be mitigated by the lower cost of retrieving information from Form 144 filings that is filed in an electronic format. Data aggregators could sell fewer subscriptions to make the same profit or lower the fee that they charge which might make their services continue to be attractive even with the electronic availability of the filings.

We recognize that the potential costs and benefits of electronic filing are sensitive to various assumptions, including the number of affected filers; the effect of electronic filing using EDGAR on the time burden of filing Form 144; printing and mailing costs incurred today; and the type and cost of staff, if any, involved in the electronic filing of Form 144. The cost savings realized by individual filers may vary across all filers depending on variables such as filer size, number of filings submitted, existing filing practices (*e.g.,* current reliance on electronic document preparation; current experience with using EDGAR; use of in-house staff, brokers, or outside counsel for the filing of Form 144; number, types, and cost of in-house staff involved in the paper

[103] This estimate does not account for filers who previously filed via EDGAR but who currently submit via email pursuant to the staff no-action position, and may therefore include filers who would not incur new costs. Based on staff review of Form 144 submissions in 2020 by filers with filings both before and after April 10th, approximately 50 percent of filers who previously used EDGAR opted to submit their Form 144s via email after April 10, 2020.

[104] *See* 17 CFR 232.10(b); *see also supra* Section I.C.2.a.

[105] Specifically, we observe that approximately 23 percent of calendar year 2019 Form 144 filers also submitted Form 4 filings in EDGAR, while a remaining two percent without Form 4 filings in EDGAR submitted a miscellany of other forms related to beneficial ownership.

[106] This estimate represents an extreme upper bound because it assumes that each named individual who filed at least one Form 144 in calendar year 2019 who is not currently associated with a unique CIK would need to file a Form ID. To the extent that some Form 144 filers are affiliates of issuers who may use the issuer's CIK to file via EDGAR, the estimate likely overstates the required number of new Form IDs required and the burden hours associated with such applications.

[107] 44 U.S.C. 3501 *et seq.*

[108] *See infra* Section III.C.2.

[109] *See supra* Section I.C.2.c. Based on filings in calendar year 2019, we estimate that approximately 23 percent of Form 144 filers are also Form 4 filers.

[110] *See supra* Section II.B.2.

[111] This estimate is based upon the average number of Form 144s submitted pertaining to such securities as a proportion of total Form 144 submissions in each of the four prior calendar years (2016–2019).

[112] *See supra* Section II.C.2.a.

filing of Form 144; actual hours and printing and mailing costs required for paper filing today), and the amount of time required for filers to be trained in the use of EDGAR and any required related processes, and the amount of time to resolve any technical issues related to electronic filing on EDGAR.

4. Efficiency, Competition, and Capital Formation

The proposed amendments are expected to increase the efficiency and decrease the costs of filing Form 144 and retrieving information from Form 144 filings. Electronic filing and the revised filing deadline in the proposed amendments are expected to make the filing process more efficient by making it easier and less costly for filers to assure timely receipt of the filing. Likewise, for investors currently using information from paper filings, the costs of accessing these filings are expected to be significantly reduced. In addition, replacing paper filing with electronic filing is expected to result in filer savings of labor, printing, and mailing costs.

The proposed amendments should facilitate the efficient and rapid incorporation of price-relevant information in Form 144 filings into the market and enhance the sum of information available to investors. To the extent that there is value-relevant information in Form 144 filings, prices may become more efficient, which should help to facilitate capital formation (*e.g.,* by enhancing valuation quality).

However, the proposal may reduce some investors' or market information aggregators' competitive advantages. Particularly, market information aggregators whose present role includes converting paper filings of Form 144 to an electronic information source may find that this service is less attractive to data users due to those users' ability to access these filings directly due to the proposed rule changes. These information aggregators' loss of competitive advantage in converting paper filings of Form 144 to an electronic information source may reduce their revenue and thus may affect their ability to offer other ancillary services that are valuable to data users.

Aligning the reporting timeline of Form 144 with that of Form 4 could cause up to a two-day delay in reporting, and thereby potentially delay the incorporation of information into markets. However, at the same time, the proposed electronic filing mandate could accelerate the incorporation of that information into the markets compared with the current system. We do not have adequate data with which to estimate the net effect of these two proposed changes. Since data users currently observe this delay with respect to filings of Forms 144 and 4 that are both publicly available immediately upon submission, such as via EDGAR, we have limited data with which to form an expected value of having Form 144 information in advance of a Form 4 filing, and consequently what related costs might be incurred by synchronizing submissions. We are therefore requesting comments and the submission of data or other information that would inform our estimates.

We do not expect marked effects on either competition or capital formation as a result of allowing Forms 4 and 5 filers to check a box to indicate that a sale or purchase of securities was made pursuant to Rule 10b5–1(c). As discussed above, due to the discretionary nature of the checkbox inclusion, we expect filers to do so only when they perceive it will increase efficiency. As a result, there may be modest increases to efficiency for both such filers and data users who access their submissions.

5. Reasonable Alternatives

Eliminating the Form 144 Filing Requirement

One alternative that we could have proposed is the elimination of the current Form 144 filing requirement for sales of securities by affiliates of issuers that are subject to Exchange Act reporting. Such an alternative would eliminate compliance costs for such affiliates. However, such an alternative would also prevent investors and various other data users from obtaining any information on such sales of securities. We are soliciting comment on the continued utility of Form 144 filings.

Email Submissions

Given the significant number of submissions via email in response to the temporary staff no-action position, we could have proposed making this manner of filing a permanent option for Form 144 filers. Such an alternative would allow filers to avoid the direct costs of transitioning to filing electronically using EDGAR. Such an alternative, however, would result in issuers incurring expenses in scanning the forms and emailing them to the Commission. Additionally, issuers would forgo potential direct benefits in the form of reduced time required to file forms electronically. Such costs could be higher for filers who make multiple submissions of Form 144 per year and for Form 144 filings with multiple pages.

Data users might also incur higher costs under this alternative since the site used to access Form 144 email submissions is distinct from EDGAR.[113] Specifically, under this alternative, a data user interested in obtaining the information from all Form 144 filings pertaining to a given issuer would be required to search both EDGAR and the daily folders posted to the Form 144 website. Furthermore, Form 144 data submitted via email submissions is not structured, therefore analysis that would require aggregating data from multiple submissions would be more difficult or most costly to perform.

Format Requirements

While the proposed rule does not expressly prescribe a specific format for Form 144 that would be required for filing in EDGAR, Form 144 would be made available as an online fillable form, similar to other fillable forms such as Forms D, 3, 4, and 5.[114] As an alternative, we could require Form 144 to be filed in the Inline eXtensible Business Reporting Language (''Inline XBRL'') format, a derivation of XML that is designed for financial reporting and is both machine-readable and human-readable. Compared to the proposal, the Inline XBRL alternative for Form 144 would provide more sophisticated validation, presentation, and reference features for filers and data users. However, the Inline XBRL alternative would also impose initial implementation costs (*e.g.,* learning how to prepare filings in Inline XBRL, licensing Inline XBRL filing preparation software) upon filers that do not have prior experience structuring data in the Inline XBRL format. By contrast, because the proposal would allow filers to submit Form 144 using an online fillable Form, filers that lack experience structuring data in a custom XML format would not incur implementation costs.

D. Request for Comment

33. What are the economic effects of the proposed amendments to Form 144, Form 4, and Regulation S–T? To the extent possible, please provide any data, studies, or other evidence that would allow us to better quantify or otherwise qualitatively assess the costs and benefits of the proposed amendments to affected parties.

[113] *See supra* note 97.

[114] *See supra* Section I.B.2.c.

34. We expect that the proposed amendments may benefit Form 144 data users by facilitating easier access to Form 144 data, potentially reducing the incentive to purchase such data from third-party data providers. At the same time, the proposed changes may affect the timing of the availability of such information. What are the economic effects of the proposed timing and format changes to Form 144? To the extent possible, please provide any data, studies, or other evidence that would allow us to better quantify or otherwise qualitatively assess the impact of these proposed changes, including the benefits and costs.

35. We seek comment on the ways that Form 144 information is used by affected parties. In particular, what data uses of Form 144 data do not coincide with information available via Form 4? Are there currently any uses of Form 144 data in advance of Form 4 filings, and if so, would there be any costs incurred by losing such information in advance?

36. Are there other methods or databases by which Form 144 data users currently access such information? If so, please provide information about those methods, including how many Form 144 filings may be accessed via those methods and how soon they are made available after they are filed with the SEC. To what extent might the availability and use of these alternative databases affect our analysis of the anticipated benefits and costs to our proposed amendments? Please provide data, studies, or other evidence.

37. Should we adopt any of the alternative approaches outlined above instead of the proposed amendments, including requiring the use of XBRL for electronic submissions of Form 144? We considered requiring the use of XBRL as a possible alternative approach but have not proposed it for the reasons stated above. In addition or instead of XBRL, should the form provide for use of a format based on a new derivation of XML or another machine readable format that the Commission may determine is appropriate in the future? If so, what would be the attendant costs and benefits of such flexibility?

38. Are there any other potential alternative approaches we should consider and what are their economic effects?

39. Because we are proposing to allow Form 4 and Form 5 filers, at their discretion, to check a box to indicate that a sale or purchase of securities was made pursuant to Rule 10b5–1(c) we expect that filers will only elect to do so when their anticipated benefits of doing so exceed their related costs. Are there other anticipated benefits, costs, or economic effects related to this proposal that we should consider?

III. Paperwork Reduction Act

A. Summary of the Collections of Information

Certain provisions of our rules and forms that would be affected by the proposed amendments contain ''collection of information'' requirements within the meaning of the PRA.[115] We are submitting the proposal to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[116] An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid OMB control number. Compliance with the information collections is mandatory. Responses to the information collections are not kept confidential and there is no mandatory retention period for the information disclosed. The titles for the collections of information are:

- Form ID (OMB Control Number 3235–0328);
- Form 144 (OMB Control Number 3235–0101);
- Form 4 (OMB Control Number 3235–0287);
- Form 5 (OMB Control Number 3235–0362) [117]

Form ID is used by registrants, individuals, third party filers, or their agents to request access codes that permit the filing of documents on EDGAR. Form 144 is used by security holders to disclose the proposed sale of securities by the holder and to indicate that the holder is not to be engaged in the distribution of the securities and therefore not an underwriter. Form 4 is used by an issuer's insiders to report the insider's changes in beneficial ownership of the issuer's equity securities. A description of the proposed amendments, including the need for the information and its proposed use, as well as a description of the likely respondents, can be found in Section I above, and a discussion of the economic effects of the proposed amendments can be found in Section II above.

As described in more detail above,[118] we are proposing to amend Rule 144 to provide that the holding period for securities acquired upon the conversion or exchange of certain, specific securities that are market adjustable and issued by unlisted issuers would not begin until the time of conversion or exchange.[119] Also, as described above,[120] we are proposing to mandate electronic filing of Form 144 with respect to securities issued by companies subject to Exchange Act reporting requirements, eliminate the requirement to file a Form 144 for resales of securities of issuers that are not subject to Exchange Act reporting, amend the filing deadline for Form 144 to coincide with the filing deadline for Form 4,[121] and amend Form 4 to include a check box that would provide the filer with the option to indicate if securities were sold or purchased pursuant to a plan intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5–1(c).

B. Summary of the Proposed Amendments' Effects on the Collections of Information

We anticipate that the proposed amendment to mandate the electronic filing of Form 144 would result in a number of filers using EDGAR to file their Form 144 electronically who do not currently do so. Filers who have not previously made an electronic filing on EDGAR are required to file a Form ID to obtain access codes that will enable them to file a document on EDGAR. As discussed above, we estimate that approximately 12,250 filers would be required to switch from paper filings of their Form 144 to electronic filings of

[115] *See supra* note 107.

[116] *See* 44 U.S.C. 3507(d); *see also* 5 CFR 1320.11.

[117] We do not believe that the proposed amendments to permit Form 4 and Form 5 filers to indicate through a check box on the forms that a sale or purchase reported on the forms was made pursuant to Rule 10b5–1(c) would affect an issuer's burden hours or costs for PRA purposes. Filers must already determine whether their sale or purchase reported on the forms was made pursuant to Rule 10b5–1(c), so adding a check a box on the forms would not substantively modify existing collection of information requirements or otherwise affect the overall burden estimates associated with Forms 4 or 5. Therefore, we are not adjusting any burden or cost estimates in connection with the check box for the proposed amendments.

[118] *See supra* Section I.B.

[119] Although the proposed amendments to the holding period are expected to reduce the number of market-adjustable securities transactions, we do not anticipate that these proposed amendments would affect the burdens and costs associated with Form 144. The requirement to file Form 144 only applies to affiliates of the issuer. The investors in these securities generally do not meet the definition of affiliate in our regulations and therefore are not required to file Form 144.

[120] *See supra* Section I.C.

[121] We do not believe that the proposed amendment to change the filing deadline for Form 144 to coincide with the filing deadline for Form 4 would affect an issuer's burden hours or costs for PRA purposes. The information in the form that must be filed would not change as a result of this amendment, so changing the filing deadline would not substantively modify existing collection of information requirements or otherwise affect the overall burden estimates associated with Form 144. Therefore, we are not adjusting any burden or cost estimates in connection with the deadline change for the proposed amendments.

that form.[122] Of those 12,250 filers, however, we estimate that 25 percent have already filed a Form ID through other EDGAR filing obligations,[123] so only approximately 75 percent of Form 144 filers would need to file a Form ID.[124] As a result, we estimate that approximately 9,188 filers would be required to file a Form ID because of the proposed amendment to mandate the electronic filing of Form 144.[125] We estimate that respondents require 0.15 hours to complete the Form ID and, for purposes of the PRA, that 100 percent of the burden of preparation for Form ID is carried by the respondent internally. Therefore, we estimate that this proposed amendment would result in an incremental increase of 1,378 annual burden hours for Form ID.[126]

We expect that the proposed amendment to eliminate the requirement to file a Form 144 to report the resale of securities of issuers that are not subject to the reporting requirements of Sections 13 or 15(d) of the Exchange Act would reduce the number of filings of the form. As discussed above, we estimate that 313 filers would no longer be subject to filing Form 144.[127] We estimate that each notice on Form 144 imposes a burden for PRA purposes of one hour and, for purposes of the PRA, that 100 percent of the burden of preparation for Form 144 is carried by the respondent internally. Therefore, we estimate that this proposed amendment would result in an incremental decrease of 313 annual burden hours for Form 144.

PRA Table 1 summarizes the estimated effects of the amendments on the paperwork burdens associated with the affected collections of information listed in Section III.A.

PRA TABLE 1—ESTIMATED PAPERWORK BURDEN EFFECTS OF THE AMENDMENTS

Proposed amendments and effects	Proposed affected collections of information	Estimated net effect
Form ID:		
• Amend Rules 101(a) and 101(b) of Regulation S–T to mandate the electronic filing of all Form 144 filings for the sale of securities of Exchange Act reporting companies.	• Form ID	• Increase of 0.15 hour compliance burden per response to the new collection of information.
Form 144:		
• Eliminate the requirement to file a Form 144 for resales of securities of issuers that are not subject to Exchange Act reporting.	• Form 144	• Decrease of 1.0 hour compliance burden per response to the new collection of information.

C. Incremental and Aggregate Burden and Cost Estimates

Below we estimate the incremental and aggregate changes in paperwork burden as a result of the amendments. These estimates represent the average burden for all issuers, both large and small. In deriving our estimates, we recognize that the burdens will likely vary among individual issuers based on a number of factors, including the nature of their business. We believe that the amendments will change the frequency of responses to the existing collections of information and the burden per response.

PRA Table 2 below illustrates the incremental change to the total annual compliance burden of affected forms, in hours and in costs, as a result of the amendments' estimated effect on the paperwork burden per response. The number of estimated affected responses shown in PRA Table 2 is based on the number of responses in the Commission's current OMB PRA filing inventory adjusted to reflect the change in the number of responses we estimate as a result of the proposed amendments.[128]

PRA TABLE 2—CALCULATION OF THE INCREMENTAL CHANGE IN BURDEN ESTIMATES OF CURRENT RESPONSES RESULTING FROM THE AMENDMENTS

	Current burden			Proposed burden change					
	Current annual responses (A)	Current burden hours (B)	Current cost burden (C)	Proposed change in annual responses (D)	Proposed change in burden hours (E)	Proposed change in professional costs (F)	Proposed annual affected responses (G) = (A) + (D)	Proposed Burden Hours for Affected Responses (H) = (B) + (E)	Proposed Cost Burden for Affected Responses (I) = (C) + (F)
Form ID	46,842	7,026	$0	9,188	1,378	$0	56,030	8,404	$0
Form 144	33,725	33,725	0	(313)	(313)	0	33,412	33,412	0

D. Request for Comment

We request comments in order to evaluate: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information; (3) whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques

[122] *See supra* note 96.

[123] *See supra* note 105.

[124] *See supra* note 106.

[125] 22,250 × 0.75 = 9,187.5.

[126] 9,188 × 0.15 = 1,378.2, which is rounded to 1,378.

[127] *See supra* note 96.

[128] The OMB PRA filing inventory represents a three-year average.

or other forms of information technology.[129]

Any member of the public may direct to us any comments concerning the accuracy of these burden estimates and any suggestions for reducing the burdens. Persons who desire to submit comments on the collection of information requirements should direct their comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and send a copy of the comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549, with reference to File No. S7–24–20. Requests for materials submitted to the OMB by us with regard to these collections of information should be in writing, refer to File No. S7–24–20 and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington DC 20549. Because the OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication, a comment to the OMB is best assured of having its full effect if the OMB receives it within 30 days of publication.

IV. Initial Regulatory Flexibility Act Analysis

This Initial Regulatory Flexibility Analysis (''IRFA'') has been prepared in accordance with the Regulatory Flexibility Act (''RFA'').[130] It relates to proposed amendments that would: (1) Amend Rule 144(d)(3)(ii) to provide that the holding period for securities acquired upon the conversion or exchange of certain, specific securities that are market adjustable and issued by unlisted issuers would not begin until the time of conversion or exchange; (2) mandate electronic filing of Form 144 with respect to securities issued by companies subject to Exchange Act reporting requirements; (3) eliminate the requirement to file a Form 144 for resales of securities of issuers that are not subject to Exchange Act reporting; (4) amend the filing deadline for Form 144 to coincide with the filing deadline for Form 4; and (5) amend Forms 4 and 5 to include a check box that would provide the filer with the option to indicate if a transaction intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5–1(c). In addition, if we adopt the proposed amendments, we plan to simplify and streamline the electronic filing of Form 144 and Form 4.

A. Reasons for, and Objectives of, the Proposed Action

One purpose of the proposed amendments is to mitigate the risk of unregistered distributions in connection with sales of market-adjustable securities. The proposed amendments are also intended to facilitate more efficient transmission, dissemination, and analysis, of certain forms, and to reduce the costs of storing and retrieving documents that are currently filed in paper.

B. Legal Basis

We are proposing the amendments under the authority set forth in Sections 4, 6, 7, 8, 10, 19(a) and 28 of the Securities Act, and Sections 3, 16, and 23(a) of the Exchange Act.

C. Small Entities Subject to the Proposed Rules

The proposed amendments would affect small entities that issue securities as well as those that hold securities. The RFA defines ''small entity'' to mean ''small business,'' ''small organization,'' or ''small governmental jurisdiction.''[131] For purposes of the RFA, under our rules, a registrant, other than an investment company, is a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its most recent fiscal year and is engaged or proposing to engage in an offering of securities that does not exceed $5 million.[132] An investment company, including a business development company,[133] is considered to be a ''small business'' if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[134] We estimate that there are 1,056 issuers that file with the Commission, other than investment companies, which may be considered small entities and are potentially subject to the final amendments.[135] In addition, we estimate that there are 37 investment companies that would be subject to the proposed amendments that may be considered small entities.[136]

D. Proposed Reporting, Recordkeeping, and Other Compliance Requirements

As noted above, the proposed amendment to Rule 144(d)(3)(ii) would provide that the holding period for securities acquired upon the conversion or exchange of certain, specific securities that are market adjustable and issued by unlisted issuers would not begin until the time of conversion or exchange. We expect the proposed amendment to reduce the number of market-adjustable securities transactions. As noted in Section III, we do not anticipate that the proposed amendments would affect the reporting or compliance burdens associated with Form 144, including those for small entities, because the requirement to file the form only applies to affiliates of the issuer and the investors in these securities generally do not meet the definition of affiliate in our regulations. Affected parties may decide to adjust their recordkeeping methods if needed to account for the change in the start date for the holding period.

Additionally, the proposed amendments would mandate electronic filing of Form 144 with respect to securities issued by companies subject to Exchange Act reporting requirements. We anticipate that this proposed amendment would cause a number of filers, including small entities, using EDGAR to file their Form 144 electronically who do not currently do so, thereby modestly increasing their compliance obligations.

Further, the proposed amendments would eliminate the requirement to file a Form 144 to report the resale of securities of issuers that are not subject to the reporting requirements of Sections 13 or 15(d) of the Exchange Act. As a result, some filers, including small entities would no longer be required to file Form 144, which would reduce their compliance obligations.

The proposed amendments to revise the filing deadline for Form 144 and to include an optional check box in Forms 4 and 5 would not change the reporting, recordkeeping, or compliance requirements or otherwise affect the overall compliance burden for small entities.

Compliance with the proposed amendments may require the use of

[129] We request comment pursuant to 44 U.S.C. 3506(c)(2)(B).

[130] 5 U.S.C. 601 *et seq.*

[131] 5 U.S.C. 601(6).

[132] *See* 17 CFR 240.0–10(a).

[133] Business development companies are a category of closed-end investment company that are not registered under the Investment Company Act [15 U.S.C. 80a–2(a)(48) and 80a–53—64].

[134] 17 CFR 270.0–10(a).

[135] This estimate is based on staff analysis of issuers, excluding co-registrants, with EDGAR filings of Form 10–K, 20–F and 40–F, or amendments filed during the calendar year of January 1, 2019 to December 31, 2019. This analysis is based on data from XBRL filings, Compustat, and Ives Group Audit Analytics.

[136] This estimate is based on staff review of Forms N–CEN filed with the Commission as of November 5, 2020 and is based on the definition of small entity under Investment Company Act Rule 0–10. *See* 17 CFR 240.0–10.

professional skills, including legal skills.

Section I discusses the proposed amendments in detail. Sections II and III discuss the economic impact, including the estimated costs and benefits, of the proposed amendments to all affected entities.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The proposed amendments would not duplicate, overlap, or conflict with other Federal rules.

F. Significant Alternatives

The RFA directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. In connection with the proposed amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements or timetables that take into account the resources available to small entities;
- Clarifying, consolidating or simplifying compliance and reporting requirements under the rules for small entities;
- Using performance rather than design standards; and
- Exempting small entities from all or part of the requirements.

We are proposing to amend Rule 144(d)(3)(ii) to provide that the holding period for the securities acquired upon conversion or exchange of certain market-adjustable securities issued by unlisted issuers would not begin until conversion or exchange. We recognize that the proposal could disproportionately affect small issuers because it is those entities that typically issue market-adjustable securities [137] but we believe this proposal would benefit issuers and investors by mitigating the risk of unregistered distributions in connection with sales of market-adjustable securities. The features of certain market-adjustable securities, combined with the tacking provisions of Rule 144, can undermine one of the key premises of Rule 144, which is that holding securities at risk for an appropriate period of time prior to resale can demonstrate that the seller did not purchase the securities with a view to distribution and, therefore, is not an underwriter. We could propose to exempt the securities of small entities from the proposed amendment or establish a different holding period for their securities, but doing so would not address the risk that holders may participate in unregistered distributions of the market-adjustable securities of these issuers.

The proposed amendments to mandate the electronic filing of Form 144 clarify and streamline the filing requirements for the form and should benefit all filers, as well as benefit users of the information in Form 144 by facilitating easier access to, and faster retrieval of such information. We do not believe that it is necessary to partially or completely exempt small entities from the proposed amendments to require the electronic filing of Form 144 because the amendments are expected to result in cost benefits on an ongoing basis compared to paper filing, and increased efficiencies for all filers who would be required to file Form 144, including small entities that are filers. We preliminarily believe that it is not necessary to establish different compliance timetables for small entities or to further clarify, consolidate, or simplify the proposed amendments' requirements. But we are proposing a six-month transition period after the effective date of the amendments to Regulation S–T to give Form 144 paper filers who would be first-time electronic filers, including any small entities, sufficient time to apply for codes to make filings on EDGAR. In addition, we solicit comment on whether we should provide a different timetable for paper Form 144 filers to transition to electronic filing.

We have used design rather than performance standards in connection with the proposed filing revisions to Form 144 in order to promote uniform filing requirements and also to facilitate a simpler and less costly filing method for Form 144 filers.

G. Request for Comment

We encourage the submission of comments with respect to any aspect of this Initial Regulatory Flexibility Analysis. In particular, we request comments regarding:

- The number of small entity issuers that may be affected by the proposed amendments;
- The existence or nature of the potential impact of the proposed amendments on small entity issuers discussed in the analysis;
- How the proposed amendments could further lower the burden on small entities; and
- How to quantify the impact of the proposed amendments.

Please describe the nature of any impact and provide empirical data supporting the extent of the impact. Such comments will be considered in the preparation of the Final Regulatory Flexibility Analysis, if the proposed amendments are adopted, and will be placed in the same public file as comments on the proposed amendments themselves.

V. Small Business Regulatory Enforcement Fairness Act

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''),[138] the Commission must advise OMB as to whether the proposed amendments constitute a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results, or is likely to result, in:

- An annual effect on the economy of $100 million or more (either in the form of an increase or a decrease);
- A major increase in costs or prices for consumers or individual industries; or
- Significant adverse effects on competition, investment or innovation.

We request comment on whether the proposed amendments would be a ''major rule'' for purposes of SBREFA. We solicit comment and empirical data on: (a) The potential effect on the U.S. economy on an annual basis; (b) any potential increase in costs or prices for consumers or individual industries; and (c) any potential effect on competition, investment or innovation. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

VI. Statutory Authority

The amendments contained in this release are being proposed under the authority set forth in Sections 4, 6, 7, 8, 10, 19(a), and 28 of the Securities Act, and Sections 3, 16, and 23(a) of the Exchange Act.

List of Subjects in 17 CFR Parts 230, 232, 239, and 249

Reporting and recordkeeping requirements, Securities.

Text of the Proposed Amendments

For the reasons set out in the preamble, the Commission is proposing to amend Title 17, chapter II of the Code of Federal Regulations as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L.

[137] *See supra* note 73 and accompanying text.

[138] Public Law 104–121, Title II, 110 Stat. 857 (1996).

112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

■ 2. Amend § 230.144 by:
■ a. Removing the Preliminary Note;
■ b. Adding introductory text and paragraph (b)(3);
■ c. Revising paragraphs (d)(3)(ii) and (h); and
■ d. Adding Notes 1 through 5 to § 230.144.

The additions and revisions to read as follows:

§ 230.144 Persons deemed not to be engaged in a distribution and therefore not underwriters.

A Notes section appears at the end of this rule to assist in understanding its provisions.

* * * * *

(b) * * *

(3) *Not part of a scheme to evade:* Section 230.144 (Rule 144) is not available to any person with respect to any transaction or series of transactions that, although in technical compliance with this § 230.144, is part of a plan or scheme to evade the registration requirements of the Act.

* * * * *

(d) * * *

(3) * * *

(ii) *Conversions and exchanges.* If the securities sold were acquired from the issuer solely in exchange for other securities of the same issuer, the newly acquired securities shall be deemed to have been acquired at the same time as the securities surrendered for conversion or exchange, even if the securities surrendered were not convertible or exchangeable by their terms, unless:

(A) The newly acquired securities were acquired from an issuer that, at the time of conversion or exchange, does not have a class of securities listed, or approved for listing, on a national securities exchange registered pursuant to Section 6 of the Exchange Act (15 U.S.C. 78f); and

(B) The convertible or exchangeable security contains terms, such as conversion rate or price adjustments, that offset, in whole or in part, declines in the market value of the underlying securities occurring prior to conversion or exchange, other than terms that adjust for stock splits, dividends or other issuer-initiated changes in its capitalization.

Note 1 to paragraph (d)(3)(ii). If the surrendered securities originally did not provide for cashless conversion or exchange by their terms and the holder provided consideration, other than solely securities of the same issuer, in connection with the amendment of the surrendered securities to permit cashless conversion or exchange, then the newly acquired securities shall be deemed to have been acquired at the same time as such amendment to the surrendered securities, so long as, in the conversion or exchange, the securities sold were acquired from the issuer solely in exchange for other securities of the same issuer.3

* * * * *

(h) *Notice of sale or proposed sale.* (1) If the issuer is, and has been for a period of at least 90 days immediately before the sale, subject to the reporting requirements of section 13 or 15(d) of the Exchange Act and the amount of securities to be sold in reliance upon this rule during any period of three months exceeds 5,000 shares or other units or has an aggregate sale price in excess of $50,000, a notice on Form 144 (§ 239.144 of this chapter) shall be filed electronically with the Commission.

(2) The Form 144 shall be signed by the security holder and shall be filed before the end of the second business day following the day on which the subject transaction has been executed. Provided however, if the transaction satisfies the affirmative defense conditions of § 240.10b5–1(c) of this chapter, and the security holder does not select the date of execution, the date on which the executing broker, dealer or plan administrator notifies the security holder of the execution of the transaction is deemed the date of execution for a transaction. Neither the filing of such notice nor the failure of the Commission to comment on such notice shall be deemed to preclude the Commission from taking any action that it deems necessary or appropriate with respect to the sale of the securities referred to in such notice. The security holder filing the notice required by this paragraph shall have sold or have a bona fide intention to sell the securities referred to in the notice within a reasonable time after the filing of such notice.

Note 1 to § 230.144. Certain basic principles are essential to an understanding of the registration requirements in the Securities Act of 1933 (the Act or the Securities Act) and the purposes underlying Rule 144. If any person sells a non-exempt security to any other person, the sale must be registered unless an exemption can be found for the transaction. Section 4(a)(1) of the Securities Act provides one such exemption for a transaction ''by a person other than an issuer, underwriter, or dealer.'' Therefore, an understanding of the term ''underwriter'' is important in determining whether or not the Section 4(a)(1) exemption from registration is available for the sale of the securities.

Note 2 to § 230.144. Section 2(a)(11) of the Securities Act defines the term ''underwriter'' broadly to mean any person who has purchased from an issuer with a view to, or offers or sells for an issuer in connection with, the distribution of any security, or participates, or has a direct or indirect participation in any such undertaking, or participates or has a participation in the direct or indirect underwriting of any such undertaking. The interpretation of this definition traditionally has focused on the words ''with a view to'' in the phrase ''purchased from an issuer with a view to . . . distribution.'' An investment banking firm which arranges with an issuer for the public sale of its securities is clearly an ''underwriter'' under that section. However, individual investors who are not professionals in the securities business also may be ''underwriters'' if they act as links in a chain of transactions through which securities move from an issuer to the public.

Note 3 to § 230.144. Since it is difficult to ascertain the mental state of the purchaser at the time of an acquisition of securities, prior to and since the adoption of Rule 144, subsequent acts and circumstances have been considered to determine whether the purchaser took the securities ''with a view to distribution'' at the time of the acquisition. Emphasis has been placed on factors such as the length of time the person held the securities and whether there has been an unforeseeable change in circumstances of the holder. Experience has shown, however, that reliance upon such factors alone has led to uncertainty in the application of the registration provisions of the Act.

Note 4 to § 230.144. The Commission adopted Rule 144 to establish specific criteria for determining whether a person is not engaged in a distribution. Rule 144 creates a safe harbor from the Section 2(a)(11) definition of ''underwriter.'' A person satisfying the applicable conditions of the Rule 144 safe harbor is deemed not to be engaged in a distribution of the securities and therefore not an underwriter of the securities for purposes of Section 2(a)(11). Therefore, such a person is deemed not to be an underwriter when determining whether a sale is eligible for the Section 4(a)(1) exemption for ''transactions by any person other than an issuer, underwriter, or dealer.'' If a sale of securities complies with all of the applicable conditions of Rule 144: Any affiliate or other person who sells

restricted securities will be deemed not to be engaged in a distribution and therefore not an underwriter for that transaction; any person who sells restricted or other securities on behalf of an affiliate of the issuer will be deemed not to be engaged in a distribution and therefore not an underwriter for that transaction; and the purchaser in such transaction will receive securities that are not restricted securities.

Note 5 to § 230.144. Rule 144 is not an exclusive safe harbor. A person who does not meet all of the applicable conditions of Rule 144 still may claim any other available exemption under the Act for the sale of the securities.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 3. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

■ 4. Amend § 232.101 by adding paragraph (a)(1)(xxii), and removing and reserving paragraphs (b)(4) and (c)(6), to read as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *

(1) * * *

(xxii) Form 144 (§ 239.144 of this chapter), where the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act (15 U.S.C. 78m or 78o(d), respectively).

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 5. The general authority citation for part 239 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78ll, 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37; and sec. 107, Pub. L. 112–106, 126 Stat. 312, unless otherwise noted.

■ 6. Amend § 239.144 by revising paragraphs (a) and (b) to read as follows:

(a) Except as indicated in paragraph (b) of this section, each person who intends to sell securities in reliance upon § 230.144 of this chapter shall file this form in electronic format by means of the Commission's Electronic Data, Gathering, Analysis, and Retrieval system (EDGAR) in accordance with the EDGAR rules set forth in Regulation S–T (17 CFR part 232 of this chapter).

(b) This form need not be filed if the amount of securities to be sold during any period of three months does not exceed 5,000 shares or other units and the aggregate sale price does not exceed $50,000.

* * * * *

■ 7. Amend Form 144 (referenced in § 239.144) by:

■ a. Removing the title text ''NOTICE OF PROPOSED SALE OF SECURITIES PURSUANT TO RULE 144 UNDER THE SECURITIES ACT OF 1933'' and add in its place ''NOTICE OF SALE OR PROPOSED SALE OF SECURITIES PURSUANT TO RULE 144 UNDER THE SECURITIES ACT OF 1933'';

■ b. Removing the text ''ATTENTION: Transmit for filing 3 copies of this form concurrently with either placing an order with a broker to execute sale or executing a sale directly with a market maker.'' and add in its place ''ATTENTION: This form must be filed in electronic format by means of the Commission's Electronic Data Gathering, Analysis, and Retrieval system (EDGAR) in accordance with the EDGAR rules set forth in Regulation S–T (17 CFR part 232). For assistance with technical questions about EDGAR or to request an access code, call the EDGAR Filer Support Office at (202) 551–8900.'';

■ c. Removing the text ''INSTRUCTION: The person filing this notice should contact the issuer to obtain the I.R.S. Identification Number and the SEC. File Number.'' and add in its place ''INSTRUCTION: The filer should contact the issuer to obtain the SEC. File Number.'';

■ d. Removing the data field box ''1(b)'';

■ e. Redesignating the data field boxes 1(c) through 1(e) as 1(b) through 1(d);

■ f. Removing the data field box ''2(c)'';

■ g. Removing Instructions 1(b) and 2(c);

■ h. Redesignating Instructions 1(c) through 1(e) as 1(b) through 1(d); and

■ i. Removing ''(d) Aggregate market value of the securities to be sold as of a specified date within 10 days prior to the filing of this notice'' and add in its place ''(d) Aggregate market value of the securities to be sold as of a specified date within 10 days prior to the filing of this notice. For completed sales, provide instead the total sales proceeds (amount of securities sold multiplied by the price per share)''.

Note: The text of Form 144 does not and this amendment will not appear in the Code of Federal Regulations.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 8. The general authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 et seq.; 18 U.S.C. 1350; Sec. 953(b) Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3) Pub. L. 112–106, 126 Stat. 309 (2012), Sec. 107, Pub. L. 112–106, 126 Stat. 313 (2012), and Sec. 72001 Pub. L. 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

* * * * *

■ 9. Amend Form 4 (referenced in § 249.104) by:

■ a. Adding new General Instruction 10; and

■ b. Adding text and a check box at the top of the first page immediately below the text ''Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).''

The additions to read as follows:

Note: The text of Form 4 does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 4

* * * * *

General Instructions

* * * * *

10. Optional Rule 10b5–1(c) Transaction Indication

If a transaction was made pursuant to a contract, instruction or written plan for the purchase or sale of equity securities of the issuer that satisfies the conditions of Rule 10b5–1(c) under the Exchange Act [§ 240.10b5–1(c) of this chapter], a reporting person may elect to check the Rule 10b5–1 box appearing on this Form. Additional information, such as the date of a Rule 10b5–1 plan, may be provided at the filer's option in the ''Explanation of Responses'' portion of the Form.

* * * * *

☐ Check this box to indicate that a transaction was made pursuant to Rule 10b5–1(c). *See* Instruction 10.

* * * * *

10. Amend Form 5 (referenced in § 249.105) by:

a. Adding new General Instruction 10; and

b. Adding text and a check box at the top of the first page immediately below the text ''Form 4 Transactions Reported''.

The additions to read as follows:

Note: The text of Form 5 does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 5

* * * * *

General Instructions

* * * * *

10. Optional Rule 10b5–1(c) Transaction Indication

If a transaction was made pursuant to a contract, instruction or written plan for the purchase or sale of equity securities of the issuer that satisfies the conditions of Rule 10b5–1(c) under the Exchange Act [§ 240.10b5–1(c) of this chapter], a reporting person may elect to check the Rule 10b5–1 box appearing on this Form. Additional information, such as the date of a Rule 10b5–1 plan, may be provided at the filer's option in the ''Explanation of Responses'' portion of the Form.

* * * * *

☐ Check this box to indicate that a transaction was made pursuant to Rule 10b5–1(c). *See* Instruction 10.

* * * * *

By the Commission.

Dated: December 22, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28790 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0523; FRL–10017–10–Region 9]

Air Plan Approval; California; Feather River Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Feather River Air Quality Management District (FRAQMD or ''District'') portion of the California State Implementation Plan (SIP). This revision concerns emissions of volatile organic compounds (VOCs) from surface preparation and clean-up operations. We are proposing to approve a local rule to regulate these emission sources under the Clean Air Act (CAA or the ''Act''). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before February 18, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. is EPA–R09–OAR–2020–0523 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4125 or by email at *vineyard.christine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal with the date that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Amended	Submitted
FRAQMD	3.14	Surface Preparation and Clean-up	08/01/16	01/24/17

On April 17, 2017, the EPA determined that the submittal for FRAQMD Rule 3.14 met the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

We approved an earlier version of Rule 3.14 into the SIP on April 23, 2015 (80 FR 22646). The FRAQMD adopted revisions to the SIP-approved version on August 1, 2016, and CARB submitted them to us on January 24, 2017.

C. What is the purpose of the submitted rule revision?

Emissions of VOCs contribute to the production of ground-level ozone, (or ''smog'') and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. Rule 3.14 was

revised to be consistent with the CARB Suggested Control Measure (SCM) for Automotive Coatings and Components by simplifying coating categories, lowering VOC limits and modifying recordkeeping and labeling requirements. The EPA's technical support document (TSD) has more information about this rule.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

Rules in the SIP must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Generally, SIP rules must require reasonably available control technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source of VOCs in ozone nonattainment areas classified as Moderate or above (see CAA section 182(b)(2)).

CAA Guidance and policy documents that we used to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''Control of Volatile Organic Emissions from Solvent Metal Cleaning,'' EPA–450/2–77–022, November 1977 (*http://www.epa.gov/ozonepollution/SIPToolkit/ctgs.html*)
5. ''Control Techniques Guidelines for Industrial Cleaning Solvents,'' EPA–453/R–06–001, September 2006 (*http://www.epa.gov/ozonepollution/SIPToolkit/ctgs.html*)

B. Does the rule meet the evaluation criteria?

The FRAQMD regulates an ozone nonattainment area classified as Severe nonattainment. The District is a bi-county agency that administers local, state, and federal air quality management programs for Yuba and Sutter Counties. Portions of the District have been designated as Moderate or above nonattainment for failure to meet the federal 8-hour ground-level ozone standard. The submitted SIP rule does not fully meet RACT because the rule contains an exemption for any solvent degreasing operations subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) requirements of 40 CFR part 63, subpart T—National Emission Standards for Halogenated Solvent Cleaning. However, EPA approved a negative declaration for this category in the FRAQMD's 2008 ozone standard RACT SIP. (80 FR 38959, July 8, 2015). Therefore, Rule 3.14 does not need to meet RACT requirements. Despite this, we believe it is helpful, for informational purposes, to compare Rule 3.14 to other RACT rules in effect in other California districts. This comparison is set forth in our TSD and we believe Rule 3.14 contains RACT-level control requirements, except for the NESHAP exemption, that will strengthen the SIP. In addition, the District has submitted a negative declaration for this source category in the FRAQMD's 2015 ozone standard RACT SIP. We will evaluate the FRAQMD's 2015 ozone standard RACT SIP in a future rulemaking.

C. The EPA's Recommendations to Further Improve the Rule

The TSD also includes recommendations for the next time the local agency modifies the rule.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rule because it fulfills all relevant requirements. We will accept comments from the public on this proposal until February 18, 2021. If we take final action to approve the submitted rule, our final action will incorporate this rule into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the FRAQMD Rule described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible

methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 23, 2020.

John Busterud,

Regional Administrator, EPA Region IX.

[FR Doc. 2021–00358 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2020–0711; FRL–10019–24–Region 7]

Air Plan Approval; Kansas; Removal of Kansas City, Kansas Reid Vapor Pressure Fuel Requirement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of revision to the Kansas State Implementation Plan (SIP), submitted by the Kansas Department of Health and the Environment (KDHE) on December 9, 2020. The proposed revision removes the Kansas City, Kansas seven pounds per square inch Reid Vapor Pressure (RVP) Fuel requirement which required gasoline sold in the Kansas City, Kansas area to have a seven pounds per square inch Reid Vapor Pressure from June 1 to September 15. The rest of the state is subject to the Clean Air Act (CAA) nine pounds per square inch Reid Vapor Pressure from June 1 to September 15. If approved the Kansas City, Kansas area would be subject to the Clean Air Act Reid Vapor Pressure Fuel requirement. In addition, EPA anticipates issuing a separate proposal for the Missouri side of the Kansas City metro area.

DATES: Comments must be received on or before February 18, 2021.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2020–0711 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jed Wolkins, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7588; email address: *wolkins.jed@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2020–0711, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The EPA is proposing to approve a revision to the Kansas SIP, submitted by the KDHE on December 9, 2020. The proposed revision removes the Kansas City, Kansas; Johnson and Wyandotte Counties; 7.0 Reid Vapor Pressure (RVP) Fuel requirement. The approved SIP, K.A.R. 28–19–719, requires gasoline sold in the two counties to have a RVP of seven pounds per square inch (psi) or less from June 1 through September 15.[1] If the SIP revision is approved, the Kansas City, Kansas area would be subject to the CAA RVP requirement of nine psi or less from June 1 through September 15.[2] Kansas has asked EPA to remove K.A.R. 28–19–719 Fuel Volatility from the SIP.

III. Have the requirements for approval of a SIP revision been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from August 27, 2020 to November 4, 2020 and received eight comments. Kansas adequately responded to all eight comments, as noted in the State submission included in the docket for this action, but did not make any changes to the removal based on the comments received.

In addition, as explained below, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

IV. Background

The EPA established a 1-hour ozone NAAQS in 1971.[3] 36 FR 8186 (April 30, 1971). On March 3, 1978, the EPA designated Johnson and Wyandotte counties (hereinafter referred to in this document as the ''Kanas City area'') in nonattainment of the 1971 1-hour ozone

[1] The Kansas rule allows an additional one psi for gasoline containing 9 to 10% ethanol.

[2] The CAA allows an additional one psi for gasoline containing up to 15% ethanol.

[3] The 1-hour ozone NAAQS was originally promulgated as a photochemical oxidant standard. See 36 FR 8186 (April 30, 1971). In 1979, the EPA substituted the word ''ozone'' for ''photochemical oxidant''. See 44 FR 8202 (February 8, 1979). In doing so, the EPA stated that ''(t)he intent of the standard (total-oxidant reduction), the control strategies, and the index of progress toward attainment (measured ozone levels) remain unchanged.'' Id. at 8203.

NAAQS, as required by the CAA Amendments of 1977. 43 FR 8996 (March 3, 1978). On February 8, 1979, the EPA revised the 1-hour ozone NAAQS, referred to as the 1979 ozone NAAQS. 44 FR 8202 (February 8, 1979).

The EPA redesignated the Kansas City area to attainment of the 1979 1-hour ozone standard and approved the ozone maintenance plan on July 23, 1992. 57 FR 27936 (June 23, 1992). Pursuant to section 175A of the CAA, the first 10-year maintenance period for the 1-hour ozone standard began on July 23, 1992, the effective date of the redesignation approval.

In 1995, the Kansas City area violated the 1979 1-hour ozone standard. Kansas revised the control strategy and contingency measures in the maintenance plan, which was approved on December 30, 2002. 67 FR 66058 (October 30, 2002). The revised control strategy included K.A.R. 28–19–719, *Fuel Volatility.*

On May 2, 1997, Kansas adopted the seven and two tenths (7.2) pounds per square inch (psi) Reid Vapor Pressure (RVP) limit from June 1 to September 15.[4] EPA approved this rule into the SIP on July 7, 1997. 62 FR 36212 (July 7, 1997). Following a violation of the ozone standard for the three-year period of 1995–1997, on April 3, 2001, Kansas revised the rule to seven (7.0) psi limit from June 1 to September 15.[5] EPA approved this rule into the SIP on February 13, 2002. 67 FR 6655 (February 13, 2002.

On April 30, 2004, the EPA published a final rule in the **Federal Register** stating the 1979 ozone NAAQS would no longer apply (*i.e.,* would be revoked) for an area one year after the effective date of the area's designation for the 8-hour ozone NAAQS. 69 FR 23951 (April 30, 2004). The Kansas City Area was designated as an unclassifiable area for the 1997 8-hour ozone NAAQS, effective June 15, 2004. *See id.* However, on May 3, 2005, EPA published a final rule designating the Kansas City area as an attainment area for the 1997 8-hour ozone NAAQS based on new monitoring data. *See* 70 FR 22801 (May 3, 2005). The effective date of the revocation of the 1979 1-hour ozone standard for the Kansas City area was June 15, 2005. *See* 70 FR 44470 (August 3, 2005). Kansas achieved the required maintenance of the 1979 1-hour ozone standard in 2014.

On, December 9, 2020, Kansas requested that the EPA remove K.A.R. 28–19–719 from the SIP. Section 110(l) of the CAA prohibits EPA from approving a SIP revision that interferes with any applicable requirement concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the CAA.

V. What is the EPA's analysis of Kansas' SIP request

EPA is making the preliminary determination that the ozone NAAQS is the primary focus for the noninterference demonstration required by section 110(l) of the CAA because the RVP requirements results primarily in emissions benefits for VOCs and NO_X. VOCs and NO_X emissions are precursors for ozone. NO_X emissions are precursors for particulate matter. NO_2 is a component of NO_X. There are no emissions reductions attributable to the emissions of carbon monoxide (CO), lead and sulfur dioxide (SO_2) from RVP requirements.

In Kansas' December 9, 2020 submission the State provided a technical demonstration to support the request to remove Kansas' 7.0 psi RVP requirement from the active measures portions of the Kansas SIP. In that technical demonstration, Kansas provided Motor Vehicle Emissions Simulator (MOVES) results, modeling the emissions of VOCs and NO_X associated with changing the high ozone season RVP requirements from the state-level requirement of 7.0 psi to the federal requirement of 9.0 psi. EPA evaluated the state's assumptions and inputs used in MOVES, and EPA finds the state analysis is appropriate. Specifically, KDHE compared what the projected emissions in the year 2020 (the year the program is requested to be rescinded) would be, assuming a RVP level of 7.0 psi and 9.0 psi, respectively, in two separate modeling simulations. The comparison revealed an increase in emissions of 0.07 tons for NO_X and 0.37 tons for VOC, per ozone season day, would result from the change to the federal requirement from June 1 through September 15. While the modeling showed a slight increase in NO_X and VOC emissions resulting from the use of 9.0 psi RVP as opposed to 7.0 psi, the most appropriate analysis is whether emissions in the future years would increase and potentially interfere with maintenance of the NAAQS. The State compared actual emissions from 2017 using a RVP of 7.0 psi to emissions modelled for the years 2020 using a RVP of 9.0 psi. Table 1 below provides the results of this analysis.

TABLE 1—COMPARATIVE EMISSIONS FOR CHANGE TO RVP

	2017 7.0 psi RVP (tons per ozone season day)	2020 7.0 psi RVP (tons per ozone season day)	2020 9.0 psi RVP (tons per ozone season day)	Decrease in 2020 9.0 psi RVP compared to 2017 7.0 psi RVP (tons per ozone season day)
NO_X	29.42	22.42	22.49	6.93
VOC	19.26	16.88	17.25	2.01

As Table 1 indicates, NO_X and VOC emissions in the Kansas City Area would decrease from 2017 to 2020, even with the increase due to ozone season fuel RVP of 9.0 psi. The modeling demonstration shows the slight increase in emissions is being mitigated area-wide by a steady decrease in tailpipe emissions. This is the result of a cleaner new vehicle fleet replacing the older fleet[6] and the decrease in the sulfur content in gasoline as required by EPA's Tier 3 motor vehicle emission and fuel standards, which were implemented beginning on January 1, 2017.[7]

[4] The Kansas rule allowed an additional one psi for gasoline containing 9 to 10% ethanol. See 62 FR 36212 (July 7, 1997).

[5] The Kansas rule allows an additional one psi for gasoline containing 9 to 10% ethanol. See 67 FR 6655 (February 13, 2002).

[6] As vehicle owners purchase new vehicles, the older vehicles slowly are removed from the vehicles on the road. A used vehicle maybe purchased and driven by several owners, but eventually the older, more polluting vehicles are removed from the road. Manufacturers' fleets in 1994 are allowed 0.6 gram/mile NO_X emissions. Manufacturers' fleets in 2004 are allowed 0.07 gram/mile No_X emissions. Manufacturers' fleets in 2025 will be allowed 0.03 gram/mile NO_X emissions.

[7] Control of Air Pollution From Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards (See 79 FR 23414, April 28, 2014.)

The Kansas City, Kansas area is designated attainment/unclassifiable or attainment for the 1979, 1997, 2008, and 2015 ozone standards. While the 1979 maintenance plan is approved into the SIP, the 1979 NAAQS has been revoked for the Kansas City area. There are no other ozone maintenance plans for the Kansas City area in the SIP. The highest monitor design value in the Kansas City area is 68 parts per billion (ppb), which is below the 2015 ozone NAAQS of 70 ppb.[8] Based on the state's modeling analysis, along with air quality data, EPA is making the preliminary determination that the slight increase in NO_X and VOC emissions resulting from the use of 9.0 psi RVP fuel will not interfere with the Kansas City area's ability to maintain the ozone NAAQS, or any other applicable requirement. The EPA is making this determination based on MOVES modeling that indicates that on-road VOC and NO_X emissions in 2020 with gasoline meeting the 9.0 psi RVP requirement remain below the emissions levels in 2017, a year in which the area's design value was also below the 2015 ozone standard of 70 ppb.

The Kansas City area is designated as attainment or unclassifiable for the 2006 24-hour $PM_{2.5}$, 2012 annual $PM_{2.5}$, 1971 annual NO_2, and 2010 1-hour NO_2 standards. There are no maintenance plans for any of these standards. The highest $PM_{2.5}$ design value is 79% of the standard. The highest NO_2 design value is 42% of the standard. As discussed above the area has a decrease from 2017 to 2020 NO_X and VOC emissions. Based on this data together with air quality data, EPA is making the preliminary determination that the slight increase in NO_X and VOC emissions in 2020 and the downward trend in on-road VOC and NO_X emissions resulting from this change will not interfere with the Area's ability to maintain the any $PM_{2.5}$ or NO_2 NAAQS, or any other applicable requirement.

The Kansas City area is designated as attainment or unclassifiable for the SO_2 standards. There are no maintenance plans for any of these standards. The most recent (2017–2019) highest SO_2 design value is less than 8% of the standard. The RVP standard has no effect on SO_2 emissions. Based on this data together with air quality data, EPA is making the preliminary determination that the change will not interfere with the Area's ability to attain or maintain the SO_2 NAAQS, or any other applicable requirement.

The Kansas City area is designated as attainment or unclassifiable for the CO and lead standards. There are no maintenance plans for any of these standards. The highest CO design value is less than 18% of the standard. There is no lead monitoring in the area. The RVP standard has no effect on CO or lead emissions. Based on this data together with air quality data, EPA is making the preliminary determination that the change will not interfere with the area's ability to maintain the CO or lead NAAQS, or any other applicable requirement.

Kansas has no federal Class I areas. EPA is making the preliminary determination that the small emission increase will not interfere with reasonable progress towards natural visibility in surrounding states Class I areas that Kansas might impact due to the small magnitude of emissions increase.

VI. What action is the EPA taking?

We are proposing to approve Kansas' removal of the state RVP requirement from the SIP for the Kansas City, Kansas area. As discussed above the removal of the RVP requirement will not affect the area's ability to attain or maintain any air quality standard. We are processing this as a proposed action because we are soliciting comments on this proposed action. Final rulemaking will occur after consideration of any comments.

VII. Incorporation by Reference

In this document, the EPA is proposing to amend regulatory text that includes incorporation by reference. As described in the proposed amendments to 40 CFR part 52 set forth below, the EPA is proposing to remove provisions of the EPA-Approved Kansas Regulations from the Kansas State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

VIII. Statutory and Executive Order Reviews

Under the Clean Air Act (CAA), the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping

[8] Based on the most recent quality assured data design values (2017–2019). The monitor in question is on the Missouri side of the Kansas City. The highest 4th high value on the Kansas side of Kansas City was 62 ppb.

requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 21, 2020.

James Gulliford,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart R—Kansas

§ 52.870 [Amended]

■ 2. In § 52.870, the table in paragraph (c) is amended by removing the entry ''K.A.R. 28–19–719'' under the heading ''Volatile Organic Compound Emissions''.

■ 3. In § 52.873, paragraph (a) is revised to read as follows:

§ 52.873 Approval status.

(a) Kansas rule K.A.R. 28–19–719 was rescinded on February 18, 2021.

* * * * *

[FR Doc. 2021–00179 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0187; FRL–10016–71–Region 4]

Air Plan Approval; North Carolina; Revisions to Exclusionary Rules and Permit Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of revisions to a State Implementation Plan (SIP) submitted by the State of North Carolina through the North Carolina Department of Environmental Quality, Division of Air Quality (DAQ), on September 18, 2009, and July 10, 2019. These SIP revisions seek to modify the State's rules that define the categories of facilities that are exempted from Title V permitting requirements by limiting their potential emissions (''exclusionary rules'') and the categories of facilities that are exempted from the State's rules that address the permitting requirements for non-Title V facilities (''permit exemption rules''). EPA is proposing to approve this revision pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before February 18, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0187 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Pearlene Williams, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. Williams can be reached via telephone at (404) 562–9144, or via electronic mail at *williams.pearlene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Submittal—September 18, 2009

On September 18, 2009, DAQ submitted revisions to 15A North Carolina Administrative Code (NCAC) Subchapter 02Q, Section .0902, *Temporary Crushers,*[1] for review and approval into the SIP. These changes are part of North Carolina's permit exemption rules at Section .0900 that define the categories of facilities that are exempted from the State's regulations that address the permitting requirements for non-Title V facilities. These changes are discussed in more detail in Section II.

B. Submittal—July 10, 2019

On July 10, 2019, DAQ submitted SIP revisions to EPA with changes to the following rules in 15A NCAC 02Q Section .0800 that define the categories of facilities that are exempted from Title V permitting requirements by limiting their potential emissions: Section .0801, *Purpose and Scope;* Section .0802, *Gasoline Service Stations and Dispensing Facilities;* Section .0803, *Coating, Solvent Cleaning, Graphic Arts Operations;* Section .0804, *Dry Cleaning Facilities;* Section .0805, *Grain Elevators;* Section .0806, *Cotton Gins;* and Section .0807, *Emergency Generators;* and Section .0809, *Concrete Batch Plants.*[2] The July 10, 2019, SIP revisions also contain changes to the following permit exemption rules: Section .0901, *Purpose and Scope;* and Section .0902, *Temporary Crushers.* These changes are discussed in more detail in Section II.

II. Analysis of the State Submittals

The revisions that are the subject of this proposed rulemaking make changes to exclusionary rules and permit exemption rules under Subchapter 2Q[3] of the North Carolina SIP. These changes revise the recordkeeping and reporting requirements of the exclusionary rules; remove Section .0809, *Concrete Batch Plants;* revise the provisions of Section .0902, *Temporary Crushers;* and revise language and reformat the regulatory citations contained in the exclusionary and permit exemption rules. Detailed descriptions of the changes are provided below.

Section .0801, *Purpose and Scope,* is revised to modify language and reformat the regulatory citations of this section. In addition, the recordkeeping and reporting requirement exemptions are removed. New paragraphs have been created using the existing text of this section. The language changes in this section pertain to updates to subject-verb agreements and word tense. EPA is proposing to approve these changes to these rules because they are grammatical and organizational in

[1] DAQ supplemented the September 18, 2009, submittal in a letter dated June 7, 2019, which includes the correct redline/strikeout of the regulatory changes and final regulations that became state effective on January 1, 2009. This letter is available in the docket for this proposed rulemaking.

[2] The State submitted the revisions following the readoption of several air regulations. These include: .0801, .0802, .0803, .0804, .0805, .0806, .0807, .0809, .0901, and .0902, and were submitted pursuant to North Carolina's 10-year regulatory readoption process at North Carolina General Statute 150B–21.3A.

[3] In the table of North Carolina regulations federally approved into the SIP at 40 CFR 52.1770(c), 15A NCAC 02Q is referred to as ''Subchapter 2Q Air Quality Permits.''

nature and therefore do not interfere with any applicable requirement concerning attainment or any other applicable requirement of the Act.

North Carolina submitted changes to several rules within Section .0800 which do not alter the meaning or make significant changes to those rules. Specifically, the following rules are submitted with changes to update a cross-reference to where the ''responsible official'' at a facility is defined in the North Carolina regulations, reformat regulatory citations, make minor language edits, and correct typographical errors, where applicable: Sections .0802, *Gasoline Service Stations and Dispensing Facilities;*[4] .0803, *Coating, Solvent Cleaning,*[5] *Graphic Arts Operations;* .0804, *Dry Cleaning Facilities;* .0805, *Grain Elevators;* .0806, *Cotton Gins;* .0807, *Emergency Generators;* and Section .0901, *Purpose and Scope.* EPA is proposing to approve these changes to these rules because they do not alter the meaning of the regulations. . . .

DAQ has repealed Section .0809, *Concrete Batch Plans* and is proposing to remove it from the SIP. This rule covered certain sizes of concrete batch plants that use fabric filters or equivalently effective control devices to control particulate emissions to limit production such that the potential to emit (PTE) would remain below applicable Title V thresholds as determined by the State. Under the rule, these facilities were not required to obtain major source operating permits pursuant to 02Q .0500, *Title V Procedures.* Section .0809 functioned as a flexible permitting mechanism to cover certain types of concrete batch plants that wished to avoid Title V permitting. Sources previously covered by this rule can elect to obtain synthetic minor operating permits pursuant to 02Q .0315, *Synthetic Minor Facilities,* or otherwise have the option to obtain a Title V permit pursuant to 02Q .0500 if their PTE is above the Title V thresholds. EPA has preliminarily determined that repealing Section .0809 does not interfere with any applicable requirement concerning attainment or any other applicable requirement of the Act because it simply removes a mechanism sources could use to avoid Title V permitting. Accordingly, EPA is proposing to remove Section .0809 from the SIP.

Section .0902, *Temporary Crushers,* is revised with edits from the September 18, 2009,[6] and July 10, 2019, submittals that include clarifying edits, changes to formatting, minor modifications to language, correction of typographical errors, and renumbering.[7] First, the permit exemption regarding temporary crushers is revised to remove language related to the diesel fuel burning equipment at these facilities. Previously, to qualify for the exemption from 02Q .0300, *Construction and Operating Permits,* temporary crushers that used a diesel-fired generator or diesel engine to drive the crusher could not burn more than 17,000 gallons of diesel at the facility. North Carolina explains that removing this language is necessary because DAQ does not regulate engines such as these, which are subject to Title II of the CAA, *Emissions Standards for Moving Sources.* Any associated engines at such temporary sources would be defined as portable and, as such, not considered part of a stationary source. Therefore, the effect of removing these engines from the rule exempting temporary crushers is clarifying in nature and does not alter existing permitting requirements. The edits also add a new paragraph (i), which requires an owner or operator of a crusher to apply for and receive an air quality permit before beginning operations (should they plan to operate for more than twelve months). Other revisions include updated cross-references to applicable rules and updated recordkeeping and reporting requirements to reflect the removal of these engines from the exemption. Remaining edits include updates to numbering, minor changes to existing language, and correction of typographical errors. EPA is proposing to approve these minor and clarifying changes to Section .0902 because they do not interfere with any applicable requirement concerning attainment or any other applicable requirement of the Act.

III. Incorporation by Reference

In this notice, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the following sections of 15A NCAC Subchapter 02Q with a state-effective date of April 1, 2018: Section .0801, *Purpose and Scope;* Section .0802, *Gasoline Service Stations and Dispensing Facilities;* Section .0803, *Coating, Solvent Cleaning, Graphic Arts Operations;* Section .0804, *Dry Cleaning Facilities;* Section .0805, *Grain Elevators;* Section .0806, *Cotton Gins;* Section .0807, *Emergency Generators;* Section .0901, *Purpose and Scope* and Section .0902, *Temporary Crushers* (with the exception of .0902(d)). EPA is also proposing to remove North Carolina regulation 15A NCAC Subchapter 02Q Section .0809, *Concrete Batch Plants,* from the North Carolina SIP, which is incorporated by reference in accordance with the requirements of 1 CFR part 51. These changes are proposed to revise the recordkeeping and reporting requirements of the permitting exclusionary rules, remove the ''Concrete Batch Plants'' regulation, revise language, and reformat the regulatory citations contained in these regulations. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve the changes described above to the North Carolina SIP submitted by the State of North Carolina on September 18, 2009, and July 10, 2019. The changes under Subchapter 02Q Section .0801, *Purpose and Scope;* Section .0802, *Gasoline Service Stations and Dispensing*

[4] 15 NCAC 02Q .0802(c) includes a typographical error that inadvertently changed the word ''for'' to ''form'' instead of the correct word ''from.''

[5] EPA previously approved changes to .0803, *Coating Solvent Cleaning,* state effective April 1, 2001 (as transmitted in an April 16, 2001, SIP revision), on August 8, 2002 (67 FR 51461). EPA inadvertently reverted the state effective date included in Table (c) of 40 CFR 52.1770 to April 1, 1999, in a subsequent action on October 22, 2002 (67 FR 64990). The April 1, 2001 change to the reporting date in paragraph (i), now recodified as paragraph (j), is included and superseded in the April 1, 2018, state effective version of 15A NCAC 02Q .0803.

[6] EPA has already taken action on the following portions of the September 18, 2009 submittal: 02D .0901—approved at 78 FR 27065 (May 9, 2013); 02D .0902—approved at 78 FR 44890 (July 25, 2013); 02D .0909—approved at 78 FR 58184 (September 23, 2013); and 02Q .0304—approved at 85 FR 43461 (June 24, 2020). Rules 02D .0953 and .0954 were repealed, state effective September 18, 2009, and removed from the SIP at 78 FR 58184 (September 23, 2013). DAQ withdrew the following portions of the September 18, 2009 submittal: 02D .0521 (withdrawn June 7, 2019) and 02D .0952 (Withdrawn November 30, 2012). Additionally, DAQ withdrew paragraph (d) of 02Q .0902 (as renumbered from paragraph (c)) in the September 18, 2009, submittal and carried forward in the July 10, 2019, submittal, from EPA consideration in a letter dated on June 1, 2020. The June 1, 2020, withdrawal letter is available in the docket for this proposed rulemaking.

[7] Except for the change to Section .0902(d) in the July 10, 2019 and September 18, 2009 SIP revisions which was withdrawn from EPA consideration in a letter dated June 1, 2020. Additionally, the withdrawal of paragraph (d) from section 02Q .0902, leaves the section with two paragraphs (c), one state effective on January 1, 2001 and one state effective on January 1, 2009. DAQ plans to submit revisions to address the two paragraphs (c) in a future submission.

Facilities; Section .0803, *Coating, Solvent Cleaning, Graphic Arts Operations;* Section .0804, *Dry Cleaning Facilities;* Section .0805, *Grain Elevators;* Section .0806, *Cotton Gins;* Section .0807, *Emergency Generators;* Section .0901, *Purpose and Scope;* and *Section* .0902, *Temporary Crushers,* are proposed to revise the recordkeeping and reporting requirements of the permitting exclusionary rules, remove Section .0809, the *Concrete Batch Plants* regulation, revise language, and reformat the regulatory citations contained in these regulations. The proposed changes are consistent with the CAA.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 16, 2020.

Mary Walker,

Regional Administrator, Region 4.

[FR Doc. 2021–00534 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0037; FRL–10018–75–OAR]

RIN 2060–AR73

National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymers Production Reconsideration; Reopening of a Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of public comment period.

SUMMARY: On November 9, 2020, the U.S. Environmental Protection Agency (EPA) proposed a rule titled ''National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymers Production Reconsideration.'' The EPA is reopening the comment period on the proposed rule that closed on January 8, 2021. The comment period will reopen until February 8, 2021, to allow additional time for stakeholders to review and comment on the proposal.

DATES: The public comment period for the proposed rule published in the **Federal Register** on November 9, 2020 (85 FR 71490), which ended on January 8, 2021, is being reopened. Written comments may now be received on or before February 8, 2021.

ADDRESSES:

Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2002–0037, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2002–0037 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2002–0037.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2002–0037, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday through Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. The EPA's policy is that all comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statue.

Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

https://www.epa.gov/dockets/commenting-epa-dockets.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA's Docket Center homepage at *https://www.epa.gov/dockets.*

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.* Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.* The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2002–0037.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Jennifer Caparoso, Sector Policies and Programs Division (E143–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4063; fax number: (919) 541–0516; and email address: *caparoso.jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION: To allow for additional time for stakeholders to provide comments, the EPA has decided to reopen the public comment period until February 8, 2021.

Dated: December 16, 2020.

Panagiotis Tsirigotis,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2021–00355 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80, 280, and 281

[EPA–HQ–OAR–2020–0448; FRL–10015–80–OAR]

RIN 2060–AU92

E15 Fuel Dispenser Labeling and Compatibility With Underground Storage Tanks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA currently requires fuel dispenser labels for gasoline-ethanol blends of greater than 10 volume percent (vol%) ethanol and up to 15 vol% ethanol (E15). The label was designed to alert consumers to the appropriate and lawful use of the fuel. EPA is co-proposing to either modify the E15 label or remove the label requirement entirely and seeking comment on whether state and local governments may be preempted from requiring different labels on fuel dispensers. To facilitate the proper storage of E15 in underground storage tank systems (USTs), EPA is proposing to modify the UST regulations to grant certain allowances for compatibility demonstration for storage of ethanol blends. EPA is also proposing compatibility requirements for future UST installations or component replacements that would ensure compatibility with higher blends of ethanol.

DATES:

Comments: Comments must be received on or before April 19, 2021. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before February 18, 2021.

Public Hearing: EPA will announce the public hearing information for this proposal in a supplemental **Federal Register** document.

ADDRESSES: You may send your comments, identified by Docket ID No. EPA–HQ–OAR–2020–0448, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2020–0448 in the subject line of the message.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Air Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://*

www.regulations.gov, including any personal information provided. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.*

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

FOR FURTHER INFORMATION CONTACT: For questions regarding the E15 fuel dispenser labeling provisions of this proposed action, contact Lauren Michaels, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4640; email address: *michaels.lauren@epa.gov.* For questions regarding the E15 compatibility with underground storage tanks provisions of this proposed action, contact Elizabeth McDermott, Office of Underground Storage Tanks, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–0646; email address: *mcdermott.elizabeth@epa.gov.*

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

Entities potentially affected by this proposed rule are those involved with the sale of gasoline. Potentially affected categories include:

Category	NAICS [1] code	Examples of potentially affected entities
Industry	111, 112	Agriculture (crop and animal production).
Industry	31–33	Manufacturing.
Industry	42, 44–45, 72 (excluding 447)	Commercial (wholesale trade, retail trade, accommodation, and food services).
Industry	447	Retail motor fuel sales.
Industry	481, 483–486, 48811	Transportation (air, water, truck, transit, pipeline, and airport operations).
Industry	5171, 2211	Communications and Utilities (wired telecommunications carriers, electric power generation, transmission, and distribution).

[1] North American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this proposed action. This table lists the types of entities that EPA is now aware could potentially be affected by this proposed action. Other types of entities not listed in the table could also be affected. To determine whether your entity would be affected by this proposed action, you should carefully examine the applicability criteria in 40 CFR part 80. If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Outline of This Preamble

I. Purpose of This Action
II. E15 Fuel Dispenser Labeling Revisions
A. Background on the E15 Label
B. E15 in the Market
C. Proposed Changes to the E15 Labeling Requirement
D. Request for Public Comment on E15 Labeling Preemption Considerations
III. E15 Compatibility With Underground Storage Tanks
A. Background on Underground Storage Tank Compatibility
B. Proposed Changes to the UST Compatibility Requirements
C. Updates to State Program Approval Requirements
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IV. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
V. Statutory Authority

I. Purpose of This Action

This action proposes modifications to EPA regulations under the Clean Air Act (CAA) and the Resource Conservation and Recovery Act (RCRA) relating to the sale and distribution of gasoline-ethanol blends containing greater than 10 volume percent (vol%) ethanol and up to 15 vol% ethanol (E15). Recently, EPA has taken actions to provide additional opportunity for E15 within the fuels marketplace. We are proposing two sets of regulatory changes to further that end. The first proposes modifications to EPA's E15 fuel dispenser labeling requirement. The second proposes changes to EPA's Underground Storage Tank (UST) regulations regarding compatibility with gasoline-ethanol blends.

II. E15 Fuel Dispenser Labeling Revisions

This section discusses our proposed revisions to the E15 label, under the CAA.

A . Background on the E15 Label

In 2010 and 2011, in response to requests for a waiver from CAA section 211(f)(1), EPA granted two partial waivers for use of E15 [1] under CAA section 211(f)(4).[2] These waivers were

[1] For purposes of this preamble, E15 refers to gasoline-ethanol blended fuels that contain greater than 10 vol% and no more than 15 vol% ethanol content.

[2] These partial waivers are collectively referred to as ''the E15 partial waivers.'' 75 FR 68094 (November 4, 2010), 76 FR 4662 (January 26, 2011). The 2010 waiver applied to MY2007 and newer light duty motor vehicles. The 2011 waiver applied to MY2001–2006 light duty motor vehicles.

partial in that they apply to model year (MY) 2001 and newer light-duty motor vehicles and do not apply to MY2000 and older light-duty motor vehicles, all heavy-duty gasoline engines and vehicles, all highway and off-highway motorcycles, and all nonroad products. Per CAA section 211(f)(4), EPA evaluated whether the use of E15 would cause or contribute to emissions failures over the useful life of all vehicles, engines, and nonroad equipment, and determined that the use of E15 in MY2000 and older vehicles, heavy-duty gasoline engines and vehicles, and highway and off-highway motorcycles could cause these motor vehicles to exceed their emissions standards. EPA also found that the use of E15 in nonroad products could cause emissions exceedances as well as durability and materials compatibility issues.

Because the partial waivers apply only to MY2001 and newer light-duty motor vehicles, EPA promulgated regulations under CAA section 211(c) (referred to as the Misfueling Mitigation Rule or MMR) to mitigate the potential for E15 to be used to fuel vehicles, engines, and equipment for which E15 has not been approved for introduction into commerce.[3] Those regulations were needed to implement EPA's affirmative determinations that the use of E15 in MY2000 and older light-duty motor vehicles, all heavy-duty gasoline engines and vehicles, all on- and off-highway motorcycles, and all nonroad products would cause or contribute to the impairment of those vehicles' and engines' emission controls and harm public health from increases in regulated emissions. The regulations include a prohibition on the use of E15 in MY2000 and older light-duty motor vehicles, all heavy-duty gasoline engines and vehicles, all on- and off-highway motorcycles, and all nonroad products. To implement this prohibition, EPA promulgated several misfueling mitigation requirements in the MMR, a key aspect being that E15 fuel dispensers must have a specific label when a retail station or wholesale-purchaser consumer chooses to sell E15. The label was designed to alert consumers to the appropriate and lawful use of the fuel.

The E15 label was designed in coordination with consumer labeling experts at the Federal Trade Commission (FTC); FTC also requires the labeling of fuel dispensers in certain circumstances.[4] EPA worked with FTC to develop the E15 label and to ensure consistency between EPA's and FTC's labels for higher level gasoline-ethanol blends such as E85 (gasoline ethanol blends containing up to 83 percent ethanol). By regulation, EPA's current E15 label can be used in lieu of FTC's label for E15.[5]

The E15 label requirement was implemented as an integral component of EPA's misfueling mitigation program. First, the E15 partial waivers include a waiver condition that fuel and fuel additive manufacturers must submit a misfueling mitigation plan (MMP) with provisions to implement all reasonable precautions to address potential misfueling, including ensuring the use of a fuel dispenser label.[6] The waiver conditions articulated in the E15 partial waivers provide that the label must convey the following information:

- The fuel being dispensed contains 15% ethanol maximum;
- The fuel is for use in only MY2001 and newer gasoline cars, MY2001 and newer light-duty trucks, and all flex-fuel vehicles;
- Federal law prohibits the use of the fuel in other vehicles and engines; and
- Using E15 in vehicles and engines not approved for use might damage those vehicles and engines.

As discussed above, the MMR also implements a label requirement for retailers and wholesale purchaser-consumers, in addition to the requirements under the waiver conditions for fuel and fuel additive manufacturers. The MMR label requirement is specified in 40 CFR 80.1501 and requires the same basic elements as required under the E15 partial waivers' label requirement. Most recently, the 2019 E15 ''substantially similar'' definition for E15 requires that fuel and fuel additive manufacturers must submit a misfueling mitigation plan with provisions to implement all reasonable precautions to address potential misfueling.[7] Thus, the E15 label is currently incorporated and required under 40 CFR 80.1501, our CAA section 211(f)(1) ''substantially similar'' definition for E15, and the CAA section 211(f)(4) E15 partial waivers.

B. E15 in the Market

In 2019, EPA extended the CAA section 211(h)(4) 1-psi volatility waiver to gasoline-ethanol blends containing between 9 and 15 percent ethanol. This has expanded the opportunity for E15 to be sold during the summer season.

In the years since the 2010 and 2011 E15 partial CAA section 211(f)(4) waivers were granted, the number of retail stations offering E15 has grown, spurred in part by the United States Department of Agriculture (USDA) biofuel infrastructure partnership (BIP) program in 2016–18[8] and the industry-sponsored Prime the Pump program, that helped provide funding for retail station upgrades. As of October 2019, there are an estimated 1,809 stations registered as selling E15 (representing only about one percent of all retail stations).[9] Figure III–1 shows the growth of E15 stations since 2012, as well as the percentage of E15 stations of all retail stations in the United States.

[3] 76 FR 44406 (July 25, 2011).

[4] FTC's regulations found at 16 CFR 306.10 (Automotive Fuel Rating Posting) require fuel dispenser labels for gasoline-ethanol fuel blends containing greater than 10 percent ethanol. The FTC regulations provide for an exemption for retailers that utilize EPA's label under 40 CFR 80.1501. See 16 CFR 306.10(a).

[5] As described later in this proposal, if we were to remove our label requirement under 40 CFR 80.1501, absent additional action from FTC, retailers would be required to use FTC's label for ethanol blends containing between 10 and 15 percent ethanol, per 16 CFR part 306.

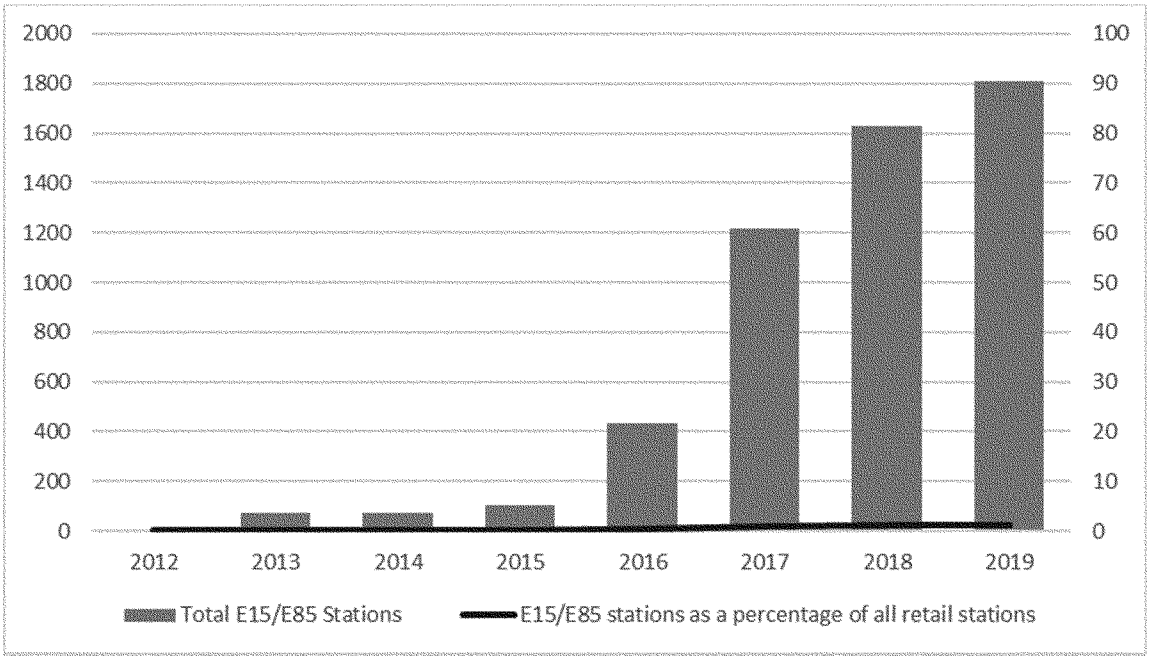
[6] 75 FR 68094 (November 4, 2010), 76 FR 4662 (January 26, 2011).

[7] 84 FR 26980, 27021 (June 10, 2019).

[8] See Biofuel Infrastructure Partnership, *https://www.fsa.usda.gov/programs-and-services/energy-programs/bip/index;* Prime the Pump press release, *https://growthenergy.org/2018/06/20/growth-energy-prime-the-pump-success-driving-ethanol-demand.*

[9] Email from Growth Energy to EPA, October 9, 2019, ''Growth Energy Higher Blend Infrastructure.'' Available in the docket for this action.

Figure II.B-1: Growth in E15 Retail Stations Over Time



The opportunities for misfueling have changed since 2011 as well. Over time, the number of light-duty vehicles on the road that are older than MY2001 have decreased due to normal fleet turnover, resulting in a corresponding decrease in the number of miles traveled by those light-duty vehicles.[10] At the same time, we have no indication that anything has changed for the other sectors (*i.e.,* nonroad vehicles, engines, and equipment, motorcycles, and heavy-duty vehicles). We continue to believe there are millions of such products in use that could potentially be misfueled on E15.

C. Proposed Changes to the E15 Labeling Requirement

EPA has received comments from some stakeholders on other actions suggesting that the existing E15 label is no longer necessary and simply interferes with additional growth of E15 in the marketplace.[11] These commenters suggest that removal of the label or changes to the color of the label or language used on the label would increase lawful use of E15 in MY2001 and newer light-duty vehicles. Other stakeholders have suggested that the growth in E15 at retail stations exacerbates concerns over misfueling of vehicles and equipment not designed for it, and suggest that the current label is no longer explicit enough about what vehicles and engines cannot use E15 making it insufficient to protect against misfueling.[12] These commenters suggested that EPA should solicit input on the size, design, and placement of the label on the dispenser, and other characteristics of the label to more clearly communicate the fuel's ethanol content to consumers.[13]

Our proposed action to modify or eliminate the E15 label requirement would rely on our CAA section 211(c) authority to control or prohibit fuel. Under CAA section 211(c)(1), EPA may issue regulations to ''control or prohibit the manufacture, introduction into commerce, offering for sale, or sale'' of any fuel or fuel additive whose emissions products may cause or contribute to air pollution ''which may be reasonably anticipated to endanger public health or welfare,'' or whose emissions products ''will impair to a significant degree the performance of any emission control device or system which is in general use.'' In the MMR, we found that E15 would significantly impair the emission control systems used in MY2000 and older light-duty motor vehicles, all heavy-duty gasoline engines and vehicles, all highway and off-highway motorcycles, and all nonroad products. This misfueling could result in increases in hydrocarbon, carbon monoxide, nitrous oxide, particulate matter, and air toxics emissions. Any action EPA takes to modify or remove the label would need to consider this finding.

We currently have no information before us that would indicate that E15, if used in MY2000 and older light-duty motor vehicles, all heavy-duty gasoline engines and vehicles, all highway and off-highway motorcycles, and all nonroad products, would no longer cause such damage to emission control systems. However, in the intervening years since the promulgation of the MMR and the label requirement, the vehicle fleet turnover toward newer light-duty vehicles, and the feedback

[10] We received comments in rulemakings suggesting that there are still vehicles newer than MY2000 for which manufacturers' owner's manuals continue to include warnings against E15 use despite E15 being allowable for introduction into commerce in those vehicles under EPA's regulations. See discussion at 84 FR 26980, 27010 (June 10, 2019).

[11] See, *e.g.,* Comments from Growth Energy (Docket Item No. EPA–HQ–OAR–2018–0227–0053) and Renewable Fuels Association (Docket Item No. EPA–HQ–OAR–2018–0227–0037). While these represent the most recent comments received on this issue, we have included all relevant comments in the docket for this action. While these comments often include many aspects of E15 use, only comments relating to the label are considered relevant for this NPRM.

[12] See, *e.g.,* Comments from National Marine Manufacturers Association (Docket Item No. EPA–HQ–OAR–2018–0775–0534) and Petroleum Marketers Association of America (Docket Item No. EPA–HQ–OAR–2018–0227–0083). While these represent the most recent comments received on this issue, we have included all relevant comments in the docket for this action. While the comments often address many aspects of E15 use, only those comments related to the label requirement are considered relevant for this NPRM.

[13] See, *e.g.,* Comments from National Marine Manufacturers Association (Docket Item No. EPA–HQ–OAR–2018–0775–0534).

from stakeholders have led us to reevaluate the E15 label at this time.

The current label is 3 inches by 5 inches in black text on an orange background and includes the following language:

- The word ''ATTENTION,'' diagonally across the upper right corner of the label;
- The word ''E15'' at the top of the label;
- The ethanol content: ''Up to 15% ethanol'' below the word E15;
- The words and symbols ''Use only in • 2001 and newer passenger vehicles • Flex-fuel vehicles''; and
- The final two sentences: ''Don't use in other vehicles, boats, or gasoline-powered equipment. It may cause damage and is prohibited by Federal law.'' [14]

In this action, we are co-proposing two options with respect to the E15 label. Under the first option, we are proposing modifications to the label intended to provide additional clarity to consumers and decrease confusion. Under the second option, we are proposing to remove the label entirely.

1. Potential Modifications to the E15 Label

Our first co-proposal is to modify the existing E15 label, including:

- Removing the ''Attention'' stripe along the upper right corner of the label.
- Removing the phrase ''E15'' from the label, while including the language ''contains up to 15% percent ethanol''.
- Revising the language ''Use only in'' to ''Safe for use in''.
- Revising the language ''Don't use in'' to ''Avoid use in''.
- Revising the format of the word ''prohibited'' such that it is not in bold and italicized type.

We additionally propose modifications to the label in accordance with our existing alternative labels. At this time, there are two approved alternative labels for E15. One label includes the term ''or'' in between ''2001 and newer passenger vehicles'' and ''flex fuel vehicles.'' We believe the inclusion of ''or'' clarifies that both MY2001 and newer light-duty motor vehicles and flex fuel vehicles can permissibly use E15. The other approved alternative label includes ''motorcycles'' in the list of vehicles and engines in which E15 use is prohibited. Our first co-proposal proposes these modifications to the E15 label as well since we believe they more clearly convey which vehicles and engines can lawfully use E15.

We believe these modifications to the label would reduce confusion about the vehicles in which E15 can be used while also alerting consumers to the vehicles and engines in which E15 should not be used. We note that these modifications would also continue to comply with the requirements under the existing E15 partial waivers and thus would not require modifications to them.

Finally, we propose a modification to the colors utilized on the label. Consistent with the FTC fuel labels, we selected the orange color for our E15 label requirement in 2011; however, we recognize that another color may be better suited for the label. Some stakeholders [15] have suggested a blue and white label, instead of the orange label we currently use. The proposed regulatory text modifies the color of the label to a blue header, with white text, and white body with black text.[16] We alternatively propose to maintain the current orange and black label color design.

We seek comment on the proposed changes to the label, and specifically request input on what combination of modifications to the label would improve clarity regarding which vehicles can use E15 while protecting vehicles and engines for which E15 use is inappropriate. We recognize that the modifications proposed may be best implemented together, or in some alternative combination that does not include all of the proposed modifications. We specifically request information on any studies (*e.g.,* public survey or focus group studies) or information on consumer interaction with the label.

2. Potential Removal of the E15 Label Requirement

In the alternative, our second co-proposal is to remove the E15 label entirely. Selection of this option could also result in the elimination of the E15 survey requirement because it is currently required in order to verify that E15 fuel dispensers are labeled consistent with EPA's regulatory requirements, and would arguably no longer be necessary if the labeling requirement were removed.[17] Some stakeholders have suggested that removing the label would encourage the use of E15 by consumers who can lawfully use E15 but who do not do so because they are confused by the label.[18]

We note that, regardless of our proposal to remove the E15 label, the prohibition on the use of E15 in MY2000 and older light duty vehicles and all nonroad engines and equipment as codified at 40 CFR 80.1504 would remain in place. We continue to believe that E15, when used in those vehicles or engines, would cause or contribute to the impairment of emission control systems which would, in turn, result in negative effects on human health and welfare.

Were EPA's E15 label requirement to be removed, we believe that FTC's regulations would require that E15 dispensers be labeled according to FTC's label requirements.[19] We seek comment on the interaction between EPA and FTC's labels, recognizing that we cannot modify FTC's regulations in this action.

In order to completely remove the E15 label, we would need to also remove it from the requirements under the CAA section 211(f)(4) waiver, and likely clarify under the CAA section 211(f)(1) ''substantially similar'' determination that the fuel dispenser label would no longer be required. We seek comment on how to address the requirements under the CAA section 211(f) provisions.

3. Modification to Regulations

We note that we intend to finalize the proposed Fuels Regulatory Streamlining Rule (''Streamlining Rule'') with an implementation date of January 1, 2021, for most provisions, including the E15 label requirement. Under the Streamlining Rule, we proposed to transpose unchanged the current E15 misfueling mitigation measures from 40 CFR part 80, subpart N, into the new 40 CFR part 1090. Since the effective date of any final rulemaking for this action would likely be after January 1, 2021, we would effectuate the proposed E15 label modifications or removal of the E15 labeling requirement in 40 CFR part 1090.

[14] An image of the existing label is available in the memorandum ''Potential Label Changes,'' available in the docket for this action.

[15] See, *e.g.,* Comments from Growth Energy (Docket Item No. EPA–HQ–OAR–2010–0448–0083).

[16] We have provided mock-ups showing potential modifications to the label that might result from this proposal in the memorandum, ''E15 Label Revisions,'' available in the docket for this action.

[17] If we do remove the E15 label, we are not proposing to remove the Product Transfer Document (PTD) language requirements around ethanol content in gasoline-ethanol blended fuels. In addition to informing retailers of ethanol content for purposes of labeling E15 fuel dispensers, the PTD language requirements for ethanol are also necessary to identify which gasoline-ethanol blends can take advantage of the 1-psi waiver for RVP compliance.

[18] See Comments from Growth Energy (Docket Item No. EPA–HQ–OAR–2015–0202–0129).

[19] See 16 CFR part 306 and supra notes 4&5.

D. Request for Public Comment on E15 Labeling Preemption Considerations

Since promulgation of the MMR in 2011, EPA has also received information from some stakeholders that confusion is caused when there is more than one label displayed on some fuel dispensers. For this reason, EPA additionally seeks comment regarding the ability of state or local governments to require labeling of E15 pump dispensers.

As stated in the MMR,[20] EPA's authority to ''control or prohibit'' specifications for E15 pump dispenser labels is provided by CAA section 211(c)(1). Under CAA section 211(c)(4)(A), a state or local government may not adopt or enforce differing controls or prohibitions respecting labeling of E15 fuel dispensers if ''for purposes of motor vehicle emission control.'' [21] In the MMR, we also stated that we would evaluate questions regarding potential E15 pump dispenser labels preemption matters on a case-specific basis.[22]

Aside from the express preemption provided by CAA section 211(c)(4)(A), a state or local control for fuels or fuel additives may be implicitly preempted under the supremacy clause of the U.S. Constitution where the state requirement conflicts with Federal law by preventing compliance with the federal requirement, or by standing as an obstacle to accomplishment of the Federal objectives. Therefore, a state or local requirement respecting E15 pump label dispensers that is not expressly preempted under CAA section 211(c)(4)(A) nevertheless may be preempted if it meets the criteria for this constitutional conflict preemption.

In this action, we seek comment on whether there are certain types of labels that may be conflict-preempted from use. We encourage commenters to include examples of other labels they have observed that may raise such preemption questions and legal analysis to support their positions, to the extent feasible.

III. E15 Compatibility With Underground Storage Tanks

This section discusses our proposed revisions regarding compatibility with USTs.

A. Background on Underground Storage Tank Compatibility

As of 2020, EPA regulates over half-a-million UST systems that contain petroleum or hazardous substances. EPA's Office of Underground Storage Tanks was formed in response to the discovery in the early 1980s that thousands of USTs had leaked and contaminated groundwater supplies in the U.S. USTs form a crucial part of our country's fueling infrastructure. It is important for USTs to be constructed, maintained, and operated in a manner so that petroleum and other regulated substances are stored safely. We developed the UST regulation in 1988 to help owners and operators meet those goals, and a critical part of the regulation included the requirement for UST systems to be compatible with the substance stored. Incompatibility between fuels stored and UST system materials can result in equipment or components such as tanks, piping, gaskets, or seals becoming brittle, elongated, thinner, or swollen when compared with their condition when first installed. When this occurs, the UST system may fail to contain the regulated substance resulting in a release to the environment and possibly a failure to detect the release.

The U.S. fuel supply has changed significantly since 1988 and use of biofuels has grown rapidly. We understand that the chemical and physical properties of biobased fuels, such as ethanol and biodiesel, can be more degrading to certain UST system materials than petroleum alone. Changes in the fuel supply have caused unintended consequences to UST systems, including equipment failure and releases to the environment. As a result, in 2015 we revised the UST regulation and required owners and operators to provide additional notification, demonstration, and recordkeeping when storing fuel blends, such as those with more than 10 percent ethanol or more than 20 percent biodiesel.[23]

The use of biofuels has continued to grow since 2015. As described in Section II.B, in June 2019, we modified fuel regulations that allow E15 to utilize the 1-psi volatility waiver, which allows for increased E15 sale in the summer. That final rule means more UST owners and operators may opt to store and sell E15 at gas stations and other fueling facilities. E15 is now used in 30 states at 1,809 stations. Because of this continued growth of biofuels in the U.S., this action proposes to revise the 2015 UST regulation to grant certain allowances for compatibility demonstration and make it less burdensome for UST owners and operators to meet the current requirements. In addition, this action proposes a requirement that UST systems installed, or UST equipment and components replaced, must be constructed with equipment and components compatible with ethanol blends up to 100 percent. This requirement would become effective one year after the effective date of the final rule.

This proposal will make it easier for owners and operators to meet compatibility requirements with their current infrastructure, if unable to demonstrate compatibility. The proposal will also help ensure the future national UST infrastructure is compatible with a broad range of biofuels that come to market so service station owners can offer more choices to consumers. The fuel supply in the U.S. is constantly evolving; because future needs are somewhat unknown, we see value in promoting UST systems that can safely store a broad range of potential emerging fuels such as higher-level ethanol blends.

B. Proposed Changes to the UST Compatibility Requirements

1. Allowance—For Secondary Containment When Unableo To Demonstrate Compatibility

In the preamble to the 2015 UST regulation, we clarified that implementing agencies could allow use of secondary containment in lieu of being able to demonstrate compatibility of all UST system equipment and components required by the regulation. EPA had not previously allowed this but is proposing to do so now in this action. Owners and operators of UST systems already in existence one year after the effective date of this rule who cannot determine compatibility (*e.g.,* cannot find installation documentation) for all equipment and components are not required to demonstrate compatibility if the UST systems have secondarily contained tanks and piping (including safe suction piping) and use interstitial monitoring. This will still sufficiently protect the environment because secondary containment will contain a leak from the primary containment of the tank and piping, and interstitial monitoring will likely detect a leak before regulated substances reach the environment.

[20] See 74 FR 44406, 44431–32 (July 25, 2011).

[21] Except that under CAA section 211(c)(4)(C)(i), states other than California may prescribe and enforce non-identical measures if they seek and obtain EPA approval of State Implementation Plan revisions containing such control measures.

[22] See 74 FR 44432 (July 25, 2011).

[23] See 80 FR 41566 (July 15, 2015).

As of 2020, all states [24] require secondary containment for new and replaced UST systems, along with the requirement for interstitial monitoring to detect potential releases. Most states' requirements target new and replaced UST systems, which avoids added expenses for owners and operators to retrofit or replace existing systems to meet the requirements. Many states, including those in New England, New York, California, and Florida, required full or partial secondary containment prior to Congress passing Title XV, Section B of the Energy Policy Act of 2005 (EPAct). This act required states receiving Federal money under Subtitle I of the Solid Waste Disposal Act to require either secondary containment and under-dispenser containment for new and replaced underground storage tank systems or evidence of manufacturer and installer financial responsibility and installer certification. By 2008, 31 states had adopted the EPAct requirement. However, states' requirements for secondary containment and interstitial monitoring can differ, including when required and allowances for use of other release detection options when owners and operators chose to install secondary containment prior to it being required.

EPA's database, populated with publicly available information gathered from the individual state UST programs, helped us understand the number of UST systems nationally that are secondarily contained and where owners and operators are using interstitial monitoring to detect releases from their UST systems. Using state-supplied data, we identified 23 states that provide data on the number of UST systems with both double-wall tanks and double-wall piping. These secondarily contained systems should generally be capable of using interstitial monitoring for release detection, although some may currently use another method. This means that approximately 24 percent of the 225,000 USTs in these 23 states should be able to use secondary containment with interstitial monitoring, if they have compatible equipment but are currently unable to demonstrate it. The percentage is likely similar across the nation, but we seek comment on this issue.

Owners and operators should be aware that only leaks from equipment or components inside secondary containment will be contained. Fuel spills may still occur if other UST system components become non-functioning due to incompatibility since the equipment or component is not inside secondary containment. For example, if spill prevention equipment (*i.e.,* spill bucket) fails due to incompatibility, small spills from the delivery hose will not be contained by the tank and piping secondary containment. We encourage owners and operators to replace equipment that they cannot demonstrate as compatible if the equipment is accessible from ground level and replaceable with minimal investment.

2. Allowance—For Already Compatible Tanks and Piping

We identified equipment for which UST owners and operators would not need to demonstrate compatibility. Based on manufacturer statements and certification by independent testing laboratories, certain categories of equipment are known to be compatible with higher blends of ethanol. We believe that steel and fiberglass tanks manufactured after July 2005 are compatible with higher blends of ethanol fuels. This means that owners and operators will not need to demonstrate compatibility for these tanks. Likewise, we understand that all fiberglass reinforced plastic (FRP) piping is compatible with higher blends of ethanol fuel, so owners will not need to demonstrate compatibility for any FRP piping.

For other equipment, we are unaware of a fixed date or fixed category in which all equipment by any manufacturer is known to be compatible. As such, other than for the tank and piping items identified earlier in this section, owners and operators must adhere to the requirement in 40 CFR 280.32 to demonstrate compatibility.

However, we understand that some models of many equipment and components that must be demonstrated compatible were already compatible with higher blends of ethanol decades before these blends became common. UST owners and operators may already have this equipment installed. If they can demonstrate compatibility of certain existing equipment, they will not need to replace all of their equipment to demonstrate compatibility with higher blends of ethanol.[25]

For example, we understand that the following UST system equipment and components were available after the 1988 UST regulation and are compatible with higher blends of ethanol:

- Unlined steel single-wall tanks
- Unlined steel double-wall tanks

In addition, we understand that the following UST system equipment and components were available in a higher ethanol compatible version from at least one manufacturer as early as the years listed below. Many owners and operators might have a compatible piece of equipment, which can be confirmed and demonstrated as compatible by verifying documentation associated with the equipment manufacturer and installation.

- Single-wall fiberglass tanks: 1995
- Double-wall fiberglass tanks: 1990
- Flexible piping: 2011
- Fiberglass containment sumps: 1995
- Pumping equipment: 2010
- Spill equipment: 2015
- Release detection equipment: 2006
- Overfill equipment: 2006

We are requesting comment on the accuracy of this information and seek additional information on this matter.

3. Compatibility Requirements for New Installations and Replacements

We are proposing that owners and operators storing motor fuel used in over-the-road vehicles must ensure that new or replaced UST system equipment and components, including pipe dopes and sealants, are compatible with ethanol blends up to 100 percent. This applies regardless of whether the UST system currently stores or will store ethanol blends. This includes UST systems storing over-the-road diesel because service stations may in the future change to storing gasoline with higher blends of ethanol. However, we believe USTs storing fuel for emergency power generators and other off-road fuel used (such as fuel for construction equipment) should be exempt from this requirement. We seek comment on other potentially applicable exemptions. If an owner or operator is replacing specific equipment or components, such as a submersible turbine pump or containment sump, then only that replacement must be compatible with ethanol blends up to 100 percent. For entirely new UST system installations or replacements, the entire system must be compatible with ethanol blends up to 100 percent. We would require UST owners and operators to retain compatibility documentation for all new system equipment and components, including pipe dope, sealants, and gaskets, which are a common source of incompatibility.

This proposed requirement would become effective one year after the effective date of the final regulation. Since UST systems typically stay in the ground for decades—40 percent of active USTs are more than 30 years old—transitioning to compatible UST

[24] States includes all 50 states, 5 territories, and the District of Columbia.

[25] See *https://flexfuelforward.com/flexcheck.*

systems for emerging fuels can be very difficult. Implementing this requirement now will help ensure future fuel storage infrastructure can reliably store a larger variety of fuels. One hundred percent ethanol compatible material is readily available on the market today for all UST system equipment and components. The additional cost of a fully ethanol compatible system would be relatively minimal as a percentage of total cost of installation. This additional up-front investment would also avoid potentially significant upgrade costs, if future fuels contain greater volumes of ethanol or other alcohols.

C. Updates to State Program Approval Requirements

EPA has long recognized that, because of the size and diversity of the regulated community, state and local governments are in the best position to oversee USTs. State and local authorities are closer to the situation in their domain and are in the best position to set priorities. The 2015 state program approval (SPA) regulation in 40 CFR part 281 sets criteria state UST programs must meet to receive EPA's approval to operate in lieu of the Federal UST program. The SPA regulation sets performance criteria states must meet to be considered no less stringent than the Federal UST regulation and provides requirements for states to have adequate enforcement.

Much of the responsibility for implementing these proposed changes falls to state agencies. EPA will work with states to update their UST regulations and will support them in achieving state program approval. These proposed changes to the 2015 UST regulation, when final, will initially only apply to UST facilities in Indian country and in states that do not have SPA (owners and operators in states that do not have SPA must comply with the Federal UST regulation and their state regulations). For states that do have SPA these proposed changes will not apply until each state undertakes its own rulemaking. As of the date of publication of this notice, 15 [26] states do not have state program approval. For a list of states with state program approval, see *www.epa.gov/ust/state-underground-storage-tank-ust-programs.*

EPA is proposing to change the 2015 SPA regulation (40 CFR part 281) and make it consistent with these proposed revisions of the compatibility requirements of the 2015 UST regulation (40 CFR part 280). Specifically, EPA proposes that states require UST systems that store motor fuel for use in over-the-road vehicles be compatible with ethanol blends up to 100 percent when a new system is installed or when equipment and components are replaced. Since this is a more stringent requirement than what EPA required in its 2015 UST regulation, states would need to have or adopt this additional provision to be considered no less stringent than the corresponding Federal requirements.

States will have three years from the effective date of a final rule to submit to EPA a revised SPA application, including this change to their states' UST regulations. Since many states have recently been through this SPA application approval process for the 2015 UST regulation, EPA intends to make this additional modification to SPA an expedited process. EPA welcomes additional feedback on this.

D. Overview of Estimated Costs

The regulatory changes proposed today would provide cost savings to UST owners and operators as well as impose costs, and EPA is seeking comments on both.

1. Allowances—For Secondary Containment When Unable To Demonstrate Compatibility and for Already Compatible Tanks and Piping

The allowance described in this proposal for UST systems with secondary containment using interstitial monitoring when unable to demonstrate compatibility will provide owners and operators cost savings. Under this allowance, UST system owners and operators seeking to store ethanol blends up to 100 percent will not have to upgrade certain equipment and components simply because they are unable to demonstrate compatibility for that equipment and those components. As described in this preamble it is EPA's understanding that approximately 24 percent of all UST systems should be able to use secondary containment with interstitial monitoring, if they have compatible equipment but are currently unable to demonstrate it. This could mean that a significant portion of all facilities that seek to store higher blends of ethanol but are unable to demonstrate may not have to replace certain equipment. A rough estimate of replacement cost avoidance from this allowance can be made from informal estimates EPA has gathered from industry and regulators:

- Replacing tanks: $150,000 per tank.
- Replacing piping: $150,000 per facility.
- Ancillary equipment upgrades (most variable and configuration dependent): $1,000 $10,000 per UST system.

In addition, the other allowance proposed in this regulation to eliminate the requirement to demonstrate compatibility for all steel and fiberglass tanks manufactured after July 2005, and all FRP piping should provide some additional cost savings. EPA is seeking to verify this understanding and is looking for additional information or data to better understand the cost implications of today's proposal.

2. Compatibility Requirements for New Installations and Replacements

This proposal imposes compatibility requirements for up to 100 percent ethanol for certain (*i.e.,* storing motor fuel used in over-the road-vehicles) new installations and replacements of UST system equipment and components regardless of whether the UST system currently stores or will store ethanol blends. This means, for example that an UST owner and operator needing to replace equipment such as a containment sump or spill bucket must make that replacement with equipment that is compatible with up to 100 percent ethanol. EPA understands that the marginal cost for any new UST system equipment or components compatible with up to 100 percent ethanol is minimal compared with the overall project costs (*i.e.,* design, construction, installation etc). EPA estimates the additional costs for purchasing up to 100 percent compatible equipment or components could be significantly less than 5% of the overall project costs and is seeking comment on this estimate. Some major UST components and equipment manufactured today (*e.g.,* tanks, piping) are all already compatible with up to 100 percent ethanol so there is no cost increase to accommodate the higher blends for those purchases. However, there is certain equipment where the cost of the up to 100 percent ethanol compatible model may be higher (*e.g.,* overfill device).

EPA is seeking to verify this understanding and is looking for additional information or data to better understand the cost implications of this action.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

[26] States and territories without SPA—AK, AZ, CA, FL, IL, MI, NJ, NY, OH, WI, WY and AS, GU, CNMI, VI.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action because it raises novel legal or policy issues. Nevertheless, after reviewing information regarding this action, the Office of Management and Budget waived review of this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action. We seek comment on any burdens and costs associated with this rulemaking.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2655.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This proposed regulation would either change the existing, approved E15 label (approved under OMB Control Number 2060–0675)—or remove it entirely. Should the E15 label be modified, then there would be a cost associated with affixing the amended label to pumps from which fuel is dispensed. We have also allowed that some parties may need to purchase labels. Parties required to affix labels are typically parties who own or operate retail stations or wholesale-purchases consumer facilities. Should the E15 labeling requirement be removed entirely, then there would no longer be any E15 label required and we would anticipate a cost savings to industry.

This proposed regulation would also require owners and operators of underground storage tanks (UST) to maintain records of compatibility at new UST installations and replacements storing motor fuels used in over the road transportation. This new requirement is only intended for UST systems storing motor fuel used in over-the-road transportation, not for UST systems fueling emergency power generators nor other UST systems used for off-road purposes such as construction equipment. In the existing regulation, owners and operators of USTs storing product containing more than 10 percent ethanol or more than 20 percent biodiesel are required to maintain records to demonstrate compatibility with the product stored. This action proposes to grant certain allowances for this current UST system compatibility demonstration requirement, which reduces information collection burden for some UST systems. The existing requirements for owners and operators of USTs are under OMB Control Number 2060–0068.

Respondents/affected entities: Retailers and wholesale purchaser-consumers who dispense E15; owners and operators of UST systems.

Respondent's obligation to respond: Mandatory under 40 CFR part 80, subpart N, (E15 labeling)—and 40 CFR part 280, subparts B and C; and 40 CFR part 281, subpart C (UST).

Estimated number of respondents: 1,801 retail and wholesale purchaser-consumers for the E15 labeling provisions and 10,331 owners and operators for the UST provisions.

Frequency of response: Once, as needed and on occasion.

Total estimated burden: 37 hours (per year) for the E15 labeling and 2,799 hours (per year) for USTs. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,785 (per year) for E15 labeling, which includes $2,952 annualized capital or operation & maintenance costs; and $65,515 for UST, which includes $0 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket for this action. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 18, 2021. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are retail motor fuels firms and small government jurisdictions.

With respect to the E15 fuel dispenser label portion of this action, the proposed changes to the E15 label under option 1 of this action do not substantively alter the regulatory requirements on parties that make and distribute E15. The removal of the E15 label under option 2 of this action would reduce burden on all regulated parties that sell E15, including small entities, and therefore would not impose any requirements on small entities.

With respect to the E15 compatibility with underground storage tanks provisions of this action, in EPA's 2015 UST rulemaking we determined that less than 1 percent of potentially affected small firms in the retail motor sector (NAICS 447) would experience an impact over 1 percent of revenues, but less than 3 percent of revenues and that no small firms would have impacts above 3 percent of revenues.[27] In the 2015 rulemaking we also determined that no small government jurisdictions would be impacted at 1 percent or 3 percent of revenues.[28] Since this action proposes a small change to the 2015 regulation, we do not expect any significant impacts to small entities. EPA seeks comment on any cost impacts.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments. Requirements for the private sector do not exceed $100 million in any one year.

F. Executive Order 13132: Federalism

This proposed action does not have federalism implications. The E15 label portion of this action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. For the E15 compatibility with underground storage tanks portion of this action, the total costs of this proposed rule (direct compliance costs, notification costs and

[27] See 80 FR 41620–21 (July 15, 2015) and Section 5.4 of the Regulatory Impact Analysis (RIA) for that action, ''Assessment Of The Potential Costs, Benefits, And Other Impacts Of The Final Revisions To EPA's Underground Storage Tank Regulations.''

[28] Id.

state program costs) will be small. In our much larger rule in 2015 these total costs were only $9 million which is not considered to be a substantial compliance costs under Federal requirements. Therefore, we believe Executive Order 13132 will not apply to this rule which we expect to have lower costs than the 2015 rule. EPA is requesting comment on the expected costs of this proposed rule. In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between EPA and State and local governments, EPA will specifically solicit comment from state and local government during the comment period.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action proposes to either change EPA's existing E15 label or remove the labeling requirement entirely. There are no additional costs for sources in the energy supply, distribution, or use sectors.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This proposed action does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). For the E15 label portion of this action, this proposed rule maintains the prohibition on the use of E15 in 2000 and older light duty vehicles, as well as all motorcycles, and nonroad vehicles, engines, and equipment, which could result in increases in emissions. For the E15 compatibility with underground storage tanks portion of this action, EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

V. Statutory Authority

Statutory authority for the E15 label portion of this action comes from section 211 of the Clean Air Act, 42 U.S.C. 7545. Statutory authority for the E15 compatibility with underground storage tanks section of this action comes from the Resource Conservation and Recovery Act sections 9001 *et seq.,* 42 U.S.C. 6991 *et seq.*

List of Subjects

40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Fuel additives, Gasoline, Labeling, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

40 CFR Parts 280 and 281

Environmental protection, Administrative practice and procedure, Hazardous substances, Petroleum, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR parts 80, 280, and 281 as follows:

PART 80—REGISTRATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

■ 2. Revise § 80.1501 to read as follows:

§ 80.1501 Labeling requirements that apply to retailers and wholesale purchaser-consumers of gasoline that contains greater than 10 volume percent ethanol and not more than 15 volume percent ethanol.

(a) Any retailer or wholesale purchaser-consumer who sells, dispenses, or offers for sale or dispensing E15 must affix the following conspicuous and legible label to the fuel dispenser:

Contains up to 15% ethanol
Safe for use in

- 2001 and newer passenger vehicles; or
- Flex-fuel vehicles

Avoid use in other vehicles, motorcycles, boats, or gasoline-powered equipment. It may cause damage and is prohibited by Federal law.

(b) Labels under this section must meet the following requirements for appearance and placement:

(1) *Dimensions.* The label must measure 3 and ⅝ inches wide by 3 and ⅛ inches high.

(2) *Placement.* The label must be placed on the upper two-thirds of each fuel dispenser where the consumer will see the label when selecting a fuel to purchase. For dispensers with one nozzle, the label must be placed above the button or other control used for selecting E15, or in any other manner which clearly indicates which control is used to select E15. For dispensers with multiple nozzles, the label must be placed in the location that is most likely to be seen by the consumer at the time of selection of E15.

(3) *Text.* The text must be justified and the fonts and backgrounds must be as described in paragraphs (b)(3)(i) through (vi) and (b)(4)(i) through (iv) of this section.

(i) The ethanol content: ''Contains up to 15% ethanol'' must be in 18-point, center-justified, white, Helvetica Black font in the top 1.25 inches of the label.

(ii) The words ''Safe for use in'' must be in 20-point, left-justified, black, Helvetica Bold font in the bottom 1.875 inches of the label.

(iii) The words, and symbols ''• 2001 and newer passenger vehicles; or
• Flex-fuel vehicles'' must be in 14-point, left-justified, black, Helvetica Bold font.

(iv) The remaining two sentences must be in 12-point, left-justified, Helvetica Bold font.

(4) *Color.* (i) The background of the top 1.25 inches of the label must be blue.

(ii) The background of the bottom 1.875 inches of the label must be white.

(5) *Alternative labels.* (i) Alternative labels to those specified in this section may be used if approved by EPA in advance. Such labels must contain all of the informational elements specified in paragraph (a) of this section, and must use colors and other design elements similar in substance and appearance to the label required by this section. Such labels may differ in size and shape from the label required by this section only to a small degree, except to the extent a larger label is necessary to accommodate additional information or translation of label information.

(ii) A request for approval of an alternative label must be sent to the attention of ''E15 Alternative Label Request'' to the address in § 80.10(a).

PART 280—TECHNICAL STANDARDS AND CORRECTIVE ACTION REQUIREMENTS FOR OWNERS AND OPERATORS OF UNDERGROUND STORAGE TANKS (UST)

■ 3. The authority citation for part 280 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991, 6991(a), 6991(b), 6991(c), 6991(d), 6991(e), 6991(f), 6991(g), 6991(h), 6991(i).

■ 4. Amend § 280.20 by adding a sentence after the first sentence in the introductory text to read as follows:

§ 280.20 Performance standards for new UST systems.

* * * Owners and operators must also comply with the requirement of § 280.32(b) when equipment or components are installed or replaced, as applicable. * * *

* * * * *

■ 5. Amend § 280.32 by revising paragraph (b) and adding paragraphs (c) and (d) to read as follows:

§ 280.32 Compatibility

* * * * *

(b) In addition to the requirements at § 280.20, owners and operators of UST systems which will store motor fuel used in over-the-road vehicles must ensure that equipment and components, including pipe dopes and sealants, that are installed or replaced on or after [1 year after effective date of final regulations] are compatible with ethanol blends up to 100 percent. Owners and operators must keep documentation of compatibility in accordance with paragraph (c)(1) of this section and keep documentation on compatibility of pipe dopes and sealants.

(c) Owners and operators must notify the implementing agency at least 30 days prior to switching to a regulated substance containing greater than 10 percent ethanol, greater than 20 percent biodiesel, or any other regulated substance identified by the implementing agency. In addition, owners and operators with UST systems storing these regulated substances must meet one of the following:

(1) Demonstrate compatibility of the UST system (including the tank, piping, containment sumps, pumping equipment, release detection equipment, spill equipment, and overfill equipment). Owners and operators may demonstrate compatibility of the UST system by using one of the following options, though no demonstration is required for tanks manufactured on or after July 2005 or for any fiberglass piping:

(i) Certification or listing of UST system equipment or components by a nationally recognized, independent testing laboratory for use with the regulated substance stored; or

(ii) Equipment or component manufacturer approval. The manufacturer's approval must be in writing, indicate an affirmative statement of compatibility, specify the range of biofuel blends the equipment or component is compatible with, and be from the equipment or component manufacturer.

(2) All UST systems must be compatible with the substance stored in accordance with paragraph (a) of this section but for any UST system installed prior to 1 year after the date of publication of the final rule in the **Federal Register** for which compatibility cannot be demonstrated in accordance with paragraph (c)(1) of this section, the regulated substance may be stored if the tank and piping are secondarily contained and use interstitial monitoring in accordance with § 280.43(g). Secondary containment must be able to contain regulated substances leaked from the primary containment until they are detected and removed and prevent the release of regulated substances to the environment at any time during the operational life of the UST system.

(3) Use another option determined by the implementing agency to be no less protective of human health and the environment than the options listed in paragraph (c)(1) of this section.

(d) Owners and operators must maintain records in accordance with § 280.34(b) documenting compliance with paragraph (b) *of this section* for the life of the UST system and paragraph (c) of this section for as long as the UST system is used to store the regulated substance.

§ 280.34 [Amended]

■ 6. Amend § 280.34 paragraph (a)(2) by removing ''(§ 280.32(b))'' and adding ''(§ 280.32(c))'' in its place; and in paragraph (b)(3) by removing ''(§ 280.32(c))'' and adding ''(§ 280.32(b) and (c))'' in its place.

PART 281—APPROVAL OF STATE UNDERGROUND STORAGE TANK PROGRAMS

■ 7. The authority citation for part 281 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991(c), 6991(d), 6991(e), 6991(i), 6991(k).

■ 8. Amend § 281.32 by revising paragraph (c) and the first sentence of paragraph (g) to read as follows:

§ 281.32 General operating requirements

* * * * *

(c) Be made of or lined with materials that are compatible with the substance stored; in order to ensure compatibility, the state requirements must also include provisions for demonstrating compatibility with new and innovative regulated substances or other regulated substances identified by the implementing agency or include other provisions determined by the implementing agency to be no less protective of human health and the environment than the provisions for demonstrating compatibility; for UST systems that will store motor fuel used in over-the-road vehicles, all newly installed or replaced equipment or components, including pipe dopes and sealants, must be compatible with ethanol blends up to 100 percent;

* * * * *

(g) Have records of monitoring, testing, repairs, compatibility demonstration, and inspections. * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 433, 447, 455, and 457

[CMS–2393–WN]

RIN 0938–AT50

Medicaid Program; Medicaid Fiscal Accountability Regulation

ACTION: Withdrawal of proposed rule.

SUMMARY: This document withdraws a proposed rule that was published in the **Federal Register** on November 18, 2019. The proposed rule would have established new reporting requirements and codified other Medicaid financing requirements, including related to permissible sources for non-federal share financing.

DATES: The proposed rule on Medicaid Fiscal Accountability Regulation, published on November 18, 2019 at 84 FR 63722 is withdrawn January 21, 2021.

ADDRESSES: In commenting, please refer to file code CMS–2393–WN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-*2393–WN,* P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2393–WN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

Andrew Badaracco, (410) 786–4589, Richard Kimball, (410) 786–2278, and Daniil Yablochnikov, (410) 786–8912, for Medicaid Provider Payments, Supplemental Payments, Upper Payment Limits, Provider Categories, Intergovernmental Transfers, and Certified Public Expenditures.

Timothy Davidson, (410) 786–1167, Jonathan Endelman, (410) 786–4738, and Stuart Goldstein, (410) 786–0694, for Health Care-Related Taxes, Provider-Related Donations, and Disallowances.

Lia Adams, (410) 786–8258, Charlie Arnold, (404) 562–7425, Richard Cuno, (410) 786–1111, and Charles Hines, (410) 786–0252, for Medicaid Disproportionate Share Hospital Payments and Overpayments.

Jennifer Clark, (410) 786–2013, and Deborah McClure, (410) 786–3128, for Children's Health Insurance Program (CHIP).

SUPPLEMENTARY INFORMATION: On November 18, 2019, we published a proposed rule that proposed to amend our regulations dealing with grants to states for medical assistance programs, state fiscal administration, payments for services, Medicaid program integrity, and allotments to states and grants. (84 FR 63722). After an internal review of the proposed rule, CMS has decided to withdraw the proposed rule.

The proposed rule sought to promote accountability and transparency for Medicaid payments by establishing new reporting requirements for states to provide CMS with certain information on supplemental payments to Medicaid providers, including supplemental payments approved under either Medicaid state plan or demonstration authority, codification of parameters for Medicaid upper payment limit calculations, provider definitions associated with data reporting and Medicaid financing, Medicaid disproportionate share hospital audit requirements and changes to some existing operational processes to better align with technology improvements. This proposed rule also sought to establish additional requirements to ensure that state plan amendments proposing new supplemental payments are consistent with the proper and efficient operation of the state plan and with efficiency, economy, and quality of care. Finally, this proposed rule sought to address the non-federal share financing of supplemental and base Medicaid payments, including states' uses of health care-related taxes and provider-related donations, and other requirements for sources of the non-federal share.

We received approximately 10,188 individual comments (4,225 unduplicated comment submissions) through the extended comment period.[1] We received significant comments on the proposed rule regarding its potential impact on states and their budgets, Medicaid providers and Medicaid beneficiary access to needed services. Many commenters stated their belief that the proposed rule did not include adequate analysis of these matters. Numerous commenters indicated that CMS, in some instances, lacked statutory authority for its proposals and was creating regulatory provisions that were ambiguous or unclear and subject to excessive Agency discretion.

While we continue to support the intent and purpose of the rule to increase fiscal accountability and improve transparency in the Medicaid program, based on the considerable feedback we received through the public comment process, we have determined it appropriate to withdraw the proposed provisions at this time. Moving forward, we want to ensure agency flexibility in re-examining these important issues and exploring options and possible alternative approaches that best implement the requirements of the Medicaid statute. We also believe it is important to re-examine and fully analyze the proposed Medicaid reporting requirements in consideration of the recent Congressional action through the Consolidated Appropriations Act of 2021 (H.R. 116–133, Pub. L. 116–260) which establishes new statutory requirements for Medicaid supplemental payment reporting. This withdrawal action does not limit our prerogative to make new regulatory proposals in the areas addressed by the withdrawn proposed rule, including new proposals that may be substantially identical or similar to those described therein.

Finally, the withdrawal of this proposed rule does not affect existing federal legal requirements or policy that were merely proposed to be codified in regulation, including certain provisions related to Medicaid financing and Medicaid Upper Payment Limit (UPL) requirements. For example, without limitation, this includes guidance in State Medicaid Director Letter (SMDL) #13–003, which discussed a submission process to comply with the UPL requirements; SMDL #14–004, which discussed Medicaid financing and provider-related donations; as well as State Health Officials (SHO) Letter #14–001, which addressed health care-related taxes. This withdrawal action does not affect CMS' ongoing application of existing statutory and regulatory requirements or its

[1] On December 30, 2019, CMS extended the comment period for the November 18, 2019, proposed rule by 15 days, from January 17, 2020, to February 1, 2020, in response to feedback from stakeholders indicating additional time was needed to review the proposed rule in light of several holidays and the complexity of the rule.

responsibility to faithfully administer the Medicaid program.

Dated: January 12, 2021.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 12, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–01078 Filed 1–14–21; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL MARITIME COMMISSION

46 CFR Part 530

[Docket No. 20–22]

RIN 3072–AC84

Service Contracts

AGENCY: Federal Maritime Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Maritime Commission proposes to amend its service contract filing requirements to permit ocean common carriers to file original service contracts up to 30 days after the contract goes into effect.

DATES: Submit comments on or before March 5, 2021.

In compliance with the Paperwork Reduction Act (PRA), the Commission is also seeking comment on revisions to an information collection. See the Paperwork Reduction Act section under Rulemaking Analyses and Notices below. Please submit all comments relating to the revised information collection requirements to the FMC and to the Office of Management and Budget (OMB) at the address listed below under **ADDRESSES** on or before March 22, 2021. Comments to OMB are most useful if submitted within 30 days after publication.

ADDRESSES: You may submit comments, identified by Docket No. 20–22, by the following methods:

- *Email: secretary@fmc.gov.* For comments, include in the subject line: ''Docket No. 20–22, Comments on Service Contract Rulemaking.'' Comments should be attached to the email as a Microsoft Word or text-searchable PDF document.

Comments regarding the proposed revisions to the relevant information collection should be submitted to the FMC through one of the preceding methods and a copy should also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Federal Maritime Commission, 725 17th Street NW, Washington, DC 20503; by Fax: (202) 395–5167; or by email: *OIRA_Submission@OMB.EOP.GOV.*

Instructions: For detailed instructions on submitting comments, including requesting confidential treatment of comments, and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to the Commission's website, unless the commenter has requested confidential treatment.

Docket: For access to the docket to read background documents or comments received, go to the Commission's Electronic Reading Room at: *https://www2.fmc.gov/readingroom/proceeding/20-22/.*

FOR FURTHER INFORMATION CONTACT: Rachel E. Dickon, Secretary; Phone: (202) 523–5725; Email: *secretary@fmc.gov.*

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I. Executive Summary

The Shipping Act of 1984, as amended (46 U.S.C. 40101–41309) (Shipping Act or Act) permits ocean common carriers and shippers to enter into individual, confidential service contracts for the international transportation of cargo, and requires that these contracts be filed with the Federal Maritime Commission. Under the current regulations in 46 CFR part 530, original service contracts must be filed on or before their effective date, while service contract amendments must be filed within 30 days *after* they go into effect. The disparate treatment of original service contracts versus amendments was the result of a 2016–2017 rulemaking in which the Commission determined to allow delayed filing for amendments while retaining the requirement that original service contracts be filed on or before their effective date.

In response to the COVID–19 pandemic and its impact on service contract negotiation and filing, the Commission recently granted a temporary exemption permitting original service contracts, like amendments, to be filed up to 30 days after their effective date. Based on the Commission's experience during the exemption period and the perceived benefits of allowing delayed filing for original service contracts, the Commission has tentatively determined to make the status quo permanent. Accordingly, the Commission is proposing to revise its service contract regulations in part 530 to allow original service contracts, like amendments, to be filed up to 30 days after they go into effect. The Commission is also proposing several technical amendments to the service contract regulations.

The Commission requests comments on these proposed amendments and any other amendments necessary to implement delayed filing for original service contracts.

II. Background

A. Service Contract Requirements

The Shipping Act permits ocean common carriers and shippers to enter into individual, confidential service contracts for the international transportation of cargo, and requires that these contracts be filed with the Federal Maritime Commission.[1] For many years, the Commission's implementing regulations required that ocean common carriers file all service contracts and amendments with the Commission before the contract or amendment could go into effect.[2]

B. 2016–2018 Rulemakings

In 2016, the Commission published an advanced notice of proposed rulemaking (ANPRM) to revise its regulations governing service contracts and non-vessel-operating common carrier (NVOCC) negotiated service arrangements (NSAs).[3] The rulemaking was based on the Commission's retrospective review of its regulations and feedback from the industry and shippers. One suggestion from ocean common carriers was to allow service contract amendments to go into effect

[1] *See* 46 U.S.C. 40502.

[2] *See, e.g.,* 46 CFR 530.8(a) (2016).

[3] ANPRM: Service Contracts and NVOCC Service Arrangements, 81 FR 10198 (Feb. 29, 2016).

before filing with the Commission, provided that the amendment was filed within 30 days after the earlier of: (1) The date the parties agreed to the amendment; or (2) the date the carrier received cargo to which the amendment applied.[4] Beneficial cargo owners and NVOCCs that provided feedback to the Commission, however, indicated that filing amendments prior to the acceptance of cargo protected rate and contract commitments, and these shippers were confident ocean common carriers would honor the rates and contract commitments knowing that the contracts were filed with the Commission.[5] Notwithstanding these concerns, the Commission requested comment on the carriers' proposal.[6]

The Commission subsequently published an NPRM in 2016 that proposed, among other things, to allow service contract amendments to be filed up to 30 days after the effective date.[7] The Commission noted that the majority of commenters to the ANPRM supported the change and some advocated extending the same relief to the filing of original service contracts.[8] Responding to the these comments, the Commission initially discussed how the existing requirements protected shipper interests by demonstrating agreement among the parties prior to the movement of cargo, and that shippers had expressed confidence in this process knowing that both the shipper and carrier would honor the commitment of their service contract filed with the Commission.[9] The Commission moved on to distinguish original service contracts from service contract amendments, describing an original service contract as ''a comprehensive agreement between the parties that encompasses the commodities that are to be shipped, the origins and destinations between which cargo is to move, the rates for the transportation of that cargo, as well as terms and conditions governing the transportation of goods for the shipper.'' [10] The Commission described service contract amendments, on the other hand, as ''more limited in scope, generally adding new commodities and/or rates.'' [11] The Commission therefore proposed to allow filing of service contract amendments up to 30 days after going into effect, but declined to propose extending the same treatment to original service contracts ''given their nature and the Commission's belief that doing so would diminish its oversight abilities.'' [12]

The Commission published a final rule in 2017 adopting, among other changes, the proposed change to permit filing of service contract amendments up to 30 days after the effective date.[13] Carriers and shippers had asserted in their comments that the service contract effective date requirement was overly restrictive, particularly with respect to service contract amendments, and stated that the majority of amendments were for minor revisions to commercial terms, such as a revised rate or the addition of a new origin/destination or commodity.[14] The Commission also cited carrier claims that, in certain instances, parties had agreed to amend a service contract, but the cargo was received before the carrier filed the amendment with the Commission, meaning that the rates and terms in the amendment could not be applied to the cargo under the Commission's regulations.[15] The Commission concluded that permitting delayed filing was warranted because: (1) It would reduce the filing burdens on the industry by allowing carriers to file multiple amendments made within a 30-day period at the same time rather than on a piecemeal basis; (2) it would avoid the commercial harm associated with failing to timely file an amendment and allow the parties to apply the agreed rates and terms to the intended shipments; and (3) the Commission would maintain the ability to protect the shipping public.[16]

In discussing a related proposal that the service contract correction process be amended to permit carriers to submit inadvertently unfiled original service contracts and amendments to the Commission within 180 days, the Commission determined that ''[i]n the case of original service contracts, shipper protections at the time of contracting and for the ensuing contract term are best assured by requiring that the agreement be contemporaneously filed as the best evidence of the actual agreement between the parties when first reached.'' [17] The Commission expressed concern that delayed filing of service contracts could negatively affect its ability to investigate and enforce the Shipping Act because ''[u]nlike those limited and modest revisions to accommodate industry needs for correction of contract amendments, failure to file the original contract may conceal the very existence of a contractual arrangement in a given trade lane or lanes, avoiding early detection of market-distorting practices by individual carriers.'' [18]

Following publication of the 2017 service contract/NSA final rule, the Commission initiated a separate rulemaking in 2017 to address regulatory revisions proposed by the National Customs Brokers and Forwarders Association of America in a 2015 petition.[19] Although this rulemaking focused on NSAs and NVOCC Negotiated Rate Arrangements (NRAs), the Commission discussed the World Shipping Council's (WSC) comments on the 2015 petition regarding the implementation of similar changes to the service contract requirements.[20] The Commission noted that these comments predated the 2016–2017 service contract/NSA rulemaking, and with the publication of the final rule in that proceeding, the Commission had substantially met the WSC's request for regulatory relief for ocean common carriers.[21] The Commission stated that any further relief related to service contracts could be undertaken after the Commission had an opportunity to analyze the impact of the recent changes on carrier operations and shippers.[22]

C. 2018 World Shipping Council Petition for Exemption

In 2018, the WSC petitioned the Commission for an exemption from the service contract filing and essential terms publication requirements.[23] The Commission denied the request for exemption from the service contract filing requirements but granted the request for exemption from the essential terms publication requirements.[24] Although the petition and subsequent Commission decision were focused on eliminating the service contract filing requirement entirely, delayed filing was discussed. For example, as part of the Commission's analysis of the potential economic harm that could result from

[4] *Id.* at 10201.

[5] *Id.*

[6] *Id.*

[7] NPRM: Amendments to Regulations Governing Service Contracts NVOCC Service Arrangements, 81 FR 56559 (Aug. 22, 2016).

[8] *Id.* at 56562.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] Final Rule: Amendments to Regulations Governing Service Contracts NVOCC Service Arrangements, 82 FR 16288 (Apr. 4, 2017).

[14] *Id.* at 16290.

[15] *Id.*

[16] *Id.*

[17] *Id.* at 16293.

[18] *Id.*

[19] NPRM: Amendments to Regulations Governing NVOCC Negotiated Rate Arrangements and NVOCC Service Arrangements, 82 FR 56781 (Nov. 30, 2017).

[20] *Id.* at 56785.

[21] *Id.*

[22] *Id.*

[23] *See Pet. of World Shipping Council for an Exemption from Certain Provisions of the Shipping Act of 1984, as amended, for a Rulemaking Proceeding,* 1 F.M.C.2d 504 (FMC 2019).

[24] *Id.*

eliminating the filing requirement, the Commission pointed to the shipper comments discussed in the 2016–2017 service contract/NSA rulemaking indicating that the filing requirement encouraged ocean common carriers to adhere to contract terms and deterred them from introducing unreasonable terms into service contract boilerplate language.[25] The Commission also stated that delayed filing for service contract amendments addressed a number of the issues raised by commenters.[26] Finally, in response to WSC's argument that maintaining the filing requirement would negatively impact the ability of NVOCCs to use the expedited contract acceptance and effective date provisions implemented by the Commission in the recent 2017–2018 NSA/NRA rulemaking, the Commission pointed out that WSC's assertion was based on the premise that service contract filing delays the effectiveness of service contracts.[27] The Commission noted that WSC had not alleged that such a delay existed nor had Commission experience shown such a delay, and in the absence of such a showing, the Commission did not believe that granting WSC's petition was necessary to give full effect to the changes made in the 2018 NSA/NRA final rule.[28]

D. 2020 Exemptions

The spread of coronavirus disease 2019 (COVID–19) in 2020 had a significant effect on the global freight delivery system, including service contract negotiation and implementation.[29] Many businesses began working remotely because of social distancing guidance and stay-at-home orders.[30] For some entities, this situation, combined with other COVID–19-related disruptions to commercial operations, made complying with service contract filing requirements difficult.

To allow parties time to adapt to the increased pressures from COVID–19 and minimize disruptions to the contracting process, the Commission issued a temporary blanket exemption on April 27, 2020, extending the filing flexibilities for service contract amendments to original service contracts.[31] The exemption is conditioned on carriers continuing to file original service contracts, subject to the same delayed filing requirements as service contract amendments (*i.e.,* original service contracts must be filed within 30 days after the effective date). The exemption was originally set to expire December 31, 2020, but the Commission recently extended it until June 1, 2021.[32]

On October 7, 2020, CMA CGM, S.A. and its corporate affiliates petitioned the Commission for an exemption from the service contract filing and tariff publishing requirements to mitigate the effects of a cyberattack on their information systems.[33] While the carriers stated that they appreciated the flexibility afforded by the temporary exemption, they requested further exemption from the filing requirements with respect to original service contracts and amendments to permit them to be filed more than 30 days after they went into effect. The Commission granted the exemption on October 20, 2020, and the exemption expired on November 26, 2020.

III. Proposed Changes

As discussed above, the Commission expressed concern during the 2016–2017 rulemaking about permitting original service contracts to be filed after their effective date, and decided to limit delayed filing to amendments. But the Commission did not permanently foreclose future changes to the service contract requirements, stating in the 2017 NSA/NRA NPRM that further relief related to service contracts could be undertaken after the Commission had an opportunity to analyze the impact of the 2017 final rule on carriers and shippers.[34] In line with this statement, the Commission has reexamined the issue of allowing delayed filing for original service contracts after considering both the agency's experience over the last three years with delayed filing of amendments and the recent experience with delayed filing of original service contracts under the current temporary exemption.

The Commission has tentatively concluded that permanently allowing delayed filing of original service contracts will provide the same type of benefits as delayed filing of service contract amendments, namely avoiding the commercial harm associated with situations in which cargo is received after the parties have agreed to a service contract but before the service contract is filed with the Commission. The need for this flexibility has been amply demonstrated by recent events, including the commercial disruption, social distancing, and stay-at-home orders stemming from COVID–19, which has impacted carriers' ability to file service contracts and prompted the Commission to grant a temporary exemption. And in CMA CGM's recent exemption petition in response to a cyberattack, the carrier cited with appreciation the flexibility afforded by the ability to file service contracts and amendments after their effective date. These recent events demonstrate that, in certain circumstances, requiring that service contracts be filed before they go into effect can potentially delay performance under the contract to the detriment of shippers.

The Commission has also tentatively concluded that allowing original service contracts to be filed up to 30 days after the effective date will not materially impact the agency's ability to provide oversight and protect the shipping public. Of particular importance, the Commission has not received any shipper complaints regarding delayed filing of amendments or the recent exemption allowing delayed filing of original service contracts. The Commission believes that the service contract filing requirement will continue to ensure adherence to service contract terms and deter the introduction of unreasonable terms, regardless of whether original service contracts are filed before, on, or after the effective date.[35] And the proposed amendments make clear that original service contracts and amendments will continue to be prospective in nature, ensuring that the parties have reached agreement *before* cargo moves under the contract.

Although the Commission continues to recognize that original service contracts are more comprehensive in scope than amendments, the Commission has tentatively concluded that this difference does not support different filing requirements. Under the proposed rule, the Commission would continue to monitor filed service contracts, and delayed filing would not negatively impact the Commission's ability to investigate potential Shipping Act violations given the relatively short

[25] *Id.* at 510 (citing ANPRM: Service Contracts and NVOCC Service Arrangements, 81 FR 10198, 10201 (Feb. 29, 2016).

[26] *Id.* at 513.

[27] *Id.* at 514–515 (referring to Final Rule: Amendments to Regulations Governing NVOCC Negotiated Rate Arrangements and NVOCC Service Arrangements, 83 FR 34780 (July 23, 2018)).

[28] *Id.* at 515.

[29] *Temporary Exemption from Certain Service Contract Requirements,* 2 F.M.C.2d 65 (FMC 2020).

[30] *Id.* at 65.

[31] *Id.* at 65–67.

[32] *Temporary Exemption from Certain Service Contract Requirements,* Docket No. 20–06, 2020 FMC LEXIS 206 (FMC Oct. 1, 2020).

[33] *Pet. of CMA CGM, S.A.,* Pet. No. P2–20, slip op. (Oct. 20, 2020).

[34] 82 FR at 56785.

[35] As discussed above, the Commission recently reaffirmed its commitment to retaining the service contract filing requirement in its decision to deny WSC's exemption request. *Pet. of World Shipping Council,* 1 F.M.C.2d 504.

filing period being proposed (30 days after the effective date).[36]

Based on the foregoing, the Commission is proposing to revise its service contract regulations in part 530 to allow original service contracts, like amendments, to be filed up to 30 days after the effective date. The proposed revisions are also intended to clarify that the trigger for the 30-day filing period is the effective date of the service contract or amendment.

In addition, the Commission is proposing technical amendments to the service contract regulations following the Commission order and subsequent rulemaking to exempt ocean common carriers from the requirement to publish service contract essential terms.[37] These amendments would: (1) Remove a reference to essential terms publication that was inadvertently retained; and (2) add language describing the exemption to ensure that ocean common carriers and other stakeholders that may not know the history of the matter are aware of the exemption.

The Commission requests comments on these proposed amendments and any other amendments necessary to implement delayed filing for original service contracts.

A. Delayed Filing for Original Service Contracts

1. Definition of ''Effective Date'' (§ 530.3)

The current definition of ''Effective date'' describes: (1) What an effective date is; (2) the relationship between the effective date and the filing date for both original service contracts and amendments (*i.e.,* the effective date may not be before the filing date for original service contracts or more than 30 days prior to the filing date for amendments); and (3) the specific time on the effective date when an original service contract or amendment is effective (12:01 a.m. Eastern Standard Time).

The Commission is proposing to amend the definition of ''Effective date'' by removing the language tying the effective date to the filing date. As described above, the Commission is proposing to extend delayed filing to original service contracts and is therefore deleting the sentence stating that the effective date for original service contracts cannot be prior to the filing date. The Commission is also proposing to delete the sentence stating that the effective date of an amendment can be no more than 30 days prior to the filing date. This sentence, in essence, simply repeats the filing requirement in § 530.8(a)(2). As described below, § 530.8(a), as amended by the proposed revisions, would adequately describe the filing requirement and the deadline for filing, and repeating the requirement in § 530.3(i) is therefore unnecessary.

The Commission is also proposing to clarify the time on the effective date when a service contract or amendment goes into effect. Currently, § 530.3(i) provides that a service contract or amendment is effective at 12:01 a.m. Eastern Standard Time. The proposed revision would add the equivalent time zone relative to Coordinated Universal Time (UTC) for added clarity (*i.e.,* UTC–05:00).

Finally, the Commission is proposing to add language to the definition to clarify that although service contracts and amendments may be filed after the effective date, the Commission is retaining the requirement that service contracts and amendments must be prospective in nature and cannot have retroactive effect. Under the current regulations, service contract amendments may only have prospective effect.[38] And, prior to the recent temporary exemption, original service contracts could not become effective prior to being filed with the Commission and were therefore also limited to having prospective effect. Because the Commission is proposing to allow original service contracts to be filed after they go into effect, the Commission is also adding language to the definition of ''Effective date'' to reflect the continuing requirement that service contracts and amendments may only have prospective effect. The added language specifies that the effective date cannot be earlier than the date on which all the parties have signed the service contract or amendment.

2. Service Contract Filing Requirements (§ 530.8)

Section 530.8 sets forth the filing requirements for service contracts and amendments. Under the current regulations, amendments must be filed no later than 30 days after cargo moves pursuant to the amendment, and, prior to the temporary exemption, original service contracts had to be filed before any cargo moved pursuant to the service contract.[39] The Commission is proposing to allow a 30-day filing period for both original service contracts and amendments and is therefore combining § 530.8(a)(1) and (2) into a single provision at § 530.8(a). The revised § 530.8(a) would require that ocean common carriers file service contracts and amendments no later than 30 days after the effective date.

The trigger for the filing period under the proposed revisions thus differs from the current requirement for service contract amendments in § 530.8(a)(2). The current regulations include two trigger events. Current § 530.3(i) requires that the effective date for the amendment be no more than 30 days prior to the filing date, while current § 530.8(a)(2) requires that an amendment be filed no later than 30 days after cargo moves pursuant to the amendment. In accordance with § 530.14(a), performance under an original service contract or amendment may not begin until the effective date, and therefore the effective date will always be earlier than the date cargo moves under the contract or amendment. Accordingly, in order to comply with both §§ 530.3(i) and 530.8(a)(2), ocean common carriers must file service contract amendments no later than 30 days after the effective date. Based on this interpretation, the Commission published guidance on its website shortly after the 2017 final rule was issued to make clear that service contract amendments must be filed no later than 30 days after their effective date.[40] The Commission is thus proposing a single trigger (effective date) for the 30-day filing period for both original service contract and amendments. This will make clear when service contracts must be filed and allow the Commission to readily assess compliance.

The Commission is also proposing amendments to § 530.8(e) to reflect the 30-day filing period for original service contracts. Section 530.8(e) currently provides that if the Commission's service contract filing system is unable to receive filings for 24 hours or more, affected parties are not subject to the requirements in §§ 530.8(a) and 530.14(a) that a service contract must be filed before cargo is shipped under the contract. This exception is conditioned on the affected service contracts being filed within 24 hours after the Commission filing system returns to service.

[36] The Commission's stated concerns in the 2017 service contract/NSA final rule regarding the impact of delayed filing on enforcement were made in response to comments stating that the correction process should allow carriers to submit inadvertently unfiled service contracts with the Commission within a much longer period (180 days).

[37] *Pet. of World Shipping Council,* 1 F.M.C.2d at 515–516. *See* Final Rule: Service Contracts, 85 FR 38086 (June 25, 2020).

[38] § 530.10(a)(1).

[39] § 530.8(a)(1), (2).

[40] *https://web.archive.org/web/20190321030253/https://www.fmc.gov/resources/amended_service_contract*_nsas_rule.aspx (last visited Nov. 24, 2020).

The proposed amendments to §§ 530.8(a) and 530.14(a) require corresponding changes to § 530.8(e). The proposed changes to § 530.8(e) would provide that if the Commission's service contract filing system is down for 24 hours or more, any service contract or amendment that must be filed during that period (*i.e.,* because the 30-day filing period concludes while the system is down) will be considered timely filed so long as the contract or amendment is filed no later than 24 hours after the Commission filing system returns to service. As explained below, the Commission is proposing to remove references to the filing date in § 530.14(a), and therefore the proposed revisions to § 530.8(e) also delete the reference to § 530.14(a).

3. Service Contract Implementation Requirements (§ 530.14)

Section 530.14 provides that performance under a service contract or amendment may not begin until the effective date and conditions performance on compliance with the relevant filing requirements, *i.e.,* performance under an original service contract may not begin until the contract is filed while performance under an amendment may begin on the effective date provided that the amendment is filed no later than 30 days after the effective date.

Given the proposed changes to § 530.8(a) would prescribe the same filing period for original service contracts and amendments (30 days after the effective date), the Commission is proposing to replace the separate requirements for original service contracts and amendments in § 530.14(a) with a single requirement that performance under either may not begin until the effective date. The Commission is also proposing to remove the language tying performance to the filing date as it simply repeats the filing requirement in § 530.8(a). As described above, § 530.8(a), as amended by the proposed revisions, would adequately describe the filing requirement and the deadline for filing, and repeating the requirement in § 530.14(a) is therefore unnecessary.

The Commission is also proposing to add an additional sentence to § 530.14(a) to clarify that original service contracts and amendments may apply only to cargo received by the carrier on or after the effective date. This is implied by the current language of §§ 530.8(a) (describing when a service contract or amendment must be filed in relation to when cargo moves under the contract) and 530.14(a) (prohibiting performance under a service contract or amendment until the effective date) and has been stated in previous rulemakings.[41] Because the Commission is proposing to amend § 530.8(a) so that the filing period is tied to the effective date rather than the date cargo moves, the Commission is proposing to include language in § 530.14(a) clearly stating that service contracts and amendments may only apply to cargo received on or after the effective date.

B. Technical Amendments

In order to implement the Commission's December 2019 decision to grant in part WSC's petition and exempt ocean common carriers from the essential terms publication requirements,[42] the Commission recently issued a final rule removing those requirements from part 530.[43] Since then, the Commission has tentatively determined that additional minor technical amendments are warranted.

1. Definition of ''Authorized Person'' (§ 530.3)

The definition of ''Authorized person'' in § 530.3(c) includes a reference to publishing statements of essential terms. The definition also cross-references a nonexistent paragraph (§ 530.5(d)) when referring to the registration requirements for filing service contracts. The Commission is proposing to amend the definition by removing the reference to essential terms publication and including the correct citation for the registration requirements (§ 530.5(c)).

2. Exceptions and Exemptions (§ 530.13)

The Commission is proposing to add a new paragraph (e) to § 530.13 to reflect the exemption granted by the Commission from the essential terms publication requirements. Although the Commission recently eliminated the essential terms publication requirements in part 530, ocean common carriers that are not aware of the exemption may be confused as to whether the statutory requirement in 46 U.S.C. 40502(d) continues to apply. Accordingly, the Commission has tentatively determined to include a new provision reflecting the exemption from section 40502(d).

[41] *See, e.g.,* 82 FR at 16290 (noting that because of the previous requirement that amendments had to filed before cargo could move under the terms of the amendment, ''[c]arriers have cited instances in which the parties have agreed to amend the contract, however, due to unavoidable circumstances, the cargo was received before the carrier filed the amendment with the Commission'' and ''[i]n such cases, the amendment's rates and terms may not be applied to that cargo pursuant to the Commission's rules.'').

[42] *Pet. of World Shipping Council,* 1 F.M.C.2d at 515–516.

[43] *See* Final Rule: Service Contracts, 85 FR 38086 (June 25, 2020).

IV. Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the docket, please include the docket number of this document in your comments.

You may submit your comments via email to the email address listed above under **ADDRESSES**. Please include the docket number associated with this document and the subject matter in the subject line of the email. Comments should be attached to the email as a Microsoft Word or text-searchable PDF document.

How do I submit confidential business information?

The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. If your comments contain confidential information, you must submit the following by email to the address listed above under **ADDRESSES**:

- A transmittal letter requesting confidential treatment that identifies the specific information in the comments for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.
- A confidential copy of your comments, consisting of the complete filing with a cover page marked ''Confidential-Restricted,'' and the confidential material clearly marked on each page.
- A public version of your comments with the confidential information excluded. The public version must state ''Public Version—confidential materials excluded'' on the cover page and on each affected page, and must clearly indicate any information withheld.

Will the Commission consider late comments?

The Commission will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments received after that date.

How can I read comments submitted by other people?

You may read the comments received by the Commission at the Commission's Electronic Reading Room at the

addresses listed above under **ADDRESSES**.

V. Rulemaking Analyses and Notices

Regulatory Flexibility Act

The Regulatory Flexibility Act (codified as amended at 5 U.S.C. 601–612) provides that whenever an agency is required to publish a notice of proposed rulemaking under the Administrative Procedure Act (APA) (5 U.S.C. 553), the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA) describing the impact of the proposed rule on small entities, unless the head of the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605. Based on the analysis below, the Chairman of the Federal Maritime Commission certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The regulated business entities that would be impacted by the rule are ocean common carriers (*i.e.,* vessel-operating common carriers). The Commission has determined that ocean common carriers generally do not qualify as small entities under the guidelines of the Small Business Administration (SBA). *See FMC Policy and Procedures Regarding Proper Consideration of Small Entities in Rulemakings* (Feb. 7, 2003), available at *https://www.fmc.gov/wp-content/uploads/2018/10/SBREFA_Guidelines_2003.pdf.*

National Environmental Policy Act

The Commission's regulations categorically exclude certain rulemakings from any requirement to prepare an environmental assessment or an environmental impact statement because they do not increase or decrease air, water or noise pollution or the use of fossil fuels, recyclables, or energy. 46 CFR 504.4. The proposed rule would allow ocean common carriers to file original service contracts up to 30 days after their effective date. This rulemaking thus falls within the categorical exclusion for actions related to the receipt of service contracts (§ 540.4(a)(5)). Therefore, no environmental assessment or environmental impact statement is required.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before collecting information from the public. 44 U.S.C. 3507. The agency must submit collections of information in proposed rules to OMB in conjunction with the publication of the notice of proposed rulemaking. 5 CFR 1320.11.

The information collection requirements associated with the service contract filing requirements in part 530 are currently authorized under OMB Control Number 3072–0065. In compliance with the PRA, the Commission has submitted the proposed revised information collection to the Office of Management and Budget and is requesting comment on the proposed revision.

Title: 46 CFR part 530—Service Contracts and Related Form FMC–83.

OMB Control Number: 3072–0065.

Abstract: 46 U.S.C. 40502 and 46 CFR part 530 require ocean common carriers to file certain service contracts confidentially with the Commission.

Current Action: The proposed rule would amend the service contract filing requirements and allow ocean common carriers to file original service contracts up to 30 days after the effective date. Currently, part 530 requires that ocean common carriers file original service contracts on or before the effective date, while amendments must be filed within 30 days after the effective date.

Type of Request: Revision of a previously approved collection.

Needs and Uses: The Commission monitors service contract filings to ensure compliance with the Shipping Act of 1984.

Frequency: Frequency of filings is determined by the ocean common carrier and its customers. When parties enter into a service contract or amend the contract, the service contract or amendment must be filed with the Commission.

Type of Respondents: Ocean common carriers or their duly appointed agents are required to file service contracts and amendments with the Commission.

Number of Annual Respondents: The Commission does not anticipate that the proposed revisions would affect the number of respondents. As a general matter, however, the number of respondents has decreased since the last revision to the information collection. The Commission estimates an annual respondent universe of 86 ocean common carriers.

Estimated Time per Response: The Commission does not anticipate that the proposed revisions would affect the estimated time per response, which would continue to range from 0.0166 to 1 person-hours for reporting and recordkeeping requirements contained in the regulations, and 0.1 person-hours for completing Form FMC–83.

Total Annual Burden: The Commission does not anticipate that the proposed revisions would affect the number of service contracts filed or the burden associated with each filing and, therefore, would not affect the total annual burden. Due to the decrease in the number of respondents since the last revision, however, the Commission expects that the total annual burden will decrease. The Commission estimates the total person-hour burden at 30,448 person-hours.

Comments are invited on:

- Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;
- Whether the Commission's estimate for the burden of the information collection is accurate;
- Ways to enhance the quality, utility, and clarity of the information to be collected;
- Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Please submit any comments, identified by the docket number in the heading of this document, by the methods described in the **ADDRESSES** section of this document.

Executive Order 12988 (Civil Justice Reform)

This proposed rule meets the applicable standards in E.O. 12988 titled, ''Civil Justice Reform,'' to minimize litigation, eliminate ambiguity, and reduce burden. Section 3(b) of E.O. 12988 requires agencies to make every reasonable effort to ensure that each new regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. This document is consistent with that requirement.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda).

The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda, available at *http://www.reginfo.gov/public/do/eAgendaMain.*

List of Subjects in 46 CFR Part 530

Freight, Maritime carriers, Report and recordkeeping requirements.

For the reasons set forth above, the Federal Maritime Commission is proposing to amend 46 CFR part 530 as follows:

PART 530–SERVICE CONTRACTS

■ 1. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40301–40306, 40501–40503, 41307.

■ 2. Amend § 530.3 by revising paragraphs (c) and (i) to read as follows:

§ 530.3 Definitions.

* * * * *

(c) *Authorized person* means a carrier or a duly appointed agent who is authorized to file service contracts on behalf of the carrier party to a service contract and is registered by the Commission to file under § 530.5(c) and appendix A to this part.

* * * * *

(i) *Effective date* means the date upon which a service contract or amendment is scheduled to go into effect by the parties to the contract. A service contract or amendment becomes effective at 12:01 a.m. Eastern Standard Time (Coordinated Universal Time (UTC)-05:00) on the effective date. The effective date may not be earlier than the date on which all parties have signed the service contract or amendment.

* * * * *

■ 3. Amend § 530.8 by:

■ a. Revising paragraph (a);

■ b. Adding a subject heading to paragraph (b); and

■ c. Revising paragraph (e).

The revisions and addition read as follows:

§ 530.8 Service Contracts.

(a) *Filing.* Authorized persons shall file with BTA, in the manner set forth in appendix A of this part, a true and complete copy of every service contract and every amendment to a service contract no later than thirty (30) days after the effective date.

(b) *Required terms.* * * *

* * * * *

(e) *Exception in case of malfunction of Commission filing system.* In the event that the Commission's filing systems are not functioning and cannot receive service contract filings for twenty-four (24) continuous hours or more, an original service contract or amendment that must be filed during that period in accordance with paragraph (a) of this section will be considered timely filed so long as the service contract or amendment is filed no later than twenty-four (24) hours after the Commission's filing systems return to service.

■ 4. Amend § 530.13 by adding paragraph (e) to read as follows:

§ 530.13 Exceptions and exemptions.

* * * * *

(e) *Essential terms publication exemption.* Ocean common carriers are exempt from the requirement in 46 U.S.C. 40502(d) to publish and make available to the general public in tariff format a concise statement of certain essential terms when a service contract is filed with the Commission.

■ 5. Amend § 530.14 by revising paragraph (a) to read as follows:

§ 530.14 Implementation.

(a) *Generally.* Performance under an original service contract or amendment may not begin until the effective date. An original service contract or amendment may apply only to cargo received on or after the effective date by the ocean common carrier or its agent, including originating carriers in the case of through transportation.

* * * * *

By the Commission.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–29173 Filed 1–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–IA–2021–0004; FF09A30000–212–FXIA16710900000]

RIN 1018–BF60

Endangered and Threatened Wildlife and Plants; Regulations Pertaining to the American Alligator (*Alligator mississippiensis*)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS or Service), are proposing to amend regulations concerning American alligators (*Alligator mississippiensis*) by revising provisions pertaining to interstate and foreign commerce. We are proposing these changes to increase clarity and eliminate unnecessary regulation while at the same time maintaining what is necessary and advisable for the conservation of this and other endangered or threatened crocodilian species under section 4(d) of the Endangered Species Act of 1973, as amended.

DATES: You may comment on this proposed rule until March 22, 2021.

ADDRESSES: You may submit written comments by one of the following methods:

- *Electronically Using the Federal eRulemaking Portal: http://www.regulations.gov* in Docket No. FWS–HQ–IA–2021–0004 (the docket number for this rulemaking).
- *U.S. Mail:* Public Comments Processing, Attn: FWS–HQ–IA–2020–XXXX; U.S. Fish and Wildlife Service Headquarters, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will not accept email or faxes. Comments and materials we receive, as well as supporting documentation, will be available for public inspection on *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Pamela Hall Scruggs, Chief, Division of Management Authority, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: IA, Falls Church, VA 22041–3803; telephone 703–358–2095 or email: *managementauthority@fws.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The American alligator (*Alligator mississippiensis*) is an iconic U.S. animal with a history of both drastic decline and complete recovery. As a result of State and Federal cooperation, its recovery is one of the most prominent successes of the Nation's endangered species program.

The American alligator is a large, semi-aquatic, armored reptile that is related to crocodiles. Alligators can be distinguished from crocodiles by head shape and color. Adult alligators, which are almost black in color, have a broad, large, long head with visible upper teeth along the edge of the jaws. Crocodiles, which are brownish in color, have a narrower snout and have lower jaw teeth that are visible even when its mouth is shut. The American alligator has a large, slightly rounded body,

which ranges for adult alligators from 6 to 14 feet long, as well as thick limbs and a very powerful tail that it uses to propel itself through water. The tail accounts for half the alligator's length. Its front feet have five toes, while the rear feet have four toes that are webbed. In the wild, the American alligator often lives to 50 years of age and possibly over 70 years of age (Wilkinson *et al.* 2016, p. 843).

The breeding range of the American alligator is distributed in the southeastern United States in Arkansas, North Carolina, South Carolina, Georgia, Florida, Louisiana, Alabama, Mississippi, Oklahoma, and Texas. Within this range, American alligators inhabit freshwater swamps, lakes, marshes, and streams (Elsey *et al.* 2019, p. 1). They also inhabit brackish water habitats and, although they have a low tolerance for salt water, will occasionally use marine environments for feeding (Rosenblatt and Heithaus 2011, p. 786).

In the late 1860s, the leather industry's demand for exotic hides led to widespread commercial hunting of the American alligator. The demand in Europe and the United States for luxury leather products was so rapacious that, within a few years, large American alligators became extremely rare. This situation created a market for exported crocodile hides from Mexico and Central America. Tens of thousands of alligator and crocodile skins entered world markets, making their way from swamps to tanneries to exclusive department stores and boutiques. The precipitous decrease in size and numbers of American alligators taken for trade reflected a species in decline.

Today, American alligator populations thrive, as a result of creative partnerships between Federal and State governments. The States led the way in providing legal protection. Alabama adopted protective legislation for its American alligator population in 1941, followed by Florida (1961), Louisiana (1962), and Texas (1970). The wild American alligator population trend is increasing and is estimated to be 3–4 million non-hatchling individuals, of which approximately 750,000–1,060,000 are mature individuals (Elsey *et al.* 2019, p. 3).

Alligator farming and ranching played a role in the conservation success. American alligator ''farming'' involves captive breeding of American alligators. American alligator ''ranching'' involves gathering eggs from the wild, returning some juveniles to the wild, and raising the remainder to market size. For example, to ensure wild alligators are not depleted as a result of egg collections, and to ensure future recruitment of subadult alligators to the breeding population, the Louisiana Department of Wildlife and Fisheries currently requires a quantity of juvenile alligators equal to 10 percent of the eggs hatched by the rancher be returned to the wild within 2 years of hatching (Louisiana's Alligator Management Program 2017–2018 Annual Report, page 5). Alligator ranching has minimal adverse effects on the environment, and it has direct positive effects on alligator conservation. It may reduce demand for poached wild alligator skins and likely creates an incentive for ranchers to contribute to maintenance of wild populations and their habitats (Nickum *et al.* 2018, p. 87). Practiced primarily in Louisiana, Florida, Georgia, and Texas, American alligator farming and ranching is an aquaculture industry worth tens of millions of dollars (Nickum *et al.* 2018, p. 88). Particularly in Louisiana and Florida, farming and ranching are now being carried out on a large scale; stocks in over 100 commercial farms and ranches throughout the country are high, with more than 923,000 American alligators on farms in Louisiana alone in 2016 (Elsey *et al.* 2019, p. 3).

The American alligator first received protection under Federal law in 1967 when it was listed as endangered throughout its range under the Endangered Species Preservation Act of 1966 (32 FR 4001, March 11, 1967), a predecessor to the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.* (Act, ESA)). Its endangered classification was transferred to the Act effective December 28, 1973, (Pub. L. 93–205, 1, Dec. 28, 1973, 87 Stat. 884).

Under the ESA, species may be listed either as ''threatened'' or as ''endangered'' (16 U.S.C. 1532(6) (defining ''endangered''); 16 U.S.C. 1532(20) (defining ''threatened'')). ESA regulations are set forth in title 50 of the Code of Federal Regulations in parts 17 and 424. Section 4(e) of the Act (16 U.S.C. 1533(e); 50 CFR 17.50–17.51) gives the Secretary of the Interior authority to list a species, subspecies, or distinct population segment as endangered or threatened by reason of similarity of appearance if: (A) Such species so closely resembles in appearance, at the point in question, an ESA-listed endangered or threatened species that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species; (B) the effect of this substantial difficulty is an additional threat to an endangered or threatened species; and (C) such treatment of an unlisted species will substantially facilitate the enforcement and further the policy of the Act. All applicable prohibitions and exceptions for species treated as threatened under section 4(e) of the Act due to similarity of appearance to a threatened or endangered species are provided in a rule issued under section 4(d) of the Act (16 U.S.C. 1533(d)), as discussed further below.

When a fish or wildlife species is listed as endangered under the ESA, certain actions are prohibited under section 9 (16 U.S.C. 1538(a)(1)), as specified at 50 CFR 17.21. These include prohibitions on ''take'' (16 U.S.C. 1532(19) (defining ''take'' to mean ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct''); 50 CFR 17.3 (defining ''harm'' and ''harass'')) within the United States, within the territorial seas of the United States, or upon the high seas; possession, sale, delivery, carrying, transport, or shipment of unlawfully taken specimens; import; export; sale and offer for sale in interstate or foreign commerce; and delivery, receipt, carrying, transport, or shipment in interstate or foreign commerce in the course of a commercial activity. It is also unlawful to attempt to commit, solicit another to commit, or cause to be committed, any of these offenses (16 U.S.C. 1538(g)).

The ESA does not specify particular prohibitions and exceptions to those prohibitions for threatened species. Instead, under section 4(d) of the ESA (16 U.S.C. 1533(d)), the Secretary of the Interior is given the discretion to issue such regulations as deemed necessary and advisable to provide for the conservation of the species. The Secretary also has the discretion to prohibit by regulation, with respect to any threatened species, any act prohibited under section 9(a)(1) of the ESA for endangered species of fish or wildlife. Accordingly, under section 4(d) of the ESA, the Service may develop specific prohibitions and exceptions tailored to the particular conservation needs of a threatened species (50 CFR 17.31(c)).

We have gained considerable experience in developing species-specific rules over the years. Where we have developed species-specific 4(d) rules, we have seen many benefits, including removing redundant permitting requirements, facilitating implementation of beneficial conservation actions, and making better use of our limited personnel and fiscal resources by focusing prohibitions on the stressors contributing to the threatened status of the species. This

proposed rule will allow us to capitalize on these benefits in tailoring the regulations to species conservation needs by eliminating unnecessary regulation while at the same time maintaining what is necessary and advisable for the conservation of this and other crocodilian species under section 4(d) of the ESA.

Section 4(d) of the Act states that the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language very similar to ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). ''Conservation'' is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary (16 U.S.C. 1532(3)). Additionally, section 4(d) states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or 9(a)(2), in the case of plants. Thus, regulations promulgated under section 4(d) of the Act provide the Secretary with broad discretion to select appropriate provisions tailored to the specific conservation needs of the threatened species. The statute grants particularly broad discretion to the Service when adopting the prohibitions under section 9. The Service also has discretion to revise or promulgate species-specific rules at any time after the final listing or reclassification determination.

The section 4(d) rule at 50 CFR 17.42(a), which currently pertains to any specimen of the American alligator, first became effective in 1975 (40 FR 44412, September 26, 1975). In 1975, American alligators in certain parts of Louisiana were reclassified from endangered to threatened because of recovery of these populations of the species and their similarity of appearance with endangered American alligators in Louisiana and elsewhere in the American alligator range (40 FR 44412, September 26, 1975). The preamble to the 1975 rule explained that the primary threat to American alligators in certain areas was the absence of adequate regulatory and enforcement mechanisms ''to prevent malicious and illicit commercially oriented killing'' and ''to control illegal commerce in products.'' To address concerns that once a legal market was established it could provide a ''screen'' for American alligator products from endangered populations, the 1975 rule established a marking and tagging regime for American alligator hides and included permitting requirements for fabricators, buyers, and tanners to allow identification throughout the marketing and processing chain. The 1975 rule allowed take of American alligators from threatened populations and captive alligators provided the take was in accordance with State of Louisiana laws and regulations, including marking and tagging requirements, and allowed sale of hides only to persons holding a valid Federal license as buyers. Sale of meat and other parts was prohibited under the 1975 section 4(d) rule. In the years that followed, the species continued to improve. See the following rulemaking documents:

- 42 FR 2071 (January 10, 1977) (reclassifying the American alligator from ''endangered'' to ''threatened'' in all of Florida and certain coastal areas of Georgia, Louisiana, South Carolina, and Texas);
- 44 FR 37130 (June 25, 1979) (expanding ''threatened due to similarity of appearance'' classification from 3 to 12 Louisiana parishes);
- 46 FR 40664 (Aug. 10, 1981) (expanding ''threatened due to similarity of appearance'' classification to all of Louisiana);
- 48 FR 46332 (Oct. 12, 1983) (all of Texas); and
- 50 FR 25672 (June 20, 1985) (all of Florida).

The American alligator 4(d) rule was also amended several times during these years:

- 42 FR 2071, January 10, 1977;
- 44 FR 51980, September 6, 1979;
- 44 FR 59080, October 12, 1979;
- 45 FR 78153, November 25, 1980;
- 46 FR 40664, August 10, 1981;
- 48 FR 46332, October 12, 1983;
- 50 FR 25672, June 20, 1985;
- 50 FR 45407, October 31, 1985;
- 52 FR 21059, June 4, 1987;
- 72 FR 48402, August 23, 2007.

For example, in 1979 (44 FR 51980, September 6, 1979), a final rule amending the 4(d) rule noted that the ''consistent intent'' throughout these rulemakings has been to authorize controlled harvest of American alligators in specified areas, subject to State and Federal law. The final rule reclassified the American alligator populations in nine additional parishes in Louisiana from endangered to threatened due to similarity of appearance to endangered American alligators in the remainder of the species' range and, among other things, authorized sale of meat and other parts, except hides, only within the State of Louisiana and subject to the laws and regulations of the State of Louisiana. Although some commenters had recommended also allowing sale of meat and parts in other States, the Service did not adopt that recommendation and explained that licensing and recordkeeping requirements imposed by the State of Louisiana had facilitated effective enforcement with respect to sale of meat and other parts in Louisiana but that no regulatory scheme existed to provide effective enforcement outside of Louisiana. On October 12, 1979 (44 FR 59080), another rulemaking revised the section 4(d) rule to allow limited commercial export and import of lawfully taken American alligator hides and products manufactured from those hides in accordance with the requirements of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), after the transfer of American alligator from CITES Appendix I to CITES Appendix II, effective June 28, 1979, allowed for international trade in American alligator for commercial purposes.

Revisions to the section 4(d) rule in 1980 (45 FR 78153, November 25, 1980) removed the requirement for fabricators to obtain Federal permits, but to ensure that fabricators only received lawfully taken hides, maintained the requirement limiting sale of raw (untanned) hides to a person holding a valid Federal permit to buy hides. The 1980 revisions also allowed interstate commerce of fully tanned hides that had been tagged by the State where the taking occurred and allowed sale or transfer of meat and other parts except hides, provided these parts were sold or otherwise transferred only in accordance with the laws and regulations of the State in which the taking occurred and the State in which the sale or transfer occurred. The 1980 section 4(d) rule also allowed interstate commerce in manufactured products.

By 1987, the American alligator had recovered enough so that it did not qualify as endangered or threatened based on its own conservation status. However, it was reclassified under the Act as ''threatened due to similarity of appearance'' throughout its range (52 FR 21063, June 4, 1987) based on its resemblance to the American crocodile and other threatened crocodilian species. As noted above, populations in Florida, Louisiana, and Texas and portions of other States had already been reclassified. This rule reclassified the remaining endangered populations in Alabama, Arkansas, Georgia, Mississippi, North Carolina, and South Carolina. The preamble to the final rule

explained that the rule ''supports a need for continued Federal controls on taking and commerce to ensure against excessive taking and to continue necessary protections for the American crocodile (*Crocodylus acutus*) in the U.S. and foreign countries, and other endangered crocodilians in foreign countries'' (52 FR 21060, June 4, 1987).

The classification of the American alligator as threatened due to similarity of appearance is intended to protect other listed species that bear a resemblance to the American alligator. Take of American alligators is regulated by States and Tribes and section 4(d) regulations at 50 CFR 17.42, Special rules—reptiles. Under 50 CFR 17.42(a), the Service regulates the harvest of American alligators, and subsequent interstate commerce and international trade in the legally harvested animals, their skins, and products made from them, as part of efforts to prevent the illegal take and trafficking of threatened and endangered reptiles that are similar in appearance to American alligators. Illegally harvested alligators cannot legally be entered into commerce or trade under the 4(d) rule.

As noted above, currently, the American alligator is listed under the Act as threatened due to similarity of appearance to the American crocodile (*Crocodylus acutus*) in the United States and foreign countries, and other ESA-listed crocodilians (50 CFR 17.11). The Service recognizes that some populations of crocodilians that are managed as a sustainable resource can be utilized for commercial purposes without adversely affecting the survival of those populations, when scientifically based management plans are implemented. When certain positive conservation conditions have been met, the Service has allowed utilization and trade from managed populations of the American alligator, and other crocodilians. For example, we have allowed the importation of commercial shipments of Nile crocodile (*Crocodylus niloticus*) from several southern and eastern African countries, and allowed for similar shipments of saltwater crocodile *(Crocodylus porosus*) specimens from Australia (61 FR 32356, June 24, 1996). In each of these examples, the species or population is not an ESA-listed endangered species, and also is not included in CITES Appendix I.

We are aware that there have been questions raised regarding proposed or recently enacted State laws that would prohibit commercial activities involving American alligator and concerns that such laws may result in a reduction in proceeds from lawful interstate commerce in alligators that is used to fund important conservation efforts for alligators and their habitat. See Section II below regarding *Petition to Amend Endangered Species Act Section 4(d) Rule Actions Concerning the American Alligator.* This proposed rule would amend the 4(d) rule to remove the requirement at 50 CFR 17.42(a)(2)(ii)(B) that ''[a]ny American alligator specimen may be sold or otherwise transferred only in accordance with the laws and regulations of . . . the State or Tribe in which the sale or transfer occurs.'' This amendment clarifies that any State law regulating commercial sale or transfer that effectively prohibits interstate commerce or foreign commerce authorized by the 4(d) rule would be preempted by section 6(f) of the ESA and would be void to the extent of the conflict (16 U.S.C. 1535(f)(2); the Supremacy Clause of the U.S. Constitution). We also explained the preemptive effect of 4(d) rules and section 6(f) in the most recent prior rulemaking amending the American alligator 4(d) rule. See 72 FR 48402, 48406 (Aug. 23, 2007) (relying on *Man Hing Ivory & Imports, Inc.* v. *Deukmejian,* 702 F.2d 760 (9th Cir. 1983)). By amending the 4(d) rule to remove the provision relating to the State or Tribe in which a sale or transfer occurs, we intend to eliminate the potential tension between those State laws and the well-regulated American alligator management regime that has been established through decades of cooperation between the Service, States in the alligator's range, and the alligator industry, and which is facilitated by the regulation of interstate commerce and international trade through the 4(d) rule.

Although it can be difficult to identify the species in products manufactured from crocodilian species, and this situation can pose a problem for law enforcement, over the more than 30 years that the provision in question has been in place, we have no reason to believe that this provision at 50 CFR 17.42(a)(2)(ii)(B) has added to the conservation benefits provided by other provisions in the current American alligator 4(d) rule. Further, the first phrase in the sentence at 50 CFR 17.42(a)(2)(ii)(B) pertaining to ''the laws and regulations of the State or Tribe in which the taking occurs'' is largely redundant, as it restates what is already stated earlier in 50 CFR 17.42(a)(2)(ii).

The conditional language in 50 CFR 17.42 (a)(2)(ii)(B) may be inhibiting interstate commerce that has developed since the American alligator was first reclassified under the Act and which provides funding to support crocodilian conservation and helps States and Tribes address threats to these populations. Confusion caused by this provision concerning the interaction between Federal, State, and Tribal rules and regulations could deter protection of American alligator habitat, upsetting regulatory protocols that have been in place for decades, and thereby undermining the conservation of this and other crocodilian species under section 4(d) of the Act.

Quotas for controlled hunting of adults, and collection of eggs and hatchlings on both private and public lands are based on annual monitoring of nests and local population densities and occur in accordance with the laws and regulations of the State or Tribe in which the taking of American alligators occurs. Commercial production of skins and meat is highly regulated by State agencies through a system of permits, licenses, periodic stock inventories, ranch inspections, and tagging requirements, which occur in accordance with the laws and regulations of the State or Tribe in which the taking of American alligators occurs. Fees collected through State and Tribal regulatory systems (also in accordance with the laws and regulations of the State or Tribe in which the taking of American alligators occurs) provide funding for management, regulation, enforcement, and research programs for the American alligator. Conservation of American alligators has succeeded by sustainable regulated harvests, protecting important alligator habitat, and providing economic incentives for private landowners to maintain alligator habitat (Elsey *et al.* 2019, p. 5). For these reasons, we reaffirm the need to ensure that take of, and interstate commerce in, American alligators may only be in accordance with the laws and regulations of the State or Tribe of taking but propose to remove as unnecessary and confusing the provision that sale or transfer may only be in accordance with the laws and regulations of the State or Tribe where the sale or transfer occurs.

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

Separate from its listing and conservation status under the ESA, the American alligator is protected under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), a treaty that regulates international trade in species included in one of three Appendices. In 1975, the American alligator was included in Appendix I of CITES. CITES Appendix I includes species threatened with

extinction that are or may be affected by trade.

In 1979, the American alligator was transferred from CITES Appendix I to Appendix II. Appendix II includes species that are not presently threatened with extinction, but may become so if their trade is not regulated. It also includes species that need to be regulated so that trade in certain other Appendix-I or -II species may be effectively controlled (due to similarity of appearance to other CITES species). Commercial international trade of Appendix-II species is allowed under CITES export permits issued by the Management Authority of the exporting country, provided specific determinations have been made, including that the Management Authority of the exporting country has determined that the specimens involved have been legally acquired and the Scientific Authority of the exporting country has determined that the trade will not be detrimental to the survival of the species. In the United States, the ESA (16 U.S.C. 1537a) designates the Secretary of the Interior as the CITES Management Authority and Scientific Authority and requires the functions of each shall be carried out by the Service.

The Parties to CITES reviewed management activities prior to transferring the American alligator from CITES Appendix I to Appendix II (thereby allowing commercial trade), reviewed assessments of population status, reviewed determinations of sustainable harvest quotas (or approval of ranching programs), and reviewed the control of the illegal harvest. Management regulations imposed after harvest included the tagging of skins and issuance of permits to satisfy the requirements for CITES Appendix-II species. As a Party to CITES, in addition to ESA requirements, the United States implements CITES requirements for trade in American alligators. The United States implements CITES through the ESA (16 U.S.C. 1537a; 16 U.S.C. 1538(c)(1)) and the Service's CITES implementing regulations (50 CFR part 23). CITES requirements for international trade specific to American alligator are found at 50 CFR 23.70.

II. Petition To Amend Endangered Species Act Section 4(d) Rule Actions Concerning the American Alligator

Petition

The Secretary of the Interior received a petition in the form of a letter dated December 9, 2019, from the State of Louisiana, titled, *Petition for Rulemaking to Correct the American Alligator Regulations at 50 CFR 17.42(a) Pertaining to the Sale of Hides.* The petition requests ''the repeal of those regulations which limit the sale or transfer of alligator hides to compliance with the State in which the sale or transfer occurs.'' The petition asserts that the language in the regulation imposing this requirement may have been included or retained as the result of administrative error or confusion. The petition asserts that, as the result of a series of proposed rules and final rules issued between 1980 and 1987, the Service inadvertently added alligator hides to the list of products required to be sold or transferred in interstate commerce only in accordance with the law of the State in which the sale or transfer occurs.

The petition requests a new rulemaking to amend 50 CFR 17.42(a)(2)(ii)(B) to eliminate the change that included alligator hides in the group of parts and products that may only be sold or transferred in interstate commerce in accordance with the law of the State or Tribe in which the sale or transfer occurs. The petition requests that the Service amend the rule to revert back to the regime set out in the 1980 alligator section 4(d) regulations, which allowed for take of American alligators wherever listed as threatened due to similarity of appearance, in accordance with the laws in the State of taking subject to certain conditions including that ''any meat or other part except the hide is sold or otherwise transferred only in accordance with the laws and regulations of the State in which the taking occurs and the State in which the sale or transfer occurs;'' (45 FR 78153, November 25, 1980).

It is true that earlier versions of the section 4(d) rule did not, in the phrase in question, include hides in the group of parts and products that could only be sold in accordance with the laws of the State or Tribe in which the sale or transfer occurred. However, those earlier versions also strictly regulated the sale and transfer of hides, including by requiring that hides could only be sold or transferred to a person holding a valid buyer permit (issued under the section 4(d) rule) and that the hides must be tagged by the State where they were taken. Tanners and, for a time, fabricators also had to obtain permits under the section 4(d) rule, and buyer, tanner, and fabricator permittees were prohibited from violating any State, Federal, or foreign laws concerning hides and other parts and products. Tagging of alligator hides by the State or Tribe of taking is still required under the current section 4(d) rule and forms the basis of the traceability regime that allows us to ensure that hides in trade (including those to be exported) have been legally acquired under an approved State or Tribal program. The current section 4(d) rule for the American alligator does not require hide buyers, tanners, or fabricators to obtain permits.

Service Response to the Petition

The ESA section 4(d) rule concerning the American alligator became effective over 45 years ago. More than 33 years have passed since publication of the 1987 revision to the rule that included the provision that the petition seeks to amend. In reviewing the conservation success story related to the alligator, we find that the requirement for interstate commerce in American alligator to adhere to laws of the States and Tribes where the sale or transfer occurs is not necessary. Under the Administrative Procedure Act (APA), any person may petition for the issuance, amendment, or repeal of a rule (5 U.S.C. 553(e)). In considering the petition, we follow Department of the Interior regulations concerning petitions for APA rulemakings, found at 43 CFR part 14 (43 CFR 14.2, Filing of petitions.). To that end, interested persons may obtain a copy of the petition on the internet at *http://www.regulations.gov,* in the docket supporting materials section provided above in **ADDRESSES**. This proposed rule addresses the petition.

III. This Proposed Rule

As a result of the petition received from the State of Louisiana, we conducted a review of our regulations at 50 CFR 17.42(a) and have determined that this proposed rulemaking action is necessary and advisable for the conservation of this and other crocodilian species under section 4(d) of the Act. The Service has the responsibility to periodically update and clarify our implementing regulations when it is necessary to do so. With this proposed rule, we reflect the outcome of our review.

We have evaluated the petition received from the State of Louisiana concerning the requested amendment to our regulations at 50 CFR 17.42(a). We have also conducted our own evaluation of our regulations at 50 CFR 17.42(a), and have concluded that there is sufficient reason for a new rulemaking that removes the requirement in the 4(d) rule's authorization of interstate or foreign commerce that American alligators, including hides and other parts and products, may only be sold or transferred in accordance with the law of the State or Tribe in which the sale or transfer occurs. As noted above, the section 4(d) rule for the American

alligator has been revised a number of times since it was first promulgated in 1975. Changes to the section 4(d) rule were adopted in response to changes in the conservation status of various populations of the species (and the reclassification of those populations) and to the related and evolving need for Federal control of taking and commerce in American alligators and American alligator parts and products, as well as for the effective protection and enforcement of requirements for other ESA-listed crocodilians.

We believe the requirement at 50 CFR 17.42(a)(2)(ii)(B) that any American alligator specimen may be sold or otherwise transferred only in accordance with the laws and regulations of the State or Tribe in which the sale or transfer occurs is unnecessary and can be removed as a condition of the 4(d) rule's authorization of interstate and foreign commerce. Through this amendment, any State law regulating commercial sale or transfer that effectively prohibits interstate or foreign commerce authorized by the 4(d) rule would be preempted by section 6(f) of the ESA and would be void to the extent of the conflict (16 U.S.C. 1535(f)(2); the Supremacy Clause of the U.S. Constitution). Further, the first phrase in the sentence at 50 CFR 17.42(a)(2)(ii)(B) is largely redundant, as it restates what is already stated in 50 CFR 17.42(a)(2)(ii), and therefore can also be removed along with conforming amendments. We believe that this proposed amendment could reduce confusion concerning the interaction between Federal, State, and Tribal rules and regulations and clarify the activities that are authorized by Federal regulation. We believe that the requirement at 50 CFR 17.42(a)(2)(ii)(B) that any American alligator specimen may be sold or otherwise transferred only in accordance with the laws and regulations of the State or Tribe in which the sale or transfer occurs, is not necessary for the conservation of the American alligator and for other crocodilian species to which the American alligator bears similarity of appearance.

IV. Public Comments Solicited

We invite interested organizations and the public to comment on this proposed rule. We analyzed the 4(d) rule in response to the petition from Louisiana and have drafted this proposed amendment to 50 CFR 17.42(a)(2)(ii)(B) following our review and analysis. We are seeking comments related to any proposed revisions to the ESA section 4(d) rule concerning the American alligator at 50 CFR 17.42(a). We will not consider comments regarding this proposed rule sent by email or fax or to an address not listed in **ADDRESSES**. If you submit a comment via *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Because we will consider all comments and information we receive during the comment period, our final 4(d) rule may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may change the parameters of the prohibitions or the exceptions to those prohibitions if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the listed crocodilians that are similar in appearance to the American alligator. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the listed crocodilians that are similar in appearance to the American alligator.

V. Required Determinations

Clarity of the Proposed Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We are required under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) to assess the impact of any Federal action significantly affecting the quality of the human environment, health, and safety. This proposed rule is being analyzed under the criteria of NEPA, the Department of the Interior procedures for compliance with NEPA (Departmental Manual (DM) and 43 CFR part 46), and Council on Environmental Quality regulations for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508). We are preparing a draft environmental assessment to determine whether this proposed rule will have a significant impact on the quality of the human environment under NEPA. We will announce the availability of the draft environmental assessment as soon as it is completed. When completed, the draft environmental assessment will be available on the internet at *http://www.regulations.gov* in the docket provided above in **ADDRESSES**.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Under the Regulatory Flexibility Act (RFA) (as amended by the Small Business Regulatory Enforcement Fairness Act [SBREFA] of 1996) (5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.''

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*) amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. According to the Small Business Administration (SBA), small

entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201).

The SBA has developed size standards to carry out the purposes of the Small Business Act. These standards can be found in 13 CFR 121.201. For a specific industry identified by the North American Industry Classification System (NAICS), small entities are defined by the SBA as an individual, limited partnership, or small company considered at ''arm's length'' from the control of any parent company, which meet certain size standards. The size standards are expressed either in number of employees or annual receipts. This proposed rule is most likely to affect entities nationwide that sell alligator products such as hides, eggs, and meat. The industries most likely to be directly affected are listed in the table below along with the relevant SBA size standards.

TABLE 1—INDUSTRIES POTENTIALLY AFFECTED BY THE PROPOSED RULE

Industry	NAICS code	Size standards in millions of dollars or employees
Full-Service Restaurants	722511	$8.0
Limited-Service Restaurants	722513	12.0
Supermarkets and Other Grocery (except Convenience) Stores	445110	35.0
Other Aquaculture	112519	1.0
Leather and Hide Tanning and Finishing	316110	* 500

* Employees.

Based on these thresholds, the proposed rule may affect small entities. In addition to determining whether a substantial number of small entities are likely to be affected by this proposed rule, the Service must also determine whether the proposed rule is anticipated to have a significant economic impact on those small entities. This rule would not significantly impact interstate commerce, as the proposed changes would not change the fact that interstate commerce is allowed under the provisions of this 4(d) rule. Therefore, we do not expect any significant impacts to these businesses because interstate commerce would continue as provisioned by the Endangered Species Act and the 4(d) regulations, and any potential positive economic impact from the preemption of any conflicting State or Tribal law is too speculative to estimate. The rule would not have a significant economic effect on a substantial number of small entities in any region or nationally.

Therefore, based on the information available to us at this time, we certify that this proposed rule would not have a significant economic effect on a substantial number of small entities as defined under the RFA. An initial regulatory flexibility analysis is not required. Accordingly, a small entity compliance guide is not required.

Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 801 et seq.)

This proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Would not have an annual effect on the economy of $100 million or more.

(b) Would not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.

(c) Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

This proposed rule would provide clarity regarding interstate commerce in alligators, whether alive or dead, including any skin, part, product, egg, or offspring thereof held in captivity or from the wild. It would reaffirm current, longstanding provisions that allow interstate commerce in lawfully harvested American alligators but would remove text conditioning sale or transfer in accordance with the law of the State or Tribe in which sale or transfer occurs. Therefore, we do not anticipate significant economic impacts because interstate commerce would continue as provisioned by the Endangered Species Act and the section 4(d) regulations and any potential economic impact from the preemption of any conflicting State or Tribal law is too speculative to estimate.

Executive Order 13771

This rule is not an Executive Order (E.O.) 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because this rule is not significant under E.O. 12866.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects when undertaking certain actions. This rule is not a significant energy action under the definition in Executive Order 13211. A statement of Energy Effects is not required. This proposed rule would revise the current regulations in 50 CFR part 17 that pertain to the harvest of American alligators and regulate legal trade in the animals, their skins, and products made from them, as part of efforts to prevent the illegal take and

trafficking of endangered reptiles that are similar in appearance to American alligators. This proposed rule will not significantly affect energy supplies, distribution, and use.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both Federal intergovernmental mandates and Federal private sector mandates. These terms are defined in 2 U.S.C. 658(5)–(7).

''Federal intergovernmental mandate'' includes a regulation that would impose an enforceable duty upon State, local, or Tribal governments with two exceptions. It excludes a condition of Federal assistance. It also excludes a duty arising from participation in a voluntary Federal program, unless the regulation relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority, if the provision would increase the stringency of conditions of assistance or place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding, and the State, local, or Tribal governments lack authority to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

(2) This proposed rule will not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule will not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of this proposed rule.

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. This proposed rule would update and clarify the regulations concerning the harvest of American alligators and regulate legal trade in the animals, their skins, and products made from them, as part of efforts to prevent the illegal take and trafficking of endangered reptiles that are similar in appearance to American alligators. A takings implication assessment is not required.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant federalism effects. A federalism summary impact statement is not required. These proposed revisions to 50 CFR part 17 do not contain significant federalism implications.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. Specifically, this proposed rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2 (Department of the Interior Manual, Series 30, Part 512, Chapter 2: *Departmental Responsibilities for Indian Trust Resources*), we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have evaluated this proposed rule under the criteria in Executive Order 13175 under the Department's consultation policy and are not aware of any substantial effects to federally recognized Indian Tribes but will consider comments from Tribes on this proposed rule. We will consult and solicit comments from Tribes. Individual Tribal members must meet the same regulatory requirements as other individuals under our regulations at 50 CFR 17.42 (Special rules—reptiles).

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* in the docket provided above in **ADDRESSES.**

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Therefore, for the reasons discussed in the preamble, we hereby propose to amend part 17 of title 50, Code of Federal Regulations, as set forth below.

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Section 17.42 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 17.42 Special rules—reptiles.

* * * * *

(a) * * *

(2) * * *

(ii) Any person may take an American alligator in the wild, or one which was born in captivity or lawfully placed in captivity, and may deliver, receive, carry, transport, ship, sell, offer to sell, purchase, or offer to purchase such alligator in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, if such activities are in accordance with the laws and regulations of the State or Tribe in which taking occurs, and subject to the following condition: Any skin of an American alligator may be sold or otherwise transferred only if the State or Tribe of taking requires skins to be tagged by State or Tribal officials or under State or Tribal supervision with a Service-approved tag in accordance with the requirements in part 23 of this subchapter.

* * * * *

Aurelia Skipwith,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–01012 Filed 1–15–21; 11:15 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 29

[Docket No. FWS–HQ–NWRS–2019–0017; FF09R50000–XXX–FVRS8451900000]

RIN 1018–BD78

Streamlining U.S. Fish and Wildlife Service Permitting of Rights-of-Way

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS), propose to revise and streamline FWS regulations for permitting of rights-of-way by aligning FWS processes more closely with those of other Department of the Interior bureaus, consistent with applicable law and to the extent practicable. The proposed rule would require a pre-application meeting and use of a standard application, the SF–299, Application for Transportation and Utility Systems and Facilities on Federal Lands; allow electronic submission of applications; and provide FWS with additional flexibility, as appropriate, to determine the fair market value or fair market rental value of rights-of-way across FWS-managed lands. This proposed rule would reduce the time and cost necessary to determine a right-of-way's fair market value or fair market rental value, and also reduce an applicant's time and cost to obtain a right-of-way permit. The proposed rule would also simplify the procedures that applicants must follow to reimburse the United States for costs that FWS incurs while processing right-of-way applications and monitoring permitted rights-of-way.

DATES: We will accept comments on this proposed rule that are received or postmarked on or before March 22, 2021. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments on this proposed rule by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–NWRS–2019–0017, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: Docket No. FWS–HQ–NWRS–2019–0017, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Public Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Ken Fowler, U.S. Fish and Wildlife Service, MS: NWRS, 5275 Leesburg Pike, Falls Church, VA 22041; (703) 358–1876.

SUPPLEMENTARY INFORMATION:

Public Comments

We request comments or information from other concerned government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

All comments submitted electronically via *http://www.regulations.gov* will be presented on the website in their entirety as submitted. For comments submitted via hard copy, we will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Background

FWS is the principal land manager and permitting authority for more than 89 million terrestrial acres of public lands, including 76.8 million acres in Alaska, 12.2 million acres in the lower 48 States, and 50,000 acres in Hawaii. The vast majority of the 89 million acres are part of the National Wildlife Refuge System (Refuge System), whose mission is to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans (16 U.S.C. 668dd(a)(2)). These acres include more than 20 million acres of designated wilderness that the Service manages to preserve the wilderness character in accordance with the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*). Subject to existing private rights, and special provisions included in wilderness-designation statutes, the Wilderness Act prohibits commercial enterprises and permanent roads. The law also prohibits temporary roads; motor vehicles, motorized equipment, motorboats, landing of aircraft, and other forms of mechanical transport; structures; and installations, unless their use can be demonstrated to be necessary to meet minimum

requirements for the administration of the area for Wilderness Act purposes.

Refuge System lands and waters are managed according to the authorities of the National Wildlife Refuge System Administration Act of 1966 (Administration Act; 16 U.S.C. 668dd–668ee), as amended by the National Wildlife Refuge System Improvement Act of 1997 (Improvement Act; Pub. L. 105–57), which authorize FWS to permit a new use on a refuge when FWS determines it is a compatible use. The term ''compatible use'' means a wildlife-dependent recreational use or any other use of a refuge that, in the sound professional judgment of the FWS Director, will not materially interfere with or detract from the fulfillment of the mission of the Refuge System or the purpose(s) of the refuge.

A ''compatibility determination'' is a written determination, signed and dated by the Refuge Manager, that an existing or new use of a refuge is compatible or not compatible with the Refuge System mission or the purpose(s) of the refuge. Currently there are over 560 national wildlife refuges, and each refuge has different establishing authorities, purposes, habitat types, wildlife species, and public uses, which can result in different compatibility determinations for the same use. The Improvement Act required FWS to issue regulations establishing a process for determining whether a proposed use is a compatible use; these regulations are set forth in title 50 of the Code of Federal Regulations at 50 CFR 26.41.

The Improvement Act authorizes FWS to grant a right-of-way when the right-of-way is a compatible use. The regulations at 50 CFR 26.41 state that, for existing rights-of-way, FWS will not make a compatibility determination and will deny any request for maintenance of an existing right-of-way that will affect a unit of the National Wildlife Refuge System, unless ''the design adopts appropriate measures to avoid resource impacts and includes provisions to ensure no net loss of habitat quantity and quality; restored or replacement areas identified in the design are afforded permanent protection as part of the national wildlife refuge or wetland management district affected by the maintenance; and all restoration work is completed by the applicant prior to any title transfer or recording of the easement, if applicable.''

In instances where an existing use is authorized for more than 10 years (such as an electric utility right-of-way), the Improvement Act directs FWS to reevaluate the permitted use to determine compliance with the authorization terms and conditions. All right-of-way permits issued by FWS include language allowing FWS to terminate the right-of-way permit if the grantee's use violates the permit terms and conditions.

The Improvement Act's compatibility requirements do not apply to FWS permitting of rights-of-way across National Fish Hatchery System lands, nor do they apply to permitting of rights-of-way on or across FWS facilities that are not located on Refuge System lands. FWS processes applications for these rights-of-way under the applicable authority cited at 43 CFR part 2800, in accordance with the application procedures at 50 CFR 29.21–2.

Title XI of the Alaska National Interest Lands Conservation Act (ANILCA; Pub. L. 96–487; 16 U.S.C. 3101 *et seq.*) requires the Secretary to provide adequate and feasible access to inholdings within Alaska refuges. The proposed access is subject to a prescribed evaluation process that ensures that the route or method of access avoids or minimizes threats to public health and safety while providing adequate and feasible access to the inholding (see 43 CFR 36.10).

The Administration Act authorizes the Secretary, acting through the FWS Director, to issue a right-of-way permit across Refuge System lands only after the applicant pays FWS the fair market value or fair market rental value of the right-of-way, unless the applicant is exempt from such payment by any other provision of Federal law. In addition, before issuing a right-of-way permit, FWS must assess the effects of the proposed use, as required by the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*); the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*), as amended; the National Historic Preservation Act of 1966 (NHPA; 54 U.S.C. 300101 *et seq.*); and other applicable laws and Executive Orders.

This Proposed Rule

Consistent with Executive Order (E.O.) 13783, ''Promoting Energy Independence and Economic Growth,'' dated March 28, 2017, and E.O. 13821, ''Streamlining and Expediting Requests to Locate Broadband Facilities in Rural America,'' dated January 8, 2018, FWS is streamlining its right-of-way permitting process for proposed uses on FWS-managed lands by aligning FWS processes more closely with those of other DOI bureaus, to the extent practicable and in a manner that is consistent with applicable law. Below, we summarize the substantive proposals included in this document.

The regulations at 50 CFR 29.21–2 currently state that applicants may submit applications for right-of-way permits in any format. However, E.O. 13821 directs Federal agencies to use the ''GSA Common Form Application,'' which refers to the Standard Form 299 (SF–299), Application for Transportation and Utility Systems and Facilities on Federal Lands. Therefore, we propose to revise 50 CFR 29.21–2 to require use of the SF–299 for all requests for right-of-way permits.

The regulations at 50 CFR 29.21–2 currently require applicants to submit applications to a FWS Regional office in hard copy, in triplicate. FWS proposes to require only one copy. Also, we propose to allow electronic application submissions, or E-Filing, as an alternative to hardcopy submissions. Improvements in technology enable FWS to process electronic application submissions more efficiently than hardcopy submissions, and accepting electronic submissions may reduce the amount of time FWS requires to issue a right-of-way permit.

Incomplete information is often the reason right-of-way application processing is delayed. The amount and type of documentation FWS requires to process an application varies depending on whether the request is for a renewal, limited additional use of an existing right-of-way with minimal or no new environmental impacts, or a new right-of-way where significant environmental disturbance may occur. We, therefore, propose to modify the right-of-way application procedures at 50 CFR 29.21–2 to require a standard, no-cost pre-application meeting (in-person or teleconference) for all new proposed rights-of-way and all modifications and renewals of existing rights-of-way, which will enable FWS to determine the documentation needed to process the application. We also propose to revise the application procedures at 50 CFR 29.21–2 to provide the FWS Regional Director more flexibility in determining the documentation required to process an application, and to reduce the documentation requirements for renewals. This change would reduce the regulatory burden on applicants by ensuring that FWS requests only the documentation that it requires to process each application.

We propose to eliminate the requirement at 50 CFR 29.21–7 for an appraisal to determine fair market value or fair market rental value, to reduce the amount of time FWS requires to issue right-of-way permits, by authorizing all Regional Directors to use any DOI-approved method to determine these values, including the use of fee

schedules. This change would reduce the time and cost necessary to determine the fair market value or fair market rental value of many rights-of-way, and, therefore, reduce an applicant's time and cost to obtain a right-of-way permit.

FWS cannot issue a right-of-way permit unless it can accurately locate the requested right-of-way. Aside from the time required to obtain appraisals, a missing or inadequately prepared legal description or survey plat, which FWS uses to accurately locate the requested right-of-way, is the most common cause of FWS delays in issuing a right-of-way permit. Therefore, we propose to clarify the requirements for the legal description and survey plat that applicants must provide with or after application submission but before FWS will issue a right-of-way permit.

FWS last updated the schedule of application fees and monitoring fees at 50 CFR 29.21–2 in 1977. FWS's cost to process applications routinely exceeds the 1977 fee amounts by a factor of five times or more. Currently, 50 CFR 29.21–2 requires applicants to pay a right-of-way application fee and then make periodic additional payments—beyond the initial application fee—to FWS for all additional application processing costs in advance of FWS incurring those costs. We propose to eliminate our application fee and require applicants to reimburse FWS for the costs it incurs while evaluating and processing right-of-way applications and monitoring permitted rights-of-way, and to waive reimbursement of these costs for all applications for rights-of-way from (a) State or local governments or agencies or instrumentalities thereof and (b) Federal Government agencies, as well as for (c) private individuals or organizations when a Regional Director has certified that the right-of-way will contribute to accomplishing the mission of the Refuge System, refuge purposes of the refuge the right-of-way will cross, or fish hatchery purposes of the fish hatchery the right-of-way will cross.

In this proposed rule, provisions for cost recovery associated with our application processing, and with our monitoring, are set forth in a separate section of the regulations. In addition, we are proposing to increase the charge for processing the transfer of a permit from $25 to $100. Finally, we are proposing to increase the amount of no-fault liability for injury and damage to the land and property of the United States from $1,000,000 to $5,000,000 to account for inflation and increased liability measures.

For clarity, we propose to establish separate sections in the regulations to set forth the requirements for pre-application meetings and our compatibility determinations.

In addition, we propose to make editorial changes for clarity and consistency in the regulations, such as removing the word ''easement'' where we simply mean ''permit,'' removing out-of-date and gender-specific references, updating and adding definitions for terms used in the regulations, and updating the amount of the FWS permit transfer fee and the maximum amount of no-fault liability for certain permits to account for the inflation since 1977.

The proposed changes to the right-of-way regulations are at the end of this document. While the proposed revisions to some sections are mostly minor updates as just described, we have set forth the sections in their entirety for the ease and convenience of the reader.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has waived their review regarding their significance determination of this proposed rule.

Executive Order (E.O.) 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

Executive Order 13771

We do not believe this proposed rule is an E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because we believe this rule is not significant under E.O. 12866; however, the Office of Information and Regulatory Affairs has waived their review regarding their E.O. 12866 significance determination of this proposed rule.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires that Federal agencies prepare a regulatory flexibility analysis for rules subject to the notice-and-comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), if the rule would have a significant economic impact, whether detrimental or beneficial, on a substantial number of small entities. *See* 5 U.S.C. 601–612. Congress enacted the RFA to ensure that government regulations do not unnecessarily or disproportionately burden small entities. Small entities include small businesses, small governmental jurisdictions, and small not-for-profit enterprises.

FWS reviewed the Small Business Size standards for the affected industries. We determined that a large share of the entities in the affected industries are small businesses as defined by the Small Business Act. However, FWS believes that the impact on the small entities is not significant, as the proposed rule would impact a small number of small entities, and FWS does not believe that these effects would be economically significant.

The proposed rule would benefit small businesses by streamlining FWS regulations for permitting rights-of-way and thereby reduce the amount of time that FWS requires to issue many right-of-way permits. The proposed rule would implement a pre-application meeting to provide small businesses with information upfront about the FWS's estimated time and cost to evaluate and process a right-of-way application, increasing regulatory certainty. Additionally, the proposed rule would eliminate the FWS application fee and provide FWS the flexibility to request only the documents that it requires to process a right-of-way application, thereby reducing the regulatory burden.

In summary, we have considered whether this proposed rule would result in a significant economic impact on a substantial number of small entities. We certify that, if made final, this proposed rule would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This proposed rule would streamline and expedite FWS processing of industry requests for rights-of-way and modifications to rights-of-way that cross FWS-managed lands, but it would not significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

Under the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

a. This proposed rule would not significantly or uniquely affect small governments. A Small Government Agency Plan is not required.

b. This proposed rule would not produce a Federal requirement of $100 million or greater in any year and is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings—Executive Order 12630

Under Executive Order 12630, this proposed rule would not have significant takings implications as it applies only to FWS permitting of rights-of-way across lands, and interests in land, owned by the United States. A takings implication assessment is not required.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects, as it waives right-of-way application processing costs and right-of-way monitoring costs for State or local governments when the right-of-way is for governmental purposes that benefit the general public, and all other application requirements are necessary for FWS to meet Improvement Act and NEPA requirements. A federalism summary impact statement is not required.

Civil Justice Reform—Executive Order 12988

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). OMB has previously approved the information collection requirements associated with FWS use of Common Form SF–299 and assigned OMB Control Number 0596–0249 (expires 02/28/2023). You may view the information collection request(s) at *http://www.reginfo.gov/public/do/PRAMain.* An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

This proposed rule has no impact on Tribal lands, as it applies only to FWS permitting of rights-of-way across lands, and interests in land, owned by the United States.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are not clearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

List of Subjects in 50 CFR Part 29

Public lands mineral resources, Public lands rights-of-way, Wildlife refuges.

Proposed Regulation Promulgation

For the reasons given in the preamble, we propose to amend part 29, subchapter C of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 29—LAND USE MANAGEMENT

■ 1. The authority citation for part 29 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd, 685, 690d, 715i, 725, 3161; 30 U.S.C. 185; 31 U.S.C. 3711, 9701; 40 U.S.C. 319; 43 U.S.C. 315a; 113 Stat. 1501A–140.

■ 2. Amend § 29.21 by revising the definition of ''*National Wildlife Refuge System land*'' and by adding a definition of ''*Right-of-way*'', in alphabetical order, to read as follows:

§ 29.21 What do these terms mean?

* * * * *

National Wildlife Refuge System land means lands and waters, and interests therein, administered by the Secretary under the National Wildlife Refuge System Administration Act (16 U.S.C. 668dd–668ee), as amended, including wildlife refuges, game ranges, wildlife management areas, conservation areas, waterfowl production areas, and other areas administered for the protection and conservation of fish, wildlife, and plant species.

* * * * *

Right-of-way means a use on, under, or over Federal lands that is authorized pursuant to a right-of-way permit issued by the U.S. Fish and Wildlife Service (Service), unless the use is included in a contract for services to a Service facility or if the use is requested by the Service to benefit the mission of the National Wildlife Refuge System or the National Fish Hatchery System.

■ 3. Amend § 29.21–1 by revising paragraphs (a) through (c) to read as follows:

§ 29.21–1 Purpose and scope.

* * * * *

(a) *National Wildlife Refuge System lands.* Applications for all forms of rights-of-way on or over such lands shall be submitted under authority of Public Law 89–669, (80 Stat. 926; 16 U.S.C. 668dd) as amended, or for oil and gas pipelines under section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*), following application procedures set out in § 29.21–4. The Service will not permit a right-of-way unless it meets the compatibility determination requirement described in § 29.21–3. See § 29.21–12 for additional requirements applicable to rights-of-way for electric power transmission lines and § 29.21–13 for additional requirements applicable to rights-of-way for pipelines for the transportation of oil, natural gas, synthetic liquid or gaseous fuels, or any refined product produced therefrom.

(b) *National Wildlife Refuge System lands—less than fee interest.* Applications for all forms of rights-of-way across lands in which the United States owns only a less than fee interest may be submitted to the Regional Director in letter form. No map exhibit is required; however, the affected land should be described in the letter or shown on a map sketch. If the requested right-of-way will not adversely affect the United States' interest, the Regional Director may issue a letter to the applicant stating that the proposed right-of-way would not affect the interest of the United States and the U.S. Fish and Wildlife Service has no objection to the fee owner granting the proposed right-of-way. If the interest of the United States will be affected, application for the right-of-way must be submitted in accordance with procedures set out in § 29.21–4.

(c) *Other lands outside the National Wildlife Refuge System.* Rights-of-way on or over other lands will be granted in accordance with controlling authorities cited in 43 CFR part 2800, or for oil and gas pipelines under section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*). See § 29.21–12 for additional requirements applicable to rights-of-way for electric power transmission lines and § 29.21–13 for additional requirements applicable to rights-of-way for pipelines for the transportation of oil, natural gas, synthetic liquid or gaseous fuels, or any other refined product produced therefrom. Applications must be submitted in accordance with procedures set out in § 29.21–4.

■ 4. Revise § 29.21–2 to read as follows:

§ 29.21–2 Pre-application meeting.

Before submitting an application for a new right-of-way or a modification of an existing right-of-way across U.S. Fish and Wildlife Service-managed lands, an applicant must contact the Regional Director or his or her designee to schedule a pre-application meeting. The required pre-application meeting (*e.g.,* in-person, web-conference, teleconference, etc.) provides the applicant the opportunity to ask questions about the application process and obtain comments from the Regional Director or his or her designee about a proposed right-of-way and its location before submitting an application. The pre-application meeting helps the Regional Director or his or her designee to understand the scope of the request so that he or she may advise the applicant of the documentation the Service requires to process the application, and provide the applicant an estimated timeline and estimated cost for the Service to review and process the application. There is no fee for this required pre-application meeting. Contact information for scheduling pre-application meetings is set forth at § 29.21–4(c).

■ 5. Redesignate §§ 29.21–3 through 29.21–9 as §§ 29.21–7 through 29.21–13, respectively, and add new §§ 29.21–3 through 29.21–6, to read as follows:

Sec.

* * * * *

§ 29.21–3 Compatibility determination requirement.

§ 29.21–4 Application procedures.

§ 29.21–5 Survey plat and legal description.

§ 29.21–6 Reimbursement of costs.

* * * * *

§ 29.21–3 Compatibility determination requirement.

Consistent with the National Wildlife Refuge System Administration Act, as amended (16 U.S.C. 668dd–668ee), and the procedures set forth in § 26.41, the U.S. Fish and Wildlife Service will not permit or renew a right-of-way if the Service determines that the use is not compatible with the Refuge System mission or the purpose(s) of the refuge, except for uses related to the access of privately owned minerals and as required by any other provision of law, such as section 1110(b) of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3101 *et seq.*) for inholdings within Alaska refuges. In the case of any right-of-way previously permitted for a period longer than 10 years (such as an electric utility right-of-way), the Service will, during the permit term, consider the permitted use to be compatible so long as the grantee is in compliance with all permit terms and conditions.

§ 29.21–4 Application procedures.

(a) *Application.* Applicants must use Standard Form 299 (SF–299), Application for Transportation and Utility Systems and Facilities on Federal Lands, to request new rights-of-way, modifications of existing rights-of-way, and renewals of existing rights-of-way. In addition to a completed and signed SF–299, each application must include the attachments described in paragraphs (a)(1) and (2) of this section. There is no application fee, but applicants must reimburse the Service for its costs to evaluate and process the application, as set forth at § 29.21–6(a). See paragraph (b) of this section for submission instructions.

(1) *Map.* The map must show a general view of the proposed right-of-way and a detailed view of the proposed project area in relationship to the Service boundary. If the proposed right-of-way is within a Public Land Survey System area, the map must show the section(s), township(s), and range(s) within which the proposed right-of-way would be located. See § 29.21–5 for requirements regarding a survey plat and legal description of the area.

(2) *Other attachments.* Following the pre-application meeting described in § 29.21–2, the Regional Director or his or her designee will determine any additional documentation the Service requires to process the application, such as:

(i) *Preliminary site and facility construction plans.* These plans must show all proposed construction work in detail. No site or facility construction plan is required for applications for renewals of existing rights-of-way that involve no changes to the permitted use.

(ii) *Environmental analysis.* The environmental analysis supplements the basic environmental information on the SF–299. It must include information concerning the impact of the proposed right-of-way on the environment, including, but not limited to, the impact on air and water quality; scenic and aesthetic features; historic, architectural, archeological, and cultural features; and wildlife, fish, and marine life.

(A) The environmental analysis must include sufficient data to enable the Service to prepare a compatibility determination; prepare an environmental assessment or environmental impact statement in accordance with section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*); and comply with the requirements of the Migratory Bird Treaty Act of 1918 (16

U.S.C. 703–712), the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*), the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*), the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271 *et seq.*), and the National Historic Preservation Act of 1966 (54 U.S.C. 300101 *et seq.*). To comply with the National Environmental Policy Act, the Regional Director may, at his or her discretion, rely on an environmental assessment or environmental impact statement prepared by another Federal agency, the applicant, or their contractor; however, in all cases, this documentation must be prepared in consultation with the Regional Director or his or her designee.

(B) For applications for renewals of existing rights-of-way that involve no changes to the permitted use, the environmental analysis need address only the impacts of the ongoing operation and maintenance of the right-of-way, as well as any statutory requirements not in place and therefore not considered at the time of original permit issuance.

(iii) *Vegetation management plan.* The vegetation management plan must describe how the applicant would conduct the following activities:

(A) Vegetation clearing that may occur as part of construction and maintenance;

(B) Routine vegetation management, including all physical and mechanical methods;

(C) Any pesticides, herbicides, or other chemicals proposed for use; and

(D) Any revegetation and restoration activities.

(b) *Submission instructions.* Applicants may submit applications for rights-of-way through E-File or certified mail.

(1) *E-file.* Application submissions through E-file must include a digital copy of the SF–299, the map, and other attachments required by the Regional Director or his or her designee after the required pre-application meeting. Additional instructions will be provided at the pre-application meeting.

(2) *Certified mail.* Application submissions through certified mail must include one printed copy of the SF–299, the map, and other attachments required by the Regional Director or his or her designee after the required pre-application meeting. Applicants must send all documents by certified mail to the Regional Director for the region where the proposed right-of-way is located. Mailing envelopes should be clearly marked ''Attn: NWRS Realty Right-of-Way Permit Processing.''

(c) *Pre-application meeting.* To request a pre-application meeting, contact the Division of Realty at Service headquarters at (703) 358–1713. That division will put you in touch with the appropriate Service office, as determined by the location of the proposed right-of-way.

§ 29.21–5 Survey plat and legal description.

(a) Before the Service will issue a right-of-way permit, the applicant must provide a final survey plat and legal description that shows and describes the proposed right-of-way in such detail that the Service can accurately locate the proposed right-of-way.

(b) Survey plats and legal descriptions of the right-of-way area must be stamped and signed by a land surveyor or other professional licensed or authorized by the State to carry out land surveying activities.

(1) Survey plats must meet the following standards:

(i) Survey plats must be geodetically referenced to the current State or national datum. In some cases, new geodetic control points will need to be set within or near the right-of-way area.

(ii) Survey plats must show ties to the monuments marking the boundaries of the Service-owned land that is being impacted, or from which those boundaries are calculated. In cases such as road construction that involve granting full control of the right-of-way area, a boundary survey is required.

(iii) The points where the right-of-way enters and leaves Service project land must be annotated on the survey with distance ties to the nearest boundary monuments.

(iv) For a linear strip right-of-way, the courses and distances of the center line and the width of the right-of-way on each side of the center line must be annotated.

(v) If the right-of-way or site is located wholly within Service land, a minimum of two ties to boundary corners or geodetic control points that can be readily recovered must be shown.

(vi) Survey plats must show the existing or proposed facilities in sufficient detail that an average person can determine the nature and extent of the proposed use.

(vii) Survey plats must include all uses of Service-managed land required as part of the right-of-way, including access roads.

(viii) Survey plats must show the location of any other right-of-way areas in the vicinity.

(ix) Survey plats must show major natural or cultural features such as roads, rivers, fences, etc., required for orientation and intelligent interpretation.

(x) The acreage contained within the right-of-way area must be shown.

(xi) Letter-sized plats are preferred, but larger format plats, such as the Right-of-Way Plan sets prepared for highway and utility projects, are acceptable as long as they meet the other requirements.

(xii) A digital version of the plat in AutoCAD, ArcGIS, or similar format must be submitted along with a signed paper or Adobe Acrobat document.

(2) The legal description must:

(i) Be in metes-and-bounds, aliquot parts, or linear strip format;

(ii) Conform to and reference the survey plat;

(iii) Be tied to the controlling monuments shown on the plat;

(iv) Reference the geodetic coordinates of the Point of Beginning or Point of Commencement, and have a clearly documented basis of bearing; and

(v) For linear corridor projects, use a ''strip description'' format, based on a geometrically defined centerline. For example: ''All that portion of [land unit description] lying within the following described strip of land.''

§ 29.21–6 Reimbursement of costs.

(a) *Application evaluation and processing activities.* (1) An applicant for a right-of-way permit must reimburse the United States for the costs the U.S. Fish and Wildlife Service incurs in evaluating and processing the application before the Service will issue a right-of-way permit. These costs may include, but are not limited to, the Service's costs to review the application and related materials; conduct resource surveys of the proposed permit area; prepare a compatibility determination; prepare documentation to comply with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*); obtain an appraisal; draft correspondence; and draft the permit.

(2) If requested by the applicant during or after the required pre-application meeting, the Regional Director or his or her designee will, within ten business days of the pre-application meeting, provide the applicant a preliminary estimate of the Service's application evaluation and processing costs using the information provided by the applicant during the pre-application meeting.

(3) After receiving an application, the Regional Director or his or her designee will estimate the Service's application evaluation and processing costs using the information the applicant provided in the application and during the required pre-application meeting.

(4) The applicant must submit a payment to reimburse the Service for its estimated costs, before the Service will evaluate and process the right-of-way permit application.

(5) If the Service's cost to evaluate and process the right-of-way application exceeds the estimated amount, the Regional Director or his or her designee will promptly notify the applicant of the deficient amount, and the applicant must submit payment for the deficient amount before the Service will issue a right-of-way permit. Any overpayments may be refunded by the Regional Director as he or she deems appropriate.

(b) *Monitoring activities.* (1) By accepting a permit under this subpart, the holder agrees to reimburse the Service for the costs it incurs in monitoring the construction, operation, maintenance, and termination of facilities to ensure compliance with the terms, conditions, and stipulations of the right-of-way permit, referred to in this paragraph as ''monitoring activities.''

(2) The Regional Director or his or her designee will estimate the total costs the Service expects to incur for monitoring activities over the first 5 years of the permit term or the entire permit term, whichever is less. The applicant must pay the estimated amount before the Service will issue a right-of-way permit.

(3) The permit holder must make an additional payment every 5 years, or for the remainder of the permit term, whichever is less, to reimburse the Service for the costs the Service expects to incur for monitoring activities during that period.

(4) If the Service's cost of monitoring activities exceeds the Service's estimated amount, then the permit holder must submit payment to the United States for the deficient amount at the end of the 5 years or the remainder of the permit term, whichever is less. Any overpayments may be refunded by the Regional Director as he or she deems appropriate.

(c) *Waiver of reimbursement for Service costs.* (1) Except as provided under paragraph (c)(2) of this section, no reimbursement for Service costs for right-of-way application evaluation and processing activities and monitoring activities will be required of:

(i) State or local governments or agencies or instrumentalities thereof;

(ii) Federal Government agencies; or

(iii) Private individuals or organizations when a Regional Director has signed a statement certifying that the proposed right-of-way contributes to accomplishing refuge or fish hatchery purposes.

(2) Reimbursement of costs is required for any right-of-way permit issued under section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*).

■ 6. Amend newly redesignated § 29.21–7 by revising paragraph (a) to read as follows:

§ 29.21–7 Nature of interest granted.

(a) Where the land administered by the U.S. Fish and Wildlife Service is owned in fee by the United States and the right-of-way is compatible with the objectives of the area, a permit may be approved and granted by the Regional Director. Generally, a permit will be issued for a term of up to 50 years, or so long as it is used for the purpose granted, or for a lesser term when considered appropriate.

(1) For rights-of-way granted under authority of section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*), for pipelines for the transportation of oil, natural gas, synthetic liquid or gaseous fuels, or any refined product produced therefrom, the permit may be for a term not to exceed 30 years.

(2) For a right-of-way issued per paragraph (a)(1) of this section, the right-of-way may not exceed 50 feet in width, plus the area occupied by the pipeline and its related facilities, unless the Regional Director finds, and records the reasons for the finding, that, in his or her judgment, a wider right-of-way is necessary for operation and maintenance after construction or to protect the environment or public safety. Related facilities include but are not limited to valves, pump stations, supporting structures, bridges, monitoring and communication devices, surge and storage tanks, terminals, etc.

(3) A temporary permit supplementing a right-of-way may be granted for additional land needed during construction, operation, maintenance, or termination of the pipeline, or to protect the natural environment or public safety.

* * * * *

■ 7. Revise newly redesignated § 29.21–8 to read as follows:

§ 29.21–8 Terms and conditions.

(a) Any right-of-way permit granted will be subject to rights reserved, if any, by a prior owner, and rights held, if any, by a third party.

(b) An applicant, by accepting a permit, agrees to such terms and conditions as may be prescribed by the Regional Director in the granting document, including special stipulations at his or her discretion. (See § 29.21–12 for special requirements for electric powerlines and § 29.21–13 for special requirements for oil and gas pipelines.) The applicant shall agree to the following terms and conditions, unless waived in all or part by the Regional Director:

(1) To comply with State and Federal laws applicable to the project within which the permit is granted, and to the lands that are included in the right-of-way, and lawful existing regulations thereunder.

(2) To clear and keep clear the lands within the permit area to the extent and in the manner directed by the project manager in charge; and to dispose of all vegetative and other material cut, uprooted, or otherwise accumulated during the construction and maintenance of the project in such a manner as to decrease the fire hazard and also in accordance with such instructions as the project manager may specify.

(3) To prevent the disturbance or removal of any public land survey monument or project boundary monument unless and until the applicant has requested and received from the Regional Director approval of measures the applicant will take to perpetuate the location of aforesaid monument.

(4) To take such soil and resource conservation and protection measures, including weed control, on the land covered by the permit as the project manager in charge may request.

(5) To do everything reasonably within his or her power, both independently and on request of any duly authorized representative of the United States, to prevent and suppress fires on or near lands to be occupied under the permit area, including making available such construction and maintenance forces as may be reasonably obtainable for the suppression of such fires.

(6) To rebuild and repair such roads, fences, structures, and trails as may be destroyed or injured by construction work and, upon request by the Regional Director, to build and maintain necessary and suitable crossings for all roads and trails that intersect the works constructed, maintained, or operated under the right-of-way.

(7) To pay the United States the full value for all damages to the lands or other property of the United States caused by him or her or by his or her employees, contractors, or agents of the contractors, and to indemnify the United States against any liability for damages to life, person, or property arising from the occupancy or use of the lands under the permit.

(i) Where the permit is granted hereunder to a State or other governmental agency that has no legal power to assume such a liability with respect to damages caused by it to lands or property, such agency in lieu thereof agrees to repair all such damages.

(ii) Where the permit involves lands that are under the exclusive jurisdiction of the United States, the holder or his or her employees, contractors, or agents of the contractors, shall be liable to third parties for injuries incurred in connection with the permit area.

(iii) Grants of permits involving special hazards will impose liability without fault for injury and damage to the land and property of the United States up to a specified maximum limit commensurate with the foreseeable risks or hazards presented. The amount of no-fault liability for each occurrence is hereby limited to no more than $5,000,000.

(8) To notify promptly the project manager in charge of the amount of merchantable timber, if any, that will be cut, removed, or destroyed in the construction and maintenance of the project, and to pay the United States in advance of construction such sum of money as the project manager may determine to be the full stumpage value of the timber to be so cut, removed, or destroyed.

(9) That all or any part of the permit granted may be terminated by the Regional Director, for failure to comply with any or all of the terms or conditions of the permit, or for abandonment.

(i) A rebuttable presumption of abandonment is raised by deliberate failure of the holder to use, for any continuous 2-year period, the permit for the purpose for which it was granted or renewed. In the event of noncompliance or abandonment, the Regional Director will notify in writing the holder of the permit of his or her intention to suspend or terminate such permit 60 days from the date of the notice, stating the reasons therefor, unless prior to that time the holder completes such corrective actions as are specified in the notice. The Regional Director may grant an extension of time within which to complete corrective actions when, in his or her judgment, extenuating circumstances not within the holder's control, such as adverse weather conditions, disturbance to wildlife during breeding periods or periods of peak concentration, or other compelling reasons, warrant.

(ii) Should the holder of a right-of-way issued under authority of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*), fail to take corrective action within the 60-day period, the Regional Director will provide for an administrative proceeding pursuant to 5 U.S.C. 554, prior to a final Departmental decision to suspend or terminate the permit. In the case of all other right-of-way holders, failure to take corrective action within the 60-day period will result in a determination by the Regional Director to suspend or terminate the permit.

(iii) No administrative proceeding shall be required where the permit terminates under its terms.

(10) To restore the land to the condition it was in prior to issuance of the permit, so far as it is reasonably possible to do so upon revocation and/or termination of the permit, unless this requirement is waived in writing by the Regional Director.

(11) To keep the project manager informed at all times of his or her address, and, in case of corporations, of the address of its principal place of business and the names and addresses of its principal officers.

(12) That in the construction, operation, and maintenance of the project, he or she must not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin and must require an identical provision to be included in all subcontracts.

(13) That the grant of the permit shall be subject to the express condition that the exercise thereof will not unduly interfere with the management, administration, or disposal by the United States of the land affected thereby. The applicant agrees and consents to the occupancy and use by the United States, its grantees, permittees, or lessees of any part of the permit area not actually occupied for the purpose of the granted rights to the extent that such use does not interfere with the full and safe utilization thereof by the holder. The holder of a permit also agrees that authorized representatives of the United States shall have the right of access to the permit area for the purpose of making inspections and monitoring the construction, operation, and maintenance of facilities.

(14) That the permit herein granted shall be subject to the express covenant that any facility constructed thereon will be modified or adapted, if such is found by the Regional Director to be necessary, without liability or expense to the United States, so that such facility will not conflict with the use and occupancy of the land for any authorized works that may hereafter be constructed thereon under the authority of the United States. Any such modification will be planned and scheduled so as not to interfere unduly with or to have minimal effect upon continuity of energy and delivery requirements.

(15) That the permit herein granted shall be for the specific use described and may not be construed to include the further right to authorize any other use within the permit area unless approved in writing by the Regional Director.

(16) The Regional Director may require permit modifications at any future date to ensure that the permitted use is compatible with the Refuge System mission and the purposes of the refuge. Required permit modifications may include changes to permit conditions and/or additional stipulations that a Regional Director deems necessary based on new information.

(17) The permittee will comply with the Archaeological Resources Protection Act (16 U.S.C. 470aa). The disturbance of archaeological or historical sites and the removal of artifacts from Federal land are prohibited. If such sites or artifacts are encountered, the permittee will immediately cease all work upon Federal land and notify the project manager.

(18) The permittee will comply with the applicable requirements of the Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–712), the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*), the Wilderness Act of 1964 (16 U.S.C. 1131 *et seq.*), the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271 *et seq.*), and the National Historic Preservation Act of 1966 (54 U.S.C. 300101 *et seq.*).

§ 29.21–9 [Amended]

■ 8. Amend newly redesignated § 29.21–9 by, in paragraph (a), adding the words ''or her'' after the word ''his''.

■ 9. Amend newly redesignated § 29.21–10 by:

■ a. Revising paragraph (b) to read as set forth below; and

■ b. In paragraph (c), adding the words ''or her'' after the word ''him''.

§ 29.21–10 Disposal, transfer or termination of interest.

* * * * *

(b) *Transfer of permit.* Any proposed transfer, by assignment, lease, operating agreement or otherwise, of a permit must be filed with the Regional Director and must be supported by a stipulation that the transferee agrees to comply with and be bound by the terms and conditions of the original grant. A $100 nonrefundable service fee must accompany the proposal. No transfer will be recognized unless and until

approved in writing by the Regional Director.

* * * * *

■ 10. Revise newly redesignated § 29.21–11 to read as follows:

§ 29.21–11 Required Payment for use and occupancy of national wildlife refuge lands.

(a) Payment for use and occupancy of lands under the regulations of this subpart is required for the fair market value or fair market rental value as determined by the Regional Director using any Department of the Interior-approved method to determine those values.

(1) At the discretion of the Regional Director, the payment may be a fair market rental payment, paid annually, or a lump sum payment, made in advance of permit issuance.

(2) If any Federal, State, or local agency is exempt from such payment under any other provision of Federal law, such agency shall inform the U.S. Fish and Wildlife Service of the applicable Federal law during the required pre-application meeting, and shall otherwise compensate the Service by any other means acceptable to the Regional Director, including, but not limited to, making other land available or loaning of equipment or personnel, except that any such compensation shall relate to, and be consistent with, the mission of the National Wildlife Refuge System. For these agencies exempted from payment by law, the Regional Director may waive such requirement for other compensation if he or she finds such requirement impracticable or unnecessary.

(b) When annual rental payments are used, such rates will be reviewed by the Regional Director not more than every 5 years after the issuance of the permit or the last revision of the permit, whichever is later. The Regional Director will furnish a notice in writing to the holder of a permit of intent to impose new charges to reflect fair market value commencing with the ensuing charge year. The revised charges will be effective unless the holder files an appeal in accordance with § 29.22.

§ 29.21–12 [Amended]

■ 11. Amend newly redesignated § 29.21–12 by:

■ a. In the introductory text, by removing the citation ''§ 29.21–4(b)'' and adding in its place the citation ''§ 29.21–8(b)'';

■ b. In paragraph (a), by adding the words ''or her'' after the word ''his'' both times that it appears; and

■ c. In paragraph (b), by adding the words ''or her'' after the word ''him'' both times that it appears.

■ 12. Revise newly redesignated § 29.21–13 to read as follows:

§ 29.21–13 Rights-of-way for pipelines for the transportation of oil, natural gas, synthetic liquid or gaseous fuels, or any refined product produced therefrom.

(a) *Application procedure.* (1) Applications for pipelines and related facilities under this section are to be filed in accordance with § 29.21–4 with the following exception: When the right-of-way or proposed facility will occupy Federal land under the control of more than one Federal agency and/or more than one bureau or office of the Department of the Interior, a single application shall be filed with the appropriate State Director of the Bureau of Land Management in accordance with regulations in 43 CFR part 2800.

(2) Any portion of the facility occupying land of the National Wildlife Refuge System will be subject to the provisions of the regulations in this part.

(b) *Right-of-way permits.* Right-of-way permits issued under this section will be subject to the special requirements of section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*). Gathering lines and associated structures used solely in the production of oil and gas under valid leases on the lands administered by the U.S. Fish and Wildlife Service are excepted from the provisions of this section.

(1) *Pipeline safety.* Rights-of-way permits issued under this section will include requirements that will protect the safety of workers and protect the public from sudden ruptures and slow degradation of the pipeline. An applicant must agree to design, construct, and operate all proposed facilities in accordance with the provisions of 49 CFR parts 192 or 195 and in accordance with the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*), including any amendments thereto.

(2) *Environmental protection.* An application for a right-of-way must contain environmental information required by § 29.21–4(a)(2). If the Regional Director determines that a proposed project will have a significant effect on the environment, there must also be furnished a plan of construction, operation, and rehabilitation of the proposed facilities. In addition to terms and conditions imposed under § 29.21–8, the Regional Director will impose such stipulations as may be required to ensure:

(i) Restoration, revegetation, and curtailment of erosion of the surface;

(ii) That activities in connection with the right-of-way or permit will not violate applicable air and water quality standards in related facilities siting standards established by law;

(iii) Control or prevention of damage to the environment including damage to fish and wildlife habitat, public or private property, and public health and safety; and

(iv) Protection of the interests of individuals living in the general area of the right-of-way who rely on the fish, wildlife, and biotic resources of the area for subsistence purposes.

(c) *Disclosure.* Applicants that are a partnership, corporation, association, or other business entity must disclose the identity of the participants in the entity. Such disclosure shall include where applicable:

(1) The name and address of each partner;

(2) The name and address of each shareholder owning 3 percentum or more of the shares, together with the number and percentage of any class of voting shares of the entity that such shareholder is authorized to vote; and

(3) The name and address of each affiliate of the entity together with, in the case of an affiliate controlled by the entity, the number of shares and the percentage of any class of voting stock of that affiliate owned, directly or indirectly, by that entity, and in the case of an affiliate which controls that entity, the number of shares and the percentage of any class of voting stock of that entity owned, directly or indirectly, by the affiliate.

(d) *Technical and financial capability.* The Regional Director may grant or renew a right-of-way permit under this section only when he or she is satisfied that the applicant has the technical and financial capability to construct, operate, maintain, and terminate the facility. At the discretion of the Regional Director, a financial statement may be required.

(e) *Reimbursement of costs.* In accordance with § 29.21–6, the holder of a right-of-way permit must reimburse the Service for the cost incurred in monitoring the construction, operation, maintenance, and termination of any pipeline or related facilities as determined by the Regional Director.

(f) *Public hearing.* The Regional Director shall give notice to Federal, State, and local government agencies, and the public, and afford them the opportunity to comment on right-of-way applications under this section. A notice will be published in the **Federal**

Register, and a public hearing may be held where appropriate.

(g) *Bonding.* Where appropriate, the Regional Director may require the holder of a right-of-way permit to furnish a bond, or other security satisfactory to him, to secure all or any of the obligations imposed by the terms and conditions of the right-of-way permit or by any rule or regulation, not to exceed the period of construction plus 1 year or a longer period if necessary for the pipeline to stabilize.

(h) *Suspension of right-of-way.* If the project manager determines that an immediate temporary suspension of activities within a right-of-way permit area is necessary to protect public health and safety or the environment, he or she may issue an emergency suspension order to abate such activities prior to an administrative proceeding. The Regional Director must make a determination and notify the holder in writing within 15 days from the date of suspension as to whether the suspension should continue and list actions needed to terminate the suspension. Such suspension shall remain in effect for only so long as an emergency condition continues.

(i) *Joint use of rights-of-way.* Each right-of-way permit shall reserve to the Regional Director the right to grant additional rights-of-way permits for compatible uses on or adjacent to rights-of-way permit areas granted under this section after giving notice to the holder and an opportunity to comment.

(j) *Common carriers.* Pipelines and related facilities used for the transportation of oil, natural gas, synthetic liquid or gaseous fuels, or any refined product produced therefrom shall be constructed, operated, and maintained as common carriers.

(1) The owners or operators of pipelines subject to this subpart shall accept, convey, transport, or purchase without discrimination all oil or gas delivered to the pipeline without regard to whether such oil or gas was produced on Federal or non-Federal lands.

(2) In the case of oil or gas produced from Federal lands or from the resources on the Federal lands in the vicinity of the pipelines, the Secretary may, after a full hearing with due notice thereof to the interested parties and a proper finding of facts, determine the proportionate amounts to be accepted, conveyed, transported, or purchased.

(3) The common carrier provisions of this section shall not apply to any natural gas pipeline operated by any person subject to regulation under the Natural Gas Act or by any public utility subject to regulation by a State or municipal regulatory agency having jurisdiction to regulate the rates and charges for the sale of natural gas to consumers within the State or municipality.

(4) Where natural gas not subject to State regulatory or conservation laws governing its purchase by pipelines is offered for sale, each such pipeline shall purchase, without discrimination, any such natural gas produced in the vicinity of the pipeline.

(k) *Required information.* The Regional Director shall require, prior to granting or renewing a right-of-way, that the applicant submit and disclose all plans, contracts, agreements, or other information or material that the Regional Director deems necessary to determine whether a right-of-way shall be granted or renewed and the terms and conditions that should be included in the right-of-way. Such information may include, but is not limited to:

(1) Conditions for, and agreements among owners or operators, regarding the addition of pumping facilities, looping, or otherwise increasing the pipeline or terminal's throughput capacity in response to actual or anticipated increases in demand;

(2) Conditions for adding or abandoning intake, offtake, or storage points or facilities; and

(3) Minimum shipment or purchase tenders.

(l) *State standards.* The Regional Director shall take into consideration, and to the extent practical comply with, applicable State standards for right-of-way construction, operation, and maintenance.

(m) *Congressional notification.* The Secretary shall promptly notify the Committee on Natural Resources of the United States House of Representatives and the Committee on Energy and Natural Resources of the United States Senate upon receipt of an application for a right-of-way for pipeline 24 inches or more in diameter, and no right-of-way for such a pipeline shall be granted until 60 days (not including days on which the House or Senate has adjourned for more than 3 days) after a notice of intention to grant the right-of-way, together with the Secretary's detailed findings as to the terms and conditions he or she proposes to impose, has been submitted to such committees.

George Wallace,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2021–00704 Filed 1–15–21; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register

Vol. 86, No. 11

Tuesday, January 19, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0050]

Monsanto Company; Determination of Nonregulated Status for Insect Resistant Cotton

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the cotton event designated as MON 88702, which has been genetically engineered for resistance to certain insects, primarily *Lygus* spp., is no longer considered regulated under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on evaluation of information Monsanto Company submitted in its petition for a determination of nonregulated status, our analyses, and public comments received in response to previous notices announcing the availability of the petition for nonregulated status and our associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: This change in regulatory status will be recognized January 19, 2021.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0050,* or in our reading room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

Supporting documents are also available on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status.*

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3892; email: *cynthia.a.eck@usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products modified or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests.

Pursuant to the terms set forth in a final rule published in the **Federal Register** on May 18, 2020 (85 FR 29790–29838, Docket No. APHIS–2018–0034),[1] any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340.

APHIS received a petition (APHIS Petition Number 19–091–01p) from Monsanto Company (Monsanto) on May 28, 2019, seeking a determination of nonregulated status for a cotton event designated as MON 88702, which has been genetically engineered for resistance to certain insects, primarily *Lygus* spp. The Monsanto petition stated that this cotton is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process[2] for soliciting public comment when considering petitions for determination of nonregulated status of organisms developed using genetic engineering, APHIS accepts written comments regarding a petition once APHIS deems it complete. On September 26, 2019, APHIS published a notice[3] in the **Federal Register** (84 FR 50818–50819, Docket No. APHIS–2019–0050) announcing the availability of the Monsanto petition for public comment. Thirty-five comments were received. Fifteen comments from the agricultural, academic, and private sector were in support of Monsanto's petition. Fourteen comments from individuals were opposed to approval of Monsanto's petition. Six comments provided input on analyses to be considered in the environmental assessment (EA), or comments on insect-resistant crops in general. APHIS evaluated the issues raised during the initial comment period and, where appropriate, incorporated a discussion of them within a draft EA.

A second opportunity for public involvement was provided on October 16, 2020, with a notice[4] published in the **Federal Register** (85 FR 65789–65790, Docket No. APHIS–2019–0050) announcing the availability of the draft EA and draft plant pest risk assessment (PPRA) for public review and comment. That comment period closed November 16, 2020. APHIS received 14 comments. Most were supportive of Monsanto's petition request; three were opposed. None of the comments identified new information or data regarding the draft EA or draft PPRA.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA, draft PPRA, and other information, APHIS has prepared a final EA, which provides the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of MON 88702 cotton. The EA was prepared in accordance with: (1) the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et*

[1] Although this final rule (termed the SECURE rule) published revisions to 7 CFR part 340 with phased effective dates beginning August 17, 2020 (*https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf*), the SECURE rule stated that the petition evaluation process found in the previous regulations would continue to be used for a period of time following that August 17, 2020 effective date. This product was evaluated in accordance with that process.

[2] On March 6, 2012, APHIS published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.*

[3] To view the notice, the petition, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0050.*

[4] See footnote 3.

seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact (FONSI) with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of MON 88702 cotton).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, the public comments, and information provided in APHIS' response to those public comments, APHIS has determined that MON 88702 cotton is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain organisms developed using genetic engineering.

Copies of the signed determination document, PPRA, final EA, and FONSI, as well as the previously published petition and supporting documents, are available as indicated under **ADDRESSES** and from the person listed under the **FOR FURTHER INFORMATION CONTACT** section in this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 12th day of January 2021.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–00956 Filed 1–15–21; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the Nebraska Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that the Nebraska State Advisory Committee to the Commission will hold virtual meetings on Monday, February 22, 2021 from 10:00 a.m.–11:00 a.m. (CT); Monday, March 1, 2021 from 9:00 a.m.–10:00 a.m. (CT); and Wednesday, March 10, 2021 from 10:00 a.m.–11:00 a.m. (CT). The purpose of these meetings is to review and approve the Committee's draft report to the Commission on the use of Native American symbols, names, and imagery in school mascots.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski at *mwojnaroski@usccr.gov,* or by phone at (202) 618–4158.

SUPPLEMENTARY INFORMATION:

Meeting Access: These meetings will be held on:

- Monday, February 22, 2021, at 10:00 a.m. to 11:00 a.m. (CT)
  - *Join online (audio/visual): https://tinyurl.com/y3h8xdo3*
  - *Join by phone (audio only):* 800–360–9505; Access code: 199 004 6752
- Monday, March 1, 2021, at 9:00 a.m. to 10:00 a.m. (CT)
  - *Join online (audio/visual): https://tinyurl.com/y6ctrto5*
  - *Join by phone (audio only):* 800–360–9505; Access code: 199 073 3890
- Wednesday, March 10, 2021 at 10:00 a.m. to 11:00 a.m. (CT)
  - *Join online (audio/visual): https://tinyurl.com/y6xucvps*
  - *Join by phone (audio only):* 800–360–9505; Access code: 199 518 6743

These meetings are available to the public through the registration links above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, according to their wireless plans. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for each meeting.

Members of the public are entitled to make comments during the open period at the end of each meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Melissa Wojnaroski at *mojnaroski@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 618–4158. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda: Monday, February 22, 2021 from 10:00 a.m.–11:00 a.m. (CT); Monday, March 1, 2021 from 9:00 a.m.–10:00 a.m.; (CT) and Wednesday, March 10, 2021 from 10:00 a.m.–11:00 a.m. (CT).

I. Welcome and Roll Call
II. Announcements and Updates
III. Approval of Minutes
IV. Discussion of draft report
V. Public Comment
VI. Next Steps
VII. Adjournment

Dated: January 13, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–01057 Filed 1–15–21; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Office of the Under Secretary for Economic Affairs

Request for Comments for the Advisory Committee on Data for Evidence Building

AGENCY: Office of the Under Secretary for Economic Affairs, Department of Commerce.

ACTION: Request for comments.

SUMMARY: The Foundations for Evidence-Based Policymaking Act of 2018 requires federal agencies to modernize their data management practices to develop and support evidence-based policymaking. The Act requires the Director of the Office of Management and Budget (OMB), or the head of an agency designated by the Director, to establish the Advisory Committee on Data for Evidence Building (Advisory Committee). In a letter dated September 3, 2019, OMB delegated managerial and administrative responsibility for this Federal advisory committee to the Department of Commerce Office of Under Secretary for Economic Affairs (OUSEA).

DATES: Comments must be received by Tuesday, February 9, 2021.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Docket ID—EAB–2021–0001–0001.
- By email directly to *Evidence@bea.gov.* Begin with the phrase

''Comments for the Advisory Committee on Data for Evidence Building;'' and indicate which numbered questions described in the **SUPPLEMENTARY INFORMATION** of this notice your comments address. Comments by fax or paper delivery will not be accepted.

Privacy Note: Comments submitted in response to this notice may be made available to the public through relevant websites. Therefore, commenters should only include information they wish to make publicly available on the internet. Do not submit confidential business information or otherwise sensitive or protected information.

Please note the confidentiality of routine communication and responses to this public comment request are treated as public comments and may therefore be made publicly available, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Lucas Hitt, Designated Federal Official, Advisory Committee on Data for Evidence Building, 4600 Silver Hill Road, Washington, DC 20233 by email Gianna Marrone (*gianna.marrone@bea.gov*) or by phone (301) 278–9282.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Advisory Committee will review, analyze, and make recommendations on how to promote the use of data for evidence building. The Advisory Committee will evaluate and provide recommendations to the Director of the Office of Management and Budget on how to facilitate data sharing, data linkage, and privacy enhancing techniques in support of evidence building. As part of its evaluation, the Advisory Committee may consider best practices to improve the safe and appropriate access to data. The Advisory Committee will consider the coordination of data sharing and availability of data for evidence building across all agencies and levels of government. The FRN commentators may respond to any question and do not need to respond to all questions.

This request for comments offers researchers, evaluators, contractors, government entities, and other interested parties the opportunity to inform the Committee's work. This is a general solicitation of comments from the public. The Advisory Committee will consider all feedback and recommendations on core topics and central issues such as:

- Capacity needs for secure data access and record linkage.
- Areas for research and development on state-of-the-art data access and data protection methods.
- How to protect privacy when using personally identifiable information or confidential business information in support of evidence building.
- How to promote transparency and facilitate public engagement with the evidence building process.
- Agency needs for data management and data stewardship services.
- How to best facilitate the needs of researchers, evaluators, and other evidence builders through a national data service or similar approach.

Please clearly indicate which question(s) you address in your response and any evidence to support assertions, where practicable.

Round 1

Central Questions—

1. What are the main challenges faced by national, state/provincial, or local governments that are trying to build a basis for evidence-based policy? Briefly describe the bottlenecks and pain-points they face in the evidence-based decision-making process.

2. What are examples of high-impact data uses for evidence-based policy making that successfully effected change, reduced costs, or improved the welfare of citizens?

3. Which frameworks, policies, practices, or methods show promise in overcoming challenges experienced by governments in their evidence building?

4. The Commission on Evidence-Based Policymaking (See: *www.cep.gov*) recommended the creation of a National Secure Data Service (See Commission Report at *www.cep.gov*). Do you agree with this recommendation, and if so, what should be the essential features of a National Secure Data Service?

5. How can federal agencies protect individual and organizational privacy when using data for evidence building? Recommend specific actions the Office of Management and Budget and/or other federal agencies can take when using data for evidence building, as well as suggested changes to federal laws, policies, and procedures.

Secure Data Access—

6. If created, how should a data service be structured to best facilitate (1) research and development of secure data access and confidentiality technologies and methods, (2) and agency adoption of those technologies and techniques?

7. Government agencies have argued that secure data access has value because it (1) improves service delivery, (2) improves efficiency (lowers costs), (3) produces metrics for performance measurement, and (4) produces new learnings/insights from the data. Which of these propositions do you agree holds value and why? Do you have examples that demonstrate these benefits? Do you have other examples of the value of secure data access?

Data Services to Federal, State, Local Agencies and the Public—

8. What are the most pressing data needs of state and local decision makers and how would making data accessible from federal agencies help meet those needs? To share data, what guarantees do data owners (or data controllers) need regarding privacy, data stewardship, and retention?

9. What are the key problems and use cases where collaborative work between federal, state, and local authorities' data analysis can inform decisions? What are key decision support tools? How would greater communication about data and tools benefit expanded evidence building?

Infrastructure for Meeting Public and Evidence Building Needs—

10. What basic public data services are essential for a data service to address existing capacity gaps and needs? What infrastructure or incentives can the federal government create that locals and states cannot?

Dated: December 9, 2020.

Gianna Marrone,

Assistant Designated Federal Official, Advisory Committee on Data for Evidence Building.

[FR Doc. 2021–01092 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–MN–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–843]

Certain Lined Paper Products From India: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on certain lined paper products from India, covering the period of review (POR), September 1, 2018 through August 31, 2019. We preliminarily find that Navneet Education Ltd. (Navneet) and Super Impex did not make sales of subject merchandise at less than normal value during the POR. We invite interested

parties to comment on these preliminary results.

DATES: Applicable January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone: (202) 482–7851.

SUPPLEMENTARY INFORMATION:

Background

On September 28, 2006, Commerce published the *Order* in the **Federal Register**.[1] On November 12, 2019, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the *Order*.[2]

On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[3] On June 11, 2020, we extended the deadline for the preliminary results to November 18, 2020.[4] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[5] The deadline for the preliminary results of this review is now January 19, 2021.

Commerce initiated this administrative review covering the following 13 companies: Cellpage Ventures Private Limited (Cellpage); Goldenpalm Manufacturers PVT Limited (Goldenpalm); Kokuyo Riddhi Paper Products Pvt. Ltd. (Kokuyo); Lodha Offset Limited (Lodha); Lotus Global Private Limited (Lotus Global); Magic International Pvt. Ltd. (Magic); Marisa International (Marisa); Navneet; Pioneer Stationery Pvt. Ltd. (Pioneer); PP Bafna Ventures Private Limited (PP Bafna); SAB International (SAB); SGM Paper Products (SGM); and Super Impex.[6] This review covers two mandatory respondents, Navneet and Super Impex. The other 11 companies were not selected for individual examination and remain subject to this administrative review.

Scope of the Order

The merchandise covered by the *Order* is certain lined paper products. The merchandise subject to this order is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4811.90.9035, 4811.90.9080, 4820.30.0040, 4810.22.5044, 4811.90.9050, 4811.90.9090, 4820.10.2010, 4820.10.2020, 4820.10.2030, 4820.10.2040, 4820.10.2050, 4820.10.2060, and 4820.10.4000. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[7]

Preliminary Determination of No Shipments

On November 19 and November 26, 2019, Lodha and Marisa, respectively, submitted responses to Commerce's quantity and value questionnaire which indicated that the companies had no exports or sales of subject merchandise into the United States during the POR.[8] To confirm Lodha and Marisa's no-shipment claims, on December 6, 2019, Commerce issued a no-shipment inquiry to U.S. Customs and Border Protection (CBP) concerning the two companies.[9] CBP reported that it had no information to contradict Marisa's no shipments claim during the POR, but it found certain inconsistencies with respect to Lodha's no shipment claim.[10]

Given that Marisa reported that it made no shipments of subject merchandise to the United States during the POR, and there is no information calling Marisa's claim into question, we preliminarily determine that Marisa did not have any reviewable transactions during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to Marisa but, rather, will complete the review and issue instructions to CBP based on the final results.[11] Concerning Lodha, for these preliminary results, we have included it among the firms subject to the rate for non-selected respondents.

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Rate for Non-Selected Respondents

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from the People's Republic of China; Notice of Antidumping Duty Orders: Certain Lined Paper Products from India, Indonesia and the People's Republic of China; and Notice of Countervailing Duty Orders: Certain Lined Paper Products from India and Indonesia,* 71 FR 56949 (September 28, 2006) (*Order*).

[2] *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 61011 (November 12, 2019) (*Initiation Notice*).

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[4] *See* Memorandum, ''Certain Lined Paper Products from India: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,'' dated June 11, 2020.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[6] *Initiation Notice,* 84 FR at 61012–61013.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Lined Paper Products from India; 2018–2019,'' dated concurrently and hereby adopted by this notice (Preliminary Decision Memorandum).

[8] *See* Lodha's Letter, ''Response to Quantity & Value Questionnaire,'' dated November 19, 2019; *see also* Marisa's Letter, ''Certain Lined Paper Products from India: Marisa International ('Marisa') No export or sales of subject merchandise,'' dated November 26, 2019.

[9] *See* Memorandum, ''No Shipment Inquiry,'' dated December 10, 2019.

[10] *See* Memorandum, ''Request for Entry Summary,'' dated January 27, 2020 at Attachment.

[11] Commerce determined not to rescind a review with respect to exporters that demonstrate that they had no knowledge of sales through resellers to the United States because we find it appropriate to instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding. Further, Commerce explained that it is more consistent with the Automatic Assessment Clarification not to rescind a review in part under these circumstances but rather to complete the review and issue appropriate instructions to CBP based on the final results of the review. *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of* Review*; 2012–2013,* 79 FR 51306, 51307 (August 28, 2014) at 6–7 (citing *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Automatic Assessment Clarification*)).

Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely.''

In this review, we have preliminarily calculated weighted-average dumping margins for Navneet and Super Impex that are zero. For the companies that were not selected for individual review, we preliminarily assigned a rate based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis,* or based entirely on facts available.[12] In accordance with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle Corp.* v. *United States,* we are applying to the ten companies that had reviewable transactions during the POR the zero percent rates calculated for Navneet and Super Impex.[13] These are the only rates determined in this review for individual respondents and, thus, should be applied to the ten firms not selected for individual review under section 735(c)(5)(B) of the Act.

Preliminary Results of the Review

As a result of this review, we preliminarily find that the following weighted-average dumping margins existed for the period September 1, 2018 through August 31, 2019.

Producer/Exporter	Weighted-Average Dumping Margin (percent)
Cellpage Ventures Private Limited	0.00
Goldenpalm Manufacturers PVT Limited	0.00
Kokuyo Riddhi Paper Products Pvt. Ltd.	0.00
Lodha Offset Limited	0.00
Lotus Global Private Limited	0.00
Magic International Pvt. Ltd.	0.00
Navneet Education Ltd.	0.00
PP Bafna Ventures Private Limited	0.00
Pioneer Stationery Pvt. Ltd.	0.00
SAB International	0.00
SGM Paper Products	0.00
Super Impex	0.00

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for Navneet or Super Impex is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[14] If the weighted-average dumping margin for the respondents listed above is zero or *de minimis* in the final results, or an importer-specific assessment rate is zero or *de minimis* in the final results, we will instruct CBP not to assess antidumping duties on any of their entries in accordance with the *Final Modification for Reviews.*[15]

In accordance with Commerce's assessment practice, for entries of subject merchandise during the POR produced by Navneet or Super Impex for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate of 3.91 percent, as established in the less-than-fair-value investigation, if there is no rate for the intermediate company(ies) involved in the transaction.[16] For a full discussion of this practice, *see Assessment Policy Notice.*[17]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for respondents noted above will be the rates established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.91 percent, the all-others rate established in the investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to parties to the proceeding any calculations performed in connection with these preliminary results of review within five days after the date of publication of this notice.[18] Interested parties may submit case briefs not later than 30 days after the date of publication of this notice in the **Federal Register**.[19] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[20] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[21] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline.

Interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and

[12] *See* section 735(c)(5)(A) of the Act.

[13] *See Albemarle Corp.* v. *United States,* 821 F.3d 1345 (Fed. Cir. 2016).

[14] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

[15] *Id.,* 77 FR at 8102.

[16] *See Order,* 71 FR at 56952.

[17] *See Automatic Assessment Clarification.*

[18] *See* 19 CFR 351.224(b).

[19] *See* 19 CFR 351.309(c)(1)(ii).

[20] *See* 19 CFR 351.309(d)(1); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[21] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

Compliance, within 30 days after the date of publication of this notice.[22] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date and time of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: January 7, 2021.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Preliminary Determination of No Shipments
V. Companies Not Selected for Individual Examination
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2021–01063 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–DS–P

[22] *See* 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–836]

Light-Walled Rectangular Pipe and Tube from Mexico: Partial Rescission of Antidumping Duty Administrative Review: 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review, in part, of the antidumping duty order on light-walled rectangular pipe and tube (LWRPT) from Mexico for the period of review August 1, 2019, through July 31, 2020, based on timely withdrawals of the requests for review.

DATES: Applicable January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 2020, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on LWRPT from Mexico for the period of review August 1, 2019, through July 31, 2020.[1] On August 28, 2020, Regiomontana de Perfiles y Tubos S. de R.L. de C.V. (Regiopytsa) filed a timely request for a review of itself.[2] On August, 31, 2020, Nucor Tubular Products Inc. (Nucor Tubular), a domestic producer, filed a timely request for review with respect to 19 companies.[3] Maquilacero S.A. de C.V. (Maquilacero),[4] and Perfiles LM, S.A. de C.V. (Perfiles),[5] timely requested reviews of themselves. Based on these requests, on October 6, 2020, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), Commerce published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on LWRPT from Mexico covering the period August 1, 2019 through July 31, 2020.[6]

On January 4, 2021, Nucor Tubular withdrew its request for administrative review with respect to Aceros Cuatro Caminos S.A. de C.V.; Arco Metal S.A. de C.V.; Fabricaciones y Servicios de Mexico; Galvak, S.A. de C.V.; Grupo Estructuras y Perfiles, Industrias Monterrey S.A. de C.V.; Internacional de Aceros, S.A. de C.V.; PEASA-Productos Especializados de Acero; Talleres Acero Rey S.A. de C.V.; Tuberias Aspe S.A de C.V.; Tuberia Laguna, S.A. de C.V.; and Tuberias y Derivados S.A. de C.V.[7]

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review.

Because Nucor Tubular's request for review, for 12 companies, was withdrawn within the 90-day deadline, and no other interested party requested a review of these 12 companies, we are rescinding this review with respect to these 12 companies. The administrative review remains active with respect to the seven remaining companies for which a review was initiated, *i.e.,* Maquilacero S.A. de C.V.; Nacional de Acero S.A. de C.V.; Perfiles LM, S.A. de C.V.; Productos Laminados de Monterrey S.A. de C.V.; Regiomontana de Perfiles y Tubos S.A. de C.V.; Regiomontana de Perfiles y Tubos S. de R.L. de C.V.; and Ternium Mexico S.A. de C.V.[8]

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of LWRPT from Mexico at a rate

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 47167 (August 4, 2020).

[2] *See* Regiopytsa's Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico, Request for Review,'' dated August 28, 2020.

[3] *See* Nucor Tubular's Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico: Request for Administrative Review,'' dated August 31, 2020; *see also* Nucor Tubular's Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico: Clarification of Request for Administrative Review,'' dated September 23, 2020. Nucor Tubular consolidated its request for review of Hylsa S.A. de C.V. (Hysla) and Ternium Mexico S.A. de C.V. (Ternium), into a request for review of Ternium, the successor-in-interest to Hylsa.

[4] *See* Maquilacero's Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico; Maquilacero S.A. de C.V.'s Request for Administrative Review,'' dated August 31, 2020.

[5] *See* Perfiles' Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico—Request for Administrative Review,'' dated August 31, 2020.

[6] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 63081 (October 6, 2020) (*Initiation Notice*).

[7] *See* Nucor Tubular's Letter, ''Light-Walled Rectangular Pipe and Tube from Mexico: Partial Withdrawal of Request for Administrative Review,'' dated January 4, 2020.

[8] *See Initiation Notice.*

equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period August 1, 2019 through July 31, 2020, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to all parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: January 12, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–01015 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–121]

Difluoromethane (R–32) From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that difluoromethane (R–32) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is July 1, 2019 through December 31, 2019. The final dumping margins of sales at LTFV are listed below in the ''Final Determination'' section of this notice.

DATES: Applicable January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua Tucker or William Miller, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2044 or (202) 482–3906, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 27, 2020, Commerce published the *Preliminary Determination* of sales at LTFV of R–32 from China,[1] in which we also postponed the final determination to January 11, 2021. The petitioner in this investigation is Arkema Inc. The mandatory respondents in this investigation are Taizhou Qingsong Refrigerant New Material Co., Ltd. (Taizhou Qingsong) and Zibo Feiyuan Chemical Co., Ltd. (Zibo Feiyuan).

A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by the parties for this final determination are discussed in the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is R–32 from China. For a complete description of the scope of this investigation, *see* Appendix I.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix II.

Verification

Commerce normally verifies information relied upon in making its final determination, pursuant to section 782(i)(1) of the Tariff Act of 1930, as amended (the Act). However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce was unable to conduct on-site verification in this investigation.[3] Consistent with section 776(a)(2)(D) of the Act, Commerce relied on the information submitted on the record, which we used in making our *Preliminary Determination,* as facts available in making our final determination.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, we made no changes to the antidumping duty margin calculations for Taizhou Qingsong and Zibo Feiyuan.

China-Wide Entity and the Use of Adverse Facts Available

We continue to find that the use of adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act, is warranted in determining the rate for the China-wide entity.[4] In selecting the AFA rate for the China-wide entity, Commerce's practice is to select a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated.[5] As AFA, we assigned the

[1] *See Difluoromethane (R–32) from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 85 FR 52950 (August 27, 2020) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Difluoromethane (R–32) from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Cancelation of Verification and Briefing Schedule,'' dated October 21, 2020.

[4] The China-wide entity includes those companies who did not submit a separate rate application, and those companies Commerce determined were ineligible to receive a separate rate.

[5] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Purified Carboxymethyl Cellulose from Finland,* 69 FR 77216 (December 27, 2004), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Purified*

China-wide entity a dumping margin of 221.06 percent, which is the highest calculated rate in this investigation. Because this constitutes primary information, the statutory corroboration requirement in section 776(c) of the Act does not apply.

Separate Rates

For the final determination, we continue to find that Taizhou Qingsong, Zibo Feiyuan, Icool International (Hong Kong) Limited, Ninhua Group Co., Ltd., Shandong Huaan New Material Co., Ltd., T.T. International Co., Ltd., and Zhejiang Sanmei Chemical Ind. Co. Ltd. are eligible for separate rates. Generally, Commerce looks to section 735(c)(5)(A) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate rate respondents that we did not individually examine. Section 735(c)(5)(A) of the Act states that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding zero or *de minimis* margins, and any margins determined entirely under section 776 of Act.[6] In this proceeding, Commerce calculated above *de minimis* rates that are not based entirely on facts available for Taizhou Qingsong and Zibo Feiyuan, the two mandatory respondents under individual examination. Thus, looking to section 735(c)(5)(A) of the Act for guidance, and consistent with our practice,[7] based on publicly ranged sales data, we assigned the weighted-average of these mandatory respondents' rates as the rate for non-individually examined companies that have qualified for a separate rate.

Combination Rates

In the *Initiation Notice,*[8] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. For a list of the respondents that established eligibility for their own separate rates and the exporter/producer combination rates applicable to these respondents, *see* Appendix III.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Producer	Exporter	Estimated weighted-average dumping margin (percent)
Taizhou Qingsong Refrigerant New Material Co., Ltd.	Taizhou Qingsong Refrigerant New Material Co., Ltd.	161.49
Zibo Feiyuan Chemical Co., Ltd.	Zibo Feiyuan Chemical Co., Ltd.	221.06
Zibo Feiyuan Chemical Co., Ltd.	T.T. International Co., Ltd.	221.06
Producers Supplying the Non-Individually—Examined Exporters Receiving Separate Rates (*see* Appendix III).	Non-Individually Examined Exporters Receiving Separate Rates (*see* Appendix III).	196.19
China-Wide Entity		221.06

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a final determination, in accordance with 19 CFR 351.224(b). However, because Commerce made no changes to its *Preliminary Determination* margin calculations for the mandatory respondents in this investigation, there are no calculations to disclose.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of R–32 from Taizhou Qingsong and Zibo Feiyuan, the separate rates companies, and the China-wide entity.

Pursuant to section 735(c)(1)(B)(ii) of the Act, upon the publication of this notice, Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which NV exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combination listed in the table above or in Appendix III will be the rate identified for that combination in that table or Appendix III; (2) for all combinations of exporters/producers of merchandise under consideration that have not received their own separate rate, the cash deposit rate will be the cash deposit rate established for the China-wide entity; and (3) for all non-Chinese exporters of the merchandise under consideration which have not received their own separate rate, the cash deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of our determination. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of R–32 from China no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Carboxymethyl Cellulose from Finland, 70 FR 28279 (May 17, 2005).

[6] *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[7] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[8] *See Initiation Notice,* 84 FR at 7335.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: January 11, 2021.

Joseph A. Laroski Jr.,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is difluoromethane (R–32), or its chemical equivalent, regardless of form, type or purity level. R–32 has the Chemical Abstracts Service (CAS) registry number of 75–10–5 and the chemical formula CH2 F2. R–32 is also referred to as difluoromethane, HFC–32, FC–32, Freon-32, methylene difluoride, methylene fluoride, carbon fluoride hydride, halocarbon R32, fluorocarbon R32, and UN 3252. Subject merchandise also includes R–32 and unpurified R–32 that are processed in a third country or the United States, including, but not limited to, purifying or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope R–32. R–32 that has been blended with products other than pentafluoroethane (R–125) is included within this scope if such blends contain 85% or more by volume on an actual percentage basis of R–32. In addition, R–32 that has been blended with any amount of R–125 is included within this scope if such blends contain more than 52% by volume on an actual percentage basis of R–32. Whether R–32 is blended with R–125 or other products, only the R–32 component of the mixture is covered by the scope of this investigation. The scope also includes R–32 that is commingled with R–32 from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

Excluded from the current scope is merchandise covered by the scope of the antidumping order on hydrofluorocarbon blends from the People's Republic of China. *See Hydrofluorocarbon Blends from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436 (August 19, 2016) (the *Blends Order*).

R–32 is classified under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2903.39.2035. Other merchandise subject to the current scope, including the abovementioned blends that are outside the scope of the Blends Order, may be classified under 2903.39.2045 and 3824.78.0020. The HTSUS subheadings and CAS registry number are provided for convenience and customs purposes. The written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. China-Wide Rate
IV. Calculation Changes Since the Preliminary Determination
V. Discussion of the Issues
  Comment 1: Whether to Apply Partial AFA to Taizhou Qingsong and Zibo Feiyuan for Reporting Issues
  Comment 2: Selection of the Primary Surrogate Country
  Comment 3: Calculation of the Surrogate Value for Russian Truck Freight
VI. Recommendation

Appendix III

Separate Rate Companies

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually—examined exporters receiving separate rates
Icool International (Hong Kong) Limited	Changshu 3F Zhonghao New Chemical Materials Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Zhiyang Chemical Co., Ltd.
Icool International (Hong Kong) Limited	Taizhou Huasheng New Refrigeration Material Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Lishui Fuhua Chemical Co., Ltd.
Icool International (Hong Kong) Limited	Zibo Feiyuan Chemical Co., Ltd.
Icool International (Hong Kong) Limited	Jiangsu Meilan Chemical Co., Ltd.
Icool International (Hong Kong) Limited	Taizhou Qingsong Refrigerant New Material Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Sanmei Chemical Industry Co., Ltd.
Icool International (Hong Kong) Limited	Shandong Huaan New Material Co., Ltd.
Icool International (Hong Kong) Limited	Liaocheng Fuer New Materials Technology Co., Ltd.
Icool International (Hong Kong) Limited	Ruyuan Dongyangguang Fluorine Co., Ltd.
Icool International (Hong Kong) Limited	Shandong Xinlong Science Technology Co., Ltd.
Icool International (Hong Kong) Limited	Linhai Limin Chemicals Co., Ltd.
Icool International (Hong Kong) Limited	Dongyang Weihua Refrigerants Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Fulai Refrigerant Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Guomao Industrial Co., Ltd.
Icool International (Hong Kong) Limited	Zhejiang Yonghe Refrigerant Co., Ltd.
Icool International (Hong Kong) Limited	Shanghai Aohong Chemical Co., Ltd.
Ninhua Group Co., Ltd.	Changshu 3F Zhonghao New Chemical Materials Co., Ltd
Ninhua Group Co., Ltd	Zhejiang Zhiyang Chemical Co., Ltd.
Ninhua Group Co., Ltd	Taizhou Huasheng New Refrigeration Material Co., Ltd.
Ninhua Group Co., Ltd	Zhejiang Lishui Fuhua Chemical Co., Ltd.
Ninhua Group Co., Ltd	Zibo Feiyuan Chemical Co., Ltd.
Ninhua Group Co., Ltd	Jiangsu Meilan Chemical Co., Ltd.
Ninhua Group Co., Ltd	Taizhou Qingsong Refrigerant New Material Co., Ltd.
Ninhua Group Co., Ltd	Zhejiang Sanmei Chemical Industry Co., Ltd.
Ninhua Group Co., Ltd	Shandong Huaan New Material Co., Ltd.
Ninhua Group Co., Ltd	Liaocheng Fuer New Materials Technology Co., Ltd.
Ninhua Group Co., Ltd	Ruyuan Dongyangguang Fluorine Co., Ltd.
Ninhua Group Co., Ltd	Shandong Xinlong Science Technology Co., Ltd.
Ninhua Group Co., Ltd	Linhai Limin Chemicals Co., Ltd.
Ninhua Group Co., Ltd	Dongyang Weihua Refrigerants Co., Ltd.
Ninhua Group Co., Ltd	Zhejiang Fulai Refrigerant Co., Ltd.

Exporter	Producer
Non-individually examined exporters receiving separate rates	Producers supplying the non-individually—examined exporters receiving separate rates
Ninhua Group Co., Ltd	Zhejiang Guomao Industrial Co., Ltd.
Ninhua Group Co., Ltd	Zhejiang Yonghe Refrigerant Co., Ltd.
Ninhua Group Co., Ltd	Shanghai Aohong Chemical Co., Ltd.
Shandong Huaan New Material Co., Ltd	Shandong Huaan New Material Co., Ltd.
T.T. International Co., Ltd	Sinochem Lantian Fluoro Materials Co., Ltd.
T.T. International Co., Ltd	Zhejiang Sanmei Chemical Industry Co., Ltd.
T.T. International Co., Ltd	Shandong Huaan New Material Co., Ltd.
Zhejiang Sanmei Chemical Ind. Co., Ltd	Jiangsu Sanmei Chemical Ind. Co., Ltd.
Zhejiang Sanmei Chemical Ind. Co., Ltd	Fujian Qingliu Dongying Chemical Co., Ltd.

[FR Doc. 2021–01014 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12: Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA request for panel review.

SUMMARY: A Request for Panel Review was filed on behalf of Resolute FP Canada Inc., the Conseil de l'Industrie forestière du Québec (''CIFQ''), and the Ontario Forest Industries Association (''OFIA'') (together, ''Central Canada'') with the United States Section of the USMCA Secretariat on December 22, 2020, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. International Trade Administration's Final Results of the Antidumping Duty Administrative Review (2017–2018) in Certain Softwood Lumber from Canada, which was published in the **Federal Register** on November 30, 2020. The USMCA Secretariat has assigned case number USA–CDA–2020–10.12–02 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, Acting United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: Article 10.12 of Chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://canmex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is January 21, 2021);

(b) A Party, an investigating authority or other interested person who does not file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is February 5, 2021);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

Dated: December 29, 2020.

Vidya Desai,

Acting U.S. Secretary, USMCA Secretariat.

[FR Doc. 2020–29126 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Generic Request for Customer Service-Related Data Collections

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 22, 2021.

ADDRESSES: Interested persons are invited to submit written comments by mail to Maureen O'Reilly, Management Analyst, NIST at *PRAcomments@doc.gov.* Please reference OMB Control Number 0693–0031 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Maureen O'Reilly, Management Analyst, NIST, via email *maureen.oreilly@nist.gov* or at 301–975–3189.

SUPPLEMENTARY INFORMATION:

I. Abstract

In accordance with Executive Order 12862, the National Institute of Standards and Technology (NIST), a non-regulatory agency of the Department of Commerce, proposes to conduct a number of individual information collections that are both quantitative and qualitative. The information collections will be designed to determine the type and quality of the products, services, and information our key customers want and expect, as well as their satisfaction with and awareness of existing products, services, and information. In addition, NIST proposes other customer service satisfaction data collections that include, but may not be limited to focus groups, reply cards that accompany product distributions, and Web-based surveys and dialog boxes that offer customers the opportunity to express their level of satisfaction with NIST products, services, and information and for ongoing dialogue with NIST. NIST will limit its inquiries to data collections that solicit voluntary options and will not collect information that is required or regulated. No assurances of confidentiality will be given. However, it will be completely optional for survey participants to provide their name or affiliation information if they wish to provide comments for which they elect to receive a response.

II. Method of Collection

NIST will collect this information by electronic means, as well as by mail, fax, telephone, and person-to-person interactions.

III. Data

OMB Control Number: 0693–0031.

Form Number(s): None.

Type of Review: Regular Submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institution.

Estimated Number of Respondents: 120,000.

Estimated Time per Response: Less than 2 minutes for a response card, 2 hours for focus group participation. The average estimated response time for the completion of a collection instrument is expected to be less than 30 minutes per response(s).

Estimated Total Annual Burden Hours: 15,000.

Estimated Total Annual Cost to Public: None.

Respondent's Obligation: Voluntary.

Legal Authority:

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01069 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Small and Medium-Sized Business Complex Event COVID–19 Survey (Wave 3)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 22, 2021.

ADDRESSES: Interested persons are invited to submit written comments by mail to Jennifer Helgeson, Research Economist, *Jennifer.helgeson@nist.gov* or *PRAcomments@doc.gov.* Please reference ''Small and Medium-Sized Business Complex Event COVID–19 Survey (Wave 3)'' in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Jennifer Helgeson, Research Economist, *Jennifer.helgeson@nist.gov,* or (240) 672–2575.

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this research is to build a dataset that allows longitudinal documentation of (1) the novel resilience-based mitigation actions employed during the COVID–19 pandemic by small- and medium-sized enterprises (SMEs) by sector, (2) challenges in implementing resilience-based mitigation actions, (3) utilization of past strategies and approaches to provide assistance to the current situation, and (4) planned resilience actions and strategies. This is a cross-Department of Commerce (DOC) effort; the offices sponsoring the proposed data collection are the (1) Applied Economics Office (AEO), in NIST's Engineering Laboratory (EL) and (2) the Climate Program Office (CPO), National Oceanic and Atmospheric Association (NOAA). There has been considerable coordination on this effort with Federal agencies and other institutions that directly provide guidance to SMEs. NIST researchers have been actively engaged for over five years in understanding community resilience to natural hazard events and have developed expertise in that area of inquiry, especially as it relates to SME resilience.

A first wave of data collection took place July–August 2020 using the Wave 1 ''Compound Risks—SME Recovery from a Pandemic in the Face of Natural Hazard Risks'' electronic survey

instrument. A second wave of data collection using the Wave 2 ''Compound Risks—SME Recovery from a Pandemic in the Face of Natural Hazard Risks'' electronic survey instrument took place in December 2020–January 2021.

The Wave 3 semi-structured survey is planned for Spring 2021. This Small- and Medium-Sized Business Complex Event COVID–19 Survey (Wave 3) is critical to the overall data collection effort. As we strive to understand recovery trajectories of SMEs, understanding the mid-term recovery during a Wave 3 provides a detailed picture of how businesses cope with and adapt to disaster circumstances and which decisions may provide the greatest level of resilience across time periods. This collection is expected to provide insight as to how SME owners and managers make decisions in the face of disaster, especially when there is deep uncertainty surrounding their timing and impact, as well as limited resources available to the owner/manager.

There is minimal primary data on business interruption following a large-scale natural hazard event, especially in the period of mid-term recovery. Furthermore, to the best of our knowledge, there is no primary data on planning for natural hazard resilience during a pandemic, which is highly relevant at a time when much of the US faces potential natural disasters as SMEs recover from COVID–19. Furthermore, the opportunity to obtain this type of longitudinal data related to SMEs' complex event experiences is truly unique. There is critical value to this data, as we seek to better understand how SME managers and owners make decisions when facing complex events—both considering them as potential future events and addressing them when they occur.

II. Method of Collection

This collection will take place entirely remotely, using online technology. During the COVID–19 transmission period this is a safe way to collect data. This mode of collection is also cost-effective and allows the researchers to reach a larger audience and a greater geographic spread.

A subset of respondents will take the structured survey element of the semi-structured surveys, which will be conducted via an online survey platform.

Furthermore, renumeration will be offered to respondents. Renumeration is justified due to (1) complex study design and (2) burden on the respondent. (1) The complex study design of this collection requires ongoing participation of various respondents, each of whom is important to the achievement of study goals. Should attrition occur at a higher rate than expected the study goals will not be met. (2) There is burden on the respondent to take time out of their workday managing/operating an SME. There will be equity in the use of renumeration; all respondents will be treated equally with regard to incentives:

III. Data

OMB Control Number: 0693–XXXX.

Form Number(s): None.

Type of Review: New information collection.

Affected Public: Businesses—individual representatives of small and medium-sized enterprises (SMEs).

Estimated Number of Respondents: 1,800; 300 take the full semi-structured survey and 1,500 take the structured survey part of the full semi-structured survey.

Estimated Time per Response: 15 minutes per structured survey (n=1,800); additional 45 minutes for the semi-structured survey add-on (n=300).

Estimated Total Annual Burden Hours: 15 min. × 1,800 = 27,000; 45 min. × 300 = 13,500; Total = 40,500 min. = 675 hours.

Estimated Total Annual Cost to Public: $15 × 300 respondents = $4,500; $5 × 1,500 = $7,500 = Total upper bound expected cost is estimated at $12,000.

Respondent's Obligation: Voluntary.

Legal Authority: None.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–00958 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA813]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Research Steering Committee (RSC) of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Thursday, March 18, 2021, beginning at 9 a.m. and conclude by 12 noon. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held via webinar. Details on the proposed agenda, webinar listen-in access, and briefing materials will be posted at the MAFMC's website: *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this RSC meeting is to discuss re-development of the research set-aside program. In doing so, the RSC will also discuss the outcomes of the April 2020 meeting, the Scientific and Statistical Committee Economic Working Group involvement, and detail workshop logistics.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for

sign language interpretation or other auxiliary aids should be directed to Kathy Collins at the Mid-Atlantic Council Office, (302) 526–5253, at least 5 days prior to the meeting date.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 13, 2021.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–01102 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Economic Impacts of Hawaii Reef Diving and Snorkeling

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 22, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0765 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Sabrina Lovell, Office of Science & Technology, NOAA Fisheries, 1315 East-West Highway, #12361, Silver Spring, Maryland 20910; 301–427–8153; *sabrina.lovell@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a currently approved information collection. The objective of the survey will be to understand divers' and snorkelers' expenditures associated with recreational coral reef diving activities in Hawaii, American Samoa, CNMI, Guam, California, Florida and the Caribbean. The survey was previously implemented in Hawaii in 2019 and this revision proposes to make the survey national in scope. The survey will also collect information on divers' attitudes, preferences, and concerns about recreational diving and coral reefs health. This survey will help to improve our understanding of divers' and snorkelers' expenditure patterns and to estimate the economic impact of coral reef related spending. Results of the survey will be used to inform coastal resource management planning and establish a baseline for outreach and education. The expenditure survey is also expected to provide useful information for local economic and business interests.

II. Method of Collection

The survey will be conducted using two modes: Mail and internet.

III. Data

OMB Control Number: 0648–0765.

Form Number(s): None.

Type of Review: Regular submission. Revision of a current information collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 3,500.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 1,458 hours.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

Respondent's Obligation: Voluntary.

Legal Authority: U.S. Code: 16 U.S.C. 6401 *et seq.* Name of Law: Coral Reef Conservation Act of 2000.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–00938 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Alaska Crab Arbitration

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 14, 2020 (*85 FR 56583*) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Crab Arbitration.

OMB Control Number: 0648–0516.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 2.

Average Hours per Response: Annual Arbitration Organization Report, 6 hours; Cost Allocation Agreement, 16 hours.

Total Annual Burden Hours: 28.

Needs and Uses: The National Marine Fisheries Service (NMFS), Alaska Regional Office, is requesting renewal of a currently approved information collection. This information collection contains the reports for the Crab Rationalization Program Arbitration System.

The Crab Rationalization Program allocates Bering Sea and Aleutian Islands (BSAI) crab resources among harvesters, processors, and coastal communities through a limited access system that balances the interests of these groups who depend on these fisheries. Under the CR Program, eligible License Limitation Program license holders were issued crab quota shares (QS), which are long term shares, based on their qualifying harvest histories. The QS yield annual individual fishing quota (IFQ), which represent a privilege to receive a certain amount of crab harvested with IFQ. Processor quota shares (PQS) are long term shares issued to processors. The PQS yield annual individual processor quota (IPQ), which represent a privilege to receive a certain amount of crab harvested with Class A IFQ.

The Crab Rationalization Program Arbitration System is a series of steps that harvesters and processors can use to negotiate delivery and price contracts. The Arbitration System allows unaffiliated Class A IFQ holders to initiate an arbitration proceeding in the event of a dispute to allow an independent third party to provide a review of harvester and processor negotiation positions and provide an independent and binding resolution to issues under dispute. To use the Arbitration System, a harvester must commit deliveries to a processor and initiate a binding arbitration proceeding in advance of the season opening. The Arbitration System is designed to minimize antitrust risks for crab harvesters and processors and is intended to ensure that a reasonable price is paid for all landings.

The Arbitration System requires several information collections that are submitted annually in accordance with the regulations at 50 CFR 680.20. The Annual Arbitration Organization Report, the Market Report, and the Non-binding Price Formula Report are the primary reports submitted to NMFS each year. Also submitted are the Contract Arbitrator Report and the Cost Allocation Agreement.

An Annual Arbitration Organization Report is compiled by each of the two arbitration organizations; one represents the processors, and the second represents the harvesters. This report includes information on the arbitration organization and its management personnel, the crab QS fisheries to which the report applies, the ownership interest and the QS/IFQ or PQS/IPQ held by each member; and the arbitration process.

The Cost Allocation Agreement provides combined shared arbitration accounting costs. Federal regulations for the CR Program require that the crab arbitration costs are shared equally between IPQ holders and Class A IFQ holders—processors pay half and fishermen pay half.

The arbitration organizations use contracted parties to meet the requirements of the Market Report, Non-binding Price Formula Report, and Contractor Arbitrator Report.

The Non-binding Price Formula Report is a pre-season report that is designed to serve as a starting point for negotiations between fishermen and processors, or as a starting point for an arbitrator in evaluating offers in an arbitration process. This report documents how each formula was developed.

The Market Report provides an analysis of the market for products of a specific crab fishery and reports on activities occurring within three months prior to its generation. The purpose of this report is to provide background information on each crab fishery, the products generated by each fishery, and position of those products in the marketplace; discuss the historical division of wholesale revenue; and provide the methods for predicting wholesale prices before the fishery occurs.

The Contract Arbitrator Report documents arbitration proceedings if they occur within a fishery.

Affected Public: Individuals or households; Business or other for-profit organizations.

Frequency: Annually; On occasion.

Respondent's Obligation: Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0516.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–01068 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA784]

Pacific Fishery Management Council; Public Meetings and Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of opportunities to submit public comments.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) has begun its annual preseason management process for the 2021 ocean salmon fisheries off the U.S. West Coast. This notice informs the public of opportunities to provide comments on the development of 2021 ocean salmon management measures.

DATES: Written comments on the salmon management alternatives adopted by the Pacific Council at its March 2021 meeting, as described in its Preseason Report II, received electronically or in hard copy by 5 p.m. Pacific Time, April 5, 2021, will be considered in the Pacific Council's final recommendation for the 2021 management measures.

ADDRESSES: Documents will be available from the Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384, and will be posted on the Pacific Council website at *http://www.pcouncil.org.* You may submit comments by any one of the following methods:

- Written comments should be sent electronically to Mr. Marc Gorelnik, Chair, Pacific Fishery Management Council, via the Pacific Council's e-Portal by visiting *https://pfmc.psmfc.org.*
- Comments can also be submitted to NMFS via the Federal e-Rulemaking Portal. Go to *http://*

www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2021-0001, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. All comments received via the Federal e-Rulemaking Portal are a part of the public record and will generally be posted for public viewing on *http://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS and the Pacific Council will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehlke, Pacific Council, telephone: 503–820–2280. For information on submitting comments via the Federal e-Rulemaking Portal, contact Peggy Mundy, NMFS West Coast Region, telephone: 206–526–4323; email: *peggy.mundy@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Pacific Council has announced the schedule of reports, public meetings, and hearings for the 2021 ocean salmon fisheries on its website (*http://www.pcouncil.org*) and in the **Federal Register** (85 FR 83896, December 23, 2020). The Pacific Council will adopt alternatives for 2021 ocean salmon fisheries at its March 2–11, 2021, meeting which will be conducted via webinar. Details of this meeting are available on the Pacific Council's website (*http://www.pcouncil.org*). On March 22, 2021, ''Preseason Report II—Proposed Alternatives and Environmental Assessment Part 2 for 2021 Ocean Salmon Fishery Regulations'' is scheduled to be posted on the Pacific Council website at *http://www.pcouncil.org.* The report will include a description of the salmon management alternatives and a summary of their biological and economic impacts. Public hearings will be held to receive comments on the proposed ocean salmon fishery management alternatives adopted by the Pacific Council. Written comments received at the public hearings and a summary of oral comments at the hearings will be provided to the Pacific Council at its April meeting.

All public hearings begin at 7 p.m. Public hearings focusing on Washington and California salmon fisheries will occur simultaneously on March 23, 2021, and the public hearing for Oregon salmon fisheries will occur on March 24, 2021. A summary of oral comments heard at the hearings will be provided to the Pacific Council at its April meeting. Specific meeting information, including instructions on how to join the meeting and system requirements will be provided in meeting announcements on the Pacific Council's website (see *www.pcouncil.org*).

Comments on the alternatives the Pacific Council adopts at its March 2021 meeting, and described in its Preseason Report II, may be submitted in writing or electronically as described under **ADDRESSES**, or verbally or in writing at any of the public hearings held on March 23–24, 2021, or at the Pacific Council's meeting, April 6–15, 2021, which will be conducted via webinar. Details of these meetings will be available on the Pacific Council's website (*http://www.pcouncil.org*) and will be published in the **Federal Register**. Written and electronically submitted comments must be received no later than 5 p.m. Pacific Time, April 5, 2021, in order to be included in the briefing book for the Pacific Council's April meeting, where they will be considered in the adoption of the Pacific Council's final recommendation for the 2021 salmon fishery management measures. All comments received accordingly will be reviewed and considered by the Pacific Council and NMFS.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 13, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–01082 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA820]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council's (Council) Social Science Planning Team (SSPT) will meet March 4, 2021.

DATES: The meeting will be held on Thursday, March 4, 2021, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/1886.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Sarah Marrinan, Council staff; phone: (907) 271–2809; email: *sarah.marrinan@noaa.gov.* For technical support please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, March 4, 2021

The SSPT agenda will meet to discuss the Economic Data Reporting (EDR) stakeholder meetings, propose alternatives for the Council to consider, and other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/1886* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/1886.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/1886.*

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 13, 2021.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–01095 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a virtual meeting of the U.S. Integrated

Ocean Observing System (IOOS®) Advisory Committee (Committee).

DATES: The meeting will be held on Friday, February 5th, 2021 from 12:30 p.m. to 2 p.m. EST. These times and the agenda topics described below are subject to change. Refer to the web page listed below for the most up-to-date agenda and dial-in information.

ADDRESSES: The meeting will be held virtually. Refer to the U.S. IOOS Advisory Committee website at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/* for the most up-to-date information.

FOR FURTHER INFORMATION CONTACT: Krisa Arzayus, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 1315 East-West Highway, Silver Spring, MD 20910; Phone 240–533–9455; Fax 301–713–3281; Email *krisa.arzayus@noaa.gov* or visit the U.S. IOOS Advisory Committee website at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/*. To register for the meeting, contact Laura Gewain, *laura.gewain@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established by the NOAA Administrator as directed by Section 12304 of the Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11), and reauthorized under the Coordinated Ocean Observations and Research Act of 2020 (Pub. L. 116–271). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in section 12302 of the Integrated Coastal and Ocean Observation System Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The Committee will provide advice on:

(A) Administration, operation, management, and maintenance of the System;

(B) expansion and periodic modernization and upgrade of technology components of the System;

(C) identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in disseminating information to end-user communities and to the general public; and

(D) additional priorities, including—

(i) a national surface current mapping network designed to improve fine scale sea surface mapping using high frequency radar technology and other emerging technologies to address national priorities, including Coast Guard search and rescue operation planning and harmful algal bloom forecasting and detection that—

(I) is comprised of existing high frequency radar and other sea surface current mapping infrastructure operated by national programs and regional coastal observing systems;

(II) incorporates new high frequency radar assets or other fine scale sea surface mapping technology assets, and other assets needed to fill gaps in coverage on United States coastlines; and

(III) follows a deployment plan that prioritizes closing gaps in high frequency radar infrastructure in the United States, starting with areas demonstrating significant sea surface current data needs, especially in areas where additional data will improve Coast Guard search and rescue models;

(ii) fleet acquisition for unmanned maritime systems for deployment and data integration to fulfill the purposes of this subtitle;

(iii) an integrative survey program for application of unmanned maritime systems to the real-time or near real-time collection and transmission of sea floor, water column, and sea surface data on biology, chemistry, geology, physics, and hydrography;

(iv) remote sensing and data assimilation to develop new analytical methodologies to assimilate data from the System into hydrodynamic models;

(v) integrated, multi-State monitoring to assess sources, movement, and fate of sediments in coastal regions;

(vi) a multi-region marine sound monitoring system to be—

(I) planned in consultation with the Interagency Ocean Observation Committee, the National Oceanic and Atmospheric Administration, the Department of the Navy, and academic research institutions; and

(II) developed, installed, and operated in coordination with the National Oceanic and Atmospheric Administration, the Department of the Navy, and academic research institutions; and

(E) any other purpose identified by the Administrator or the Council.

The meeting will be open to public participation with a 10-minute public comment period on February 5th, 2021 from 1:50 p.m. to 2 p.m. EST (check agenda on website to confirm time). The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by the Designated Federal Official by February 1, 2021, to provide sufficient time for Committee review. Written comments received after February 1, 2021, will be distributed to the Committee, but may not be reviewed prior to the meeting date. To submit written comments, please email your comments, your name as it appears on your driver's license, and the organization/company affiliation you represent to Krisa Arzayus, *Krisa.Arzayus@noaa.gov* and Laura Gewain, *Laura.Gewain@noaa.gov.*

Matters to be Considered: The meeting will focus on updates from committee working groups on ongoing committee priorities, including the role of ocean observations in forecasting, strategy and vision for the System, partnerships for a successful System, and requirements for the System, in order to develop the next set of recommendations to NOAA and the IOOC. The committee will also finalize language and messaging for a memo to be sent to the incoming Presidential Administration. The latest version of the agenda will be posted at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

Special Accomodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Krisa Arzayus, Designated Federal Official at *Krisa.Arzayus@noaa.gov* and *Laura.Gewain@noaa.gov* or 240–533–9455 by February 1, 2021.

Krisa M. Arzayus,

Deputy Director, U.S. Integrated Ocean Observing System Office, National Ocean Service.

[FR Doc. 2021–00731 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA817]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a meeting.

DATES: The meeting will be held on Tuesday, March 9, 2021, from 9:30 a.m. through 5:30 p.m. and Wednesday, March 10, 2021, from 8:30 a.m. through 12:30 p.m. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: The meeting will take place over webinar with a telephone-only connection option. Details on how to connect to the webinar by computer and by telephone will be available at: *http://www.mafmc.org/ssc.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to make multi-year acceptable biological catch (ABC) recommendations for Blueline tilefish for the 2022–24 fishing years. The SSC will review the results of the 2020 bottom longline survey for Golden tilefish and provide feedback on the future direction of the survey and upcoming management track assessment. The SSC Economic Work Group will update the full SSC on the Research Set-Aside economic case study the Council selected for development in 2021. The SSC will also review and provide feedback on the most recent Mid-Atlantic State of the Ecosystem report and other Ecosystem Approach to Fisheries Management (EAFM) related activities. The Northeast Fisheries Science Center will give a presentation on the results and findings from the recently completed research track assessment on Index Based Methods and Harvest Control Rules. The SSC will also receive an update on ongoing Council actions, including the Recreational Reform Initiative and discuss potential opportunities for SSC engagement. In addition, the SSC may take up any other business as necessary.

A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Kathy Collins, (302) 526–5253, at least 5 days prior to the meeting date.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 13, 2021.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–01097 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA818]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Advisory Subpanel (GAP) will hold an online meeting, which is open to the public.

DATES: The meeting will be held Tuesday, February 16, 2021, from 9 a.m. to 12 p.m., Pacific Standard Time, or until business for each day is completed.

ADDRESSES: The meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Brett Wiedoff, Staff Officer, Pacific Council; *Brett.L.Wiedoff@noaa.gov;* telephone: (503) 820–2424.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the GAP to discuss potential fishery management changes regarding non-trawl rockfish conservation area management and future implementation of fishing gear used under the Emley/Platt exempted fishing permit. This discussion is in support of a tentatively scheduled agenda item for the April 2021 Pacific Council meeting. The GAP may also discuss other items on the Pacific Council's March or April agenda, particularly ecosystem or administrative matters.

Although nonemergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 business days prior to the meeting date.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 13, 2021.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–01096 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Petitions Related to Application and Reexamination Processing Fees

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on October 1, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Patent Petitions Related to Application and Reexamination Processing Fees.

OMB Control Number: 0651–0059.

Form Number(s): (AIA = American Invents; SB = Specimen Book).

- PTO/AIA/17P (Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal).
- PTO/AIA/24A (Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)).
- PTO/SB/17P (Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal).
- PTO/SB/23 (Petition for Extension of Time Under 37 CFR 1.136(b)).
- PTO/SB24A, (Petition for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c)).
- PTO/SB/28 (Petition to Make Special Under Accelerated Examination Program).
- PTO/SB/140 (Petition to Withdraw an Application from Issue 1.313).

Type of Request: Extension and revision of a currently approved information collection.

Number of Respondents: 40,922 respondents per year.

Average Hour per Response: The USPTO estimates that it will take the public between 5 minutes (0.08 hours) to 12 hours to complete a response, depending on the complexity of the particular item. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the completed response to the USPTO.

Estimated Total Annual Respondent Burden Hours: 72,958 hours.

Estimated Total Annual Non-Hour Cost Burden: $3,195,134.

Needs and Uses: The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 131 *et seq.* to examine an application for patent and, when appropriate, issue a patent. The USPTO also is required to publish patent applications, with certain exceptions, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under Title 35, U.S.C.

Many actions taken by the USPTO during its examination of an application for patent or for reissue of a patent, or during its reexamination of a patent, are subject to review by an appeal to the Patent Trial and Appeal Board. For other USPTO actions, review is in the form of administrative review obtained via submission of a petition to the USPTO. USPTO petitions practice also provides an opportunity for a patent applicant or owner to supply additional information that may be required in order for the USPTO to further process an application or patent.

This information collection covers petitions filed in patent applications and reexamination proceedings that, when submitted to the USPTO, must be accompanied by the fee set forth in 37 CFR 1.17(f), (g), or (h). This information collection also covers the transmittals for the petition fees.

Affected Public: Private sector; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0059.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0059 information request'' in the subject line of the message.
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2021–00943 Filed 1–15–21; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0074: Core Principles and Other Requirements for Swap Execution Facilities

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the proposed renewal of a collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments, as described below, on the proposed Information Collection Requests (''ICR'') titled: OMB Control Number 3038–0074 and Part 37, Relating to Core Principles and Other Requirements for Swap Execution Facilities.

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: You may submit comments, and ''OMB Control No. 3038–0074'' by any of the following methods:

- The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method and identify that it is for the renewal of Collection Number 3038–0074. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Roger Smith, Associate Chief Counsel, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–5344; email: *rsmith@cftc.gov;* or Richard Mo, Assistant Chief Counsel, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418–7637; email: *rmo@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed amendment to

the collection listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Title: Core Principles and Other Requirements for Swap Execution Facilities (OMB Control No. 3038–0074). This is a request for extension of a currently approved information collection.

Abstract: Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') added new section 5h to the Commodity Exchange Act (''CEA'') to impose requirements concerning the registration and operation of swap execution facilities (''SEFs''), which the Commission has incorporated in part 37 of its regulations. These information collections are needed for the Commission to ensure that SEFs comply with these requirements. Among other requirements, part 37 of the Commission's regulations imposes SEF registration requirements for a trading platform or system, obligates SEFs to provide transaction confirmations to swap counterparties, and requires SEFs to comply with 15 core principles. Collection 3038–0074 was created in response to the part 37 regulatory requirements for SEFs.

In April 2018, the Commission published a 30-Day Notice of Intent to Renew Collection 3038–0074 (30-Day Renewal Notice) and stated that 25 SEFs were registered with the Commission.[1] However, since publication of the 30-Day Renewal Notice, the Commission has granted permanent registration to several additional SEFs, while others SEFs have had their registrations vacated or have been deemed dormant under part 40 of the Commission regulations, for a total of 21 registered SEFs.[2] Therefore, the Commission is revising the below burden statement for OMB Control No. 3038–0074 to account for the decrease in the number of registered SEFs.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[3]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its estimate of the burden for this collection to account for the change in the number of SEFs currently registered with the Commission. The respondent burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 21.

Estimated Average Burden Hours per Respondent: 21,000.

Estimated Total Annual Burden Hours: 21,000.[4]

Frequency of Collection: As applicable.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: January 13, 2021.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2021–01081 Filed 1–15–21; 8:45 am]

BILLING CODE 6351–01–P

[1] 83 FR 15557 (Apr. 21, 2018).

[2] This includes 20 SEFs that are currently registered with the Commission and one dormant SEF that is in the process of filing for reinstatement in accordance with Commission regulation 37.3(d) and is currently operating under staff no-action relief. *See* CFTC Letter No. 20–29, available at *https://www.cftc.gov/csl/20-29/download.*

[3] 17 CFR 145.9.

[4] The Commission notes that collection 3038–0074 includes an additional 1,200 burden hours for SEF registration applicants that have not been affected by this amendment. Therefore, the total burden for this collection is 22,200 hours.

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2020–0021]

Agency Information Collection Activities; Submission for OMB Review; Comment Request—Child Strength Study

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that CPSC has submitted to the Office of Management and Budget (OMB) a new proposed collection of information for a study that will assess the strength capabilities of children. On August 31, 2020, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of this collection of information. After reviewing and considering the comments CPSC received, by publication of this notice, the Commission announces that CPSC has submitted to OMB a request for approval of this collection of information.

DATES: Submit written comments on this request for approval of information collection requirements by February 18, 2021.

ADDRESSES: Send written comments and recommendations for the proposed information collection within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 30-day Review—Open for Public Comments,'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2020–0021.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: *CGillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3520),

federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency data-collection studies. The PRA establishes procedures agencies must follow to obtain OMB approval for a collection of information, including notice and a review of comments, among others. Agencies must provide notice of the proposed collection of information in the **Federal Register**, and provide a 60-day comment period, before submitting the collection to OMB for approval. 44 U.S.C. 3506(c)(2)(A). Agencies then must evaluate any public comments and publish another notice in the **Federal Register**. *Id.* 3507(a)(1).

In accordance with these procedures, on August 31, 2020, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of a new collection of information on a CPSC Child Strength Study that will assess the strength capabilities of children. 85 FR 53800 (Aug. 31, 2020). Section C. Comments, below, summarizes and addresses the comments CPSC received.

B. Study

Section 5(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051–2089) authorizes the Commission to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. 15 U.S.C. 2054(a). Section 5(b) of the CPSA further provides that the Commission may conduct research, studies, and investigations on the safety of consumer products or test consumer products and develop product safety test methods and testing devices. *Id.* 2054(b).

CPSC uses data on human strength capabilities to develop product safety standards and inform other CPSC staff activities. CPSC's product safety work includes developing mandatory standards, enforcing existing safety requirements, and working with voluntary standards organizations to improve the safety of consumer products, including children's products. Products that are intended for children, and products that are not intended for children, can pose a hazard to a child (*e.g.,* if the product or a component of it breaks, collapses, or liberates a small part). Information about children's strength capabilities is essential to improving product safety, because it can inform the development of performance requirements that consider children's interactions with product components. Manufacturers can also use this information when designing products.

In the 1970s, CPSC sponsored studies to conduct research on human size and strength; specifically, Snyder et al. (1975 [1] and 1977 [2]), studied child anthropometry and Owings *et al.* (1975 [3] and 1977 [4]), studied child strength. The research results were instrumental for many years in developing product safety standards; however, because the strength studies occurred more than 40 years ago, the information needs to be updated. Moreover, more recent studies lack information on younger children and additional strength measures, and only collected data from a very small number of children. CPSC expects that the proposed information-collection activity would provide CPSC staff with information that reflects more accurately the strength capabilities of children today, as well as data that are not available in literature currently, including data on younger children and additional strength measures.

The proposed study would collect data from a sample of up to approximately 800 children between the ages of 3 months and 5 years to assess children's strength capabilities. The proposed study would collect data on bite strength for children ages 3 months through 5 years, and strength data for children ages 6 months through 5 years. The information collected from the proposed study would provide CPSC staff with updated child strength measures, including upper and lower extremities and bite strength for expanded age ranges. With this information, CPSC would have more accurate and current data for developing voluntary and mandatory safety standards. This information will also help staff to analyze injuries and deaths of children interacting with consumer products and determine whether a product presents a safety hazard.

CPSC has contracted with the University of Michigan to conduct the proposed study and collect the data. A team of researchers at the University of Michigan Transportation Research Institute (UMTRI) will lead the study, and the study will be conducted at UMTRI Laboratories in Ann Arbor, MI. The contractor will recruit children to participate through their caregivers, using the University of Michigan Engage site, Craigslist, and flyers placed at UMTRI. The contractor will create a customized tool for data collection and feedback. The contractor will assign participants a random identification number that is not linked to any personal identifying information and will de-identify photos and videos of participants, taken to document their exertion postures, by blurring the faces. Participation will be voluntary, and information collected from participants will be kept confidential and used only for research purposes. Following data collection, the contractor will provide CPSC staff with raw strength and position data (with identifying information removed), as well as a final report. After CPSC staff has reviewed and approved the final report, CPSC will release the report on the agency's website and through presentations at meetings and conferences related to the subject matter, in accordance with applicable laws and Commission policy.

A copy of the proposed study, titled, ''Child Strength Study-Final Supporting Statement and Justification,'' is available at: *www.regulations.gov* under Docket No. CPSC–2020–0021, Supporting and Related Material.

C. Comments

CPSC received four comments in response to the August 31, 2020 notice. All four commenters supported the information collection; however, two of the commenters also suggested specific or additional measures to collect or analyze as part of the study.

One commenter recommended collecting metrics on children's hand grip strength, push strength, pull strength, push-up head strength, and seated leg press strength. CPSC already plans to collect information about children's hand grip strength, push strength, pull strength, and seated leg press strength, as part of this study. Although CPSC does not plan to collect information about children's push up head strength, the commenter suggested this measure for purposes of evaluating entrapment hazards, and CPSC already plans to collect children's head

[1] Snyder, R.G., Spencer, M.L., Owings, C.L., and Schneider, L.W. (1975). The Physical Characteristics of Children as Related to Death and Injury for Consumer Product Design and Use (Report No. UM–HSRI–BI–75–5). Prepared for the U.S. Consumer Product Safety Commission. Ann Arbor, MI: The Highway Safety Research Institute, University of Michigan.

[2] Snyder, R.G., Schneider, L.W., Owings, C.L., Reynolds, H.M., Golomb, D.H., and Schork, M.A. (1977). Anthropometry of Infants, Children, and Youths to Age 18 for Product Safety Design.Final Report UM–HSRI–77–17. University of Michigan Transportation Research Institute, Ann Arbor, MI. Prepared for the U.S. Consumer Product Safety Commission, Washington, D.C. 014926–F.

[3] Owings, C.L., Chaffin, D.B., Snyder, R.G., and Norcutt, R.H. (1975). Strength Characteristics of U.S. Children for Product Safety Design. U.S. Consumer Product Safety Commission, Bethesda, MD.

[4] Owings, C.L., Norcutt, R.H., Snyder, R.G., Golomb, D.H., and Lloyd, K.Y. (1977). Gripping Strength Measurements of Children for Product Safety Design (Contract No. CPSC–C–76–0119).

entrapment measures as part of the study.

The same commenter also recommended directly correlating data with the age of the child tested, to provide more detailed information to identify safe product designs. CPSC plans to group data into 3-month, 6-month, and 1-year age ranges, with smaller groupings for younger ages. Each age group will include approximately 50 participants. This approach will provide more age-specific information than previous studies, which grouped children into 3-year age ranges. CPSC could provide results for specific ages, however, this information would have limited use, because each specific age likely will have a small number of participants.

Another commenter recommended collecting a wide range of information on static anthropometry, functional anthropometry, physical abilities, and psychological abilities. The static anthropometry measures (*e.g.,* weight, head breadth) that the commenter requested would not require any modifications to the study. Rather, they would involve additional analysis of information that will already be collected as part of the body scan data in the study. CPSC agrees that this information may be useful and plans to request this additional data analysis as part of the final study report.

In contrast, the functional anthropometry measures (*e.g.,* overhead reach to grip) that the commenter requested would require modifying the study to collect additional measures. Based on study design and participant fatigue, child participants can only be in the laboratory for 2 hours. The data collection that is already part of the study will take 2 hours; additional measures would exceed the 2-hour allotted time. If CPSC determines, upon review of the final study report, that more information is necessary, and that additional measures need to be evaluated, staff will consider collecting supplemental information at that time.

CPSC already plans to collect most of the physical abilities measures (*e.g.,* pushing forward, pinch force) that the commenter recommended. CPSC is not collecting the psychological abilities measures (*e.g.,* reaction time to visual stimuli) that the commenter requested because those measures are not within the scope of this study. The focus of this study is on children's anthropometrics and strength.

This commenter also recommended compiling data for children from various countries, so that a comprehensive data set is available for companies that distribute products globally. CPSC cannot collect data from participants in other countries or compel other countries to collect child strength data. However, the data CPSC collects as part of this study will be publicly available, so interested parties may combine it with information from other countries to create a comprehensive data set.

CPSC's review and consideration of the comments yielded no basis for modifying the supporting statement for the study. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to OMB a request for approval of this collection of information.

D. Burden Hours

The only change to the supporting statement corrects typographical errors to the burden hours for the federal government. The correct burden hours and costs are below. Although CPSC's 60-day **Federal Register** notice correctly stated these numbers, the supporting statement on *www.Regulations.gov* reflected slightly different numbers based on older Employer Costs for Employee Compensation. The final supporting statement, which is available in the docket for this notice, corrects those errors.

CPSC estimates that the study will involve 3,050 respondents and take a total of 1,813 hours over the duration of the study. The monetized hourly cost for the adult caregiver of a participant is $37.73, as defined by the average total hourly cost to employers for employee compensation for all civilian employees across all occupations as of March 2020, reported by the Bureau of Labor Statistics, Employer Costs for Employee Compensation. Accordingly, CPSC estimates the total cost burden to be $68,404 (1,813 hours × $37.73 = $68,404).

The estimated cost to the federal government for the contract to design and conduct the study issued to the University of Michigan under contract number 61320618D0004 is $1,134,502. The estimated salary and benefits costs for government personnel assigned to this study are $170,356, based on 12 staff months in 2020, at an average level of GS–13 step 5 in the Washington, DC area, effective January 2020 ($116,353) and a 68.3 percent ratio of wages and salary to total compensation (all civilian management, professional, and related workers) from Table 2 of the March 2020 Employer Costs for Employee Compensation, published by the Bureau of Labor Statistics. Therefore, the total estimated cost to the federal government is $1,134,502 for the contract, plus $170,356 in government labor costs, for a total of $1,304,858.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2021–00974 Filed 1–15–21; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2020–0041; OMB Control Number 0704–0525]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Prohibition of Foreign Commercial Satellite Services From Certain Foreign Entities—Representations

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance the following proposed revision and extension of a collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 18, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, 571–372–6174.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS), Prohibition on Acquisition of Commercial Satellite Services from Certain Foreign Entities-Representations; OMB Control Number 0704–0525.

Type of Request: Revision and extension of a currently approved collection.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Obligation to Respond: Required to obtain or retain benefits.

Number of Respondents: 235.

Responses Per Respondent: 1.

Annual Responses: 235.

Average Burden Per Response: 0.25 hours.

Annual Burden Hours: 58.

Frequency: On Occasion.

Needs and Uses: DFARS provision 252.225–7049, Prohibition on Acquisition of Commercial Satellite Services from Certain Foreign Entities—Representations, is used by contracting

officers to determine whether the offeror is subject to the statutory prohibition on award of contracts for commercial satellite services to certain foreign entities. The provision is included in solicitations for the acquisition of foreign commercial satellite services and requires the offeror to represent whether it is or is not a foreign entity subject to the prohibitions of the statute, and whether it is or is not offering foreign commercial satellite services provided by such a foreign entity. If the offeror responds affirmatively to any of the representations, then the offeror must provide further information.

Comments and recommendations on the proposed information collection should be sent to Ms. Susan Minson, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer D. Johnson,

Regulatory Control Officer,Defense Acquisition Regulations System.

[FR Doc. 2021–01197 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2020–0037; OMB Control Number 0704–0390]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS) Part 229, Taxes, and Related Clause at DFARS 252.229–7010

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance, the following proposed revision and extension of a collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 18, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, 571–372–6104.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 229, Taxes, and related clause at DFARS 252.229–7010; OMB Control Number 0704–0390.

Type of Request: Revision and extension.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Number of Respondents: 12.

Responses per Respondent: 2.33, approximately.

Annual Responses: 28.

Average Burden Per Response: 4 hours.

Annual Burden Hours: 112.

Reporting Frequency: On occasion.

Needs and Uses: DoD uses this information to determine if DoD contractors in the United Kingdom have attempted to obtain relief from customs duty on vehicle fuels in accordance with contract requirements. The clause at DFARS 252.229–7010, Relief from Customs Duty on Fuel (United Kingdom), is prescribed at DFARS 229.402–70(j) for use in solicitations issued and contracts awarded in the United Kingdom that require the use of fuels (gasoline or diesel) and lubricants in taxis or vehicles other than passenger vehicles. The clause requires the contractor to provide the contracting officer with evidence that the contractor has initiated an attempt to obtain relief from customs duty on fuels and lubricants, as permitted by an agreement between the United States and the United Kingdom.

Comments and recommendations on the proposed information collection should be sent to Ms. Susan Minson, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2021–01202 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2020–0043; OMB Control Number 0704–0259]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Part 216, Types of Contracts

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance the following proposed extension of a collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 18, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, 571–372–6093.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 216, Types of Contracts, and associated clauses at Part 252.216; OMB Control Number 0704–0259.

Type of Request: Extension.

Affected Public: Businesses or other for-profit and not-for profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Reporting Frequency: On occasion.

Number of Respondents: 132.

Responses per Respondent: Approximately 4.

Annual Responses: 533.

Average Burden per Response: 4 hours.

Annual Burden Hours: 2,132.

Needs and Uses: The clauses at DFARS 252.216–7000, Economic Price Adjustment—Basic Steel, Aluminum, Brass, Bronze, or Copper Mill Products; DFARS 252.216–7001, Economic Price Adjustment—Nonstandard Steel Items; and DFARS 252.216–7003, Economic Price Adjustment—Wage Rates or Material Prices Controlled by a Foreign Government, require contractors with fixed-price economic price adjustment

contracts to submit information to the contracting officer regarding changes in established material prices or wage rates. The contracting officer uses this information to make appropriate adjustments to contract prices.

Comments and recommendations on the proposed information collection should be sent to Ms. Susan Minson, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2021–01195 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2021–0003; OMB Control Number 0704–0483]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS); Independent Research and Development Technical Descriptions

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed revision and extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed revision and extension of a public information collection requirement and seeks public comment on the provisions thereof.

DoD invites comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through April 30, 2021. DoD proposes that OMB extend its approval for three additional years.

DATES: DoD will consider all comments received by March 22, 2021.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0483, using any of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

Email: osd.dfars@mail.mil. Include OMB Control Number 0704–0483 in the subject line of the message.

Mail: Defense Acquisition Regulations System, Attn: Ms. Heather Kitchens, OUSD(A&S)DPC(DARS), 3060 Defense Pentagon, Room 3B938, Washington, DC 20301–3060.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, 571–372–6104.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS), Independent Research and Development Technical Descriptions; OMB Control Number 0704–0483.

Affected Public: Businesses and other for-profit entities.

Respondent's Obligation: Required to obtain or retain benefits.

Type of Request: Revision and extension of a currently approved collection.

Reporting Frequency: On occasion.

Number of Respondents: 69.

Responses Per Respondent: 90.49, approximately.

Annual Responses: 6,244.

Average Burden Per Response: 0.5 hours.

Annual Response Burden Hours: 3,122.

Needs and Uses: DFARS 231.205–18 requires contractors to report independent research and development (IR&D) projects to the Defense Technical Information Center (DTIC) using DTIC's online IR&D database. The inputs must be updated at least annually and when the project is completed. The data provide in-process information on IR&D projects for which DoD reimburses the contractor as an allowable indirect expense. In addition to improving the Department's ability to determine whether contractor IR&D costs are allowable, the data provide visibility into the technical content of industry IR&D activities to meet DoD needs.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2021–01196 Filed 1–15–21; 8:45 am]

BILLING CODE 6820–ep–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0002]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by March 22, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* The Department of Defense (DoD) cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public

viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Rand Corporation, 1200 South Hayes Street, Arlington, VA 22202, Towanda Street, 703–614–0823.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Needs Assessment of Child and Youth Non-Medical Counseling; OMB Control Number 0704–XXXX.

Needs and Uses: In order for the DoD to best and most efficiently serve the needs of military children, it is important to know how the CYB–MFLC program fits within the landscape of family and child support systems to meet the needs and expectations of stakeholders. It is also important to identify where gaps in services remain and to identify the emerging needs of military children and youth that could be potentially filled or addressed by the CYB–MFLC program. Assessing how prevalent those needs and gaps are, and whether there is variation in these needs across locations, will inform modifications to the program to strengthen alignment of the scope of its services with other sources of support, resulting in improved coordinated care for military children in the school environment.

Affected Public: Individuals or Households.

Annual Burden Hours: 45.

Number of Respondents: 180.

Responses per Respondent: 1.

Annual Responses: 180.

Average Burden per Response: 15 minutes.

Frequency: Once.

Respondents are school principals at civilian schools involved with the CYB–MFLC program. Respondents will provide information, currently not available in any other source, about the breadth and depth of the unique non-medical counseling needs of military children and the ways in which the CYB–MFLC program is or is not meeting those needs.

Dated: January 12, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–00997 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0096]

Submission for OMB Review; Comment Request

AGENCY: Pentagon Force Protection Agency, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Computer Aided Dispatch and Record Management System (CAD/RMS); OMB Control Number 0704–0522.

Type of Request: Extension.

Number of Respondents: 693.

Responses per Respondent: 1.

Annual Responses: 693.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 231.

Needs and Uses: The information collection requirement is necessary to obtain information regarding incidents that occur at the Pentagon and other facilities under the jurisdiction of the Pentagon Force Protection Agency.

Afected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: January 12, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–00999 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0092]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: 30-day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or

whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Revitalizing Base Closure Communities, Economic Development Conveyance Annual Financial Statement; OMB Control Number 0790–0004.

Type of Request: Extension.

Number of Respondents: 24.

Responses per Respondent: 1.

Annual Responses: 24.

Average Burden per Response: 40 hours.

Annual Burden Hours: 960.

Needs and Uses: The information collection requirement is necessary to verify that Local Redevelopment Authority (LRA) recipients of Economic Development Conveyances (EDCs) are in compliance with the requirement that the LRA reinvest proceeds from the use of EDC property for seven years. Respondents are LRAs that have executed EDC agreements with a Military Department that transferred property from a closed military installation. As provided by 32 CFR 174.9, such agreements require that the LRA reinvest the proceeds from any sale, lease or equivalent use of EDC property (or any portion thereof) during at least the first seven years after the date of the initial transfer of the property to support the economic redevelopment of, or related to, the installation. The Secretary of Defense may recoup from the LRA such portion of these proceeds not used to support the economic redevelopment of, or related to, the installation. LRAs are subject to this same seven-year reinvestment requirement if their EDC agreement is modified to reduce the debt owed to the Federal Government. Military Departments monitor LRA compliance with this provision by requiring an annual financial statement certified by an independent Certified Public Accountant. No specific form is required.

Affected Public: State and local governments.

Frequency: Annually.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: January 12, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–00998 Filed 1–15–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Promise Neighborhoods (PN) Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for fiscal year (FY) 2021 for the PN Program, Assistance Listing Number 84.215N. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES: *Applications Available:* January 19, 2021.

Deadline for Notice of Intent to Apply: February 3, 2021.

Date of Pre-Application Meetings: The Department will hold a pre-application meeting on January 29, 2021 via webinar for prospective applicants. Detailed information regarding pre-application webinar(s) will be provided on the PN website at *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/school-choice-improvement-programs/promise-neighborhoods-pn/.*

Deadline for Transmittal of Applications: March 5, 2021.

Deadline for Intergovernmental Review: May 4, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW, Room 4W220, Washington, DC 20202. Telephone: (202) 453–5638. Email: *Adrienne.Hawkins@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The PN program is authorized under the Elementary and Secondary Education Act of 1965, as amended (ESEA). The purpose of the PN program is to significantly improve the academic and developmental outcomes of children living in the most distressed communities of the United States, including ensuring school readiness, high school graduation, and access to a community-based continuum of high-quality services. The program serves neighborhoods with high concentrations of low-income individuals; multiple signs of distress, which may include high rates of poverty, childhood obesity, academic failure, and juvenile delinquency, adjudication, or incarceration; and schools implementing comprehensive support and improvement activities or targeted support and improvement activities under section 1111(d) of the ESEA. All strategies in the continuum of solutions must be accessible to children with disabilities and English learners.

Priorities: This competition includes three absolute priorities, four competitive preference priorities, and one invitational priority.

Absolute Priorities 1 and 3 and Competitive Preference Priorities 1 and 4 are from the notice of final priorities, requirements, definitions, and selection criteria for this program published elsewhere in this issue of the **Federal Register** (NFP). Absolute Priority 2 and Competitive Preference Priority 3 are from the notice of final priorities published in the **Federal Register** on March 9, 2020 (85 FR 13640) (Administrative Priorities). Competitive Preference Priority 2 is from the notice of final priority published in the **Federal Register** on November 27, 2019 (84 FR 65300) (Opportunity Zones NFP).

Absolute Priorities: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider

only applications that meet one or more of these priorities.

These priorities are:

Absolute Priority 1—Non-Rural and Non-Tribal Communities.

To meet this priority, an applicant must propose to implement a PN strategy that serves one or more non-rural or non-Tribal communities.

Absolute Priority 2—Rural Applicants.

Under this priority, an applicant must demonstrate one or more of the following:

(a) The applicant proposes to serve a local educational agency (LEA) that is eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title V, Part B of the ESEA.

(b) The applicant proposes to serve a community that is served by one or more LEAs with a locale code of 32, 33, 41, 42, or 43.

(c) The applicant proposes a project in which a majority of the schools served have a locale code of 32, 33, 41, 42, or 43.

(d) The applicant is an institution of higher education (IHE) with a rural campus setting, or the applicant proposes to serve a campus with a rural setting. Rural settings include any of the following: Town-Fringe, Town-Distant, Town-Remote, Rural Fringe, Rural-Distant, Rural-Remote, as defined by the National Center for Education Statistics (NCES) College Navigator search tool.

Note: To determine whether a particular LEA is eligible for SRSA or RLIS, refer to the Department's website at *https://oese.ed.gov/offices/office-of-formula-grants/rural-insular-native-achievement-programs/rural-education-achievement-program/.* Applicants are encouraged to retrieve locale codes from the NCES School District search tool (*https://nces.ed.gov/ccd/districtsearch/*), where LEAs can be looked up individually to retrieve locale codes, and Public School search tool (*https://nces.ed.gov/ccd/schoolsearch/*), where individual schools can be looked up to retrieve locale codes. Applicants are encouraged to retrieve campus settings from the NCES College Navigator search tool (*https://nces.ed.gov/collegenavigator/*) where IHEs can be looked up individually to determine the campus setting.

Absolute Priority 3—Tribal Communities.

To meet this priority, an applicant must propose to implement a PN strategy that serves one or more Indian Tribes (as defined in this notice).

Competitive Preference Priorities: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 10 points to an application, depending on how well the application meets one or more of these priorities; the total possible points for each priority are noted in parentheses.

These priorities are:

Competitive Preference Priority 1—Community-Level Opioid Abuse Prevention Efforts (0 to 3 points).

To meet this priority, an applicant must: (1) Demonstrate how it will partner with an organization that conducts high-quality, community-level activities to prevent opioid abuse, such as an organization supported by an Office of National Drug Control Policy, Drug-Free Communities Support Program grant, in PN communities; (2) describe the partner organization's record of success in approaching opioid abuse prevention at the community level; and (3) provide, in its application, a memorandum of understanding between it and the partner organization responsible for managing the effort. The memorandum of understanding must indicate a commitment on the part of the applicant to coordinate implementation and align resources to the greatest extent practicable.

Competitive Preference Priority 2—Spurring Investment in Qualified Opportunity Zones (0 to 3 points).

Under this priority, an applicant must demonstrate that the area in which the applicant proposes to provide services overlaps with a Qualified Opportunity Zone (QOZ), as designated by the Secretary of the Treasury under section 1400Z–1 of the Internal Revenue Code.

An applicant must—

(1) Provide the census tract number of the QOZ(s) in which it proposes to provide services (1 point); and

(2) Describe how the applicant will provide services in the QOZ(s) (Up to 2 points).

Competitive Preference Priority 3—Applications from New Potential Grantees (0 or 1 point).

Under this priority, an applicant must demonstrate that it has never received a grant, including through membership in a group application submitted in accordance with 34 CFR 75.127–75.129, under the program from which it seeks funds.

Note: For new potential grantees unfamiliar with grantmaking at the Department, please consult our funding basics resource at *www2.ed.gov/documents/funding-101/funding-101-basics.pdf* or a more detailed resource at *www2.ed.gov/documents/funding-101/funding-101.pdf.*

Competitive Preference Priority 4—Evidence-Based Activities to Support Academic Achievement (0 to 3 points).

Projects that propose to use evidence-based (as defined in 34 CFR 77.1(c)) activities, strategies, or interventions that support teaching practices that will lead to increasing student achievement (as defined in this notice), graduation rates, and career readiness.

Invitational Priority: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Community-Based Crime Reduction Efforts.

To meet this priority, an applicant must: (1) Demonstrate how it will partner with an organization that conducts high-quality activities focused on the re-entry of formerly incarcerated individuals or on community-based crime reduction activities, such as an organization supported by a U.S. Department of Justice (DOJ) Innovations in Community-Based Crime Reduction Program grant, a grant authorized under the Second Chance Act, as reauthorized under the Formerly Incarcerated Reenter Society Transformed Safely Transitioning Every Person (FIRST STEP) Act, or DOJ Office of Justice Programs competitive grants related to juvenile justice and delinquency prevention; (2) describe the partner organization's record of success with supporting the re-entry of formerly incarcerated individuals or community-based crime reduction and how their efforts will be coordinated with the PN activities of this grant; and (3) provide, in its application, a memorandum of understanding between it and a partner organization managing the effort. The memorandum of understanding must indicate a commitment on the part of the applicant to coordinate implementation and align resources to the greatest extent practicable.

Requirements: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, applicants must meet the following application and program requirements from section 4624 of the ESEA and the NFP.

Application Requirements:

(1) A plan to significantly improve the academic outcomes of children living in the geographically defined area (neighborhood) that is served by the eligible entity by providing pipeline services that address the needs of children in the neighborhood, as

identified by the needs analysis; and that is supported by effective practices.

(2) A description of the neighborhood the eligible entity will serve.

Note: Applicants may propose to serve multiple, non-contiguous geographically defined areas, that is to say geographic areas that are not adjacent to one another. In cases where target areas are non-contiguous, the applicant should explain its rationale for including non-contiguous areas.

(3) An applicant must demonstrate that its proposed project—

(a) Is representative of the geographic area proposed to be served (as defined in this notice); and

(b) Would provide a majority of the solutions from the applicant's proposed pipeline services in the geographic area proposed to be served.

(4) An analysis of the needs and assets of the neighborhood, including:

(a) The size and scope of the population affected;

(b) A description of the process through which the needs analysis was produced, including a description of how parents, families, and community members were engaged in such analysis;

(c) An analysis of community assets and collaborative efforts (including programs already provided from Federal and non-Federal sources) within, or accessible to, the neighborhood, including, at a minimum, early learning opportunities, family and student supports, local businesses, local educational agencies, and institutions of higher education;

(d) The steps that the eligible entity is taking at the time of the application to address the needs identified in the needs analysis; and

(e) Any barriers the eligible entity, public agencies, and other community-based organizations have faced in meeting such needs.

(5) A description of (i) all information the entity used to identify the pipeline services to be provided, which shall not include information that is more than 3 years old; and (ii) how the eligible entity will collect data on children served by each pipeline service and increase the percentage of children served over time.

(6) A description of how the pipeline services will facilitate the coordination of the following activities:

(a) Providing early learning opportunities for children, including by:

(i) Providing opportunities for families to acquire the skills to promote early learning and child development; and

(ii) Ensuring appropriate diagnostic assessments and referrals for children with disabilities and children aged 3 through 9 experiencing developmental delays, consistent with the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*), where applicable.

(b) Supporting, enhancing, operating, or expanding rigorous, comprehensive, effective educational improvements, which may include high-quality academic programs, expanded learning time, and programs and activities to prepare students for postsecondary education admissions and success.

(c) Supporting partnerships between schools and other community resources with an integrated focus on academics and other social, health, and familial supports.

(d) Providing social, health, nutrition, and mental health services and supports, for children, family members, and community members, which may include services provided within the school building.

(e) Supporting evidence-based programs that assist students through school transitions, which may include expanding access to postsecondary education courses and postsecondary education enrollment aid or guidance, and other supports for at-risk youth.

(7) Each applicant must submit, as part of its application, a preliminary memorandum of understanding, signed by each organization or agency with which it would partner in implementing the proposed PN program. Within the preliminary memorandum of understanding, all applicants must detail each partner's financial, programmatic, and long-term commitment with respect to the strategies described in the application. Under section 4624(c) of the ESEA, applicants that are non-profit entities must submit a preliminary memorandum of understanding signed by each partner entity or agency, which must include at least one of the following: A high-need LEA; an institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002); the office of a chief elected official of a unit of local government; or an Indian Tribe or Tribal organization as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(8) A description of the process used to develop the application, including the involvement of family and community members. In addressing this paragraph, an applicant must provide a description of the process used to develop the application, which must include the involvement of an LEA(s) (including but not limited to the LEA's or LEAs' involvement in the creation and planning of the application and a signed Memorandum of Understanding) and at least one public elementary or secondary school that is located within the identified geographic area that the grant will serve.

(9) A description of the strategies that will be used to provide pipeline services (including a description of which programs and services will be provided to children, family members, community members, and children within the neighborhood) to support the purpose of the Promise Neighborhoods program.

(10) An explanation of the process the eligible entity will use to establish and maintain family and community engagement, including:

(a) Involving representative participation by the members of such neighborhood in the planning and implementation of the activities of each grant awarded;

(b) The provision of strategies and practices to assist family and community members in actively supporting student achievement and child development;

(c) Providing services for students, families, and communities within the school building; and

(d) Collaboration with institutions of higher education, workforce development centers, and employers to align expectations and programming with postsecondary education and workforce readiness.

(e) In addressing this paragraph, an applicant must describe the process it will use to establish and maintain a family navigation system (as defined in this notice), including an explanation of the process the applicant will use to establish and maintain family and community engagement.

(11) An explanation of how the eligible entity will continuously evaluate and improve the continuum of high-quality pipeline services to provide for continuous program improvement and potential expansion.

(12) In addressing the application requirements in paragraphs (4), (5), and (6), an applicant must clearly demonstrate needs, including a segmentation analysis, gaps in services, and any available data from within the last 3 years to demonstrate needs. The applicant must also describe proposed activities that address these needs and the extent to which these activities are evidence-based. The applicant must also describe its, or its partner organization's, if applicable, experience providing these activities, including any data demonstrating effectiveness.

Program Requirements:

(1) Each grantee under the PN competition must use the grant funds to implement the pipeline services and continuously evaluate the success of the program and improve the program based

on data and outcomes. Section 4624(d) of the ESEA.

(2) Grantees may use not less than 50 percent of grant funds in year one, and not less than 25 percent of grant funds in year two for planning activities to develop and implement pipeline services.

(3) Grantees that operate a school in a neighborhood served by a grant program must provide such school with the operational flexibility, including autonomy over staff, time, and budget, needed to effectively carry out the activities described in this notice.

(4) Grantees cannot, in carrying out activities to improve early childhood education programs, use PN funds to carry out the following activities: (1) Assessments that provide rewards or sanctions for individual children or teachers. (2) A single assessment that is used as the primary or sole method for assessing program effectiveness. (3) Evaluation of children, other than for the purposes of improving instruction, classroom environment, professional development, or parent and family engagement, or program improvement.

Definitions: The definitions for ''eligible entity'' and ''pipeline services'' are from section 4622 of the ESEA. The definitions of ''family navigation system,'' ''graduation rate,'' ''Indian Tribe,'' ''indicators of need,'' ''regular high-school diploma,'' ''representative of the geographic area to be served,'' ''segmentation analysis,'' ''student achievement,'' and ''student mobility rate'' are from the NFP. The remaining definitions are from 34 CFR 77.1.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Family navigation system means a service delivery model that includes coordinators who teach, mentor, and collaborate with students and their families, as well as community members, to choose interventions, treatments, or solutions provided by the grantee and that best meet the needs of students and their families. Students and their families can select services and supports based on available services and individual needs, as well as advocate for additional services.

Graduation rate means the four-year adjusted cohort graduation rate or extended-year adjusted cohort graduation rate as defined in section 8101(25) and (23) of the ESEA.

Indian Tribe means an Indian Tribe or Tribal organization as defined in section 4 of the Indian Self-determination Act (25 U.S.C. 5304(e)).

Indicators of need means currently available data that describe—

(a) Education need, which means—

(1) All or a portion of the neighborhood includes or is within the attendance zone of a low-performing school that is a high school, especially one in which the graduation rate (as defined in this notice) is less than 60 percent or a school that can be characterized as low-performing based on another proxy indicator, such as students' on-time progression from grade to grade; and

(2) Other indicators, such as significant achievement gaps between subgroups of students (as identified in section 1111(b)(2)(B)(xi) of the ESEA), within a school or LEA, high teacher and principal turnover, or high student absenteeism; and

(b) Family and community support need, which means—

(1) Percentages of children with preventable chronic health conditions (*e.g.,* asthma, poor nutrition, dental problems, obesity) or avoidable developmental delays;

(2) Immunization rates;

(3) Rates of crime, including violent crime;

(4) Student mobility rates;

(5) Teenage birth rates;

(6) Percentage of children in single parent or no-parent families;

(7) Rates of vacant or substandard homes, including distressed public and assisted housing; or

(8) Percentage of the residents living at or below the Federal poverty threshold.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on

relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Pipeline services means a continuum of coordinated supports, services, and opportunities for children from birth through entry into and success in postsecondary education, and career attainment. Such services shall include, at a minimum, strategies to address through services or programs (including integrated student supports) the following:

(a) High-quality early childhood education programs.

(b) High-quality school and out-of-school-time programs and strategies.

(c) Support for a child's transition to elementary school, from elementary school to middle school, from middle school to high school, and from high school into and through postsecondary education and into the workforce, including any comprehensive readiness assessment determined necessary.

(d) Family and community engagement and supports, which may include engaging or supporting families at school or at home.

(e) Activities that support postsecondary and work-force readiness, which may include job training, internship opportunities, and career counseling.

(f) Community-based support for students who have attended the schools in the area served by the pipeline, or students who are members of the community, facilitating their continued connection to the community and success in postsecondary education and the workforce.

(g) Social, health, nutrition, and mental health services and supports.

(h) Juvenile crime prevention and rehabilitation programs.

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks.

Regular high school diploma has the meaning set out in section 8101(43) of the ESEA.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Representative of the geographic area proposed to be served means that residents of the geographic area proposed to be served have an active role in decision-making and that at least one-third of the applicant's governing board or advisory board is made up of—

(a) Residents who live in the geographic area proposed to be served, which may include residents who are representative of the ethnic and racial composition of the neighborhood's residents and the languages they speak;

(b) Residents of the city or county in which the neighborhood is located but who live outside the geographic area proposed to be served, and who earn less than 80 percent of the area's median income as published by the U.S. Department of Housing and Urban Development;

(c) Public officials who serve the geographic area proposed to be served (although not more than one-half of the governing board or advisory board may be made up of public officials); or

(d) Some combination of individuals from the three groups listed in paragraphs (a), (b), and (c) of this definition.

Segmentation analysis means the process of grouping and analyzing data from children and families in the geographic area proposed to be served according to indicators of need or other relevant indicators to allow grantees to differentiate and more effectively target interventions based on the needs of different populations in the geographic area.

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Student achievement means—

(a) For tested grades and subjects—

(1) A student's score on the State's assessments under the ESEA; and

(2) As appropriate, other measures of student learning, such as those described in paragraph (b) of this definition, provided they are rigorous and comparable across classrooms and programs; and

(b) For non-tested grades and subjects, alternative measures of student learning and performance, such as student scores on pre-tests and end-of-course tests; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across classrooms.

Student mobility rate is calculated by dividing the total number of new student entries and withdrawals at a school, from the day after the first official enrollment number is collected through the end of the academic year, by the first official enrollment number of the academic year.

What Works Clearinghouse (WWC) Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation.

Authority: *Program Authority:* 20 U.S.C. 7273–7274.

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFP. (e) The notice of final priorities, requirements, definitions, and selection criteria published in the **Federal Register** on July 6, 2011 (76 FR 39589) (2011 Promise Neighborhoods NFP). (f) The Administrative Priorities. (g) The Opportunity Zones NFP.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: $36,993,970.

Contingent upon the availability of funds and the quality of applications, we may make additional awards later in FY 2021 or in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $4,000,000 to $6,000,000.

Estimated Average Size of Awards: $5,000,000.

Maximum Award: We will not make an award exceeding $6,000,000 for a single budget period of 12 months.

Estimated Number of Awards: 5–7.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Under section 4623 of the ESEA, a grant awarded under this competition will be for a period of not more than five years, and may be extended for an additional period of not more than two years.

III. Eligibility Information

1. *Eligible Applicants:* Under section 4622 of the ESEA, an eligible entity must be one of the following:

(a) An institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002);

(b) An Indian Tribe or Tribal organization, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); or

(c) One or more nonprofit entities working in formal partnership with not less than one of the following entities:

(i) A high-need LEA.

(ii) An institution of higher education, as defined in section 102 of the HEA (20 U.S.C. 1002).

(iii) The office of a chief elected official of a unit of local government.

(iv) An Indian Tribe or Tribal organization, as defined under section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* Under section 4623(d)(1)(A) of the ESEA, to be eligible for a grant under this competition, an applicant must demonstrate a commitment from one or more entities in the public or private sector, which may include Federal, State, and local public agencies, philanthropic organizations, and private sources, to provide matching funds.

An applicant proposing a project that meets Absolute Priority 1—Non-rural and Non-Tribal Communities must obtain matching funds or in-kind donations equal to at least 100 percent of its grant award.

Under section 4623(d)(1)(C) of the ESEA, an applicant proposing a project that meets Absolute Priority 2—Rural Applicants or Absolute Priority 3—Tribal Communities must obtain matching funds or in-kind donations equal to at least 50 percent of its grant award.

Eligible sources of matching funds include sources of funds used to pay for solutions within the pipeline services, initiatives supported by the LEA, or public health services for children in the neighborhood. Under section 4623(d)(1)(B) of the ESEA, at least 10 percent of an applicant's total match must be cash or in-kind contributions from the private sector, which may include philanthropic organizations or private sources.

Applicants must demonstrate a commitment of matching funds in the application. Applicants must specify the source of the funds or contributions and in the case of a third-party in-kind contribution, a description of how the value was determined for the donated or contributed goods or service. Applicants must demonstrate the match commitment by including letters in their applications explaining the type and quantity of the match commitment

with original signatures from the executives of organizations or agencies providing the match.

Under section 4623(d)(1)(C) of the ESEA, the Secretary may consider decreasing the matching requirement in the most exceptional circumstances, on a case-by-basis.

An applicant that is unable to meet the matching requirement must include in its application a request to the Secretary to reduce the matching requirement, including the amount of the requested reduction, the total remaining match contribution, and a statement of the basis for the request. The Secretary will grant this request only if an applicant demonstrates a significant financial hardship.

An applicant should review the Department's cost-sharing and cost matching regulations, which include specific limitations, in 2 CFR 200.306 and the cost principles regarding donations, capital assets, depreciations, and allowable costs, set out in subpart E of 2 CFR part 200.

The Secretary does not, as a general matter, anticipate waiving the matching requirement. Furthermore, given the importance of matching funds to the long-term success of the project, eligible entities must identify appropriate matching funds in the proposed budget.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the PN competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

4. *Funding Restrictions:* We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts,
- tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- *Use one of the following fonts:* Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria ''Need for project'' and ''Project design'' are from the NFP. The remaining selection criteria are from 34 CFR 75.210 and the 2011 Promise Neighborhoods NFP. The maximum score for each criterion is indicated in parenthesis; the maximum score that an application may receive under the selection criteria, and the competitive preference priorities, is 110 points.

The selection criteria are as follows:

(a) *Need for project (up to 20 points).*

In determining the need for the proposed project, the Secretary considers the following factors:

(1) The magnitude or severity of the problems to be addressed by the proposed project as described by indicators of need and other relevant indicators identified in part by the needs assessment and segmentation analysis (up to 5 points);

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including—

(i) The nature and magnitude of those gaps or weaknesses (up to 5 points); and

(ii) A pipeline of solutions addressing the identified gaps and weaknesses, including solutions targeted to early childhood, K–12, family and community supports, and college and career (up to 10 points).

(b) *Quality of project services (up to 30 points).*

The Secretary considers the quality of the services to be provided by the proposed project. In determining the

quality of the project services, the Secretary considers:

(1) The quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (34 CFR 75.210) (up to 10 points); and

(2) The likelihood that the services to be provided by the proposed project will lead to improvement in the achievement of students as measured against rigorous academic standards (34 CFR 75.210) (up to 20 points).

(c) *Quality of project design (up to 20 points).*

In determining the quality of project design for the proposed project, the Secretary considers the following factors:

(1) The extent to which the applicant describes a plan to create a complete pipeline of services, without time and resource gaps, that is designed to prepare all children in the neighborhood to attain a high-quality education and successfully transition to college and a career (up to 5 points);

(2) The extent to which the project will significantly increase the proportion of students in the neighborhood that are served by the complete continuum of high-quality services (up to 5 points); and

(3) The extent to which the proposed family navigation system is high-quality and provides students and their families sufficient services and supports based on available services and individual needs (up to 10 points).

(d) *Quality of the management plan (up to 15 points).*

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (34 CFR 75.210) (up to 5 points); and

(2) The experience, lessons learned, and proposal to build capacity of the applicant's management team and project director in collecting, analyzing, and using data for decision-making, learning, continuous improvement, and accountability, including whether the applicant has a plan to build, adapt, or expand a longitudinal data system that integrates student-level data from multiple sources in order to measure progress while abiding by privacy laws and requirements (2011 Promise Neighborhoods NFP) (up to 10 points).

(e) *Adequacy of resources (up to 15 points).*

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers:

(1) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits (34 CFR 75.210) (up to 5 points);

(2) The extent to which the applicant demonstrates that it has the resources to operate the project beyond the length of the grant, including a multi-year financial and operating model and accompanying plan; the demonstrated commitment of any partners; evidence of broad support from stakeholders (*e.g.,* State educational agencies, teachers' unions) critical to the project's long term success; or more than one of these types of evidence (34 CFR 75.210) (up to 5 points); and

(3) The extent to which the applicant identifies existing neighborhood assets and programs supported by Federal, State, local, and private funds that will be used to implement a continuum of solutions (2011 Promise Neighborhoods NFP) (up to 5 points).

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department of Education will review and consider applications for funding pursuant to this notice inviting applications in accordance with the following:

- Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);
- Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);
- Promoting the freedom of speech and religious liberty in alignment with Promoting Free Speech and Religious Liberty (E.O. 13798) and Improving Free Inquiry, Transparency, and Accountability at Colleges and Universities (E.O. 13864) (34 CFR 200.300, 200.303, 200.339, and 200.341);

• Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

• Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html*.

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* The Secretary has established performance indicators (*i.e.,* performance measures) for PN as required under section 4624(h) of the ESEA. Performance indicators established by the Secretary include improved academic and development outcomes for children, including indicators of school readiness, high school graduation, postsecondary education and career readiness, and other academic and developmental outcomes. These outcomes promote data-driven decision-making and access to a community-based continuum of high-quality services for children living in the most distressed communities of the United States, beginning at birth. All grantees will be required to submit data annually against these performance measures as part of their annual performance report.

The Secretary establishes, in Table 1, the following performance indicators under section 4624(h) of the ESEA and 34 CFR 75.110:

TABLE 1—PROMISE NEIGHBORHOODS PERFORMANCE INDICATORS

Result	Indicator	Recommended source
1. Children enter kindergarten ready to succeed in school.	1. Number and percentage of children in kindergarten who demonstrate at the beginning of the program or school year age-appropriate functioning across multiple domains of early learning as determined using developmentally appropriate early learning measures.	Administrative data from LEA.
2. Students are proficient in core academic subjects.	2.1 Number and percentage of students at or above grade level according to State mathematics assessments in at least the grades required by the ESEA (3rd through 8th grades and once in high school). 2.2 Number and percentage of students at or above grade level according to State English language arts assessments in at least the grades required by the ESEA.	
3. Students successfully transition from middle school grades to high school.	3.1 Attendance rate of students in 6th, 7th, 8th, and 9th grade as defined by average daily attendance. 3.2 Chronic absenteeism rate of students in 6th, 7th, 8th, and 9th grades.	
4. Youth graduate from high school.	4. Four-year adjusted cohort graduation rate.	
5. High school graduates obtain a postsecondary degree, certification or credential.	5.1 Number and percentage of Promise Neighborhood students who enroll in a two-year or four-year college or university after graduation. 5.2 Number and percent of Promise Neighborhood students who graduate from a two-year or four-year college or university or vocational certification completion.	Third party data such as the National Student Clearinghouse.
6. Students are healthy	6. Number and percentage of children who consume five or more servings of fruits and vegetables daily.	Neighborhood survey, school climate survey or other reliable data source for population level data collection.

TABLE 1—PROMISE NEIGHBORHOODS PERFORMANCE INDICATORS—Continued

Result	Indicator	Recommended source
7. Students feel safe at school and in their community.	7. Number and percentage of children who feel safe at school and traveling to and from school as measured by a school climate survey.	
8. Students live in stable communities.	8. Student mobility rate (as defined in the notice).	
9. Families and community members support learning in promise Neighborhood Schools.	9.1 Number and percentage of parents or family members that read to or encourage their children to read three or more times a week or reported their child read to themselves three or more times a week (birth–8th grade). 9.2 Number and percentage of parents/family members who report talking about the importance of college and career (9th–12th grade).	
10. Students have access to 21st century learning tools.	10. Number and percentage of students who have school and home access to broadband internet and a connected computing device.	

Note: The indicators in Table 1 are not intended to limit an applicant from collecting and using data from additional Family and Community Support indicators proposed to the Department. Applicants are strongly encouraged, but not required, to propose additional performance indicators aligned to the specific pipeline services proposed in their application.

Each eligible entity that receives a grant under this program is required to prepare and submit an annual report to the Secretary that must include the following: (1) Information about the number and percentage of children in the neighborhood who are served by the grant program, including a description of the number and percentage of children accessing each support service offered as part of the pipeline of services; and (2) information relating to the metrics established under the PN Performance Indicators.

In addition, grantees are required to make these data publicly available, including through electronic means. To the extent practicable, and as required by law, such information must be provided in an accessible form and a language accessible to parents and families in the neighborhood served under the PN grant. In addition, data on academic indicators pertinent to the PN program will be, in most cases, part of statewide longitudinal data systems already.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Also, in making continuation awards for years four and five, the Department will consider whether the grantee is achieving the intended goals and outcomes of the grant and shows substantial improvement against baseline data on performance indicators and performance measures.

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Frank T. Brogan,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2021–00907 Filed 1–15–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Native Hawaiian Career and Technical Education Program (NHCTEP)

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2021 for the Native Hawaiian Career and Technical Education Program (NHCTEP), Assistance Listing number 84.259A. This notice relates to the approved information collection under OMB control number 1830–0564.

DATES:

Applications Available: January 19, 2021.

Deadline for Notice of Intent to Apply: Applicants are strongly encouraged, but not required, to submit a notice of intent to apply by February 18, 2021.

Date of Pre-Application Meeting: February 2, 2021.

Deadline for Transmittal of Applications: March 22, 2021.

Deadline for Intergovernmental Review: May 19, 2021.

Pre-Application Webinar Information: The Department will hold a pre-application meeting via webinar for prospective applicants on February 2, 2021. More information about the webinar can be found in the application package.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common

Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Jim Means, U.S. Department of Education, 400 Maryland Avenue SW, Potomac Center Plaza, Room 11–076, Washington, DC 20202. Telephone: (202) 245–8222. Email: *NHCTEPgrant@ed.gov.* If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program

NHCTEP provides grants to improve career and technical education (CTE) programs that are consistent with the purposes of the Carl D. Perkins Career and Technical Education Act of 2006, as amended by the Strengthening Career and Technical Education for the 21st Century Act (Perkins V) and that benefit Native Hawaiians. Section 116(e) of Perkins V provides that programs, services, and activities funded under NHCTEP must support and improve career and technical education programs. (20 U.S.C. 2326(e)

Background

This notice invites applications for a competition for NHCTEP grants under Perkins V. Section 116(h) of Perkins V authorizes the Secretary of Education (Secretary) to award grants to community-based organizations primarily serving and representing Native Hawaiians to plan, conduct, and administer programs, or portions of programs, that are for the benefit of Native Hawaiians and authorized by and consistent with Perkins V.

Statutory Changes Affecting NHCTEP

For the convenience of applicants, we summarize in this notice some of the major statutory changes made to the Carl D. Perkins Career and Technical Education Act of 2006 by Perkins V that are relevant to NHCTEP. This summary is not meant to be comprehensive of all Perkins V changes applicable to NHCTEP.

(a) Purpose. Congress amended the statement of purpose of the law in Perkins V, most significantly by adding, as a new purpose, increasing employment opportunities for populations who are chronically unemployed or underemployed, including individuals with disabilities; individuals from economically disadvantaged families; out-of-workforce individuals; youth who are in or have aged out of the foster care system; and homeless individuals (20 U.S.C. 2301(8)). Other amendments to the purpose incorporate references to programs of study and the development of employability skills by students; delete the term ''tech-prep education''; and change a reference to ''high-demand occupations'' to ''in-demand occupation,'' a new term defined by Perkins V (20 U.S.C. 2302(26)).

(b) Definitions. Congress amended the definitions of certain terms that affect NHCTEP. Most significant among these are changes to the definition of ''career and technical education'' in section 3(5) of Perkins V (20 U.S.C. 2302(5)). The new definition of CTE now allows CTE programs to provide ''a recognized postsecondary credential,'' as defined in section 3 of the Workforce Innovation and Opportunity Act (WIOA),[1] and allows CTE to include ''career exploration at the high school level or as early as the middle grades (as such term is defined in section 8101 of the Elementary and Secondary Education Act of 1965, as amended (ESEA).'' [2] The amended definition of CTE also provides that, to the extent practicable, CTE should include coordination between secondary and postsecondary education programs through programs of study, which may include coordination through articulation agreements, early college high school programs, dual or concurrent enrollment program opportunities, or other credit transfer agreements that provide postsecondary credit or advanced standing.

Additionally, the definition of CTE now includes work-based learning (20 U.S.C. 2302(55)). For NHCTEP grantees, this means that students may be paid stipends not only for time they spend in class receiving instruction, but also for participating in unpaid work-based learning that is part of a CTE program that meets the Perkins V definition of CTE.

Congress also made significant changes to the definition of ''special populations'' (20 U.S.C. 2302(48)). Perkins V now includes three additional subpopulations within this definition: Homeless individuals described in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a); youth who are in or have aged out of the foster care system; and youth with a parent who is a member of the armed forces (as defined in 10 U.S.C. 101(a)(4)) and who is on active duty (as defined in 10 U.S.C. 101(d)(1)). Also, the term ''displaced homemakers'' has been removed and replaced by the term ''out-of-workforce individuals,'' which includes: Displaced homemakers, as defined in section 3 of WIOA (29 U.S.C. 3102); and unemployed or underemployed individuals who are experiencing difficulty in obtaining or upgrading employment who are either an individual who has worked primarily without remuneration to care for a home and family, and for that reason has diminished marketable skills, or is a parent whose youngest dependent child will become ineligible to receive assistance under the Temporary Assistance for Needy Families (TANF) program not later than two years after the date on which the parent applies for TANF assistance (20 U.S.C. 2302(36)). Additionally, the term ''individuals with limited English proficiency'' has been changed to ''English learners'' and the definition of this latter term has been aligned with the definition of this term in ESEA so that it now includes any secondary student who is an English learner as defined by section 8101 of ESEA (20 U.S.C. 2302(22)).

(c) Authorized activities. A new allowable use of funds in Perkins V permits NHCTEP grant funds to be used to provide preparatory, refresher, and remedial education services that are designed to enable students to achieve success in CTE programs or programs of study (20 U.S.C. 2326(c)(2)).

Finally, section 134(c) of Perkins V requires subrecipients of funds under Perkins V to conduct a local comprehensive needs assessment that must include a description of how CTE programs are aligned to State, regional, Tribal, or local in-demand industry sectors or occupations and are designed to meet local education or economic needs. The assessments must be updated every two years. Eligible applicants for NHCTEP may wish to review the comprehensive local needs assessment and use its data to inform project design and to better prepare Native Hawaiian students for successful careers.

[1] Section 3(52) of WIOA defines the term ''recognized postsecondary credential'' to mean ''a credential consisting of an industry-recognized certificate or certification, a certificate of completion of an apprenticeship, a license recognized by the State involved or Federal Government, or an associate or baccalaureate degree.''

[2] Section 8101(32) of the ESEA defines the term ''middle grades'' to mean ''any of grades 5 through 8.''

Fiscal Year 2021 Competition

For this competition, through the absolute priority, we require applicants to incorporate evidence into their project design. Evidence-based interventions are practices or programs that have evidence to show that they are supported by research or an evaluation. Applicants for this competition must submit evidence that demonstrates a rationale, as defined in this notice.

Requirements and Selection Criteria

This notice includes program requirements and selection criteria that are from statutory requirements or from the Notice of Final Requirements, Definitions, and Selection Criteria published in the **Federal Register** on March 24, 2009 (Notice of Final Requirements) (74 FR 12341). In addition, some requirements are based on those in the Notice of Final Requirements but established in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA) in order to make some modifications to those requirements and selection criteria due primarily to changes in the program's authorizing statute.

Priorities: This competition includes one absolute priority and one competitive preference priority. The absolute priority is from the notice of final priorities for discretionary grant programs, published in the **Federal Register** on March 9, 2020 (85 FR 13640) (Administrative Priorities). The competitive preference priority is from the Secretary's notice of final supplemental priorities and definitions, published in the **Federal Register** on March 2, 2018 (83 FR 9096) (Supplemental Priorities).

Absolute Priority: For FY 2021, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet the absolute priority.

This priority is:

Demonstrates a Rationale.

Under this priority, an applicant proposes a project that demonstrates a rationale (as defined in this notice).

Note: Applicants may wish to review the following technical assistance resources on evaluation and logic models:

(1) The Logic Model Workshop Toolkit developed by the Institute of Education Sciences: *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf;*

(2) The Ideas that Work website hosted by the Office of Special Education Programs: *https://osepideasthatwork.org/evaluation.* This page includes additional resources on planning and conducting evaluation activities and developing logic models and high-quality objectives and performance measures.

Competitive Preference Priority: For FY 2021, and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to an additional five points to an application, depending on how well the application meets this competitive preference priority. If an applicant chooses to address this competitive preference priority, the project narrative section of its application must identify its response to the competitive preference priority.

This priority is:

Promoting Science, Technology, Engineering, or Math (STEM) Education, With a Particular Focus on Computer Science (up to 5 points).

Projects designed to improve student achievement or other educational outcomes in one or more of the following areas: Science, technology, engineering, math, or computer science (as defined in this notice). These projects must address increasing access to STEM coursework, including computer science, and hands-on learning opportunities, such as through expanded course offerings, dual-enrollment, high-quality online coursework, or other innovative delivery mechanisms.

Requirements: These program requirements are established in accordance with section 437(d)(1) of GEPA unless a specific statutory or regulatory citation for the requirement is provided.

The program requirements are:

Requirement 1—Authorized Programs:

(a) Section 116 of Perkins V requires the Secretary to ensure that activities funded under NHCTEP ''will improve career and technical education programs'' (20 U.S.C. 2326(e)), as the term ''career and technical education'' is defined by Perkins V (20 U.S.C. 2302(5)). Therefore, under NHCTEP, the Assistant Secretary will award grants to carry out projects that—

(1) Propose organized educational activities offering a sequence of courses that—

(A) Provide individuals with rigorous academic content and relevant technical knowledge and skills needed to prepare for further education and careers in current or emerging professions, which may include high-skill, high-wage, or in-demand industry sectors or occupations, which shall be, at the secondary level, aligned with the challenging State academic standards adopted by a State under section 1111(b)(1) of the ESEA;

(B) Provide technical skill proficiency or a recognized postsecondary credential, which may include an industry-recognized credential, a certificate, or an associate degree; and

(C) May include prerequisite courses that meet the requirements of this subparagraph;

(2) Include competency-based, work-based, or other applied learning that supports the development of academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, employability skills, technical skills, and occupation-specific skills, and knowledge of all aspects of an industry, including entrepreneurship, of an individual;

(3) To the extent practicable, coordinate between secondary and postsecondary education programs through programs of study, which may include coordination through articulation agreements, early college high school programs, dual or concurrent enrollment program opportunities, or other credit transfer agreements that provide postsecondary credit or advanced standing; and

(4) May include career exploration at the high school level or as early as the middle grades (as such term is defined in section 8101 of ESEA).

(b) Special rule. Notwithstanding section 3(5)(A)(iii) of the Act, which excludes remedial courses from the definition of ''career and technical education,'' funds made available under NHCTEP for CTE may be used to provide preparatory, refresher, and remedial education services that are designed to enable students to achieve success in CTE programs or programs of study.

Requirement 2—Evaluation:

To help ensure the high quality of NHCTEP projects and the achievement of the goals and purposes of section 116 of the Act, each grantee must budget for and conduct an ongoing evaluation of its NHCTEP project. An independent evaluator must conduct the evaluation. The evaluation must be appropriate for the project and be both formative and summative in nature.

Requirement 3—Student Stipends:

(1) A portion of an award under this program may be used to provide stipends (as defined in this notice) to help students meet the costs of participation in a NHCTEP project.

(2) To be eligible for a stipend a student must—

(i) Be enrolled in a CTE project funded under this program;

(ii) Be in regular attendance in a NHCTEP project and meet the training institution's attendance requirement;

(iii) Maintain satisfactory progress in his or her program of study according to the training institution's published standards for satisfactory progress; and

(iv) Have an acute economic need that—

(A) Prevents participation in a project funded under this program without a stipend; and

(B) Cannot be met through a work-study program.

(3) The amount of a stipend is the greater of either the minimum hourly wage prescribed by State or local law, or the minimum hourly wage established under the Fair Labor Standards Act.

(4) A grantee may only award a stipend if the stipend combined with other resources the student receives does not exceed the student's financial need. A student's financial need is the difference between the student's cost of attendance and the financial aid or other resources available to defray the student's cost of participating in a NHCTEP project.

(5) To calculate the amount of a student's stipend, a grantee must multiply the number of hours a student actually attends CTE instruction by the amount of the minimum hourly wage that is prescribed by State or local law, or by the minimum hourly wage that is established under the Fair Labor Standards Act. The grantee must reduce the amount of a stipend if necessary to ensure that it does not exceed the student's financial need.

Example: If a grantee uses the Fair Labor Standards Act minimum hourly wage of $7.25 and a student attends classes for 20 hours a week, the student's stipend would be $145 for the week during which the student attends classes ($7.25 × 20 = $145.00). If the program lasts 16 weeks and the student's total financial need is $2,000, the grantee must reduce the weekly stipend to $125, because the total stipend for the course would otherwise exceed the student's financial need by $320 (or $20 a week).

Note: Grantees must maintain records that fully support their decisions to award stipends to students, as well as the amounts that are paid, such as proof of a student's enrollment in the NHCTEP project, stipend applications, timesheets showing the number of hours of student attendance that are confirmed in writing by an instructor, student financial status information, and evidence that a student would not be able to participate in the NHCTEP funds without a stipend. (*See generally* 20 U.S.C. 1232f; 34 CFR 75.700–75.702; 75.730; and 75.731.)

(6) An eligible student may receive a stipend when taking a course for the first time, although a stipend may not be provided to a student for a particular course if the student has already taken, completed, and had the opportunity to benefit from a course and is merely repeating the course.

(7) An applicant must include, in its application, the procedure it intends to use to determine student eligibility for stipends and stipend amounts, and its oversight procedures for the awarding and payment of stipends. (Notice of Final Requirements).

Requirement 4—Direct Assistance to Students:

A grantee may provide direct assistance (as defined in this notice) to a student only if the following conditions are met:

(1) The recipient of the direct assistance is an individual who is a member of a special population (as defined in section 3(48) of Perkins V) and who is participating in a NHCTEP project.

(2) The direct assistance is needed to address barriers to the individual's successful participation in a NHCTEP project.

(3) The direct assistance is part of a broader, more generally focused program or activity for addressing the needs of an individual who is a member of a special population.

Note: Direct assistance to individuals who are members of special populations is not, by itself, a ''program or activity for special populations.''

(4) The grant funds used for direct assistance must be expended to supplement, and not supplant, assistance that is otherwise available from non-Federal sources. For example, generally, a community-based organization could not use NHCTEP funds to provide child care for single parents if non-Federal funds previously were made available for this purpose, or if non-Federal funds are used to provide child care services for single parents participating in non-career and technical education programs and these services otherwise (in the absence of NHCTEP funds) would have been available to CTE students.

(5) In determining how much of the NHCTEP grant funds it will use for direct assistance to an eligible student, a grantee—

(i) May only provide assistance to the extent that it is needed to address barriers to the individual's successful participation in CTE; and

(ii) Considers whether the specific services to be provided are a reasonable and necessary cost of providing CTE programs for special populations. However, the Secretary does not envision a circumstance in which it would be a reasonable and necessary expenditure of NHCTEP project funds for a grantee to utilize a majority of a project's budget to pay direct assistance to students, in lieu of providing the students served by the project with CTE. (Notice of Final Requirements.)

Requirement 5—Career and Technical Education Memorandum of Understanding:

Any applicant that is not proposing to provide CTE directly to Native Hawaiian students and proposes instead to pay one or more qualified educational entities to provide such CTE to Native Hawaiian students must include with its application a signed memorandum of understanding (MOU) between the applicant and the educational entity. The MOU must describe the commitment between the applicant and the educational entity and must include, at a minimum, a statement of the responsibilities of the applicant and the entity. The MOU must be signed by the appropriate individuals on behalf of each party, such as the authorizing official or administrative head of the applicant Native Hawaiian community-based organization.

Definitions: These definitions are from Perkins V, the Supplemental Priorities, the Notice of Final Requirements, or 34 CFR 77.1. The source of each definition is noted after the definition.

Acute economic need means an income that is at or below the national poverty level according to the latest available data from the U.S. Department of Commerce or the U.S. Department of Health and Human Services Poverty Guidelines. (Notice of Final Requirements).

Career and technical education (CTE) means organized educational activities that—

(a) Offer a sequence of courses that—

(1) Provides individuals with rigorous academic content and relevant technical knowledge and skills needed to prepare for further education and careers in current or emerging professions, which may include high-skill, high-wage, or in-demand industry sectors or occupations, which shall be, at the secondary level, aligned with the challenging State academic standards adopted by a State under section 1111(b)(1) of the ESEA;

(2) Provides technical skill proficiency or a recognized postsecondary credential, which may include an industry-recognized credential, a certificate, or an associate degree; and

(3) May include prerequisite courses (other than a remedial course)[3] that meet the requirements of this paragraph (a);

(b) Include competency-based, work-based, or other applied learning that supports the development of academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, employability skills, technical skills, and occupation-specific skills, and knowledge of all aspects of an industry, including entrepreneurship, of an individual;

(c) To the extent practicable, coordinate between secondary and postsecondary education programs through programs of study, which may include coordination through articulation agreements, early college high school programs, dual or concurrent enrollment program opportunities, or other credit transfer agreements that provide postsecondary credit or advanced standing; and

(d) May include career exploration at the high school level or as early as the middle grades (as such term is defined in section 8101 of the ESEA). (20 U.S.C. 2302(5)).

Computer science means the study of computers and algorithmic processes and includes the study of computing principles and theories, computational thinking, computer hardware, software design, coding, analytics, and computer applications.

Computer science often includes computer programming or coding as a tool to create software, including applications, games, websites, and tools to manage or manipulate data; or development and management of computer hardware and the other electronics related to sharing, securing, and using digital information.

In addition to coding, the expanding field of computer science emphasizes computational thinking and interdisciplinary problem-solving to equip students with the skills and abilities necessary to apply computation in our digital world.

Computer science does not include using a computer for everyday activities, such as browsing the internet; use of tools like word processing, spreadsheets, or presentation software; or using computers in the study and exploration of unrelated subjects. (Supplemental Priorities).

[3] Section 116(c)(2) of Perkins V provides that, notwithstanding the exclusion of remedial courses from Perkins V's definition of CTE, funds made available under NHCTEP ''may be used to provide preparatory, refresher, and remedial education services that are designed to enable students to achieve success in career and technical education programs or programs of study.''

CTE concentrator means—

(a) At the secondary school level, a student served by an eligible recipient who has completed at least two courses in a single career and technical education program or program of study; and

(b) At the postsecondary level, a student enrolled in an eligible recipient who has—

(1) Earned at least 12 credits within a career and technical education program or program of study; or

(2) Completed such a program if the program encompasses fewer than 12 credits or the equivalent in total. (20 U.S.C. 2302(12))

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes. (34 CFR 77.1).

Direct assistance to students means tuition, dependent care, transportation, books, and supplies that are necessary for a student to participate in a project funded under this program. (Notice of Final Requirements).

In-demand industry sector or occupation means—

(a) An industry sector that has a substantial current or potential impact (including through jobs that lead to economic self-sufficiency and opportunities for advancement) on the State, regional, or local economy, as appropriate, and that contributes to the growth or stability of other supporting businesses, or the growth of other industry sectors; or

(b) An occupation that currently has or is projected to have a number of positions (including positions that lead to economic self-sufficiency and opportunities for advancement) in an industry sector so as to have a significant impact on the State, regional, or local economy, as appropriate. (29 U.S.C. 3102(23)).

Institution of higher education means—

(a) An educational institution in any State that—

(1) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate or persons who meet the requirements of section 1091(d) of this title;

(2) Is legally authorized within such State to provide a program of education beyond secondary education;

(3) Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association or, if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the Secretary for the granting of pre-accreditation status, and the Secretary has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

(b) The term also includes—

(1) Any school that provides not less than a one-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provisions of paragraphs (1), (2), (4), and (5) of paragraph (a); and

(2) A public or nonprofit private educational institution in any State that, in lieu of the requirement in paragraph (a)(1) of this definition, admits as regular students individuals—

(A) Who are beyond the age of compulsory school attendance in the State in which the institution is located; or

(B) Who will be dually or concurrently enrolled in the institution and a secondary school. (20 U.S.C. 1001(a) and (b)).

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. (34 CFR 77.1).

Native Hawaiian means any individual any of whose ancestors were natives, prior to 1778, of the area which now comprises the State of Hawaii. (20 U.S.C. 2326(a)(3))

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1).

Professional development means activities that—

(a) Are an integral part of eligible agency, eligible recipient, institution, or

school strategies for providing educators (including teachers, principals, other school leaders, administrators, specialized instructional support personnel, career guidance and academic counselors, and paraprofessionals) with the knowledge and skills necessary to enable students to succeed in career and technical education, to meet challenging State academic standards under section 1111(b)(1) of ESEA, or to achieve academic skills at the postsecondary level; and

(b) Are sustained (not stand-alone, one-day, or short-term workshops), intensive, collaborative, job-embedded, data-driven, and classroom-focused, to the extent practicable evidence-based, and may include activities that—

(1) Improve and increase educators'—

(A) Knowledge of the academic and technical subjects;

(B) Understanding of how students learn; and

(C) Ability to analyze student work and achievement from multiple sources, including how to adjust instructional strategies, assessments, and materials based on such analysis;

(2) Are an integral part of eligible recipients' improvement plans;

(3) Allow personalized plans for each educator to address the educator's specific needs identified in observation or other feedback;

(4) Support the recruitment, hiring, and training of effective educators, including educators who became certified through State and local alternative routes to certification;

(5) Advance educator understanding of—

(A) Effective instructional strategies that are evidence-based; and

(B) Strategies for improving student academic and technical achievement or substantially increasing the knowledge and teaching skills of educators;

(6) Are developed with extensive participation of educators, parents, students, and representatives of Indian Tribes (as applicable), of schools and institutions served under the Act;

(7) Are designed to give educators of students who are English learners in career and technical education programs or programs of study the knowledge and skills to provide instruction and appropriate language and academic support services to those students, including the appropriate use of curricula and assessments;

(8) As a whole, are regularly evaluated for their impact on increased educator effectiveness and improved student academic and technical achievement, with the findings of the evaluations used to improve the quality of professional development;

(9) Are designed to give educators of individuals with disabilities in career and technical education programs or programs of study the knowledge and skills to provide instruction and academic support services to those individuals, including positive behavioral interventions and supports, multi-tier system of supports, and use of accommodations;

(10) Include instruction in the use of data and assessments to inform and instruct classroom practice;

(11) Include instruction in ways that educators may work more effectively with parents and families;

(12) Provide follow-up training to educators who have participated in activities described in this definition that are designed to ensure that the knowledge and skills learned by the educators are implemented in the classroom;

(13) Promote the integration of academic knowledge and skills and relevant technical knowledge and skills, including programming jointly delivered to academic and career and technical education teachers; or

(14) Increase the ability of educators providing career and technical education instruction to stay current with industry standards. (20 U.S.C. 2302(40)).

Program of study means a coordinated, nonduplicative sequence of academic and technical content at the secondary and postsecondary level that—

(A) Incorporates challenging State academic standards, including those adopted by a State under section 1111(b)(1) of ESEA;

(B) Addresses both academic and technical knowledge and skills, including employability skills;

(C) Is aligned with the needs of industries in the economy of the State, region, Tribal community, or local area;

(D) Progresses in specificity (beginning with all aspects of an industry or career cluster and leading to more occupation-specific instruction);

(E) Has multiple entry and exit points that incorporate credentialing; and

(F) Culminates in the attainment of a recognized postsecondary credential. (20 U.S.C. 2302(41)).

Recognized postsecondary credential means a credential consisting of an industry-recognized certificate or certification, a certificate of completion of an apprenticeship, a license recognized by the State involved or Federal Government, or an associate or baccalaureate degree. (29 U.S.C. 3102(52)).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1).

Secondary school means a nonprofit institutional day or residential school, including a public secondary charter school, that provides secondary education, as determined under State law, except that the term does not include any education beyond grade 12. (20 U.S.C. 7801(45)).

Special populations means—

(a) Individuals with disabilities;

(b) Individuals from economically disadvantaged families, including low-income youth and adults;

(c) Individuals preparing for non-traditional fields;

(d) Single parents, including single pregnant women;

(e) Out-of-workforce individuals;

(f) English learners;

(g) Homeless individuals described in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a);

(h) Youth who are in, or have aged out of, the foster care system; and

(i) Youth with a parent who—

(i) Is a member of the armed forces (as such term is defined in section 101(a)(4) of title 10, United States Code); and

(ii) Is on active duty (as such term is defined in section 101(d)(1) of such title). (20 U.S.C. 2302(48)).

Stipend means a subsistence allowance—

(a) For a student who is enrolled in a career and technical education program funded under the NHCTEP;

(b) For a student who has an acute economic need that cannot be met through work-study programs; and

(c) That is necessary for the student to participate in a project funded under this program. (Notice of Final Requirements).

Support services means services related to curriculum modification, equipment modification, classroom modification, supportive personnel (including paraprofessionals and specialized instructional support personnel), and instructional aids and devices. (20 U.S.C. 2302(50)).

Work-based learning means sustained interactions with industry or community professionals in real workplace settings, to the extent practicable, or simulated environments at an educational institution that foster in-depth, firsthand engagement with the tasks required of a given career field, that are aligned to curriculum and instruction. (20 U.S.C. 2302(55)).

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act

(5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed selection criteria and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this substantially revised program under section 116 of the Carl D. Perkins Career and Technical Education Act of 2006, as amended by the Strengthening Career and Technical Education for the 21st Century Act, 20 U.S.C. 2326, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on certain requirements and selection criteria under section 437(d)(1) of GEPA. These requirements and selection criteria will apply to the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 2301, *et seq.,* particularly 2326(a)–(h).

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Notice of Final Requirements. (e) The Supplemental Priorities. (f) The Administrative Priorities.

Note: The regulations in 34 CFR 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $3,176,000 for the first 12 months of the project period. Funding for years two, three, four, and five is subject to the availability of funds and to a grantee meeting the requirements of 34 CFR 75.253.

Contingent upon the availability of funds and the quality of applications, we may make additional awards later in FY 2021 or in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $250,000 to $500,000.

Estimated Average Size of Awards: $350,000.

Estimated Number of Awards: 9–10.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* The following entities are eligible to apply under this competition:

(a) Community-based organizations primarily serving and representing Native Hawaiians. For purposes of the NHCTEP, a community-based organization means a public or private organization that provides career and technical education, or related services, to individuals in the Native Hawaiian community.

(b) Any community-based organization may apply individually or as part of a consortium with one or more eligible community-based organizations. (Eligible applicants seeking to apply for funds as a consortium must meet the requirements in 34 CFR 75.127–75.129.).

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements. In accordance with section 211(a) of Perkins V (20 U.S.C. 2391(a)), funds under this program may not be used to supplant non-Federal funds used to carry out CTE activities.

We caution applicants not to plan to use funds under NHCTEP to replace otherwise available non-Federal funding for direct assistance to students and family assistance programs. For example, NHCTEP funds must not be used to supplant other non-Federal funds with Federal funds in order to pay the costs of students' tuition, dependent care, transportation, books, supplies, and other costs associated with participation in a CTE program.

Funds under NHCTEP should not be used to replace Federal student financial aid. Perkins V does not authorize the Secretary to fund projects that serve primarily as entities through which students may apply for and receive tuition and other financial assistance.

c. *Indirect Cost Rate Information:* This program uses a restricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see: *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

e. *Limitation on Services:* Section 215 of Perkins V (20 U.S.C. 2395) forbids the use of Perkins funds for the education of students prior to the middle grades. The term ''middle grades'' refers to grades 5 through 8, as defined in section 8101 of ESEA.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: Institutions of higher education, nonprofit organizations, local educational agencies. The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the NHCTEP program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public on the Department's website, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to 35 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; the one-page abstract; the resumes; the bibliography; or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do not submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 or are established in accordance with section 437(d)(1) of GEPA. The source and maximum score for each criterion are indicated in parentheses.

(a) *Quality of the project design* (Up to 50 points). The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the services to be provided by the proposed project will create and offer activities that focus on enabling participants to obtain the skills necessary to gain employment in high-skill, high-wage, and in-demand occupations in emerging fields or in a specific career field. (Section 437(d)(1) of GEPA). (Up to 20 points).

(2) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice. (34 CFR 75.210). (Up to 15 points).

(3) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (34 CFR 75.210). (Up to 5 points).

(4) The extent to which the proposed project will integrate with or build on similar or related efforts to improve relevant outcomes (as defined in 34 CFR 77.1(c)), using existing funding streams from other programs or policies supported by community, State, and Federal resources. (34 CFR 75.210). (Up to 5 points).

(5) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services. (34 CFR 75.210). (Up to 5 points).

(b) *Quality of the management plan and project personnel* (Up to 25 points). The Secretary considers the quality of the management plan for, and the quality of the personnel who will carry out, the proposed project. In determining the quality of the management plan and the project personnel for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (34 CFR 75.210). (Up to 10 points).

(2) The extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (34 CFR 75.210). (Up to 5 points).

(3) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (34 CFR 75.210). (Up to 5 points).

(4) The qualifications, including relevant training and experience, of the project director or principal investigator, key project personnel, and project consultants or subcontractors. (34 CFR 75.210). (Up to 5 points).

(c) *Adequacy of resources* (Up to 10 points). The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(1) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization. (34 CFR 75.210). (Up to 2 points).

(2) The extent to which the budget is adequate to support the proposed project and the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (34 CFR 75.210). (Up to 5 points).

(3) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project. (34 CFR 75.210). (Up to 3 points).

(d) *Quality of the project evaluation* (Up to 10 points). The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (34 CFR 75.210). (Up to 5 points).

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (34 CFR 75.210). (Up to 5 points).

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management (SAM). You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

a. Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

b. Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

c. Promoting the freedom of speech and religious liberty in alignment with Promoting Free Speech and Religious Liberty (E.O. 13798) and Improving Free Inquiry, Transparency, and Accountability at Colleges and Universities (E.O. 13864) (2 CFR 200.300, 200.303, 200.339, and 200.341);

d. Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

e. Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN), or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirement:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. The dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements, please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report

that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* The Department has established the following performance measures for purposes of GPRA and for Department reporting under 34 CFR 75.110, which it will use to evaluate the overall performance of the grantee's project, as well as NHCTEP as a whole:

(a) *At the secondary level:* An increase in—

(1) The percentage of CTE concentrators who graduate high school, as measured by—

(A) The four-year adjusted cohort graduation rate (defined in section 8101 of ESEA); and

(B) At the grantee's discretion, the extended-year adjusted cohort graduation rate (defined in section 8101 of ESEA);

(2) The percentage of CTE concentrators graduating from high school having attained postsecondary credits in the relevant CTE program earned through a dual or concurrent enrollment program or another credit transfer agreement;

(3) The percentage of CTE concentrators graduating from high school having participated in work-based learning;

(4) The percentage of CTE concentrators graduating from high school having attained a recognized postsecondary credential; and

(5) The percentage of CTE concentrators who, after exiting from secondary education, are in postsecondary education or advanced training, military service, or a service program, or are employed.

(b) *At the postsecondary level:* An increase in—

(1) The percentage of CTE concentrators who remain enrolled in postsecondary education, are in advanced training, military service, or a service program, or are employed; and

(2) The percentage of CTE concentrators who receive a recognized postsecondary credential.

Project-Specific Performance Measures:

In addition to these measures, applicants may propose project-specific performance measures and performance targets consistent with the objectives of the proposed project. Examples of such project-specific performance measures could include student recruitment, student participation in work-based learning at the postsecondary level, and teacher and faculty participation in professional development.

Note: All grantees will be expected to submit a semi-annual and an annual performance report addressing these performance measures, to the extent that these performance measures apply to each grantee's NHCTEP project.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; Whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Scott Stump,

Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2021–00809 Filed 1–15–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of the Rescission of Outdated Guidance Documents

AGENCY: Office of the Secretary, Department of Education.

ACTION: Notice; correction.

SUMMARY: On August 31, 2020, we published in the **Federal Register** a notice announcing the guidance documents the Department of Education (Department) is rescinding because they are outdated, after conducting a review of its guidance under Executive Order (E.O.) 13891 (85 FR 54148). This notice makes corrections to the included list of documents for the Office of Postsecondary Education.

DATES: This correction is applicable on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Lynn Mahaffie, Department of Education, 400 Maryland Avenue SW, Room 6E–231, Washington, DC 20202. Telephone: (202) 453–7862. Email: *Lynn.Mahaffie@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On October 9, 2019, the President issued E.O. 13891 titled ''Promoting the Rule of Law Through Improved Agency Guidance Documents.'' 84 FR 55235. Section 3(b) of the E.O. requires the Department to ''review its guidance documents and, consistent with applicable law, rescind those guidance documents that it determines should no longer be in effect.'' On August 31, 2020, we published a notice in the **Federal Register** notifying the public, including the Department's stakeholders, of the guidance documents the Department was rescinding as outdated (*e.g.,* superseded by subsequent statutory amendments or enactments), in accordance with section

3(b) of E.O. 13891 (85 FR 54148) (the August 31 Notice).

The August 31 Notice inadvertently included 18 documents that were not intended to be rescinded. We are revising the list of rescinded documents for the Office of Postsecondary Education to remove the inadvertently included documents.

Corrections

In FR Doc 2020–19144 appearing on page 54148 in the **Federal Register** of August 31, 2020, the following corrections are made:

1. On page 54167, the 27th entry from the top of the page, entitled ''Sample Default Prevention and Management Plan . . . 9/30/2005'' is removed.

2. On page 54169, the 17th entry from the top of the page, entitled ''FWS Community Service Requirements . . . 5/17/2007'' is removed.

3. On page 54171, the third entry from the bottom of the page, entitled ''Guidance to Institutions and Accrediting Agencies Regarding a Credit Hour as Defined in the Final Regulations Published on October 29, 2010 . . . 3/18/2011'' is removed.

4. On page 54172, the third entry from the top of the page, entitled ''Implementation of Program Integrity regulations . . . 7/20/2011'' is removed.

5. On page 54172, the 36th entry from the top of the page, entitled ''Title IV Eligibility for Students Without a Valid High School Diploma . . . 12/6/2012'' is removed.

6. On page 54172, the 39th entry from the top of the page, entitled ''Charges Incurred at Bookstores . . . 11/28/2012'' is removed.

7. On page 54173, the 26th entry from the bottom of the page, entitled ''Competency-Based Education Programs—Q&A . . . 12/19/2014'' is removed.

8. On page 54173, the fourth entry from the bottom of the page, entitled ''FY 2016 Sequester Required Changes to the Title IV Student Aid Programs . . . 4/23/2015'' is removed.

9. On page 54174, the 29th entry from the top of the page, entitled ''2017–2018 Award Year: FAFSA® Information to be Verified and Acceptable Documentation . . . 4/5/2016'' is removed.

10. On page 54174, the 30th entry from the top of the page, entitled ''Changes to Title IV Eligibility for Students Without a Valid High School Diploma Who Are Enrolled in Eligible Career Pathway Programs . . . 5/9/2016'' is removed.

11. On page 54174, the 31st entry from the top of the page, entitled ''FY 2017 Sequester Required Changes to the Title IV Student Aid Programs . . . 5/31/2016'' is removed.

12. On page 54174, the 34th entry from the top of the page, entitled ''2017–2018 Federal Pell Grant Payment and Disbursement Schedules . . . 10/18/2016'' is removed.

13. On page 54174, the 19th entry from the bottom of the page, entitled ''Withdrawal of Dear Colleague Letter 15–14 . . . 3/16/2017'' is removed.

14. On page 54174, the 17th entry from the bottom of the page, entitled ''Subject: 2018–2019 Award Year: FAFSA® Information to be Verified and Acceptable Documentation . . . 5/25/2017'' is removed.

15. On page 54174, the third entry from the bottom of the page, entitled ''Subject: Modifications to the Campus-Based Programs for institutions and students affected by Hurricanes or Tropical Storms Harvey, Irma, and Maria . . . 3/26/2018'' is removed.

16. On page 54174, the second entry from the bottom of the page, entitled ''Subject: REVISED 2018–2019 Federal Pell Grant Payment and Disbursement Schedules . . . 4/10/2018'' is removed.

17. On page 54175, the second entry from the top of the page, entitled ''Subject: Webinar Recording–How to Correct Historical Enrollment Reporting in NSLDS . . . 6/19/2019'' is removed.

18. On page 54175, the fourth entry from the top of the page, entitled ''Subject: Online Training Resource–Financial Aid Administrator's Took Kit . . . 9/10/2019'' is removed.

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Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Mitchell Zais,

Acting Secretary of Education.

[FR Doc. 2021–01123 Filed 1–15–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

High-Level Radioactive Waste Interpretation Limited Change to DOE Manual 435.1–1, Radioactive Waste Management Manual and Administrative Change to DOE Order 435.1, Radioactive Waste Management

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice.

SUMMARY: The Department of Energy (Department or DOE) announces the availability of a limited change to DOE Manual 435.1–1, *Radioactive Waste Management Manual,* to formally incorporate the Department's interpretation of the statutory definition of high-level radioactive waste (HLW). In support of that effort, DOE made an administrative change to DOE Order 435.1, *Radioactive Waste Management.* The HLW interpretation was described in the *Supplemental Notice Concerning U.S. Department of Energy Interpretation of High-Level Radioactive Waste,* published in the **Federal Register** on June 10, 2019 (Supplemental Notice). The revised Manual includes DOE's interpretation of the statutory term HLW as defined in the Atomic Energy Act of 1954, as amended (AEA), and the Nuclear Waste Policy Act of 1982, as amended (NWPA).

ADDRESSES: This **Federal Register** Notice (Notice), the Supplemental Notice (which contains responses to public comments on the HLW interpretation) and other documents relevant to DOE's HLW interpretation are available on the Department's website at: *https://www.energy.gov/em/high-levelradioactive-waste-hlw-interpretation.* The revised Order and Manual are available at the DOE Office of Management's DOE Directives website at: *https://www.directives.doe.gov/directives-browse#c8-operator=or&b_start=0.*

FOR FURTHER INFORMATION CONTACT: Theresa Kliczewski and/or James Joyce, U.S. Department of Energy, Office of Environmental Management, Office of Waste and Materials Management (EM–4.2), 1000 Independence Avenue SW, Washington, DC 20585. Emails:

Theresa.Kliczewski@em.doe.gov and *James.Joyce@em.doe.gov.* Phone number: (202) 586–5000.

SUPPLEMENTARY INFORMATION:

I. Background

DOE Order 435.1, *Radioactive Waste Management,* establishes the requirements that DOE programs must follow in managing DOE radioactive waste to protect human health, safety, and the environment. The Order is accompanied by DOE Manual 435.1–1, *Radioactive Waste Management Manual,* which establishes the requirements that DOE must follow in managing DOE radioactive waste.

In October 2018, the Department issued a **Federal Register** notice [1] (October 10, 2018, FRN) seeking public comments on its HLW interpretation. The 90-day public comment period, including a 30-day extension to submit comments, invited public input in order to better understand stakeholder perspectives. The **Federal Register** notice sought to enhance public understanding of DOE's views of its legal authority and to increase transparency. DOE received a total of 5,555 comments from a variety of stakeholders: Members of the public, Native American tribes, members of Congress, numerous state and local governments, and one federal agency, the Nuclear Regulatory Commission (NRC). Of that number, there were roughly 360 distinct comments (that is, excluding duplicative form comments). DOE received both critical and supportive comments, with the majority of comments expressing concerns or questions relating to health and safety and environmental outcomes associated with the interpretation. Positive comments on the HLW interpretation were received from, among others, the NRC; the nuclear industry; DOE contractors; the Energy Facility Contractors Group; the city of Carlsbad, NM; Nye County, NV; Idaho Falls, ID, stakeholder groups such as Energy Communities Alliance; Savannah River Site (SRS) Community Reuse Organization; Tri-Cities Washington Economic Development Council; Hanford Communities; DOE National Laboratories; and individuals. Critical or negative comments were received from, among others, the Washington Department of Ecology; the Yakama Nation; the Consolidated Tribes of the Umatilla Indian Reservation; the Seneca Nation; the Shoshone-Bannock Tribes; and stakeholder groups such as the Natural Resources Defense Council, Nuclear Watch New Mexico, and Alliance for Nuclear Accountability; and individuals.

In June 2019, after careful consideration of all comments received on the October 2018 FRN, DOE issued the *Supplemental Notice Concerning U.S. Department of Energy Interpretation of High-Level Radioactive Waste* [2] (June 10, 2019 FRN). The Supplemental Notice provided additional explanation of DOE's interpretation as informed by public review and comment and further consideration by DOE following the October 2018 FRN. The Supplemental Notice also provided responses to significant comments received through the public comment process. In the Supplemental Notice, DOE did not make any changes or revisions to current policies, legal requirements, or agreements with respect to HLW.

In its Supplemental Notice, DOE explained its interpretation of the term HLW, as defined in the AEA and NWPA.[3] DOE has the long-standing authority and responsibility under the AEA to ensure that all DOE radioactive waste—including reprocessing waste—is managed and disposed of in a safe manner. The AEA and NWPA define HLW as:

(A) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and

(B) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

42 U.S.C. 10101(12); see 42 U.S.C. 2014(dd). In Paragraph A, Congress limited HLW to those materials that are ''highly radioactive.'' This limiting term applies to all reprocessing waste, including the ''liquid waste produced directly in reprocessing'' and ''any solid material derived from such liquid waste.'' The use of the limiting term ''highly radioactive'' demonstrates that Congress intended to distinguish between reprocessing waste that is ''highly radioactive'' and waste that is not. If Congress had intended to define all reprocessing waste as HLW regardless of its radiological characteristics, it would not have included the ''highly radioactive'' requirement and instead defined HLW as ''all waste material resulting from the reprocessing of spent nuclear fuel.'' Similarly, for ''any solid material derived from'' the ''liquid waste produced directly in reprocessing,'' Congress also specified that in addition to being ''highly radioactive'' it must also contain fission products in ''sufficient concentrations.'' The terms ''highly radioactive'' and ''sufficient concentrations'' are not defined in the AEA or the NWPA. By providing in Paragraph A that liquid reprocessing waste is HLW only if it is ''highly radioactive,'' and that solid material derived from liquid reprocessing waste is HLW only if it is ''highly radioactive'' and contains fission products in ''sufficient concentrations'' without further defining these standards, Congress left it to DOE, for its reprocessing wastes, to determine when the standards are met. That is what DOE has done through its interpretation. DOE has evaluated the meaning of those terms based on its historical knowledge, experience, and expertise in managing reprocessing wastes. DOE's interpretation is an articulation of the technical criteria that can be applied to individual waste streams on a case-by-case basis to determine whether the standard for HLW has been met. DOE also notes that in their comments on the interpretation, the NRC staff stated that they ''agree with the concept proposed in **Federal Register** October 10 Notice (83 FR 50909) that radioactive waste may be classified and disposed of in accordance with its radiological characteristics.'' DOE places significant weight on the NRC's views of matters relating to the safe management and disposal of radioactive waste, including this HLW interpretation.

As explained in the Supplemental Notice, DOE has the legal authority to interpret the term HLW in these statutes to determine that certain of its reprocessing wastes are not HLW based on their radiological characteristics. Accordingly, DOE interpreted those statutes to provide that reprocessing wastes are properly classified as non-HLW where the radiological characteristics of the waste, in combination with appropriate disposal facility requirements for safe disposal demonstrate that disposal of such waste are fully protective of human health and the environment. DOE revised the interpretation set forth in the October 2018 FRN after consideration of public comments, in particular those of the NRC and affected state and local stakeholders, in order to clarify its meaning and import. Based on comments received in response to the October 2018 FRN, DOE interpreted the statutes to provide that a reprocessing waste may be determined to be non-

[1] 83 FR 50909.

[2] 84 FR 26835.

[3] 42 U.S.C. 10101 *et seq.*

HLW if the waste meets either of the following two criteria:

(I) Does not exceed concentration limits for Class C low-level radioactive waste as set out in section 61.55 of title 10, Code of Federal Regulations, and meets the performance objectives of a disposal facility; or

(II) Does not require disposal in a deep geologic repository and meets the performance objectives of a disposal facility as demonstrated through a performance assessment conducted in accordance with applicable requirements.

Reprocessing waste meeting either I or II of the above criteria is non-HLW, and—pursuant to appropriate processes—may be classified and disposed in accordance with its radiological characteristics in an appropriate disposal facility provided all applicable requirements of the disposal facility are met.

During 2019–2020, in determining whether and how to implement the HLW interpretation specific to a particular waste stream, DOE initiated a public process pursuant to the National Environmental Policy Act (NEPA) to analyze the potential environmental impacts associated with disposing of that waste. DOE completed its environmental analysis and decided to apply the HLW interpretation to a specific waste stream, shipping eight gallons of the SRS Defense Waste Processing Facility (DWPF) recycle wastewater to the Waste Control Specialists, LLC Federal Waste Facility, a licensed commercial low-level radioactive waste facility located near Andrews, Texas, for stabilization and disposal as non-HLW.[4]

Each reprocessing waste stream has unique radiological characteristics and, accordingly, the interpretation will continue to be implemented for subsequent proposed actions on a case-by-case basis, following consideration of: Evaluation and characterization of specific reprocessing waste streams in conjunction with the waste acceptance criteria and requirements of a specific waste disposal facility; input from affected stakeholders (*e.g.,* federal, state, local and tribal officials; and members of the public); and compliance with applicable federal and state laws, regulations, and agreements.

II. Summary Description of Changes

DOE Manual 435.1–1 has been updated to include as Departmental policy DOE's interpretation of the statutory term HLW, as defined in the AEA and NWPA and consistent with the Supplemental Notice. Specifically, Chapter II of the Manual is revised to include a new Section C that sets forth the HLW interpretation and provides a basis for its use by DOE. DOE Manual 435.1–1 also is revised to set forth the roles and responsibilities of Field Managers and the Deputy Assistant Secretary for Waste and Materials Management with respect to the application of the HLW interpretation.

The HLW interpretation limited change to DOE Manual 435.1–1 does not affect DOE's current policies and practices relating to determinations under Chapter II.B of the Manual or under Section 3116 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005.[5] Section 3116 will continue to apply to reprocessing waste covered under Section 3116. Chapter II.B of the Manual will continue to be used for tank closures not covered by Section 3116 and may be used in other cases determined to be appropriate by DOE.

In addition, DOE is canceling DOE Guide 435.1–1, *Implementation Guide for Use with DOE Manual 435.1–1,* as it is out of date. The cancellation of DOE Guide 435.1–1 is recognized in the administrative change to DOE Order 435.1. The definition of ''reprocessing waste'' in the Guide has now been incorporated in DOE Manual 435.1–1.

These directives can be viewed at *https://www.directives.doe.gov/.*

III. Reviews Under the National Environmental Policy Act

The objective of the limited change to DOE Manual 435.1–1 is to continue to ensure that all DOE radioactive waste, including reprocessing waste, is managed in a manner that protects worker and public health and safety, and the environment. When proposing to apply the HLW interpretation to future waste streams, DOE will prepare the necessary environmental analyses and documentation in accordance with Council on Environmental Quality regulations and DOE NEPA implementing procedures at 40 CFR parts 1500 through 1508 and 10 CFR part 1021, respectively, as was done with the application of the interpretation to the disposal of SRS DWPF recycle wastewater[6] (August 10, 2020 FRN).

Signing Authority

This document of the Department of Energy was signed on January 13, 2021, by William I. White, Senior Advisor for Environmental Management to the Under Secretary for Science, Office of Environmental Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, January 13, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–01053 Filed 1–15–21; 8:45 am]

BILLING CODE 6450–01–P

[4] *https://www.energy.gov/nepa/doeea-2115-commercial-disposal-defense-waste-processing-facility-recycle-wastewater-savannah.*

[5] Public Law 108–375.

[6] 85 FR 48236.

DEPARTMENT OF ENERGY

Draft Environmental Assessment for the Commercial Disposal of Savannah River Site Contaminated Process Equipment

AGENCY: Office of Environmental Management, U.S. Department of Energy.

ACTION: Notice.

SUMMARY: The U.S. Department of Energy (DOE) announces its intent to prepare a draft environmental assessment (EA) pursuant to the National Environmental Policy Act of 1969 (NEPA) to dispose of contaminated process equipment from the Savannah River Site (SRS) at a commercial low-level radioactive waste (LLW) disposal facility located outside of South Carolina licensed by either the Nuclear Regulatory Commission (NRC) or an Agreement State. This effort will analyze capabilities for alternative disposal options through the use of existing, licensed, off-site commercial disposal facilities. The SRS contaminated process equipment would be characterized, stabilized as appropriate, and packaged, and if the waste acceptance criteria and performance objectives of a specific disposal facility are met, DOE could consider whether to dispose of the waste as LLW under the Department's interpretation of the statutory term ''high-level radioactive waste'' (HLW) as defined in the Atomic Energy Act of 1954, as amended (AEA), and Nuclear

Waste Policy Act of 1982, as amended (NWPA). As a result of this NEPA process, DOE may consider what actions, if any, are needed and appropriate to implement any decision to dispose of the SRS contaminated process equipment as LLW.

ADDRESSES: This **Federal Register** Notice is available on *https://www.energy.gov/em/high-level-radioactive-waste-hlw-interpretation.* The Draft Environmental Assessment for the Commercial Disposal of Savannah River Site Contaminated Process Equipment (Draft EA) will also be made available at this website.

FOR FURTHER INFORMATION CONTACT: Theresa Kliczewski and/or James Joyce, U.S. Department of Energy, Office of Environmental Management, Office of Waste and Materials Management (EM–4.2), 1000 Independence Avenue SW, Washington, DC 20585. Emails: *Theresa.Kliczewski@em.doe.gov* and *James.Joyce@em.doe.gov.* Phone number: (202) 586–5000.

SUPPLEMENTARY INFORMATION:

Background

SRS occupies approximately 300 square miles primarily in Aiken and Barnwell Counties, South Carolina. Until the early 1990s, the primary SRS mission was the production of special radioactive isotopes to support national defense programs. More recently, the SRS mission has emphasized waste management, environmental restoration, and the decontamination and decommissioning of facilities that are no longer needed for SRS's traditional defense activities.

The SRS contaminated process equipment is generated during the on-site treatment of the reprocessing waste. The Draft EA will analyze commercial disposal options for three specific types of process equipment contaminated with reprocessing waste: Tank 28F salt sampling drill string, glass bubblers, and glass pumps. These waste streams do not meet the criteria for disposal at existing SRS disposal facilities given the waste form, radionuclide inventory, dose rates, and internal lead shielding.

The Tank 28F salt sampling drill string was used to collect reprocessing waste samples from the waste storage tank. The drill string consists of steel piping measuring 2.25 inches outer diameter by 41 feet long, contaminated with reprocessing waste (supernatant) from Tank 28F. Contaminants include a mixture of beta, gamma, and alpha emitting radionuclides (*e.g.,* cesium 137 and plutonium 238). The drill string is currently stored in a large container on-site until a disposal path can be established.

The glass bubblers are used to increase efficiency of Defense Waste Processing Facility (DWPF) melter operations, where high-activity tank waste is vitrified into glass under high-temperature. Each bubbler is comprised of a ¾ inch Schedule 160 Inconel pipe, which is inserted into the DWPF melter and through which an inert gas is introduced to increase melter efficiency. Approximately three feet of the lower portion of the bubbler was in the melt pool and contains contaminated glass, including transuranic radionuclides (*e.g.,* plutonium 238) and short-lived radionuclides (*e.g.,* cesium 137). SRS currently has approximately 60 contaminated bubblers in storage and will generate four contaminated glass bubblers every six months until DWPF operations are completed in the 2034 timeframe.

The glass pumps were used to support melter efficiency and are no longer in use at SRS having been replaced by the glass bubblers. Each pump is comprised of an Inconel pipe, measuring approximately 3 ⅝ inches in outer diameter. The lower two feet was in the melt pool and contains contaminated glass similar to the glass bubblers. There are approximately 10 glass pumps in storage at SRS requiring final disposal.

In August 2020, DOE completed its first NEPA analysis and waste determination for a waste stream (SRS DWPF recycle wastewater) under the HLW interpretation.[1] This was implemented in accordance with the June 10, 2019 *Supplemental Notice Concerning U.S. Department of Energy Interpretation of High-Level Radioactive Waste*[2] (Supplemental Notice) in which DOE provided its interpretation of the statutory term HLW as defined in the AEA[3] and NWPA.[4]

Purpose and Need for Action

Currently there is no disposal pathway for the SRS process equipment contaminated with reprocessing waste (Tank 28F salt sampling drill string, glass bubblers, and glass pumps). DOE's purpose and need for this action is to dispose of SRS contaminated process equipment at a commercial LLW facility outside of South Carolina and licensed by either the NRC or an Agreement State under 10 CFR part 61. Therefore, no NEPA analyses on disposal at Federal facilities will be conducted. Any proposal to dispose of additional SRS process equipment contaminated with reprocessing waste, other than those identified and analyzed in the Draft EA, would be evaluated in separate NEPA documentation. Disposal of the SRS contaminated process equipment at a licensed off-site commercial LLW facility would help to mitigate on-site storage constraints, improve worker safety, and support accelerated completion of the environmental cleanup mission at SRS.

Proposed Action and Alternatives

Under the proposed action, DOE would dispose of the SRS contaminated process equipment (Tank 28F salt sampling drill string, glass bubblers, and glass pumps) at a commercial LLW facility outside of South Carolina and licensed by either the NRC or an Agreement State under 10 CFR part 61. The Draft EA will analyze the potential environmental impacts associated with the proposed commercial disposal of the contaminated process equipment. Prior to a disposal decision, DOE would characterize the contaminated process equipment to verify with the licensed off-site commercial LLW disposal facility whether the waste meets DOE's HLW interpretation for disposal as non-HLW, in accordance with DOE Order 435.1, *Radioactive Waste Management,* DOE Manual 435.1–1, *Radioactive Waste Management Manual,* and consistent with the Supplemental Notice. DOE would also demonstrate compliance with the waste acceptance criteria and all other requirements of the disposal facility, including any applicable regulatory requirements (*e.g.,* Resource Conservation and Recovery Act) for treatment of the waste prior to disposal and applicable Department of Transportation requirements for packaging and transportation from SRS to the commercial disposal facility. DOE has identified two action alternatives for the proposed action:

- *Alternative 1*—If determined to be Class A LLW,[5] stabilize and package the waste at SRS and ship to either Energy*Solutions*[6] in Clive, Utah or Waste Control Specialists, LLC (WCS) in Andrews County, Texas for disposal.

[1] NEPA documents and technical documents for the commercial disposal of DWPF recycle wastewater from SRS under the HLW interpretation can be found at: *https://www.energy.gov/em/program-scope/high-level-radioactive-waste-hlw-interpretation.*

[2] 84 FR 26835.

[3] 42 U.S.C. 2011 *et seq.*

[4] 42 U.S.C. 10101 *et seq.*

[5] In its 10 CFR part 61 regulations, NRC has identified classes of LLW—Class A, B, or C—for which near-surface disposal is safe for public health and the environment. This waste classification regime is based on the concentration levels of a combination of specified short-lived and long-lived radionuclides in a waste stream, with Class C LLW having the highest concentration levels.

[6] Energy*Solutions* is currently licensed to only dispose of Class A LLW and mixed LLW.

This is dependent upon waste content and compliance with facility waste acceptance criteria.

• *Alternative 2*—If determined to be Class B or C LLW, stabilize and package the waste at SRS and ship to WCS. This is dependent upon waste content and compliance with facility waste acceptance criteria.

The EA will also analyze a no action alternative under which the contaminated process equipment would remain in storage at SRS until disposition occurs.

Potential Areas of Environmental Analysis

DOE has tentatively identified the following areas for detailed analysis in the EA: Human health and safety; land use; air quality; water, cultural, and ecological resources; waste management; socioeconomics; and transportation. This list is not intended to be comprehensive or to predetermine the potential impacts to be analyzed. The level of analysis for different impacts will be in proportion to their significance.

NEPA Process and Public Participation

DOE will prepare the Draft EA in accordance with the Council on Environmental Quality regulations at 40 CFR parts 1500–1508 and DOE NEPA implementing procedures at 10 CFR part 1021. DOE plans to issue a **Federal Register** notice in 2021 on the availability of the Draft EA. Based on the EA analysis, DOE will either issue a Finding of No Significant Impact or announce its intention to prepare an environmental impact statement.

Signing Authority

This document of the Department of Energy was signed on January 12, 2021 by Mark A. Gilbertson, Associate Principal Deputy Assistant Secretary for Regulatory and Policy Affairs, Office of Environmental Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed at Washington, DC, on January 13, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–01052 Filed 1–15–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP21–377–000.
Applicants: Gas Transmission Northwest LLC.
Description: Compliance filing Report of Refunds—Coyote Springs Lateral IT Revenue (Nov 2019–Oct 2020).
Filed Date: 1/8/21.
Accession Number: 20210108–5216
Comments Due: 5 p.m. ET 1/21/21.

Docket Numbers: RP21–378–000.
Applicants: Carolina Gas Transmission, LLC.
Description: Compliance filing 2020 Interruptible Revenue Sharing Report.
Filed Date: 1/11/21.
Accession Number: 20210111–5118.
Comments Due: 5 p.m. ET 1/25/21.

Docket Numbers: RP21–379–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Maritimes & Northeast Pipeline, L.L.C RCA Modifications to be effective 3/1/2021.
Filed Date: 1/11/21.
Accession Number: 20210111–5166.
Comments Due: 5 p.m. ET 1/25/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01038 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4718–039]

Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments; Cocheco Falls Associates

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.
b. *Project No.:* 4718–039.
c. *Date filed:* December 29, 2020.
d. *Applicant:* Cocheco Falls Associates.
e. *Name of Project:* Cocheco Falls Dam Project.
f. *Location:* On the Cocheco River in Dover, Strafford County, New Hampshire. The project does not occupy any federal land.
g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).
h. *Applicant Contact:* Mr. John Webster, Cocheco Falls Associates, P.O. Box 178, South Berwick, ME 03908; Phone at (207) 384–5334, or email at *Hydromagnt@gwi.net.*
i. *FERC Contact:* Amy Chang at (202) 502–8250, or *amy.chang@ferc.gov.*
j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC 61,076 (2001).
k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file

a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* February 27, 2021.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Cocheco Falls Dam Project (P–4718–039).

m. The application is not ready for environmental analysis at this time.

n. *Project Description:* The existing Cocheco Falls Dam Project consists of: (1) A 150-foot-long, 13.5-foot-high stone masonry arch dam that includes the following sections: (a) A left abutment section; (b) a 140-foot-long spillway section with 24-inch-high flashboards, a 5-foot-wide, 10-foot-high low-level outlet gate, and a crest elevation of 37.0 feet mean sea level (msl) at the top of the flashboards; and (c) a right abutment section with a debris sluice gate; (2) a 20-acre impoundment with a storage capacity of 150 acre-feet at an elevation of 37.0 feet msl; (3) a 64-foot-wide, 10-foot-high intake structure equipped with a trashrack with 1-inch clear bar spacing; (4) an 8.5-foot-diameter, 184-foot-long gated steel penstock that trifurcates into three 5-foot-diameter, 8-foot-long sections, each controlled by a 5-foot-diameter butterfly valve; (5) a 40-foot-long, 40-foot-wide concrete and brick masonry powerhouse containing three 238-kilowatt (kW) vertical Flygt submersible turbine-generator units for a total installed capacity of 714 kW; (6) a 40-foot-long, 40-foot-wide tailrace that discharges into the Cocheco River; (7) a 1,000-foot-long, 34.5-kilovolt (kV) underground transmission line and a 34.5-kV transformer that connects the project to the local utility distribution system; and (8) appurtenant facilities.

Cocheco Falls Associates voluntarily operates the project in a run-of-river mode using an automatic pond level control system to regulate turbine operation, such that outflow from the project approximates inflow. The project creates an approximately 100-foot-long bypassed reach of the Cocheco River.

Downstream fish passage is provided by a bypass facility located on the left side of the dam and consist of a 5.6-foot-wide, 7-foot-long fish collection box, a trashrack with 6-inch clear bar spacing, and a 24-inch-diameter PVC fish passage pipe. Upstream fish passage is provided by a Denil fish ladder located on the right side of the dam.

The current license requires the release of: (1) 20 cubic feet per second (cfs) from the upstream fish passage facility from April 15 until June 30; (2) 20 cfs through the trash sluiceway from April 15 until June 15, to attract anadromous fish to the fish ladder; and (3) 20 cfs through the downstream fish passage facility from April 15 until ice forms on the river. The average annual generation of the project is approximately 3,000 megawatt-hours.

Cocheco Falls Associates proposes to: (1) Continue to operate the project in a run-of-river mode; (2) continue to facilitate upstream and downstream fish passage by providing the minimum flows required by the current license; (3) design and install an upstream eel passage facility at the Denil fish ladder location within 4 years of the effective date of a subsequent license; and (4) consult with the New Hampshire State Historic Preservation Officer before beginning any land-disturbing activities or alterations to known historic structures within the project boundary.

o. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–4718). At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19) issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary) February 2021
Request Additional Information February 2021
Issue Acceptance Letter May 2021
Issue Scoping Document 1 for comments June 2021
Request Additional Information (if necessary) August 2021
Issue Scoping Document 2 September 2021
Issue Notice of Ready for Environmental Analysis September 2021

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: January 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–01032 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–856–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; PGR Lessee P, LLC

This is a supplemental notice in the above-referenced proceeding of PGR Lessee P, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 1, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: January 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01036 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–67–000.
Applicants: Aquamarine Westside, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Aquamarine Westside, LLC.
Filed Date: 1/12/21.
Accession Number: 20210112–5074.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: EG21–68–000.
Applicants: Aquamarine Lessee, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Aquamarine Lessee, LLC.
Filed Date: 1/12/21.
Accession Number: 20210112–5075.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: EG21–69–000.
Applicants: Westlands Transmission, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Westlands Transmission, LLC.
Filed Date: 1/12/21.
Accession Number: 20210112–5076.
Comments Due: 5 p.m. ET 2/2/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1985–001; ER20–1988–002; ER20–2179–002; ER20–2622–003.
Applicants: Northern Colorado Wind Energy Center, LLC, Northern Colorado Wind Energy Center II, LLC, Baldwin Wind Energy, LLC, Wilmot Energy Center, LLC.
Description: Notice of Non-Material Change in Status of Northern Colorado Wind Energy Center, LLC, et al.
Filed Date: 1/11/21.
Accession Number: 20210111–5207.
Comments Due: 5 p.m. ET 2/1/21.

Docket Numbers: ER20–2019–002; ER19–2398–006; ER20–1879–003.
Applicants: Gray County Wind, LLC, Oliver Wind I, LLC, Hancock County Wind, LLC.
Description: Notice of Non-Material Change in Status of Gray County Wind, LLC, et al.
Filed Date: 1/11/21.
Accession Number: 20210111–5175.
Comments Due: 5 p.m. ET 2/1/21.

Docket Numbers: ER20–2415–001; ER10–2421–004; ER10–2457–002; ER10–2590–007; ER10–2593–007; ER10–2616–018; ER11–4400–015; ER12–1769–007; ER12–2250–005; ER12–2251–005; ER12–2252–006; ER12–2253–005; ER12–75–008; ER14–1569–011; ER14–2245–005; ER14–883–012; ER15–1596–011; ER15–1599–011; ER19–102–004; ER19–158–006; ER19–2803–003; ER19–2806–003; ER19–2807–003; ER19–2809–003; ER19–2810–003; ER19–2811–003.
Applicants: Moss Landing Energy Storage 2, LLC, Moss Landing Power Company LLC, Oakland Power Company LLC, Ambit Northeast, LLC, Cincinnati Bell Energy LLC, Connecticut Gas & Electric, Inc., Dynegy Commercial Asset Management, LLC, Dynegy Energy Services, LLC, Dynegy Energy Services (East), LLC, Dynegy Marketing and Trade, LLC, Dynegy Power Marketing, LLC, Energy Rewards, LLC, Energy Services Providers, Inc., Everyday Energy, LLC, Everyday Energy NJ, LLC, Illinois Power Marketing Company, Luminant Energy Company LLC, Massachusetts Gas & Electric, Inc., Public Power, LLC, Public Power, LLC (PA), LLC, Public Power & Utility of Maryland, LLC, Public Power & Utility of NY, Inc., TriEagle Energy, LP, Viridian Energy, LLC, Viridian Energy PA, LLC, Viridian Energy NY, LLC.
Description: Notice of Change in Status of Vistra Southwest MBR Sellers.
Filed Date: 1/11/21.
Accession Number: 20210111–5197.
Comments Due: 5 p.m. ET 2/1/21.

Docket Numbers: ER21–454–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: Refile TOT Revisions to Incorporate Letter Agreements to be effective 12/31/9998.
Filed Date: 1/12/21.
Accession Number: 20210112–5079.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–455–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: Refile WDAT Revisions to Incorporate Curtailment and Qualifying Facilities to be effective 12/31/9998.
Filed Date: 1/12/21.
Accession Number: 20210112–5103.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–456–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: Refile WDAT Revisions to Incorporate Letter Agreements to be effective 12/31/9998.
Filed Date: 1/12/21.
Accession Number: 20210112–5102.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–531–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1885R10 Evergy Kansas Central, Inc. NITSA NOA—Bronson to be effective 9/1/2020.
Filed Date: 1/12/21.
Accession Number: 20210112–5028.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–532–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1891R9 Evergy Kansas Central, Inc. NITSA NOA—Mulberry to be effective 9/1/2020.
Filed Date: 1/12/21.
Accession Number: 20210112–5073.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–533–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1894R9 Evergy Kansas Central, Inc. NITSA NOA—Vermillion to be effective 9/1/2020.
Filed Date: 1/12/21.
Accession Number: 20210112–5080.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–539–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1895R9 Evergy Kansas Central, Inc. NITSA NOA—Wathena to be effective 9/1/2020.
Filed Date: 1/12/21.
Accession Number: 20210112–5044.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–862–000.
Applicants: Pacific Gas and Electric Company.
Description: Notice of Termination of Generator Interconnection Agreement for San Joaquin Cogen, LLP, Service Agreement (No. 129) of Pacific Gas and Electric Company.
Filed Date: 1/11/21.
Accession Number: 20210111–5171.
Comments Due: 5 p.m. ET 2/1/21.

Docket Numbers: ER21–863–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 205 filing of tariff revisions to remove Notarization Requirement to be effective 3/13/2021.
Filed Date: 1/11/21.
Accession Number: 20210111–5174.
Comments Due: 5 p.m. ET 2/1/21.

Docket Numbers: ER21–864–000.
Applicants: Meyersdale Storage, LLC.
Description: Baseline eTariff Filing: Meyersdale Storage, LLC PJM Schedule 2 Reactive Power Rate to be effective 3/16/2021.
Filed Date: 1/12/21.
Accession Number: 20210112–5000.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–865–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3356R1 Milligan 1 Wind LLC Generator Interconnection Agr to be effective 12/23/2020.
Filed Date: 1/12/21.
Accession Number: 20210112–5002.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–866–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3635R1 Enel Trading & Evergy Kansas Central Meter Agent Agr to be effective 1/1/2021.
Filed Date: 1/12/21.
Accession Number: 20210112–5005.
Comments Due: 5 p.m. ET 2/2/21.

Docket Numbers: ER21–867–000.
Applicants: The Connecticut Light and Power Company.
Description: Notice of Cancellation of Small Generator Interconnection Agreement (No. IA–NU–16) of The Connecticut Light and Power Company.
Filed Date: 1/11/21.
Accession Number: 20210111–5209.
Comments Due: 5 p.m. ET 2/1/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01033 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–34–000]

Upper Missouri G. & T. Electric Cooperative, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On January 11, 2021, the Commission issued an order in Docket No. EL21–34–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether Upper Missouri G. & T. Electric Cooperative, Inc.'s proposed Formula Rate and Wholesale Power Contracts are unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Upper Missouri G. & T. Electric Cooperative, Inc.,* 174 FERC 61,019 (2021).

The refund effective date in Docket No. Docket No. EL21–34–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL21–34–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2020), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: January 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01031 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–857–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; Trent River Solar, LLC

This is a supplemental notice in the above-referenced proceeding of Trent River Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability. Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 1, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: January 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–01035 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2456–086]

CRP NH Ayers Island, LLC; Notice of Application for Amendment of License, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Application for non-capacity amendment of license.

b. *Project No.:* 2456–086.

c. *Date Filed:* December 17, 2020.

d. *Licensee:* CRP NH Ayers Island, LLC.

e. *Name of Project:* Ayers Island Hydroelectric Project.

f. *Location:* The project is located on the Pemigewasset River in Belknap and Grafton counties, New Hampshire.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Licensee Contact:* Curt Mooney, Central Rivers Power MA, LLC, 670 N Commercial Street, Suite 204, Manchester, NH 03101, (603) 744–0846, *cmooney@centralriverspower.com.*

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov.*

j. *Deadline for filing comments, interventions, and protests Deadline for filing comments, motions to intervene, and protests:* February 12, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2456–086. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant proposes to formally change the Project operating regime from ''modified'' peaking to run-of-river mode and to eliminate the top one-foot flashboard section from the spillway, which typically is installed for a limited seasonal period during the summer. Historically the project was operated in a daily peaking mode with maximum daily drawdowns of approximately two feet. The Licensee has not utilized peaking operations for many years and is therefore proposing to eliminate peaking operations and formally amend the license to require run-of-river operations, except when whitewater flow releases are provided, and during temporary modification of operations for maintenance or emergency operations.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via

email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: January 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–01034 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13–039]

Green Island Power Authority and Albany Engineering Corporation; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed an application submitted by Green Island Power Authority and Albany Engineering Corporation to amend its Green Island Hydroelectric Project license (FERC No. 13) and has prepared an environmental assessment (EA) for the project. The Green Island Project is located at the U.S. Army Corps of Engineers (Corps) Green Island-Troy Lock and Dam on the Hudson River in Albany County, New York. The project occupies federal land under the jurisdiction of the Corps.

The EA contains staff's analysis of the potential environmental effects of the proposed action and concludes that approval of the amendment application, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The EA may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–13–039.

For further information, contact Joseph Enrico at (212) 273–5917 or by email at *joseph.enrico@ferc.gov.*

Dated: January 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–01037 Filed 1–15–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0322; FRL–10011–04–OAR]

Notice of Receipt of Petitions for a Waiver of the 2019 and 2020 Renewable Fuel Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for comment on petitions received.

SUMMARY: EPA has received a number of petitions last year for a waiver of the Renewable Fuel Standard (RFS) obligations that apply in 2019 and 2020. These petitions argue that recent events warrant EPA exercising its general waiver authority on the basis of severe economic harm. In late March, a group of small refineries requested a waiver of the 2019 and 2020 obligations of their individual small refineries. In April and May, the Governors of several states submitted three separate petitions for waivers of the nationwide volumes. The Clean Air Act grants EPA the discretion to waive the requirements of the RFS program in whole or in part if the Administrator determines, after notice and comment, that implementation of the applicable annual volume requirements would severely harm the economy or environment of a State,

region, or the United States. EPA is inviting comment on the petitions we have received.

DATES: *Comments:* Comments must be received on or before February 18, 2021.

ADDRESSES: You may send your comments, identified by Docket ID No. EPA–HQ–OAR–2020–0322, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* (our preferred method) Follow the online instructions for submitting comments.
- *Email: a-and-r-Docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2020–0322 in the subject line of the message.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/commenting-epa-dockets.*

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room will be closed to public visitors beginning at the close of business on March 31, 2020 (4:30 p.m.) to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov* or email, as there will be a delay in process mail and no hand deliveries will be accepted. For further information on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lauren Michaels, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4640; email address: *michaels.lauren@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Renewable Fuel Standard (RFS) program began in 2006 pursuant to the requirements in Clean Air Act (CAA) section 211(o) that were added through the Energy Policy Act of 2005 (EPAct). The statutory requirements for the RFS program were subsequently modified through the Energy Independence and Security Act of 2007 (EISA), leading to the publication of major revisions to the regulatory requirements on March 26, 2010.[1] EISA's stated goals include moving the United States (U.S.) toward ''greater energy independence and security [and] increas[ing] the production of clean renewable fuels.'' [2]

The statute includes annual volume targets and requires EPA to translate those volume targets (or alternative volume requirements established by EPA in accordance with statutory waiver authorities) into compliance obligations that obligated parties must meet every year. EPA promulgated a rulemaking establishing the RFS volume obligations for 2019 that was published in the **Federal Register** on December 11, 2018.[3] EPA promulgated a rulemaking establishing the RFS volume obligations for 2020 that was published in the **Federal Register** on February 6, 2020.[4] In those rulemakings, EPA waived the statutory volumes for cellulosic biofuel, advanced biofuel, and total renewable fuel utilizing EPA's cellulosic waiver authority; determined the biomass-based diesel volume for the subsequent year; and established annual percentage standards for obligated parties. Under the RFS program, obligated parties, typically gasoline or diesel refiners or importers, are required to meet annual percentage standards to be in compliance.

Section 211(o)(7)(A) of the CAA provides the Administrator the discretion to waive the national quantity of renewable fuel required under the RFS program, in whole or in part, upon petition by one or more States, or by any party subject to the requirements of the RFS program. The Administrator may also waive the volume requirements on his own motion. The Administrator may do so only after consultation with the Secretary of Agriculture and the Secretary of Energy, and after public notice and opportunity for comment. A waiver may be issued if the Administrator determines that implementation of the RFS volume requirement would severely harm the economy or environment of a State, region, or the United States, or that there is an inadequate domestic supply. EPA has previously interpreted this waiver authority in prior denials of requests for a waiver of the RFS volume requirements [5] and in annual rulemakings.[6]

II. Petitions Before the Agency

Last year EPA received several petitions from a group of small refineries and several states seeking a waiver under CAA section 211(o)(7)(A) on the basis of severe economic harm. These petitions are described below.

A group of small refineries submitted a petition to the Administrator, dated March 30, 2020, requesting a waiver of the 2019 and 2020 RFS obligations. These parties seek a waiver of their individual renewable volume obligations (RVOs). They argue that EPA must grant the waiver under CAA section 211(o)(7)(A) to avoid severe economic harm to the States and regions in which they operate. The petition argues that the harm to their individual small refineries is caused by the coronavirus pandemic and the ensuing drop in transportation fuel demand; the court decision in *Renewable Fuels Association* v. *EPA,* 948 F.3d 1206, (10th Cir. 2020) (*RFA*), if the decision is implemented nationwide; and a rise in RIN prices. The petition also puts forth a new legal interpretation allowing EPA to waive individual obligations under the general waiver authority; EPA's prior interpretations of the general waiver authority only allowed a reduction in the nationwide volume requirements. EPA also received a petition from a single small refinery, dated December 30, 2020, requesting a waiver of its 2019 and 2020 RFS obligations. This petition provided similar justifications as the above described petition.

Subsequently, several Governors submitted three separate petitions under CAA section 211(o)(7)(A) on the basis of severe economic harm. These petitions ask EPA to lower the nationwide renewable volume obligations. They argue that reduced gasoline and diesel demand due to the coronavirus pandemic has harmed refiners, and that the 2020 RFS volume requirements are and will continue to inflict further harm on these parties. Specifically, the Governor of Louisiana submitted a petition to the Administrator, dated April 7, 2020, seeking a waiver of the RFS obligations by an amount commensurate with the current projected shortfall in national gasoline and diesel consumption. The Governors of Oklahoma, Texas, Utah, and Wyoming submitted a single similar petition, dated April 15, 2020; unlike

[1] 75 FR 14670, March 26, 2010.

[2] Pub. L. 110–140, 121 Stat. 1492 (2007) (''EISA'').

[3] 83 FR 63704.

[4] 85 FR 7016.

[5] See 73 FR 47168 (August 13, 2008) and 77 FR 70752 (November 27, 2012).

[6] See, *e.g.,* Renewable Fuel Standard Program—Standards for 2020 and Biomass-Based Diesel Volume for 2021 and Other Changes: Response to Comments, EPA–420–R–19–018; see also *American Fuel & Petrochemical Manufacturers* v. *EPA,* 937 F.3d 559, 580 (D.C. Cir. 2019) (upholding EPA's interpretation of the severe economic harm waiver authority in the 2018 RFS rulemaking).

the Louisiana petition, this petition does not specify the volume that should be waived.

Finally, the Governor of Pennsylvania submitted a similar petition on May 11, 2020, seeking a waiver of the RFS volume requirements. The Pennsylvania petition alleges that increasing annual RFS volume obligations severely harmed Pennsylvania and the East Coast region, and that such harm was compounded both by the Tenth Circuit's *RFA* decision, and the coronavirus pandemic and ensuing fall in gasoline and diesel demand.

Several organizations and individuals, including the environmental group National Wildlife Federation (NWF), and Members of Congress, have submitted letters expressing support for the granting of a waiver. Other organizations and individuals, including the Renewable Fuels Association and various mayors, have submitted letters expressing opposition to the granting of a waiver. These petitions and related letters are available in the docket for this action. Should we receive additional petitions and letters, we will also add those petitions and letters to the docket and consider them together with requests already received. We encourage commenters to carefully review both the petitions and the letters in the docket in formulating their comments.

EPA is seeking comment on the above-described petitions and the discrete issues the petitions raise, including:

- In general, whether the petitioners have satisfied the criteria for granting a waiver that EPA previously set forth and/or whether EPA should modify those criteria as requested by the petitioners; [7]
- Whether the petitioners have demonstrated severe economic harm to a State, a region, or the United States;
- Whether the petitioners have demonstrated a sufficient causal nexus between the RFS volume requirements and such harm (including whether that nexus is actual causation, significant contribution, or some other relationship);
- Whether the petitioners have accurately assessed the impacts of a waiver on other directly and indirectly affected persons (including but not limited to biofuel producers, farmers, consumers of transportation fuel, and any affected petroleum refiners and importers), and how such impacts should affect EPA's decision on the petitions;
- Whether, as requested by the petition from the group of small refineries, EPA may target relief to certain refineries under the general waiver authority; and
- Ultimately, whether EPA should exercise the general waiver authority in response to any of the petitions. If the commenter believes EPA should waive volumes, we ask that the commenter identify the specific obligation that should be waived (*e.g.,* the 2019 or 2020 RFS volume obligations), the amount of the waiver, and any other details of the remedy desired.

We strongly encourage commenters to include data, specific supporting examples, and technical analysis, to the extent feasible.

EPA also received a letter from the National Wildlife Federation suggesting that relief could be granted on the basis of severe environmental harm. The NWF letter suggests there is evidence of environmental harm due to land conversion to cropland resulting in habitat loss and climate change, agricultural runoff and resulting water quality impacts, an increase in water use to irrigate crop fields, and increasing smog and corresponding impacts on air quality due to increasing ethanol content in gasoline. We also solicit comment on the discrete issues raised by this letter and whether the evidence presented in the letter would support a waiver on the basis of severe environmental harm.

EPA is publishing and seeking comment on these petitions to foster public dialogue on these issues and to inform our future decision-making. At this time, we are not reconsidering or otherwise reexamining the 2019 or 2020 RFS rulemakings or any other prior action,[8] or soliciting comment on any issues beyond those specifically raised by the petitions and the NWF letter in support.[9] We are also not proposing to either grant or to deny any of the petitions.

Dated: January 7, 2021.

Anne L. Austin,

Principal Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2021–01017 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

[7] See 73 FR 47168 (August 13, 2008) and 77 FR 70752 (November 27, 2012).

[8] See *Nat'l Mining Ass'n* v. *United States Dep't of the Interior,* 70 F.3d 1345, 1351 (D.C. Cir. 1995) (''The decision to publish a petition for rulemaking . . . is not evidence of a reexamination of the policy at issue in the petition.''); *P & V Enterprises* v. *U.S. Army Corps of Engineers,* 516 F.3d 1021, 1026 (D.C. Cir. 2008) (''an agency must be able to initiate a public dialogue without inadvertently reopening established precedent, or its communications with the public would be unnecessarily stifled'').

[9] For example, we are not soliciting comment on EPA's small refinery exemption policy, the point of obligation, the generation of RINs for exported fuel, or any other issue beyond those discrete issues raised by the petitions and the NWF letter.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0579; FRL–10018–63–OAR]

Proposed Information Collection Request; Comment Request; Mobile Air Conditioner Retrofitting Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Mobile Air Conditioner Retrofitting Program (Renewal)'' (EPA ICR No. 1774.08, OMB Control No. 2060–0350) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through August 31, 2021. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2020–0579, online using *https://www.regulations.gov* (our preferred method), or by email to *a-and-r-docket@epa.gov.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

EPA's policy is that all comments received will be included in the public

docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Christina Thompson, Environmental Protection Agency, Stratospheric Protection Division, Office of Atmospheric Programs, MC 6205T, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–0983; email address: *thompson.christina@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov.* The EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. The telephone number for the Docket Center is 202–566–1744. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: EPA's Significant New Alternatives Policy (SNAP) program implements Section 612 of the 1990 Clean Air Act (CAA) Amendments which authorized the Agency to establish regulatory requirements to ensure that ozone-depleting substances (ODS) are replaced by alternatives that reduce overall risks to human health and the environment, and to promote an expedited transition to safe substitutes. To promote this transition, CAA specified that EPA establish an information clearinghouse of available alternatives, and coordinate with other Federal agencies and the public on research, procurement practices, and information and technology transfers.

Since the program's inception in 1994, SNAP has reviewed close to 500 new chemicals and alternative manufacturing processes for a wide range of consumer, industrial, space exploration, and national security applications. Roughly 90% of alternatives submitted to EPA for review have been listed as acceptable for a specific use, typically with some condition or limit to minimize risks to human health and the environment.

Regulations promulgated under SNAP require that Motor Vehicle Air Conditioners (MVACs) retrofitted to use a SNAP substitute refrigerant include basic information on a label to be affixed to the air conditioner. The label includes the name of the substitute refrigerant, when and by whom the retrofit was performed, environmental and safety information about the substitute refrigerant, and other information. This information is needed so that subsequent technicians working on the MVAC system will be able to service the equipment properly, decreasing the likelihood of significant refrigerant cross-contamination and potential failure of air conditioning systems and recovery/recycling equipment.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are new and used car dealers, gas service stations, top and body repair shops, general automotive repair shops, automotive repair shops not elsewhere classified, including air conditioning and radiator specialty shops.

Respondent's obligation to respond: Mandatory under 40 CFR 82.180.

Estimated number of respondents: 3 (total).

Frequency of response: Once per retrofit of a motor vehicle air conditioner.

Total estimated burden: 0.08 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3.64 (per year), includes $0.10 (per year) annualized capital or operation & maintenance costs.

Changes in Estimates: There is a decrease of 0.3 hours in the total estimated respondent burden compared with the ICR currently approved by OMB (per year). This decrease is based on the decline of MVACs in service today using chlorofluorocarbons (CFCs), specifically CFC–12. After 1994, new cars in the U.S. were no longer manufactured with CFC–12 MVACs. The number of MVACs originally designed to use CFC–12 as well as the number of those retrofitted has been decreasing every year and EPA estimates a continued reduction in the number of CFC–12 MVAC retrofits will occur during the next three years. EPA estimates that in 2020 there were 1,500 MVACs originally designed to use CFC–12 operating in the U.S., and estimates that in 2021, 2022 and 2023 the number of cars originally designed to use CFC–12 will decrease to 600, 200 and 100, respectively. Of these, EPA estimates that 1 MVAC will be retrofitted annually to use alternative refrigerants. Therefore, EPA estimates that in 2021, 2022 and 2023 the number of MVACs to be retrofitted is 1 for each year; resulting in a total of 3 MVAC retrofits over the three years of this ICR. These reductions are due to the decrease of CFC–12 MVACs available on the road for retrofitting.

Hans Christopher Grundler,

Director, Office of Atmospheric Programs.

[FR Doc. 2021–01062 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10016–81–Region 3]

Delegation of Authority to the State of West Virginia To Implement and Enforce Additional or Revised National Emission Standards for Hazardous Air Pollutants Standards and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation of authority.

SUMMARY: On October 8, 2020, the Environmental Protection Agency (EPA) sent the State of West Virginia (West Virginia) a letter acknowledging that West Virginia's delegation of authority to implement and enforce the National Emissions Standards for Hazardous Air Pollutants (NESHAP) and New Source

Performance Standards (NSPS) had been updated, as provided for under previously approved delegation mechanisms. To inform regulated facilities and the public, EPA is making available a copy of EPA's letter to West Virginia through this notice.

DATES: On October 8, 2020, EPA sent West Virginia a letter acknowledging that West Virginia's delegation of authority to implement and enforce Federal NESHAPs and NSPS had been updated.

ADDRESSES: Copies of documents pertaining to this action are available for public inspection during normal business hours at the Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103–2029. Copies of West Virginia's submittal are also available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE, Charleston, WV 25304.

FOR FURTHER INFORMATION CONTACT: Riley Burger, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103. The telephone number is (215) 814–2217. Mr. Burger can also be reached via electronic mail at *burger.riley@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 6, 2019, West Virginia notified EPA that West Virginia had updated its incorporation by reference of Federal NESHAP and NSPS to include many such standards as found in Title 40 of the Code of Federal Regulations (CFR), parts 60, 61, and 63 as of June 1, 2018. On June 3, 2020, West Virginia notified EPA that West Virginia had updated its incorporation by reference of Federal NESHAP and NSPS to include many such standards as found in Title 40 of the CFR, parts 60, 61, and 63 as of June 1, 2019. On October 8, 2020, EPA sent West Virginia a letter acknowledging that West Virginia now has the authority to implement and enforce the NESHAP and NSPS as specified by West Virginia in its notices to EPA, as provided for under previously approved automatic delegation mechanisms. All notifications, applications, reports, and other correspondence required pursuant to the delegated NESHAP and NSPS must be submitted to both EPA Region III and to the West Virginia Department of Environmental Protection, unless the delegated standard specifically provides that such submittals may be sent to EPA or a delegated State. In such cases, the submittals should be sent only to the West Virginia Department of Environmental Protection. A copy of EPA's October 8, 2020 letter to West Virginia follows:

Mr. Laura M. Crowder, Director
Division of Air Quality
West Virginia Department of Environmental Protection
601 57th Street SE
Charleston, West Virginia 25304

Dear Ms. Crowder:

The United States Environmental Protection Agency (EPA) has previously delegated to the State of West Virginia the authority to implement and enforce various federal National Emissions Standards for Hazardous Air Pollutants (NESHAP) and New Source Performance Standards (NSPS), which are found at 40 CFR parts 60, 61, and 63. In those actions EPA also delegated to West Virginia the authority to implement and enforce any future EPA NESHAP or NSPS on the condition that West Virginia legally adopt the future standards, make only allowed wording changes, and provide specified notice to EPA.

In a letter dated May 6, 2019, West Virginia informed EPA that West Virginia had updated its incorporation by reference of federal NESHAP and NSPS to include many such standards as found in 40 CFR parts 60, 61, and 63 as of June 1, 2018. In a letter dated June 3, 2020, West Virginia informed EPA that West Virginia had updated its incorporation by reference of federal NESHAP and NSPS to include many such standards as found in 40 CFR parts 60, 61, and 63 as of June 1, 2019. West Virginia noted in both letters that it understood it was automatically delegated the authority to implement these standards. West Virginia committed to enforcing the standards in conformance with the terms of EPA's previous delegations of authority. West Virginia made only allowed wording changes.

West Virginia provided copies of the revised West Virginia Legislative Rules which specify the NESHAP and NSPS which West Virginia has adopted by reference. These revised Legislative Rules are entitled 45 CSR 34—''Emission Standards for Hazardous Air Pollutants,'' and 45 CSR 16—''Standards of Performance for New Stationary Sources.'' These revised Rules have an effective date of June 1, 2019 for the 2019 letter and June 1, 2020 for the 2020 letter.

Accordingly, EPA acknowledges that West Virginia now has the authority, as provided for under the terms of EPA's previous delegation actions, to implement and enforce the NESHAP and NSPS standards which West Virginia adopted by reference in West Virginia's revised Legislative Rules 45 CSR 34 and 45 CSR 16, as effective on June 1, 2019 and subsequently on June 1, 2020.

Please note that on December 19, 2008 in Sierra Club vs. EPA,[1] the United States Court of Appeals for the District of Columbia Circuit vacated certain provisions of the General Provisions of 40 CFR part 63 relating to exemptions for startup, shutdown, and malfunction (SSM). On October 16, 2009, the Court issued the mandate vacating these SSM exemption provisions, which are found at 40 CFR part 63, 63.6(f)(1), and (h)(1).

Accordingly, EPA no longer allows sources to use the SSM exemption as provided for in the vacated provisions at 40 CFR 63.6(f)(1), and (h)(1), even though EPA has not yet formally removed the SSM exemption provisions from the General Provisions of 40 CFR part 63. Because West Virginia incorporated 40 CFR part 63 by reference, West Virginia should also no longer allow sources to use the former SSM exemption from the General Provisions of 40 CFR part 63 due to the Court's ruling in Sierra Club vs. EPA.

EPA appreciates West Virginia's continuing NESHAP and NSPS enforcement efforts, and also West Virginia's decision to take automatic delegation of additional and more recent NESHAP and NSPS by adopting them by reference.

If you have any questions, please contact me or Ms. Mary Cate Opila, Chief, Permits Branch, at 215–814–2041.

Sincerely,

Cristina Fernandez, Director
Air and Radiation Division
EPA Region III

This notice acknowledges the updates of West Virginia's delegation of authority to implement and enforce NESHAP and NSPS.

Dated: November 17, 2020.

Cristina Fernandez,

Director, Air & Radiation Division, Region III.

[FR Doc. 2021–00965 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

[1] *Sierra Club* v. *EPA,* 551 F.3rd 1019 (D.C. Cir. 2008).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2016–0731; FRL–10017–49–OAR]

Proposed Information Collection Request; Renewal; EPA's Methane Challenge Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit a renewal information collection request (ICR), ''EPA's Natural Gas STAR and Methane Challenge Programs'' (EPA ICR No. 2547.01, OMB Control No. 2060–0722) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. Specifically, EPA is proposing to merge the ICR with ''EPA's Natural Gas STAR Program'' (EPA ICR

No. 2004–0082, OMB Control No. 2060–0328). This is a renewal with modification of the existing ICR, which is currently approved through August 31, 2021. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2016–0731 online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Lau, Office of Atmospheric Programs, Climate Change Division, (6207A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–7312; email address: *lau.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents for the two existing ICR, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR and the Natural Gas STAR ICR (Docket ID: EPA–HQ–OAR–2016–2004–0082). The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is Necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The Natural Gas STAR and Methane Challenge programs (''Gas STAR Programs'') are voluntary programs sponsored by the U.S. Environmental Protection Agency (EPA) that encourage oil and natural gas companies to adopt cost effective technologies and practice that improve operational efficiency and reduce methane emissions. Methane is the primary component of natural gas and a potent greenhouse gas. The Programs work with oil and natural gas companies in the production, gathering & boosting, processing, transmission & storage, and distribution segments to remove barriers that inhibit the implementation of technologies and practices that reduce methane emissions. The Programs effectively promote the adoption of emission reduction technologies and practices by helping partners evaluate Best Management Practices (BMPs) in the context of their current operations and implement them where cost-effective. Implementation of the Programs' BMPs saves participants money, improves operational efficiency, and enhances the protection of the environment. Combining the ICR's for the Methane Challenge and the Natural Gas STAR programs is expected to streamline partners' engagement with the programs and simplify communications about reporting.

Form Numbers: The Natural Gas STAR and Methane Challenge Programs each have Partnership Agreements (''PA'') that describe the terms of participation in the Program. A company that wishes to become a Natural Gas STAR or Methane Challenge partner signs and submits the applicable PA to EPA. The PA forms covered under this ICR include:

- *Natural Gas STAR Program—Partnership Agreement:* EPA Form No. 5900–105
- *Methane Challenge Program—Partnership Agreement for Best Management Practice Commitment Option:* EPA Form No. 5900–412
- *Methane Challenge Program—Partnership Agreement for ONE Future Emissions Intensity Commitment Option:* EPA Form No. 5900–411

Partners agree to complete and submit a Natural Gas STAR or Methane Challenge Implementation Plan (as applicable) within six to twelve months of signing the PA. The Implementation Plan forms covered under this ICR include:

- *Natural Gas STAR Program—Production Implementation Plan:* EPA Form No. 5900–103
- *Natural Gas STAR Program—Transmission Implementation Plan:* EPA Form No. 5900–109
- *Natural Gas STAR Program—Distribution Implementation Plan:* EPA Form No. 5900–97
- *Natural Gas STAR Program—Gathering and Processing Implementation Plan:* EPA Form No. 5900–100
- *Methane Challenge Program—Implementation Plan Template:* EPA Form No. 5900–410

After one full year of participation in either Program, partners submit an annual report documenting the previous year's methane emission reduction activities. Partners only need to submit the applicable form(s) for the Program/commitment option/segments they have joined. The annual reporting forms covered under this ICR include:

- *Natural Gas STAR Program—Production Reporting Form:* EPA Form No. 5900–104
- *Natural Gas STAR Program—Transmission Reporting Form:* EPA Form No. 5900–95
- *Natural Gas STAR Program—Distribution Reporting Form:* EPA Form No. 5900–99
- *Natural Gas STAR Program—Gathering and Processing Reporting Form:* EPA Form No. 5900–102
- *Methane Challenge Program—BMP Commitment Option Reporting Form:* EPA Form No. 5900–434
- *Methane Challenge Program—ONE Future Commitment Option Reporting Form:* EPA Form No. 5900–435

Upon becoming a partner in the Methane Challenge Program, companies are given an opportunity to draft and submit a Historical Actions Fact Sheet, which provides information on historical methane reduction actions taken prior to joining Methane Challenge. A two-page fact sheet template is made available to partner companies and allows entry of up to five key methane mitigation activities, including text, photos, and graphics.

Submitting this document is *not* a requirement of the Methane Challenge Program partnership. The fact sheet template covered under this ICR is:

- *Methane Challenge Program—Historical Actions Fact Sheet Template:* EPA Form No. 5900–413

Respondents/affected entities: The Natural Gas STAR Programs are open to companies in the production segment of the oil industry, and to companies in the production, gathering & boosting, processing, transmission & storage, and distribution segments of the natural gas industry.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 97 (Natural Gas STAR) and 58 (Methane Challenge) partners, and 50 vendors (total).

Frequency of response: Annual for partners and semi-annual for vendors.

Total estimated burden: 2,846 hours (per year) for the Natural Gas STAR Program plus 2,978 hours (per year) for the Methane Challenge Program. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $268,577.00 (per year) for the Natural Gas STAR Program plus $268,952 hours (per year) for the Methane Challenge Program. There are no capital/start-up costs or O&M costs associated with this information collection.

Changes in Estimates: EPA expects that the burden associated with the final ICR submission for the Methane Challenge Program will increase compared to its previous estimated burden due to modifying this ICR to include the addition of respondents from the Natural Gas STAR Program. However, the final total burden for the total of the two programs is not expected to exceed the sum of the burdens for Natural Gas STAR and Methane Challenge Programs.

Hans Christopher Grundler,

Director, Office of Atmospheric Programs.

[FR Doc. 2021–01070 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10016–80-Region 3]

Delegation of Authority to the Commonwealth of Virginia To Implement and Enforce Additional or Revised National Emission Standards for Hazardous Air Pollutants Standards and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of delegation of authority.

SUMMARY: On October 8, 2020, the Environmental Protection Agency (EPA) sent the Commonwealth of Virginia (Virginia) a letter acknowledging that Virginia's delegation of authority to implement and enforce the National Emissions Standards for Hazardous Air Pollutants (NESHAPs) and New Source Performance Standards (NSPS) had been updated, as provided for under previously approved delegation mechanisms. To inform regulated facilities and the public, EPA is making available a copy of EPA's letter to Virginia through this notice.

DATES: On October 8, 2020, EPA sent Virginia a letter acknowledging that Virginia's delegation of authority to implement and enforce Federal NESHAPs had been updated.

ADDRESSES: Copies of documents pertaining to this action are available for public inspection during normal business hours at the Air and Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103–2029. Copies of Virginia's submittal are also available at the Virginia Department of Environmental Quality, 1111 East Main Street, Richmond, VA 23219.

FOR FURTHER INFORMATION CONTACT: Riley Burger, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103. The telephone number is (215) 814 2217, or by Mr. Burger can also be reached via electronic mail at *burger.riley@epa.gov.*

SUPPLEMENTARY INFORMATION: On March 5, 2020, Virginia notified EPA that Virginia had updated its incorporation by reference of Federal NESHAP, NSPS, and Maximum Achievable Control Technology (MACT) standards to include many such standards, as they were published in final form in the Code of Federal Regulations (CFR) dated July 1, 2019. On October 8, 2020, EPA sent Virginia a letter acknowledging that Virginia now has the authority to implement and enforce the NESHAPs as specified by Virginia in its notice to EPA, as provided for under previously approved automatic delegation mechanisms. All notifications, applications, reports, and other correspondence required pursuant to the delegated NESHAPs must be submitted to both EPA, Region III and to the Virginia Department of Environmental Quality, unless the delegated standard specifically provides that such submittals may be sent to EPA or a delegated State. In such cases, the submittals should be sent only to the Virginia Department of Environmental Quality. A copy of EPA's letter to Virginia follows:

''Michael G. Dowd, Director,
Air Division,
Virginia Department of Environmental Quality,
P.O. Box 1105,
Richmond, Virginia 23218
Dear Mr. Dowd:

The United States Environmental Protection Agency (EPA) has previously delegated to the Commonwealth of Virginia (Virginia) the authority to implement and enforce various federal New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAP), and National Emission Standards for Hazardous Air Pollutants for Source Categories (MACT standards) which are found at 40 CFR parts 60, 61 and 63, respectively. In those actions, EPA also delegated to Virginia the authority to implement and enforce any future federal NSPS, NESHAP or MACT Standards on the condition that Virginia legally adopt the future standards, make only allowed wording changes, and provide specified notice to EPA.

In a letter dated March 5, 2020, Virginia submitted to EPA revised versions of Virginia's regulations which incorporate by reference specified federal NSPS, NESHAP and MACT standards, as those federal standards had been published in final form in the Code of Federal Regulations dated July 1, 2019. Virginia committed to enforcing the federal standards in conformance with the terms of EPA's previous delegations of authority and made only allowed wording changes.

Virginia stated that it had submitted the revisions ''to retain its authority to enforce the NSPSs and NESHAPs under the delegation of authority granted by EPA on August 27, 1981 (46 FR 43300) and to enforce the MACT standards under the delegation of authority granted by EPA on January 26, 1999 (64 FR 3938) and January 8, 2002 (67 FR 825).''

Virginia provided copies of its revised regulations which specify the NSPS, NESHAP and MACT Standards which it had adopted by reference. Virginia's revised regulations are entitled 9 VAC 5–50 ''New and Modified Stationary Sources,'' and 9 VAC 5–60 ''Hazardous Air Pollutant Sources.'' These revised regulations have an effective date of March 4, 2020.

Based on Virginia's submittal, EPA acknowledges that EPA's delegations to Virginia of the authority to implement

and enforce EPA's NSPS, NESHAP, and MACT standards have been updated, as provided for under the terms of EPA's previous delegation of authority actions, to allow Virginia to implement and enforce the federal NSPS, NESHAP and MACT standards which Virginia has adopted by reference as specified in Virginia's revised regulations 9 VAC 5–50 and 9 VAC 5–60, both effective on March 4, 2020.

Please note that on December 19, 2008, in *Sierra Club* v. *EPA*,[1] the United States Court of Appeals for the District of Columbia Circuit vacated certain provisions of the General Provisions of 40 CFR part 63 relating to exemptions for startup, shutdown, and malfunction (SSM). On October 16, 2009, the Court issued a mandate vacating these SSM exemption provisions, which are found at 40 CFR 63.6(f)(1) and (h)(1).

Accordingly, EPA no longer allows sources the SSM exemption as provided for in the vacated provisions at 40 CFR 63.6(f)(1) and (h)(1), even though EPA has not yet formally removed these SSM exemption provisions from the General Provisions of 40 CFR part 63. Because Virginia incorporated 40 CFR part 63 by reference, Virginia should also no longer allow sources to use the former SSM exemption from the General Provisions of 40 CFR part 63 due to the Court's ruling in Sierra Club vs. EPA.

EPA appreciates Virginia's continuing NSPS, NESHAP and MACT standards enforcement efforts, and also Virginia's decision to take automatic delegation of additional or updated NSPS, NESHAP and MACT standards by adopting them by reference.

Sincerely,
Cristina Fernandez,
Director Air and Radiation Division''

This notice acknowledges the update of Virginia's delegation of authority to implement and enforce NESHAP, NSPS, and MACT standards.

Dated: November 17, 2020.

Cristina Fernandez,

Director, Air and Radiation Division, Region III.

[FR Doc. 2021–00964 Filed 1–15–21; 8:45 am]

BILLING CODE P

[1] *Sierra Club* v. *EPA,* 551 F.3rd 1019 (D.C. Cir. 2008).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–SFUND–2012–0104; FRL—10019–10–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Brownfields Program—Accomplishment Reporting (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Brownfields Program—Accomplishment Reporting (EPA ICR Number 2104.08, OMB Control Number 2050–0192) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2021. Public comments were previously requested via the **Federal Register** on June 18, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 18, 2021.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–SFUND–2012–0104, online using *www.regulations.gov* (our preferred method), by email to *docket.superfund@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Kelly Gorini, Office of Brownfields and Land Revitalization, (5105T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1702; fax number: (202) 566–1476; email address: *gorini.kelly@epa.gov*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR covers the collection of information from those organizations that receive cooperative agreements from EPA under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Brownfields Utilization, Investment, and Local Development (BUILD) Act (Pub. L. 115–141). CERCLA, as amended, authorizes EPA to award grants or cooperative agreements to states, tribes, local governments, and other eligible entities to support the assessment and cleanup of brownfields sites. Under the Brownfields Amendments, a brownfields site means real property, the expansion, redevelopment, or reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant. For funding purposes, EPA uses the term ''brownfields property(ies)'' synonymously with the term ''brownfields sites.'' The Brownfields Amendments authorize EPA to award several types of cooperative agreements to eligible entities on a competitive basis.

Under subtitle A of the Small Business Liability Relief and Brownfields Revitalization Act, states, tribes, local governments, and other eligible entities can receive assessment cooperative agreements to inventory, characterize, assess, and conduct planning and community involvement related to brownfields properties; cleanup cooperative agreements to carry out cleanup activities at brownfields properties; multipurpose cooperative agreements to conduct activities

allowed under both assessment and cleanup cooperative agreements; cooperative agreements to capitalize revolving loan funds and provide subgrants for cleanup activities; area-wide planning cooperative agreements to develop revitalization plans for brownfields; and environmental workforce and development job training and placement programs. Under subtitle C of the Small Business Liability Relief and Brownfields Revitalization Act, states and tribes can receive cooperative agreements to establish and enhance their response programs through the four elements and meet the public record requirements under the statute. Cooperative agreement recipients (''recipients'') have general reporting and record keeping requirements as a condition of their cooperative agreement that result in burden. A portion of this reporting and record keeping burden is authorized under 2 CFR part 1500 and identified in the EPA's general grants ICR (OMB Control Number 2030–0020). EPA requires Brownfields program recipients to maintain and report additional information to EPA on the uses and accomplishments associated with funded brownfields activities. EPA uses several forms to assist recipients in reporting the information and to ensure consistency of the information collected. EPA uses this information to meet Federal stewardship responsibilities to manage and track how program funds are being spent, to evaluate the performance of the Brownfields Cleanup and Land Revitalization Program, to meet the Agency's reporting requirements under the Government Performance Results Act, and to report to Congress and other program stakeholders on the status and accomplishments of the program.

Respondents/affected entities: State/local/tribal governments; Non-Profits.

Respondent's obligation to respond: Required to obtain or Retain Benefits (2 CFR part 1500).

Estimated number of respondents: 2969 (total).

Frequency of response: Bi-annual for subtitle C recipients; quarterly for subtitle A recipients.*Total estimated burden:* 6,144 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $712,108 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: The overall burden has increased slightly by 379 hours since the last ICR submittal. This is the result of an increased response total of 123 additional responses. Respondents indicated that improvements in the ACRES reporting system and increased familiarity with the program lead to a lower burden per individual entry.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–01065 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2020–0689; FRL–10018–16–OLEM]

Hazardous and Solid Waste Management System: Land Disposal Restrictions; Information for Petitioners Seeking a No-Migration Variance Under the RCRA Land Disposal Restrictions for Temporary Placement of Treated Hazardous Waste Within a Permitted Subtitle C Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is requesting comment on guidance on petitions for a No Migration Variance (NMV) under the Land Disposal Restrictions (LDRs) pursuant to the Resource Conservation and Recovery Act (RCRA). Under existing regulations, persons may apply for an NMV to allow for the land placement (*e.g.,* landfill, impoundment, waste pile) of hazardous waste that, if approved, would allow for the placement of hazardous waste in such a unit where the waste does not meet applicable LDR treatment standards. This guidance provides information to persons applying for an NMV for a waste pile temporarily located within a RCRA-permitted landfill cell.

DATES: Comments must be received on or before February 18, 2021.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2020–0689, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Land and Emergency Management Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this notice. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Bethany Russell, Waste Characterization Branch, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 404–562–8542; email address: *russell.bethany@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Docket

EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2020–0689. All documents in the docket are listed in the *https://www.regulations.gov* index. Publicly available docket materials are available either electronically at *https://www.regulations.gov* or in hard copy at the EPA Docket Center. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

B. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2020–0689, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

C. Submitting CBI

Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address: ORCR Document Control Officer, Mail Code 5305–P, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Attn: Docket ID No. EPA–HQ–OLEM–2020–0689.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in Title 40 of the Code of Federal Regulations (CFR) Part 2.

II. General Information

A. Purpose of This Notice

The Land Disposal Restrictions (LDRs) are a key part of the hazardous waste regulatory program under the Resource Conservation and Recovery Act (RCRA) and require that hazardous wastes meet certain treatment standards prior to land disposal. If these standards are not met, land disposal of the waste is prohibited. The RCRA statute and implementing regulations allow land disposal of hazardous waste not meeting applicable treatment standards where a No Migration Variance (NMV) is approved by EPA. An NMV is a formal decision that can be rendered by EPA in response to a petition filed with the Agency, to allow the land disposal at a particular facility of specific prohibited waste, *i.e.,* a waste not meeting the applicable LDR treatment standards. In Section III of this notice, EPA is providing information for persons who may wish to apply for an NMV for one or more temporary waste piles, where treated hazardous waste that is expected to meet LDR standards is temporarily stored within the boundary of a hazardous waste landfill prior to moving that waste within the landfill to its final disposal or removing it for further treatment.

B. Background

The regulatory requirements for an NMV under the RCRA LDRs were first established in 1986,[1] and in 1992, EPA issued guidance on these requirements.[2] The 1992 guidance is applicable to landfills, surface impoundments, and waste piles, and also acknowledges temporary placement of waste under an approved NMV; however, the guidance did not address the specific situation identified in this notice where temporary piles of treated waste are placed within the boundary of a RCRA-permitted hazardous waste landfill.

Some commercial hazardous waste landfill facilities offer services for treating hazardous waste in addition to providing landfill disposal. In determining the appropriate treatment, facilities evaluate the incoming waste streams to identify the best treatment strategy (*e.g.,* type and quantity of reagents, mixing times). Facilities rely on information in waste profiles provided by generators, waste characterization conducted by the facility (including characterization specified in their Waste Analyses Plan or WAP), as well as familiarity with waste streams (*e.g.,* if a waste stream is received on a routine basis from the same source). Once treated, facilities may store the treated (*e.g.,* stabilized) waste temporarily in units such as tanks, containers or containment buildings to allow the treated waste to ''cure'' and/or to confirm that the treated waste meets the applicable LDR standards. The treated waste is then moved into the landfill for disposal.

EPA is aware that some facilities have established procedures whereby a pile of treated hazardous waste is temporarily staged within the boundaries of the permitted subtitle C landfill while awaiting confirmation by the facility through testing results that the treatment program is performing as expected and that the treated waste meets the applicable LDR standards. Where the treated waste is confirmed to meet the LDR standards, the pile is moved to the ''working face'' of the landfill for final disposal. If there is an exceedance of an LDR standard, the pile is picked up and returned to the treatment process for further treatment. Any instance where a pile does not meet the applicable LDR standards and has not been granted an NMV would be a violation of the LDR requirements—the hazardous waste must either meet the LDR standards, or an approved NMV must be in place.[3]

C. The NMV Process

The NMV petition submittal and decision process is found in 40 CFR 268.6. Review and approval of an NMV petition is delegated to the EPA Regional Administrator for the EPA Region in which the waste management unit is located. EPA does not authorize states to implement the NMV authority. As part of the petition process, EPA may request additional information from the petitioner to evaluate the demonstration. EPA will provide notice in the **Federal Register** of the intent to approve or deny the NMV petition with an opportunity for public comment. The final decision is to be published in the **Federal Register**, and petitions to renew must undergo notice and comment procedures as well. An NMV that has been issued can be revoked for cause, including if migration occurs. Once approved, the term of an NMV shall be no longer than the term of the RCRA subtitle C permit for a permitted disposal unit, and no longer than 10 years for a unit operating under interim status. The 1992 guidance should be

[1] 51 FR 40572, November 7, 1986.

[2] *No Migration Variances to the Hazardous Waste Land Disposal Prohibitions: A Guidance Manual for Petitioners,* EPA Office of Solid Waste, July 1992, EPA–530–R92–023.

[3] Memorandum from Barnes Johnson to EPA Regional Division Directors, April 11, 2014; *https://rcrapublic.epa.gov/files/14843.pdf.*

considered a resource for preparation of any submittal, in addition to the considerations described here for which EPA is requesting comment.

III. NMV for Temporary Waste Piles Within a Subtitle C Landfill

EPA is requesting comment on the information provided below. The contents of the guidance document do not have the force and effect of law and the Agency does not bind the public in any way and intends only to provide clarity to the public regarding existing requirements under the law or Agency policies, except as authorized by law or as incorporated into a contract. This information is not a substitute for compliance with 40 CFR 268.6, but provides additional information in the specific situation where hazardous waste is treated and then is temporarily stored in piles within a permitted subtitle C landfill, prior to either transfer to the working face of the landfill, or removal for retreatment if necessary.

A. Demonstration Addressed by This Guidance

This guidance addresses how to make a demonstration that the treated waste and constituents will not migrate beyond the temporary waste pile. The RCRA statutory language requires a demonstration ''to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the disposal unit or injection zone for as long as the waste remains hazardous'' (RCRA § 3004(d)(1)). EPA has interpreted this language to mean that it must be demonstrated, to a reasonable degree of certainty, that hazardous constituents will not exceed Agency-approved health-based levels (or environmentally protective levels, if they are appropriate) beyond the boundary of the disposal unit. While it is EPA's interpretation that man-made barriers or engineered systems (*e.g.,* liner systems) alone generally will not meet the ''no migration'' standard, this is not the case for temporary land-based storage of treated waste as is being considered in this document. The containment of hazardous waste within engineered barriers can be considered in making the ''no migration'' demonstration for waste awaiting the results of verification sampling after treatment, provided that wastes are to be removed after a reasonably short storage period that may be conservatively projected to be well before the failure of the engineered barrier system.[4]

B. Information To Be Submitted to EPA

EPA expects that petitioners will be able to take advantage of existing facility information (*e.g.,* existing monitoring, inspections, engineered barriers, waste analyses), where appropriate, as part of any demonstration. In developing an NMV petition, a petitioner must satisfy the no migration criteria set forth in 40 CFR 268.6, and petitioners should describe any and all controls that will be applied to the temporary waste pile to prevent the migration of hazardous constituents from the pile, and, the monitoring that will be used to detect migration at the earliest practicable time. For example, the use of temporary barriers, such as plastic covers above and below the piles; visual monitoring and prompt responses to possible releases; and generally good housekeeping practices that ensure the treated waste remains in the pile during the temporary storage period would be elements to consider. Attributes of the permitted landfill cell (*e.g.,* design, existing controls, monitoring) in which the pile or piles are located should also be taken into account to the extent that they support the demonstration criteria being applied to the piles themselves. In other words, if a particular control or requirement is in place for the landfill cell, and can prevent potential releases from the pile or piles, it should be described in the petition (and petitioners should specify how that control or requirement prevents migration from the boundary of the temporary waste pile).

The regulations in 40 CFR 268.6(a) describe the components of what a demonstration must address; § 268.6(b) specifies certain criteria that must be satisfied for that demonstration, and § 268.6(c) describes the monitoring program that will be used to verify that the conditions of the NMV are being met. The components for an NMV demonstration outlined in § 268.6(a) are:

- Descriptions of the specific waste(s) and specific unit for which the demonstration will be made;
- Waste analysis describing the chemical and physical characteristics of the waste;
- Comprehensive characterization of the disposal unit site, including air, soil, and water quality;
- Monitoring plan to detect migration at the earliest practicable time;
- Sufficient information to assure EPA that the owner/operator of the unit receiving the wastes will comply with other applicable federal, state, and local laws.

Below are some considerations regarding these components with respect to NMV petition submittals for piles temporarily storing waste within a subtitle C landfill that has been treated with the expectation that it meets the applicable LDR standards for permanent disposal in the landfill.

Facility Description—The NMV petition should include a description of the hazardous waste management facility where the waste will be treated, temporarily stored, and permanently disposed in sufficient detail to familiarize the reviewer with its overall operation. This type of information and level of detail will be similar to those included in the facility's RCRA permit application. The facility name, mailing address, and physical location should be provided, together with information on a point of contact for correspondence concerning the petition. Detailed design, layout, and operating plans should be provided for the unit covered by the petition. Unit descriptions should focus on waste isolation capabilities of the unit.

Unit(s) Covered by the NMV—While the temporary waste piles addressed in this document are located within the boundaries of the RCRA-permitted landfill cell, the unit to which the variance applies, as envisioned in this guidance, is the pile itself. The information presented here is for a demonstration that the treated waste and constituents will not migrate beyond the temporary waste pile. Where different piles containing different types of treated hazardous waste are simultaneously staged within the landfill cell, each pile should be described and will be evaluated, as necessary, individually by EPA in order to properly assess potential releases when evaluating petitions, and for evaluating the monitoring that will be part of implementing any approved variance. Where multiple piles contain the same or similar wastes, the petition can address these units as a group. For example, where two or more piles are similar in terms of the nature and concentration of constituents, treatment used, waste matrices, etc., the petition need not separately specify or discuss such information for each individual pile where such piles are effectively being managed as a single unit. Similarly, where the design, inspection, and monitoring of the pile coverings and liners that will be used to prevent releases from the piles are the same for multiple piles, such information on each individual pile need not be specified. In other words, a successful petition could include several categories of treated waste piles, but sufficient

[4] *No Migration Variances to the Hazardous Waste Land Disposal Prohibitions: A Guidance Manual for Petitioners,* EPA Office of Solid Waste, July 1992, EPA–530–R92–023.

information must be included so that the potential for releases, and proposed inspection and monitoring, can be evaluated by EPA.

While the unit(s) to be evaluated under this guidance are the temporary waste piles, petitioners should also submit information related to the landfill to the extent the information aids in any demonstration that hazardous constituents will not migrate beyond the boundary of the temporary waste pile. For example, hazardous waste landfill design and operating requirements (40 CFR 264.301) include run-on and run-off controls that may be important in any demonstration that hazardous waste will not migrate from the pile. The specific location of where the temporary waste piles will be placed within the landfill cell should be identified in the petition, together with any pertinent information as to why this location was selected and how it will prevent the migration of hazardous constituents from the pile. These locations will be identified as part of any approved variance.

This document only applies where wastes managed in the temporary waste piles have been treated with the expectation that the waste meets the applicable LDR standards for permanent disposal in the landfill. A facility should include information about what types and quantities of waste are to be managed in the temporary waste piles and what treatment standards apply. Most of this information is presumed to already be available as part of the facility's WAP and associated program for sampling and monitoring for compliance with the LDRs.

Duration of Temporary Storage—The NMV is necessary to ensure that any temporary storage of treated hazardous waste complies with the stringent statutory and regulatory standards in those instances where the hazardous waste that was treated and placed in a temporary waste pile does not meet LDRs. The approach described in this document is conditioned upon the temporary nature of the storage of treated hazardous waste within the landfill, and is intended for situations where the temporary waste piles are used as part of an overall strategy to confirm consistent and compliant treatment that meets the applicable LDR treatment standards.

The petition should include a description of the length of time the waste is managed in the pile before either transfer to the working face of the landfill, or removal for retreatment, if necessary. A range of time may be provided, but EPA emphasizes that the temporary nature of the pile must be clearly characterized in the petition, such as through maximum storage times or other procedures described in the application, that may become part of the conditions established in an approved variance.

However, if any particular staging location *routinely* receives treated waste that does not meet applicable LDR standards, then the ''temporary'' aspect of storage for a given location may be called into question, which could affect the ability for EPA to grant the NMV. This also raises the separate question of whether the overall treatment process is operating as well as it should. Therefore, it is important for the petition to describe in sufficient detail the procedures used to treat, test, and confirm that wastes meet LDR standards, and how this information will be used to determine when a pile will be removed either for retreatment, or for final disposal. Such information should be available as part of the facility's WAP and may include:

- Number and type (*e.g.,* random grab) of samples taken after treatment for LDR compliance;
- Methodology used to select number and type of samples;
- Level of confidence that all waste is treated to LDR treatment standards (level of confidence related to number of samples achieving LDRs);
- List of regulated constituents (suite of metals, selected organics, cyanide).

Monitoring Plan—40 CFR 268.6(a)(4) requires a petition to include a monitoring plan to verify continued compliance with the conditions of the no migration variance. Pursuant to 40 CFR 268.6(a)(4), the monitoring plan must be designed to detect migration ''at the earliest practicable time.'' 40 CFR 268.6(c) lays out the specific information required in the monitoring plan. In addition to these requirements, the monitoring plan should also describe the sampling and analysis of the treated waste that determines *when* the temporary waste pile will be moved to the working face of the landfill for final disposal. The demonstration should allow EPA to understand the process and timing of LDR treatment and confirmation that LDRs are met; this is fundamental to defining the scope and duration of storing treated waste temporarily.

Peter Wright,

Assistant Administrator, Office of Land and Emergency Management.

[FR Doc. 2021–00585 Filed 1–15–21; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of Information Collection—Extension Without Change: State and Local Government Information (EEO–4).

SUMMARY: In accordance with the Paperwork Reduction Act (PRA), the Equal Employment Opportunity Commission (EEOC or Commission) announces that it intends to submit to the Office of Management and Budget (OMB) a request for a three-year extension without change of the State and Local Government Information (EEO–4).

DATES: Written comments on this notice must be submitted on or before March 22, 2021.

ADDRESSES: You may submit comments by any of the following methods—please use only one method:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions on the website for submitting comments.

Mail: Comments may be submitted by mail to Rachel See, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE, Washington, DC 20507.

Fax: Comments totaling six or fewer pages can be sent by facsimile (''fax'') machine to (202) 663–4114. (This is not a toll-free number.) Receipt of fax transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or 800–669–6820 (TTY). (These are not toll-free telephone numbers.)

Instructions: All comments received must include the agency name and docket number. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. However, the EEOC reserves the right to refrain from posting libelous or otherwise inappropriate comments, including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; that contain hate speech directed at race, color, sex, national origin, age, religion, disability, or genetic information; or that promote or endorse services or products.

Although copies of comments received are usually also available for

review at the Commission's library, given the EEOC's current 100% telework status due to the Coronavirus Disease 2019 (COVID–19) public health emergency, the Commission's library is closed until further notice. Once the Commission's library is re-opened, copies of comments received in response to this notice will be made available for viewing by appointment only at 131 M Street NE, Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Rashida Dorsey, Employer Data Team, Data Development and Information Products Division, Equal Employment Opportunity Commission, 131 M Street NE, Room 4SW32J, Washington, DC 20507; (202) 663–4355 (voice), (202) 663–7063 (TTY) or email at *Rashida.dorsey@eeoc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 and OMB regulation 5 CFR 1320.8(d)(1), the Commission solicits public comment to enable it to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the Commission's functions, including whether the information will have practical utility; (2) Evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of Information Collection

Collection Title: State and Local Government Information (EEO–4).

OMB-Number: 3046–0008.

Frequency of Report: Biennial, odd years.

Type of Respondent: State and local governments with 100 or more employees within the 50 U.S. states and District of Columbia.

Description of Affected Public: State and local governments with 100 or more employees within the 50 U.S. states and District of Columbia.

Reporting Hours: 95,542 per biennial collection.

Respondent Cost: $4,719,509.02 per biennial collection.

Federal Cost: $386,609.20 per biennial collection.

Number of Respondents: 5,687.

Number of Responses: 13,649.

Number of Forms: 1.

Form Number: EEOC Form 164.

Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–8(c), requires State and local governments to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed and produce reports required by the EEOC. Accordingly, the EEOC issued regulations, 29 CFR 1602.30 and 1602.32–.37, which set forth the reporting requirements and related record retention policies for State and local governments. 29 CFR 1602.30 requires every covered State and local government to make or keep all records necessary for completion of an EEO–4 submission and retain those records for three years. 29 CFR 1602.32 requires filers to retain a copy of each filed EEO–4 report for three years. These requirements are related to record keeping which is part of standard administrative practices, and as a result, the EEOC believes that any impact on burden would be negligible and nearly impossible to quantify. State and local governments with 100 or more employees have been required to submit EEO–4 reports since 1974 (biennially since 1993). The EEOC uses EEO–4 data for research and to investigate charges of discrimination. The individual reports are confidential.

Burden Statement: The methodology for calculating annual burden reflects the different staff that are responsible for preparing and filing the EEO–4. These estimates are based on the estimated submission time of 7 hours per reporting unit, as published in the 2018 EEO–4 Information Collection Review as required by the Paperwork Reduction Act.[1] The EEOC accounts for time to be spent biennially on EEO–4 reporting by senior and administrative staff, as well as time spent by attorneys who may consult briefly during the reporting process. The estimated number of respondents included in the biennial EEO–4 survey is 5,687 State and local governments, as this is the average number of reporting units between 2005 and 2019. These 5,687 respondents will submit an estimated 13,649 reports during each biennial reporting cycle. The estimated hour burden per report will be 7 hours, and the estimated total biennial respondent burden hours will be 95,542. Burden hour cost was calculated using median hourly wage rates for administrative staff and legal counsel, and average hourly wage rates for State and local government staff. The burden hour cost per report will be $214.77, and the estimated total burden hour cost per biennial collection will be $4,719,509.02 (See Table 1 for calculations).

TABLE 1—ESTIMATE OF BURDEN FOR EEO–4 REPORT

	Hourly wage rate[2]	Burden hours per government entity	Cost per local	Total burden hours	Total burden hour cost[3]
	Number Reporting Units = 5,687.				Number of Records Submitted= 13,649
Chief Executive	$52.90	0.35	$18.52	4,777.1	$88,447.64
Legal Counsel	50.50	0.35	17.68	4,777.1	84,434.89
Computer Support Specialist (IT Professional).	29.75	0.7	20.83	9,554.2	198,965.38
Executive Administrative Staff.	27.40	1.4	38.36	19,108.3	732,995.16
Human Resource Specialist	32.59	2.45	79.85	33,439.6	2,669,998.39
Payroll Clerks	22.60	1.75	39.55	23,885.4	944,667.57

[1] Please see here for more information: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201804-3046-001.*

TABLE 1—ESTIMATE OF BURDEN FOR EEO–4 REPORT—Continued

	Hourly wage rate [2]	Burden hours per government entity	Cost per local	Total burden hours	Total burden hour cost [3]
Sub Total	N/A	7	214.77	95,542	4,719,509.02

These estimates are based upon filers' use of the EEO–4 online filing system to submit reports. The EEOC has made electronic submission much easier for respondents required to file the EEO–4 Report and as a result, more respondents are using this electronic filing method. During the 2019 EEO–4 data collection cycle, 4,988 EEO–4 filers completed and certified their submission. Of the 4,988 EEO–4 filers who submitted data in 2019, 5% uploaded a data file, 91% filed through the online application, and 4% submitted paper records. Electronic filing remains the most efficient, accurate, and secure means of reporting for respondents required to submit the EEO–4 report. Accordingly, the EEOC will continue to encourage EEO–4 filers to submit data through electronic filing, and will only accept paper records from filers who have secured permission to submit data via paper submission.

For the Commission.

Janet Dhillon,

Chair.

[FR Doc. 2021–01056 Filed 1–15–21; 8:45 am]

BILLING CODE 6570–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Notice: Cancellation of Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 1966, January 11, 2021.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: January 14, 2021 at 1:00 p.m. ET.

SUMMARY: The Equal Employment Opportunity Commission is issuing this notice to cancel the audio-only conference scheduled to be held at 1:00 p.m. on January 14, 2021.

CONTACT PERSON FOR MORE INFORMATION: Rachel V. See, Acting Executive Officer, (202) 921–2545.

Dated: January 13, 2021.

Rachel V. See,

Acting Executive Officer, Executive Secretariat.

[FR Doc. 2021–01158 Filed 1–14–21; 11:15 am]

BILLING CODE 6570–01–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 16–185; DA 21–35; FRS 17387]

World Radiocommunication Conference Advisory Committee Meetings of Informal Working Groups One, Two, Three and Four

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This notice advises interested persons that Informal Working Group 1 (IWG–1), Informal Working Group 2 (IWG–2), Informal Working Group 3 (IWG–3) and Informal Working Group 4 (IWG–4) of the 2023 World Radiocommunication Conference Advisory Committee (WRC–23 Advisory Committee) have scheduled meetings as set forth below. The meetings are open to the public.

DATES: IWG–3: Tuesday, January 26, 2021 (11:00 a.m.–1:00 p.m. EST); IWG–4: Tuesday, January 26, 2021 (1:00 p.m.–3:00 p.m. EST); IWG–1: Thursday, January 28, 2021 (1:00 p.m.–3:00 p.m. EST); IWG–3: Tuesday, February 2, 2021 (11:00 a.m.–1:00 p.m. EST); IWG–2: Tuesday, February 2, 2021 (1:00 p.m.–3:00 p.m. EST); IWG–1: Thursday, February 4, 2021 (11:00 a.m.–1:00 p.m. EST).

ADDRESSES: The meetings will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dante Ibarra, Designated Federal Official, World Radiocommunication Conference Advisory Committee, FCC International Bureau, Global Strategy and Negotiation Division, at *Dante.Ibarra@fcc.gov,* (202)–418–0610 or *WRC-23@fcc.gov.*

SUPPLEMENTARY INFORMATION: The FCC established the Advisory Committee to provide advice, technical support and recommendations relating to the preparation of United States proposals and positions for the 2023 World Radiocommunication Conference (WRC–23).

In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons of the IWG–1, IWG–2, IWG–3 and IWG–4 of the WRC–23 Advisory Committee scheduled meetings. The Commission's WRC–23 website (*www.fcc.gov/wrc-23*) contains the latest information on all scheduled meetings and WRC–23 Advisory Committee matters.

The schedule of Informal Working Group meetings are as follows:

WRC–23 Advisory Committee Schedule of Meetings of Informal Working Groups 1, 2, 3 and 4

Informal Working Group 1: Maritime, Aeronautical and Radar Services

Contacts:

Chair — Damon Ladson, *dladson@hglaw.com,* telephone: 202–730–1315

Vice Chair — Vacant

FCC Representatives

Louis Bell, telephone: 202–418–1641

Allen Yang, telephone: 202–418–0738

Dante Ibarra, telephone: 202–418–0610

IWG–1 Meeting 1

Date: Thursday, January 28, 2021

Time: 1:00 p.m.–3:00 p.m. EST

WebEx Meeting Number: 178 955 2750

WebEx Meeting Password: Arm5TZ7Mbh5

Teleconference Only: 1–888–858–2144

Participant Code: 7971467

IWG–1 Meeting 2

Date: Thursday, February 4, 2021

Time: 11:00 a.m.–1:00 p.m. EST

WebEx Meeting Number: 178 397 6446

WebEx Meeting Password: YHhDrbRP735

Teleconference Only: 1–888–858–2144

Participant Code: 7971467

Informal Working Group 2: Terrestrial Services

Contacts:

Chair — Jayne Stancavage, *jayne.stancavage@intel.com,* telephone: 408–887–3186

[2] Occupational titles and wages are from the Bureau of Labor Statistics' National Industry-Specific Occupational Employment and Wage Estimates—NAICS 999000—Federal, State, and local Government, excluding state and local schools and hospitals and the U.S. Postal Service: *https://www.bls.gov/oes/current/naics3_999000.htm#11-0000.* The wages cited are median hourly wages.

[3] Burden hour cost is estimated by multiplying the 'Cost Per Local' column by the 'Total Burden Hours' column.

Vice Chair – Jennifer Oberhausen, *joberhausen@ctia.org,* telephone: 202–736–3235
FCC Representatives
Dante Ibarra, telephone: 202–418–0610
Louis Bell, telephone: 202–418–1641
Date: Tuesday, February 2, 2021
Time: 1:00 p.m.–3:00 p.m. EST
WebEx Meeting Number: 178 105 9661
WebEx Meeting Password: j5UZEetk65c
Teleconference Only: 1–888–858–2144
Participant Code: 7971467

Informal Working Group 3: Space Services

Contacts:
Chair—Zachary Rosenbaum, *zachary.rosenbaum@ses.com,* telephone: 814–233–7373
Vice Chair—Vacant
FCC Representatives
Clay DeCell, telephone: 202–418–0803
Kathyrn Medley, telephone: 202–418–1211
Eric Grodsky, telephone: 202–418–0563
Sankar Persaud, telephone: 202–418–2441
Dante Ibarra, telephone: 202–418–0610

IWG–3 Meeting 1

Date: Tuesday, January 26, 2021
Time: 11:00 a.m.–1:00 p.m. EST
WebEx Meeting Number: 178 127 6739
WebEx Meeting Password: 3KZm8g3ZrMP
Teleconference Only: 1–888–858–2144
Participant Code: 7971467

IWG–3 Meeting 2

Date: Tuesday, February 2, 2021
Time: 11:00 a.m.–1:00 p.m. EST
WebEx Meeting Number: 178 146 7452
WebEx Meeting Password: 4tTFm25vtep
Teleconference Only: 1–888–858–2144
Participant Code: 7971467

Informal Working Group 4: Regulatory Issues

Contacts:
Chair — David Goldman, *david.goldman@spacex.com,* telephone: 202–649–2641
Vice Chair—Giselle Creeser, *giselle.creeser@intelsat.com,* telephone: 703–559–7851
FCC Representatives
Dante Ibarra, telephone: 202–418–0610
Clay DeCell, telephone: 202–418–0803
Date: Tuesday, January 26, 2021
Time: 1:00 p.m.–3:00 p.m. EST
WebEx Meeting Number: 178 689 2114
WebEx Meeting Password: vySJ4sCM9m3
Teleconference Only: 1–888–858–2144
Participant Code: 7971467

Federal Communications Commission.

Troy Tanner,

Deputy Chief, International Bureau.

[FR Doc. 2021–01087 Filed 1–15–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than February 18, 2021.

A. Federal Reserve Bank of Cleveland (Mary S. Johnson, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to *Comments.applications@clev.frb.org:*

1. *Huntington Bancshares Incorporated, Columbus, Ohio;* to acquire TCF Financial Corporation, Detroit, Michigan, and thereby indirectly acquire TCF National Bank, Sioux Falls, South Dakota.

B. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *First Cahawba Bancshares, Inc., Selma, Alabama;* to become a bank holding company by acquiring First Cahawba Bank, Selma, Alabama.

Board of Governors of the Federal Reserve System, January 13, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–01075 Filed 1–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Placement and Transfer of Unaccompanied Alien Children Into ORR Care Provider Facilities (0970–0554)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is inviting public comments on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Alien Children (UAC) Program to place UAC referred to ORR by Federal agencies into care provider facilities and to transfer UAC within the ORR care provider network.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street, SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR plans to revise all 13 instruments currently approved under OMB #0970–0554, all of which will be incorporated into ORR's new case management system, UAC Path. Five of the instruments contain revisions to the formatting, organization, or wording of field labels with no

changes to the content. The remaining eight instruments contain changes in content. In addition, ORR plans to add four new instruments to this collection that will also be incorporated into UAC Path.

1. Placement Authorization (Form P–1): This instrument is used by ORR to authorize a care provider to provide care and services to UAC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UAC. ORR revised the formatting, but no changes were made to the content. The average burden minutes per response was increased from 1 to 5 minutes.

2. Authorization for Medical, Dental, and Mental Health Care (Form P–2): This instrument is used by ORR to authorize a care provider to provide medical, dental, and mental health care services to UAC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UAC. ORR revised the formatting, but no changes were made to the content. The average burden minutes per response was increased from 1 to 5 minutes.

3. Notice of Placement in a Restrictive Setting (Form P–4/4s): This instrument is used by care providers to document and inform UAC of the reason they have been placed in a restrictive setting. ORR revised the formatting, but no changes were made to the content.

4. Long Term Foster Care Placement Memo (Form P–5): This instrument is used by care providers to ensure placement in a foster home that meets the UAC's needs and continuity of services. ORR revised the formatting and the order in which the fields appear. ORR added two new questions asking respondents to (1) describe any specials skills or training of the foster family or group home, and (2) provide any further available information and/or considerations about the time line for physical transfer of the minor.

5. UAC Referral (formerly titled Intakes Placement Checklist and Add New UAC) (Form P–7): This instrument is used by Federal agencies to refer UAC to ORR custody and by ORR Intakes staff to place UAC in an ORR care provider facility. It also contains a checklist that is used by ORR Intakes staff to determine whether initial placement in a restrictive setting is appropriate for a UAC. ORR combined 2 of its current instruments, *Intakes Placement Checklist* and *Add New UAC,* into 1 instrument. The average burden minutes per response was increased from 15 to 60 minutes, plus an additional 30 minutes if the placement checklist must be completed. In addition, ORR made the following revisions:

○ Moved the ''Immigration Status at Referral'' field to the *UAC Profile* instrument.

○ Created a new ''Parent/Legal Guardian Separation'' section. This section contains 5 fields, and replaces the single question on the current version of the *Add New UAC* instrument.

○ Created a new ''MPP Information'' section to capture information about enrollment in the Migrant Protection Protocol (MPP) program. This section contains 2 fields.

○ Moved the field ''Related to Other UAC(s)?'' to the *UAC Profile* instrument.

○ Moved fields related to family groups to the *UAC Profile* and *Family Group Entity* instruments.

○ Added the following fields to the ''Apprehension and Referral Information'' section: ''Referring Sector Name'', ''POC Primary Email'', ''POC Secondary Email'', ''Referring Sector Code''.

○ Moved fields in the ''Parent/Relative Information'' section to the *UAC Profile* instrument.

○ Renamed the ''Notes'' field in the ''Referral Notes'' section to ''Apprehension/Journey Notes'' and added a new field, ''Referral Cancellation Reason''.

○ Renamed the ''ORR Placement Information'' section to ''Placement Request'' and added the following fields: ''Required Placement Request'', ''Placement Requested Date/Time'', ''Program/Facility'', ''Not Accepted Reason'', ''Placement Decision Date/Time'', ''Placement Notes'', and ''Override Stop Placement Reason''.

○ Added a new section titled ''Special Placement Request'' that contains the fields found in the ''Placement Determination'' section of the current version of the *Intakes Placement Checklist.*

○ Created a new ''Criminal Information'' section. This section contains 9 fields, and replaces the two questions on criminal charges and acting as a footguide on the current version of the *Add New UAC* instrument.

○ A new section titled ''Criminal Charges'' as added to capture more detailed information if the UAC has any criminal charges, which contains 9 fields.

○ A new ''Detention Facilities'' section as created to capture more detailed information if the UAC was ever held in a detention facility. This section contains 9 fields.

○ Added a new ''Documents'' section where documents related directly to the UAC's referral may be uploaded.

○ Added a new ''Entry Team'' section in which read and/or write access can be granted to individuals who need access privileges to the record, but do not typically need such privileges for a referral record.

○ Revised the *Intakes Placement Checklist* as follows:

▪ Reorganized the checklist into distinct sections for staff secure and secure placement criteria.

▪ Removed ''UAC will be turning 18 year of age in the next month'' as an escape risk criteria.

▪ Removed the ''Danger to Self'' section.

▪ Revised the lists of criminal offenses in both the staff secure and secure sections.

○ Added a new ''Initial Health Information'' section to capture more detailed information about the UAC's health. This section contains 31 fields.

6. Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8): This instrument is used by care providers to ensure that all criteria for transfer of a UAC to an influx care facility have been met. ORR revised the formatting and reworded some field labels, but no changes were made to the content.

7. Medical Checklist for Non-Influx Transfers (Form P–9A): This instrument is used by care providers to ensure that UAC are medically cleared for transfer within the ORR care provider network, excluding transfer to an influx care facility. ORR revised the formatting and reworded the questions. In addition, ORR removed the question asking if the child is free of all medical conditions requiring specialist care.

8. Medical Checklist for Transfers to Influx Care Facilities (Form P–9B): This instrument is used by care providers to ensure that UAC are medically cleared for transfer to an influx care facility. ORR revised the formatting and instructions, reworded most questions, and clarified which questions are only applicable to influx care facilities located on Department of Defense (DOD) sites. ORR also added 4 new questions that ask about sexually transmitted disease, injection drug use, allergies, and the completion of lab and diagnosis field in UAC Path.

9. Transfer Request (Form P–10A): This instrument is used by care provider facilities, ORR contractor staff, and ORR Federal staff to process recommendations and decisions for transfer of a UAC within the ORR care provider network for non-influx transfers. ORR revised the formatting

and reworded many of the section titles and fields. In addition, ORR made the following revisions to this instrument:

○ In the ''Transfer Request'' section, ORR removed the field ''Requested Date'' and added the following fields: ''Status'', ''Transfer Type'', ''High Priority'', ''Transfer Cancellation Reason'', ''Case Coordinator'', and ''Legal Eligibility''.

○ Added the following fields to the ''Case Coordinator Recommendation'' section: ''Pending Information'', ''FFS Authorized to Proceed'', and ''Add to Waitlist?''.

○ Moved fields related to the UAC's attorney of record from the ''Reason for Transfer Request'' section to the ''Casefile Summaries'' section.

○ Added a new ''Transfer Designation'' section containing 3 fields.

○ Added a ''Remand for Further Information'' to the ''ORR Decision'' section.

○ Removed the ''Transfer Packet'' section.

○ Added the following fields to the ''COA–COV'' section: ''Specify UAC Special Needs'' and ''Other Change Venue Cause''.

○ Added a new ''Entry Team'' section in which read and/or write access can be granted to individuals who need access privileges to the record, but do not typically need such privileges for a referral record.

○ Added a new ''Documents'' sections where documents related directly to the UAC's transfer may be uploaded.

○ Added a new ''Program Referrals'' section in which care providers can search for programs that fit the UAC's transfer criteria and make referrals.

10. Influx Transfer Request (Form P–10B): This instrument is used by care provider facilities and ORR Federal staff to process recommendations and decisions for transfers to an influx care facility. This is a new instrument that ORR plans to add to this collection.

11. Transfer Summary and Tracking (formerly titled Transfer Request and Tracking Form) (Form P–11): This instrument is used by care providers to track the physical transfer of the UAC and their belongings. ORR revised the formatting and reworded some of the fields. ORR also removed the field ''FINS Number'' and added the fields ''Gender'' and Gender Other.''

12. Program Entity (formerly titled UAC Portal Capacity Report) (Form P–12): This instrument is used by care providers and ORR to track certain information related to care provider programs, such as location, contact information, bed capacity, state licensure, grant information, monitoring, and program census. ORR greatly expanded this instrument to track multiple types of information related to care provider programs. The average burden minutes per response was increased from 5 to 30 minutes. In addition to bed capacity, this instrument contains the following information:

○ An overview of the program that includes name, status, parent entity, type, address, region, and acceptable placement types.

○ Various program points of contact.

○ Stakeholder information (child advocate program, legal service provider, field office juvenile coordinator (FOJC)).

○ Information related to the program's State licensing agency and licensing status.

○ Information related to the program's Administration for Children and Families grant.

○ Fields tracking the reason and dates of stop placements, if applicable.

○ Information related to the program's ORR monitoring schedule.

○ Sections that list all events and incident reports created for the program (cleared as separate instruments in OMB #0970–0547).

○ Census information and the ability to initiate prescreening for transfers to influx care facilities (cleared as *Influx Transfer Manual and Prescreen Review* in this collection).

○ An area to add individuals to the program's team (*e.g.,* assigned Federal Field Specialist, Project Officer).

○ An area to upload document relation to the facility and its operations and/or compliance.

13. UAC Profile (formerly titled Add New UAC) (Form P–13): This instrument is used by referring Federal agencies and care providers to create a profile for a UAC from which all information related to their case can be accessed. Previously, the purpose of this instrument was to (1) create an initial profile and (2) receive/process referrals. The function of receiving/processing referrals and the related fields from the *Add New UAC* instrument were moved to the *UAC Referral* instrument, as noted above in the description of changes for *UAC Referral.* The function of creating an initial profile in the system and related fields containing basic UAC information remain with this instrument. However, this purpose of this instrument has been expanded. It now acts as a hub where users can assess all records related to a UAC's case. Most of the records accessible from the UAC Profile are being cleared as separate instruments, either in this or another one of ORR's information collections. The sections being cleared under this instrument are as follows: Profile Information, Program Designation, Legal-Immigration, Legal-Administrative, System Information, Apprehended Relationships, Other Relationships, Adult Contact Relationships, Entity Team, and Documents. The average burden minutes per response was increased from 15 to 45 minutes.

14. ORR Transfer Notice—Notice of Transfer to ICE Chief Counsel—Change of Address/Change of Venue (Form P–14): This instrument is used by care providers to notify DHS of the transfer of a UAC within the ORR care provider network so that DHS may file a Motion for Change of Venue and/or Change of Address with the Executive Office for Immigration Review to ensure the UAC's immigration case is transferred to the local immigration court, if applicable. ORR revised the formatting, but no changes were made to the content.

15. Family Group Entity (Form P–15): This instrument is used by the ORR Intakes Team to associate UACs who are members of the same family with each other. This is a new instrument that ORR plans to add to this collection.

16. Influx Transfer Manifest (Form P–16): This instrument is used by designated care provider staff and ORR staff to plan, track, and notify stakeholders of group transfers to an influx care facility. This is a new instrument that ORR plans to add to this collection.

17. Influx Transfer Manual and Prescreen Review (Form P–17): This instrument is used by designated care provider staff to evaluate each UAC's eligibility to be transferred to an influx care facility. Care provider staff review and update information on daily during times of influx. This is a new instrument that ORR plans to add to this collection.

Respondents: ORR grantee and contractor staff; other Federal agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden *minutes* per response	Annual total burden *hours*
Placement Authorization (Form P–1)	216	278	5	5,004
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	216	278	5	5,004
Notice of Placement in a Restrictive Setting (Form P–4/4s)	15	34	20	170
Long Term Foster Care Placement Memo (Form P–5)	30	3	15	23
UAC Referral (Form P–7)	16	3,250	60	52,000
UAC Referral—Intakes Placement Checklist (Form P–7)	16	9	30	72
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	216	10	15	540
Medical Checklist for Transfers (Form P–9A)	216	27	5	486
Medical Checklist for Influx Transfers (Form P–9B)	216	63	10	2,268
Transfer Request (Form P–10A)—Grantee Case Manager	216	37	25	3,330
Transfer Request (Form P–10A)—Contractor Case Coordinator	250	37	20	3,083
Influx Transfer Request (Form P–10B)	216	63	25	5,670
Transfer Summary and Tracking (Form P–11)	216	37	10	1,332
Program Entity (Form P–12)	216	12	30	1,296
UAC Profile (Form P–13)	216	241	45	39,042
ORR Transfer Notification—ORR Notification to ICE Chief Counsel of Transfer of UAC and Request to Change Address/Venue (Form P–14)	216	37	10	1,332
Family Group Entity (Form P–15)	16	188	5	251
Influx Transfer Manifest (Form P–16)	3	12	20	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	216	43,333	30	4,679,964
Estimated Annual Burden Hours Total:				4,800,879

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–01085 Filed 1–15–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Program for Successful Transition to Adulthood—Extension (OMB #0970–0489)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) requests an extension to continue data collection for the Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Program for Successful Transition to Adulthood (OMB #0970–0489; Previously titled: Phase II Evaluation Activities for Implementing a Next Generation Evaluation Agenda for the Chafee Foster Care Independence Program). Information collection activities requested include interviews, focus group discussions and administrative data collection. There are no changes proposed to the currently approved materials.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ACF, Office of Planning, Research, and Evaluation (OPRE) requests public comment on a proposed extension to a currently approved information collection for the Chafee Foster Care Program for Successful Transition to Adulthood (previously known as the Chafee Foster Care Independence Program). Activities include preliminary visits to discuss the evaluation process with program administrators and site visits to each program to speak with program leaders, partners and key stakeholders, front-line staff, and participants. These formative evaluations will determine programs' readiness for more rigorous evaluation

in the future. The activities and products from this project will help ACF to fulfill the ongoing legislative mandate for program evaluation specified in the Foster Care Independence Act of 1999.

Respondents: Semi-structured interviews will be held with program leaders, partners and stakeholders, and front-line staff as well as young adults being served by the programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Outreach email for discussion with program administrators and staff	38	1	8	304	152
Outreach email for Focus Group Recruiters	96	1	8	768	384
Discussion Guide for program leaders	23	1	1	23	12
Discussion Guide for program partners and stakeholders	14	1	1	14	7
Discussion Guide for program front-line staff	66	1	1	66	33
Focus Group Guide for program participants	240	1	2	480	240

Estimated Total Annual Burden Hours: 828.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Title IV–E of the Social Security Act, IV–E § 477(g) (1–2), as amended by the Foster Care Independence Act of 1999.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–01086 Filed 1–15–21; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2358]

Authorizations of Emergency Use of Two Biological Products During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for biological products for use during the COVID–19 pandemic. FDA issued one Authorization for a biological product as requested by Pfizer, Inc, and one Authorization for a biological product as requested by ModernaTX, Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Pfizer, Inc. is effective as of December 11, 2020; the Authorization for ModernaTX, Inc. is effective as of December 18, 2020.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack

with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorizations

The Authorizations follow the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. Notice of the Secretary of HHS's determination was provided in the **Federal Register** on February 7, 2020 (85 FR 7316). On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary of HHS's declaration was provided in the **Federal Register** on April 1, 2020 (85 FR 18250). Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA issued two authorizations for the emergency use of biological products during the COVID–19 pandemic. On December 11, 2020, FDA issued an EUA to Pfizer, Inc. for the Pfizer-BioNTech COVID–19 Vaccine, subject to the terms of the Authorization. On December 18, 2020, FDA issued an EUA to ModernaTX, Inc. for the Moderna COVID–19 Vaccine, subject to the terms of the Authorization. The Authorizations, which are included below after section IV. Electronic Access in their entirety (not including the authorized versions of the fact sheets and other written materials), provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuances of these Authorizations can be found on FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

December 11, 2020

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

This letter is in response to a request from Pfizer Inc. that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 16 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.[2]

Pfizer-BioNTech COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review has considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s)[4], who will distribute to emergency response stakeholders[5] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[6] and used only to prevent COVID-19 in individuals ages 16 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. After dilution, each vial contains 5 doses of 0.3 mL per dose. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg

[4] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[5] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[6] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration.* 85 FR 79190 (December 9, 2020).

2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 16 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for Pfizer-BioNTech COVID-19 Vaccine, that do not alter the analysis of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER), the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER, and the

Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist/Office of the Commissioner (OCS).

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Vaccine administration errors whether or not associated with an adverse event;
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals, within 15 days after the last day of a month, beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest.
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due July 2021.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (16 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The study(ies) should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older; and

- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

December 18, 2020

ModernaTX, Inc.
Attention: Ms. Carlota Vinals
200 Technology Square
Cambridge, MA 02139

Dear Ms. Vinals:

This letter is in response to a request from ModernaTX, Inc. that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.[2]

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial has enrolled participants 18 years of age and older.

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

FDA's review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA's assessment of safety of the vaccine.

FDA's analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8).

Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Moderna COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- ModernaTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)[4], to emergency response stakeholders[5] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[6] and used only to prevent COVID-19 in individuals ages 18 and older; and
- The Moderna COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] "Authorized Distributor(s)" are identified by ModernaTX, Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Moderna COVID-19 Vaccine.

[5] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[6] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration.* 85 FR 79190 (December 9, 2020).

Product Description

The Moderna COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials.. The Moderna COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The dosing regimen is two doses of 0.5 mL each, one month apart.

The manufacture of the authorized Moderna COVID-19 Vaccine is limited to those facilities identified and agreed upon in the ModernaTX, Inc. request for authorization.

The Moderna COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Moderna COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

The Moderna COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Moderna COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Moderna COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Moderna COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Moderna COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

ModernaTX, Inc. and Authorized Distributor(s)

A. ModernaTX, Inc. and authorized distributor(s) will ensure that the authorized Moderna COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. ModernaTX, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. ModernaTX, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Moderna COVID-19 Vaccine. ModernaTX, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. ModernaTX, Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. ModernaTX, Inc. may request changes to this authorization, including to the authorized Fact Sheets for Moderna COVID-19 Vaccine, that do not alter the analysis

of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER), the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist/Office of the Commissioner (OCS).

F. ModernaTX, Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Vaccine administration errors whether or not associated with an adverse event;
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to ModernaTX, Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by ModernaTX, Inc.

G. ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports at monthly intervals, within 15 days after the last day of a month, beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest.
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. ModernaTX, Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. ModernaTX, Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot

quarantine or rejection must be included in the report. The first report is due July 2021.

L. ModernaTX, Inc. and authorized distributor(s) will maintain records regarding release of Moderna COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. ModernaTX, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. ModernaTX, Inc. will conduct post-authorization observational studies to evaluate the association between Moderna COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Moderna COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. ModernaTX, Inc. will provide protocols and status update reports to the IND 19745 with agreed-upon study designs and milestone dates.

O. ModernaTX, Inc., working with its contract research organization, will continue to monitor the performance of its clinical investigators in ongoing clinical studies of its vaccine and will report to FDA promptly any significant deviations from the protocols.

Emergency Response Stakeholders

P. Emergency response stakeholders will identify vaccination sites to receive authorized Moderna COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

Q. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

R. Emergency response stakeholders receiving authorized Moderna COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

S. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

T. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

U. Vaccination providers administering Moderna COVID-19 Vaccine must report the following information associated with the administration of Moderna COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words " Moderna COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to ModernaTX, Inc., by contacting 1-866-663-3762, by providing a copy of the VAERS form to ModernaTX, Inc., Fax: 1-866-599-1342 or by email; ModernaPV@modernatx.com.

V. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

W. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

X. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine shall be consistent with the authorized

Page 9 – ModernaTX, Inc.

labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Z. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

Dated: January 12, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–01022 Filed 1–15–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0345]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 18, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0695. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data to Support Drug Product Communications as Used by the Food and Drug Administration

OMB Control Number 0910–0695—Extension

This information collection supports Agency outreach efforts. Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an indepth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual indepth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews, all on a voluntary basis.

The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have two major purposes: (1) To obtain information that is useful for developing variables and measures for formulating the basic objectives of risk

communication campaigns and (2) to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. We will use these methods to test and refine our ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies. We will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education.

Annually, we project about 45 communication studies using the variety of test methods listed in this document. We are requesting an extension of these burden hours so as not to restrict our ability to gather information on public sentiment for FDA's proposals in its regulatory and communications programs.

In the **Federal Register** of June 17, 2020 (85 FR 36591), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	43,875	1	43,875	0.21925 (12 minutes)	9,620

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–01030 Filed 1–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915–0126—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915–0126—Revision.

Abstract: This is a request for OMB's approval for a revision to the information collection contained in regulations found at 45 CFR part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from the NPDB. Administrative forms are also included to aid in monitoring compliance with federal reporting and querying requirements. Responsibility for NPDB implementation and operation resides in HRSA's Bureau of Health Workforce.

The intent of the NPDB is to improve the quality of health care by encouraging entities such as hospitals, State licensing boards, professional societies, and other eligible entities [1] providing health care services to identify and discipline those who engage in unprofessional behavior, and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from state to state without disclosure or discovery of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care practitioners, providers, or suppliers by health plans, federal agencies, and state agencies. Users of the NPDB include reporters (entities that are required to

[1] ''Other eligible entities'' that participate in the NPDB are defined in the provisions of Title IV, Section 1921, Section 1128E, and implementing regulations. In addition, a few federal agencies also participate with the NPDB through federal memorandums of understanding. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity. Each eligible entity must certify its eligibility in order to report to the NPDB, query the NPDB, or both. Information from the NPDB is available only to those entities specified as eligible in the statutes and regulations. Not all entities have the same reporting requirements or level of query access.

submit reports) and queriers (entities and individuals that are authorized to request for information).

The reporting forms, request for information forms (query forms), and administrative forms (used to monitor compliance) are accessed, completed, and submitted to the NPDB electronically through the NPDB website at *https://www.npdb.hrsa.gov/.* All reporting and querying is performed through the secure portal of this website.

This revision proposes changes to improve overall data integrity. In addition, this revision contains the five NPDB forms that were originally approved in: ''NPDB Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Certain Other Health Care Entities, OMB No. 0906–0028'' which will be discontinued upon approval of this ICR.

A 60-day notice published in the **Federal Register** on October 16, 2020, vol. 85, No. 201; pp. 65834–65837. There were two public comments that addressed ways to enhance the quality, utility, and clarity of the information to be collected by the NPDB.

Need and Proposed Use of the Information: The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB as authorized in Title 45 CFR part 60 of the Code of Federal Regulations) on the following: (1) Medical malpractice payments, (2) licensure actions taken by Boards of Medical Examiners, (3) State licensure and certification actions, (4) Federal licensure and certification actions, (5) negative actions or findings taken by peer review organizations or private accreditation entities, (6) adverse actions taken against clinical privileges, (7) federal or state criminal convictions related to the delivery of a health care item or service, (8) civil judgments related to the delivery of a health care item or service, (9) exclusions from participation in Federal or State health care programs, and (10) other adjudicated actions or decisions. It is intended that NPDB information should be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

Likely Respondents: Eligible entities or individuals that are entitled to query and/or report to the NPDB as authorized in regulations found at 45 CFR part 60.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision-to-Action, Void, Notice of Appeal (manual).	11,918	1	11,918	.25	2,980
	Correction, Revision-to-Action, Void, Notice of Appeal (automated).	18,301	1	18,301	.0003	5
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual).	11,481	1	11,481	.75	8,611
	Medical Malpractice Payment (automated).	296	1	296	.0003	1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners.	State Licensure or Certification (manual).	19,749	1	19,749	.75	14,812
§ 60.9: Reporting licensure and certification actions taken by States.	State Licensure or Certification (automated).	17,189	1	17,189	.0003	5
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	600	1	600	.75	450
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization.	10	1	10	.75	8
	Accreditation	10	1	10	.75	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions.	978	1	978	.75	734
	Professional Society	41	1	41	.75	31
§ 60.13: Reporting Federal or State criminal convictions related to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial) (manual).	1,174	1	1,174	.75	881

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
	Criminal Conviction (Guilty Plea or Trial) (automated).	683	1	683	.0003	1
	Deferred Conviction or Pre-Trial Diversion.	70	1	70	.75	53
	Nolo Contendere (no contest plea).	127	1	127	.75	95
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	9	1	9	.75	7
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion or Debarment (manual).	1,707	1	1,707	.75	1,280
	Exclusion or Debarment (automated).	2,506	1	2,506	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative (manual).	1,750	1	1,750	.75	1,313
	Government Administrative (automated).	39	1	39	.0003	1
	Health Plan Action	488	1	488	.75	366
§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.	One-Time Query for an Individual (manual).	1,958,176	1	1,958,176	.08	156,654
	One-Time Query for an Individual (automated).	3,349,778	1	3,349,778	.0003	1,005
	One-Time Query for an Organization (manual).	50,681	1	50,681	.08	4,054
	One-Time Query for an Organization (automated).	25,610	1	25,610	.0003	8
§ 60.18 Requesting Information from the NPDB.	Self-Query on an Individual.	168,557	1	168,557	.42	70,794
	Self-Query on an Organization.	1,059	1	1,059	.42	445
	Continuous Query (manual).	806,971	1	806,971	.08	64,558
	Continuous Query (automated).	619,001	1	619,001	.0003	186
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute.	3,264	1	3,264	.75	2,448
	Request for Dispute Resolution.	74	1	74	8	592
Administrative	Entity Registration (Initial).	3,484	1	3,484	1	3,484
	Entity Registration (Renewal & Update).	13,245	1	13,245	.25	3,311
	State Licensing Board Data Request.	60	1	60	10.5	630
	State Licensing Board Attestation.	325	1	325	1	325
	Authorized Agent Attestation.	350	1	350	1	350
	Health Center Attestation.	722	1	722	1	722
	Hospital Attestation	3,416	1	3,416	1	3,416
	Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation.	274	1	274	1	274
	Other Eligible Entity Attestation.	1,884	1	1,884	1	1,884

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
	Corrective Action Plan (Entity).	10	1	10	.08	1
	Reconciling Missing Actions.	1,491	1	1,491	.08	119
	Agent Registration (Initial).	44	1	44	1	44
	Agent Registration (Renewal & Update).	304	1	304	.08	24
	Electronic Funds Transfer (EFT) Authorization.	644	1	644	.08	52
	Authorized Agent Designation.	183	1	183	.25	46
	Account Discrepancy ...	85	1	85	.25	21
	New Administrator Request.	600	1	600	.08	48
	Purchase Query Credits.	1,786	1	1786	.08	143
	Education Request	40	1	40	.08	3
	Account Balance Transfer.	10	1	10	.08	1
	Missing Report From Query Form.	10	1	10	.08	1
Total	.....	7,101,274	.....	7,101,274	.....	347,294

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–00989 Filed 1–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Incident Report Form.

Type of Collection: New.

OMB No. 0990–NEW—Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting approval for three years of a new information collection on the OHRP Incident Report Form. This form will facilitate prompt reporting of specific human subject protection incidents to OHRP by organizations and institutions conducting or reviewing human subjects research, and will provide a simplified standardized format for the reports. The information collected on the form will help OHRP to ensure the safety of human research subjects involved in non-exempt HHS-conducted or -supported research and to ensure that the research is conducted in accordance with the HHS Protection of Human Subjects regulations at 45 CFR part 46.

Likely Respondents: Institutions or organizations conducting non-exempt HHS-conducted or -supported human subjects research.

ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents	Responses per respondent	Number of responses	Hours per response	Total burden hours
Incident Report Form	500	*1*	500	0.5	250
Incident Report Form	200	*2*	400	0.5	200
Incident Report Form	100	*3*	300	0.5	150
Total					600

Dated: January 12, 2021.

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2021–00939 Filed 1–15–21; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Mentored Career Development Awards (Ks).

Date: March 1, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Xinli Nan, M.D., Ph.D., Scientific Review Officer, Division of Scientific Programs, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–594–7784, *Xinli.Nan@nih.gov.*

Dated: January 12, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00979 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; SBIR PHASE I, Topic 021.

Date: February 2, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892–4878 (Virtual Meeting).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892–4878, 301–435–0813, *henriquv@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 12, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–01047 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Multisite clinical trial evaluation for interventions in older individuals.

Date: February 26, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 496–9374, *grimaldim2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 12, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00980 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK KUH Training Grants Review Committee.

Date: February 10, 2021.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Xiaodu Guo, M.D., Ph.D. Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7023 Bethesda, MD 20892–5452 (301) 594–4719 *guox@extra.niddk.nih.gov*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 12, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00985 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; GENETIC COUNSELING PROCESSES AND PRACTICES.

Date: February 8, 2021.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3184, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3184, Bethesda, MD 20817, (301) 402–0838, *pozzattr@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 12, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00946 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the National Toxicology Program Special Emphasis Panel was renewed for an additional two-year period on January 7, 2021.

It is determined that the National Toxicology Program Special Emphasis Panel is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Stop Code 4875), Telephone (301) 496–2123, or *harriscl@mail.nih.gov.*

Dated: January 12, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00947 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Review of NIGMS Pathway to independence Award K99/R00 Applications.

Date: March 25, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Isaah S. Vincent, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12L, Bethesda, MD 20892, 301–594–2948, *isaah.vincent@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry

Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 12, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00984 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 16–17, 2021.

Closed: February 16, 2021, 10:00 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Division of Extramural Research and Training, National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Virtual Meeting).

Open: February 16, 2021, 10:45 a.m. to 1:45 p.m.

Agenda: Discussion of program policies and issues.

Place: Division of Extramural Research and Training, National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709, *https://www.niehs.nih.gov/news/webcasts/* (Virtual Meeting).

Open: February 17, 2021, 10:00 a.m. to 2:00 p.m.

Agenda: Proposed DERT Actions/Discussion about UNITE Committees/DEI Discussion—roll out of WG.

Place: Division of Extramural Research and Training, National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709, *https://www.niehs.nih.gov/news/webcasts/* (Virtual Meeting).

Contact Person: Patrick Mastin, Ph.D., Acting Division Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709 984–287–3285, *mastin@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.niehs.nih.gov/about/boards/naehsc/index.cfm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 12, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00945 Filed 1–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review Group, Training and Workforce Development Subcommittee—A Review of Predoctoral Institutional Research Training and MSTP T32 Grant applications.

Date: March 4–5, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Video Meeting).

Contact Person: Isaah S. Vincent, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12L, Bethesda, MD 20892, (301) 594–2948, *isaah.vincent@nih.gov*.

Name of Committee: NIGMS Initial Review Group, Training and Workforce Development Subcommittee—C Review of IRACDA and Bridges to the Baccalaureate applications.

Date: March 12, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Video Meeting).

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institutes of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18A, Bethesda, MD 20814, (301) 435–0807, *slicelw@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 12, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2101]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before April 19, 2021.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2101, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Weld County, Colorado and Incorporated Areas Project: 19–08–0010S Preliminary Date: September 17, 2020	
City of Evans	City Hall, 1100 37th Street, Evans, CO 80620.
City of Fort Lupton	City Hall, 130 South McKinley Avenue, Fort Lupton, CO 80621.
City of Greeley	City Hall, 1000 10th Street, Greeley, CO 80631.
Town of Firestone	Town Hall, 151 Grant Avenue, Firestone, CO 80520.
Town of Frederick	Town Hall, 401 Locust Street, Frederick, CO 80530.
Town of Kersey	Town Hall, 446 1st Street, Kersey, CO 80644.
Town of LaSalle	Town Hall, 128 North 2nd Street, LaSalle, CO 80645.
Town of Mead	Town Hall, 441 3rd Street, Mead, CO 80542.
Town of Milliken	Town Hall, 1101 Broad Street, Milliken, CO 80543.
Town of Platteville	Town Hall, 400 Grand Avenue, Platteville, CO 80651.
Town of Windsor	Town Hall, 301 Walnut Street, Windsor, CO 80550.
Unincorporated Areas of Weld County	Weld County Commissioner's Office, 1150 O Street, Greeley, CO 80631.

Community	Community map repository address
Norfolk County, Massachusetts (All Jurisdictions) Project: 15–01–0633S Preliminary Date: June 19, 2020	
City of Quincy	City Hall, 1305 Hancock Street, Quincy, MA 02169.
Town of Avon	Town Hall, 65 East Main Street, Avon, MA 02322.
Town of Bellingham	Municipal Center, 10 Mechanic Street, Bellingham, MA 02019.
Town of Braintree	Town Hall, 1 John F. Kennedy Memorial Drive, Braintree, MA 02184.
Town of Brookline	Town Hall, 333 Washington Street, Brookline, MA 02445.
Town of Canton	Town Hall, 801 Washington Street, Canton, MA 02021.
Town of Cohasset	Town Hall, 41 Highland Avenue, Cohasset, MA 02025.
Town of Dedham	Town Hall, 450 Washington Street, Dedham, MA 02026.
Town of Dover	Town House, 5 Springdale Avenue, Dover, MA 02030.
Town of Foxborough	Town Hall, 40 South Street, Foxborough, MA 02035.
Town of Franklin	Town Hall, 355 East Central Street, Franklin, MA 02038.
Town of Holbrook	Town Hall, 50 North Franklin Street, Holbrook, MA 02343.
Town of Medfield	Town Hall, 459 Main Street, Medfield, MA 02052.
Town of Medway	Town Hall, 155 Village Street, Medway, MA 02053.
Town of Millis	Veterans Memorial Building, 900 Main Street, Millis, MA 02054.
Town of Milton	Town Office Building, 525 Canton Avenue, Milton, MA 02186.
Town of Needham	Town Hall, 1471 Highland Avenue, Needham, MA 02492.
Town of Norfolk	Town Hall, 1 Liberty Lane, Norfolk, MA 02056.
Town of Norwood	Town Hall, 566 Washington Street, Norwood, MA 02062.
Town of Plainville	Town Hall, 190 South Street, Plainville, MA 02762.
Town of Randolph	Town Hall, 41 South Main Street, Randolph, MA 02368.
Town of Sharon	Town Office Building, 90 South Main Street, Sharon, MA 02067.
Town of Stoughton	Town Hall, 10 Pearl Street, Stoughton, MA 02072.
Town of Walpole	Town Hall, 135 School Street, Walpole, MA 02081.
Town of Wellesley	Town Hall, 525 Washington Street, Wellesley, MA 02482.
Town of Westwood	Town Hall, 580 High Street, Westwood, MA 02090.
Town of Weymouth	Town Hall, 75 Middle Street, Weymouth, MA 02189.
Town of Wrentham	Town Hall, 79 South Street, Wrentham, MA 02093.
Plymouth County, Massachusetts (All Jurisdictions) Project: 15–01–0633S Preliminary Date: June 19, 2020	
Town of Abington	Town Hall, 500 Gliniewicz Way, Abington, MA 02351.
Town of Hanover	Town Hall, 550 Hanover Street, Hanover, MA 02339.
Town of Hingham	Town Hall, 210 Central Street, Hingham, MA 02043.
Town of Hull	Town Hall, 253 Atlantic Avenue, Hull, MA 02045.
Town of Norwell	Town Hall, 345 Main Street, Norwell, MA 02061.
Town of Rockland	Town Hall, 242 Union Street, Rockland, MA 02370.
Suffolk County, Massachusetts (All Jurisdictions) Project: 15–01–0633S Preliminary Date: June 19, 2020	
City of Boston	City Hall, 1 City Hall Square, Boston, MA 02201.
City of Chelsea	City Hall, 500 Broadway, Chelsea, MA 02150.
City of Revere	City Hall, 281 Broadway, Revere, MA 02151.
Town of Winthrop	Public Works Building, 100 Kennedy Drive, Winthrop, MA 02152.
Bradford County, Pennsylvania (All Jurisdictions) Project: 16–03–0615S Preliminary Date: July 1, 2020	
Borough of Athens	Municipal Building, 2 South River Street, Athens, PA 18810.
Borough of Sayre	Borough Hall, 110 West Packer Avenue, Sayre, PA 18840.
Borough of South Waverly	Borough Hall, 2523 Pennsylvania Avenue, South Waverly, PA 18840.
Borough of Towanda	Municipal Building, 724 Main Street, Towanda, PA 18848.
Township of Asylum	Asylum Township Building, 19981 Route 187, Towanda, PA 18848.
Township of Athens	Athens Township Municipal Building, 45 Herrick Avenue, Sayre, PA 18840.
Township of Litchfield	Litchfield Township Building, 1391 Hill Road, Sayre, PA 18840.
Township of North Towanda	North Towanda Township Office, 292 Old Mills Road, Towanda, PA 18848.
Township of Sheshequin	Sheshequin Township Office, 1774 North Middle Road, Ulster, PA 18850.
Township of Towanda	Township Office, 44 Chapel Street, Towanda, PA 18848.
Township of Ulster	Municipal Building, 23849 Route 220, Ulster, PA 18850.
Township of Wysox	Township Building, 103 Lake Road, Wysox, PA 18854.
Wyoming County, Pennsylvania (All Jurisdictions) Project: 16–03–0615S Preliminary Date: July 1, 2020	
Borough of Laceyville	Municipal Building, 342 Church Street, Laceyville, PA 18623.
Borough of Meshoppen	Municipal Building, 154 Oak Street, Meshoppen, PA 18630.
Borough of Tunkhannock	Municipal Building, 126 Warren Street, Tunkhannock, PA 18657.

Community	Community map repository address
Township of Braintrim	Braintrim Municipal Building, 220 Main Street, Laceyville, PA 18623.
Township of Eaton	Eaton Municipal Building, 1331 Hunter Highway, Tunkhannock, PA 18657.
Township of Falls	Municipal Building, 220 Buttermilk Road, Falls, PA 18615.
Township of Mehoopany	Municipal Building, 237 Schoolhouse Road, Mehoopany, PA 18629.
Township of Meshoppen	Municipal Building, 527 Benninger Road, Meshoppen, PA 18630.
Township of Tunkhannock	Municipal Building, 113 Tunkhannock Township Drive, Tunkhannock, PA 18657.
Township of Washington	Washington Municipal Building, 184 Keiserville Road, Tunkhannock, PA 18657.
Township of Windham	Windham Municipal Building, 149 Palen Street, Mehoopany, PA 18629.
Grayson County, Texas and Incorporated Areas Project: 20–06–0067S Preliminary Date: July 24, 2020	
City of Sherman	Engineering Department, 220 West Mulberry Street, Sherman, TX 75090.
Unincorporated Areas of Grayson County	Grayson County Courthouse, 100 West Houston Street, Sherman, TX 75090.
Lancaster County, Virginia and Incorporated Areas Project: 18–03–0032S Preliminary Date: July 1, 2019	
Town of Kilmarnock	Town Hall Office, 1 North Main Street, Kilmarnock, VA 22482.
Unincorporated Areas of Lancaster County	Lancaster County Administration Building, Department of Planning and Land Use, 8311 Mary Ball Road, Lancaster, VA 22503.
Nottoway County, Virginia and Incorporated Areas Project: 19–03–0017S Preliminary Date: August 28, 2020	
Town of Blackstone	Town Hall, 100 West Elm Street, Blackstone, VA 23824.
Town of Burkeville	Town Hall, 224 2nd Street Northwest, Burkeville, VA 23922.
Town of Crewe	Town Office, 125 East Carolina Avenue, Crewe, VA 23930.
Unincorporated Areas of Nottoway County	Nottoway County Administrator's Office, 344 West Courthouse Road, Nottoway, VA 23955.
Richmond County, Virginia and Incorporated Areas Project: 18–03–0034S Preliminary Date: July 19, 2019	
Town of Warsaw	Robert W. Lowery Municipal Building, 78 Belle Ville Lane, Warsaw, VA 22572.
Unincorporated Areas of Richmond County	Richmond County Administrator's Office, 101 Court Circle, Warsaw, VA 22572.
Westmoreland County, Virginia and Incorporated Areas Project: 19–03–0001S Preliminary Date: July 1, 2019	
Town of Montross	Town Hall, 15869 Kings Highway, Montross, VA 22520.
Unincorporated Areas of Westmoreland County	Westmoreland County George D. English, Sr. Memorial Building, 111 Polk Street, Montross, VA 22520.
Goshen County, Wyoming and Incorporated Areas Project: 15–08–0154S Preliminary Date: June 30, 2020	
City of Torrington	Lincoln Community Complex, 436 East 22nd Avenue, Torrington, WY 82240.
Town of Fort Laramie	Town Hall, 102 West Otis Street, Fort Laramie, WY 82212.
Town of LaGrange	Town Hall, 200 C Street, LaGrange, WY 82221.
Town of Lingle	Town Hall, 220 Main Street, Lingle, WY 82223.
Town of Yoder	Town Hall, 321 Main Street, Yoder, WY 82244.
Unincorporated Areas of Goshen County	Goshen County Courthouse, 2125 East A Street, Room 120, Torrington, WY 82240.

[FR Doc. 2021–01106 Filed 1–15–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2100]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Adams.	City of Thornton (20–08–0251P).	The Honorable Janifer Kulmann, Mayor, City of Thornton, 9500 Civic Center Drive, Thornton, CO 80229.	City Hall, 9500 Civic Center Drive, Thornton, CO 80229.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 26, 2021	080007
Adams.	Unincorporated areas of Adams County (20–08–0251P).	The Honorable Emma Pinter, Chair, Adams County Board of Commissioners, 4430 South Adams County Parkway, Suite C5000A, Brighton, CO 80601.	Adams County Community and Economic Development Department, 4430 South Adams County Parkway, Suite W2000, Brighton, CO 80601.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 26, 2021	080001

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Douglas.	Town of Castle Rock (20–08–0462P).	The Honorable Jason Gray, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Water Department, 175 Kellog Court, Castle Rock, CO 80109.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 12, 2021	080050
Douglas.	Unincorporated areas of Douglas County (20–08–0462P).	Mr. Doug DeBord, Douglas County, Manager, 100 3rd Street, Castle Rock, CO 80104.	Department of Public Works, Engineering Department, 100 3rd Street, Castle Rock, CO 80104.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 12, 2021	080049
Florida:						
Collier.	City of Naples (20–04–5222P).	The Honorable Teresa Heitmann, Mayor, City of Naples, 735 8th Street South, 2nd Floor, Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 8, 2021	125130
Collier.	City of Naples (20–04–5396P).	The Honorable Teresa Heitmann, Mayor, City of Naples, 735 8th Street South, 2nd Floor, Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2021	125130
Hillsborough.	Unincorporated areas of Hillsborough County (20–04–1456P).	Ms. Bonnie M. Wise, Hillsborough County, Administrator, 601 East Kennedy Boulevard, 26th Floor, Tampa, FL 33602.	Hillsborough County Center, 601 East Kennedy Boulevard, 22nd Floor, Tampa, FL 33602.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 18, 2021	120112
Hillsborough.	Unincorporated areas of Hillsborough County (20–04–4569P).	Ms. Bonnie M. Wise, Hillsborough County, Administrator, 601 East Kennedy Boulevard, 26th Floor, Tampa, FL 33602.	Hillsborough County Center, 601 East Kennedy Boulevard, 22nd Floor, Tampa, FL 33602.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2021	120112
Miami-Dade.	City of Miami (20–04–6068P).	The Honorable Francis X. Suarez, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133.	Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2021	120650
Monroe.	City of Marathon (21–04–0493P).	The Honorable Steve Cook, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2021	120681
Monroe.	Village of Islamorada (20–04–6217P).	The Honorable Mike Forster, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2021	120424
Palm Beach.	Town of Jupiter (20–04–3713P).	Mr. Matt Benoit, Manager, Town of Jupiter, 210 Military Trail, Jupiter, FL 33458.	Building and Stormwater Utility Department, 210 Military Trail, Jupiter, FL 33458.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 24, 2021	125119
Palm Beach.	Village of Royal Palm Beach (20–04–0312P).	The Honorable Fred Pinto, Mayor, Village of Royal Palm Beach, 1050 Royal Palm Beach Boulevard, Royal Palm Beach, FL 33411.	Village Hall, 1050 Royal Palm Beach Boulevard, Royal Palm Beach, FL 33411.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 23, 2021	120225
Pinellas.	Town of Belleair (20–04–5570P).	Mr. J.P. Murphy, Manager, Town of Belleair, 901 Ponce de Leon Boulevard, Belleair, FL 33756.	Building Department, 901 Ponce de Leon Boulevard, Belleair, FL 33756.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2021	125088
New Mexico:						
Taos.	Town of Taos (20–06–1193P).	The Honorable Daniel R. Barrone, Mayor, Town of Taos, 400 Camino De La Placita, Taos, NM 87571.	Planning Department, 400 Camino De La Placita, Taos, NM 87571.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 9, 2021	350080
Taos.	Unincorporated areas of Taos County (20–06–1193P).	Mr. Brent Jaramillo, Taos County Manager, 105 Albright Street, Suite G, Taos, NM 87571.	Taos County Planning Department, 105 Albright Street, Taos, NM 87571.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 9, 2021	350078
Pennsylvania:						
Allegheny.	Township of Moon (20–03–0739P).	Ms. Dawn Lane, Manager, Township of Moon, 1000 Beaver Grade Road, Moon Township, PA 15108.	Township Hall, 1000 Beaver Grade Road, Moon Township, PA 15108.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 12, 2021	421082

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Dauphin.	Borough of Middletown (20–03–1407P).	The Honorable Ian Reddinger, President, Borough of Middletown Council, 60 West Emaus Street, Middletown, PA 17057.	Borough Hall, 60 West Emaus Street, Middletown, PA 17057.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 26, 2021	420388
Rhode Island:						
Washington.	Town of South Kingstown (20–01–1104P).	The Honorable Abel G. Collins, President, Town of South Kingstown Council, 180 High Street, Wakefield, RI 02879.	Building Inspection and Zoning Department, 180 High Street, Wakefield, RI 02879.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 19, 2021	445407
Texas:						
Bexar.	City of San Antonio (20–06–1037P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Stormwater Division, 114 West Commerce, 7th Floor, San Antonio, TX 78205.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 16, 2021	480045
Bexar.	Unincorporated areas of Bexar County (20–06–1037P).	The Honorable Nelson W. Wolff, Bexar County, Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 16, 2021	480035
Collin.	City of Wylie (20–06–2188P).	The Honorable Eric Hogue, Mayor, City of Wylie, 300 Country Club Road, Building 100, Wylie, TX 75098.	City Hall, 300 Country Club Road, Building 100, Wylie, TX 75098.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2021	480759
Dallas.	City of Carrollton (20–06–2233P).	Ms. Erin Rinehart, Manager, City of Carrollton, 1945 East Jackson Road, Carrollton, TX 75006.	Engineering Department, 1945 East Jackson Road, Carrollton, TX 75006.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2021	480167
Dallas.	City of Coppell (20–06–1839P).	The Honorable Karen Hunt, Mayor, City of Coppell, P.O. Box 9478, Coppell, TX 75019.	Department of Public Works, 265 East Parkway Boulevard, Coppell, TX 75019.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 22, 2021	480170
Dallas.	City of Dallas (20–06–1839P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Floodplain and Drainage Management Department, 320 East Jefferson Boulevard, Room 312, Dallas, TX 75203.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 22, 2021	480171
Dallas.	City of Dallas (20–06–3047P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Floodplain and Drainage Management Department, 320 East Jefferson Boulevard, Room 312, Dallas, TX 75203.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 1, 2021	480171
Dallas.	City of Irving (20–06–1839P).	The Honorable Rick Stopfer, Mayor, City of Irving, 825 West Irving Boulevard, Irving, TX 75060.	Engineering Department, 825 West Irving Boulevard, Irving, TX 75060.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 22, 2021	480180
Tarrant.	City of Arlington (20–06–2033P).	The Honorable Jeff Williams, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works and Transportation Department, 101 West Abram Street, Arlington, TX 76010.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2021	485454
Tarrant.	City of Arlington (20–06–2035P).	The Honorable Jeff Williams, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works and Transportation Department, 101 West Abram Street, Arlington, TX 76010.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 1, 2021	485454
Tarrant.	City of Arlington (20–06–2038P).	The Honorable Jeff Williams, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works and Transportation Department, 101 West Abram Street, Arlington, TX 76010.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 22, 2021	485454
Tarrant.	City of Arlington (20–06–2039P).	The Honorable Jeff Williams, Mayor, City of Arlington, P.O. Box 90231, Arlington, TX 76004.	Public Works and Transportation Department, 101 West Abram Street, Arlington, TX 76010.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 25, 2021	485454
Travis.	City of Lakeway (20–06–3378P).	The Honorable Sandy Cox, Mayor, City of Lakeway, 1102 Lohmans Crossing Road, Lakeway, TX 78734.	City Hall, 1102 Lohmans Crossing Road, Lakeway, TX 78734.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 26, 2021	481303

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Williamson.	Unincorporated areas of Williamson County, (20–06–2228P).	The Honorable Bill Gravell, Jr., Williamson County, Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County, Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2021	481079
Vermont: Windsor.	Town of Springfield (20–01–0533P).	Mr. Steve Neratko, Town of Springfield, Manager, 96 Main Street, Springfield, VT 05156.	Town Hall, 96 Main Street, Springfield, VT 05156.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 14, 2021	500154
Virginia: Loudoun.	Unincorporated areas of Loudoun County (20–03–0990P).	Mr. Tim Hemstreet, Loudoun County, Administrator, P.O. Box 7000, Leesburg, VA 20177.	Loudoun County, Office of Mapping and Geographic Information, 1 Harrison Street Southeast, Leesburg, VA 20175.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 29, 2021	510090
Washington DC	District of Columbia (20–03–1674P).	The Honorable Muriel Bowser, Mayor, District of Columbia, 1350 Pennsylvania Avenue, Northwest, Washington, DC 20004.	Department of Energy and Environment, 1200 1st Street Northeast, Suite 500, Washington, DC 20002.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 19, 2021	110001
West Virginia:						
Greenbrier.	City of White Sulphur Springs (20–03–1111P).	The Honorable Bruce Bowling, Mayor, City of White Sulphur Springs, 589 Main Street West, White Sulphur Springs, WV 24986.	City Hall, 589 Main Street West, White Sulphur Springs, WV 24986.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2021	540045
Greenbrier.	Unincorporated areas of Greenbrier County (20–03–1111P).	The Honorable Lowell Rose, President, Greenbrier County, Commission, 912 Court Street North, Lewisburg, WV 24901.	Greenbrier County, Planning, Department, 912 Court Street North, Lewisburg, WV 24986.	*https://msc.fema.gov/portal/advanceSearch.*	Apr. 12, 2021	540040

[FR Doc. 2021–01105 Filed 1–15–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The date of May 4, 2021 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Logan County, Colorado and Incorporated Areas Docket No.: FEMA–B–1977	
City of Sterling	City Administration Building, Public Works Department, 421 North 4th Street, Sterling, CO 80751.
Town of Crook	Town Hall, 212 4th Street, Crook, CO 80726.
Town of Iliff	Town Hall, 405 West 2nd Avenue, Iliff, CO 80736.
Town of Merino	Town Hall, 208 Colorado Avenue, Merino, CO 80741.
Unincorporated Areas of Logan County	Logan County Courthouse, Planning, Zoning and Building Department, 315 Main Street, Suite 2, Sterling, CO 80751.
Marshall County, Mississippi and Incorporated Areas Docket No.: FEMA–B–1946	
City of Holly Springs	Utility Department, 1050 Highway 4 East, Holly Springs, MS 38635.
Town of Byhalia	Town Hall, 161 Highway 309 South, Byhalia, MS 38611.
Unincorporated Areas of Marshall County	Marshall County Zoning Department, 590 Highway 178 East, Holly Springs, MS 38635.
Quitman County, Mississippi and Incorporated Areas Docket No.: FEMA–B–1946	
Unincorporated Areas of Quitman County	Quitman County Courthouse, 220 Chestnut Street, Suite 3, Marks, MS 38646.
Tate County, Mississippi and Incorporated Areas Docket No.: FEMA–B–1946	
Unincorporated Areas of Tate County	Tate County Emergency Management Office, 910 East F. Hale Drive, Senatobia, MS 38668.
Tunica County, Mississippi and Incorporated Areas Docket No.: FEMA–B–1946	
Town of Tunica	Town Hall, 909 River Road, Tunica, MS 38676.
Unincorporated Areas of Tunica County	Tunica County Office of Planning and Development, 1061 South Court Street, Tunica, MS 38676.
Niagara County, New York (All Jurisdictions) Docket Nos: FEMA–B–1832 and B–1975	
City of Niagara Falls	City Hall, 745 Main Street, Niagara Falls, NY 14301.
City of North Tonawanda	City Hall, 216 Payne Avenue, North Tonawanda, NY 14120.
Town of Lewiston	Town Hall, 1375 Ridge Road, Lewiston, NY 14092.
Town of Newfane	Town Hall/Community Center, 2737 Main Street, Newfane, NY 14108.
Town of Porter	Porter Town Hall, 3265 Creek Road, Youngstown, NY 14174.
Town of Somerset	Somerset Town Hall, 8700 Haight Road, Barker, NY 14012.
Town of Wheatfield	Town Hall, 2800 Church Road, Wheatfield, NY 14120.
Town of Wilson	Town Hall, 375 Lake Street, Wilson, NY 14172.
Village of Lewiston	Village Hall, 145 North 4th Street, Lewiston, NY 14092.
Village of Wilson	Wilson Town Hall, 375 Lake Street, Wilson, NY 14172.
Village of Youngstown	Village Hall, 240 Lockport Street, Youngstown, NY 14174.
Greenville County, South Carolina and Incorporated Areas Docket No.: FEMA–B–1966	
City of Greer	City Hall, 301 East Poinsett Street, Greer, SC 29651.
Unincorporated Areas of Greenville County	Greenville County Square, Code Compliance Division, 301 University Ridge, Suite 4100, Greenville, SC 29601.
Lake County, Ohio and Incorporated Areas Docket Nos.: FEMA–B–1806 and B–1961	
City of Eastlake	City Hall, 35150 Lakeshore Boulevard, Eastlake, OH 44095.
City of Mentor	Municipal Center, 8500 Civic Center Boulevard, Mentor, OH 44060.
City of Mentor-on-the-Lake	City Hall, 5860 Andrews Road, Mentor-on-the-Lake, OH 44060.
City of Willoughby	City Hall, One Public Square, Willoughby, OH 44094.
City of Willowick	Building Inspector's Office, 31230 Vine Street, Willowick, OH 44095.
Unincorporated Areas of Lake County	County Engineer's Office, 550 Blackbrook Road, Painesville, OH 44077.
Village of Fairport Harbor	Village Hall, 220 Third Street, Fairport Harbor, OH 44077.
Village of Grand River	Village Hall, 205 Singer Avenue, Grand River, OH 44045.
Village of Lakeline	Village Hall, 33801 Lakeshore Boulevard, Lakeline, OH 44095.
Village of North Perry	Village Hall, 4449 Lockwood Road, North Perry, OH 44081.

Community	Community map repository address
Village of Timberlake	Municipal Building, 11 East Shore Boulevard, Timberlake, OH 44095.
Spartanburg County, South Carolina and Incorporated Areas Docket No.: FEMA–B–1966	
City of Spartanburg	City Hall, 145 West Broad Street, Spartanburg, SC 29306.
City of Wellford	City Hall, 127 Syphrit Road, Wellford, SC 29385.
Town of Duncan	Town Hall, 153 West Main Street, Duncan, SC 29334.
Unincorporated Areas of Spartanburg County	Spartanburg County Administration Building, 366 North Church Street, Spartanburg, SC 29303.
Union County, South Carolina and Incorporated Areas Docket No.: FEMA–B–1966	
City of Union	City Hall, 101 Sharpe Avenue, Union, SC 29379.
Unincorporated Areas of Union County	Union County Court House, 210 West Main Street, Union, SC 29379.

[FR Doc. 2021–01107 Filed 1–15–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2020–N163; FXES11130200000–212–FF02ENEH00]

Endangered and Threatened Wildlife and Plants; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications for a permit to conduct activities intended to recover and enhance endangered species survival. With some exceptions, the Endangered Species Act of 1973, as amended (ESA), prohibits certain activities that may impact endangered species unless a Federal permit allows such activity. The ESA also requires that we invite public comment before issuing these permits.

DATES: To ensure consideration, please submit your written comments by February 18, 2021.

ADDRESSES: *Document availability:* Request documents by phone or email: Beth Forbus, 505–248–6681, *beth_forbus@fws.gov.*

Comment submission: Submit comments by email to *fw2_te_permits@fws.gov.* Please specify the permit you are interested in by number (*e.g.,* Permit No. TE–123456).

FOR FURTHER INFORMATION CONTACT: Beth Forbus, Supervisor, Classification and Restoration Division, 505–248–6681. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes hunting, shooting, harming, wounding, or killing but also such activities as pursuing, harassing, trapping, capturing, or collecting.

The ESA and our implementing regulations in the Code of Federal Regulations (CFR) at title 50, part 17, provide for issuing such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit we issue under the ESA, section 10(a)(1)(A), authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or enhance the species' propagation or survival. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Documents and other information submitted with these applications are available for review by any party who submits a request as specified in **ADDRESSES**. Releasing documents is subject to Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552) requirements.

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. We invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Please refer to the application number when submitting comments.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE72324B	Dill, Lauren; Austin, Texas	Golden-cheeked warbler (*Setophaga chrysoparia*).	Texas	Presence/absence surveys.	Harm, harass	Renew.
TE83399D	Johnson, James; Canyon, Texas.	Pecos gambusia (*Gambusia nobilis).*	New Mexico, Texas	Sampling using minnow traps.	Capture, harm, harass.	New.
TE37484A	Balcones Canyonlands National Wildlife Refuge; Marble, Texas.	Golden-cheeked warbler (*Setophaga chrysoparia*).	Texas	Presence/absence surveys, banding, mist netting, nest monitoring.	Capture, harm, harass.	Renew.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE80520D	USGS, Grand Canyon Monitoring and Research Center; Flagstaff, Arizona.	humpback chub (*Gila cypha*), razorback sucker (*Xyrauchen texanus*).	Arizona	Presence/absence surveys, monitoring.	Harm, harass	Renew.
TE87767D	Canvas Natural Resource Solutions, LLC;. Longview, Texas	Red-cockaded woodpecker (*Picoides borealis*).	Louisiana, Mississippi, Texas.	Presence/absence surveys.	Harm, harass	New.
TE87758D	UnderWing Biological, LLC; Silvery City, New Mexico.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Arizona, California, Nevada, New Mexico, Texas.	Presence/absence surveys, nest monitoring.	Harm, harass	New.
TE833866	Texas A&M Forest Service; Lufkin, Texas.	Red-cockaded woodpecker (*Picoides borealis*).	Texas	Presence/absence surveys.	Harm, harass	Renew.
TE174552	Animas Biological Studies, LLC; Durango, Colorado.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Arizona, Colorado, New Mexico, Utah.	Presence/absence surveys, nest monitoring.	Harm, harass	Renew.
TE59580A	Rocky Mountain Ecology, LLC; Rio Rancho, New Mexico.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Colorado, New Mexico.	Presence/absence surveys.	Harass, harm	Renew.
TE73317B	Britt, Charles; Las Cruces, New Mexico.	Southwestern willow flycatcher (*Empidonax traillii extimus*), northern aplomado falcon (*Falco femoralis septentrionalis*).	Arizona, New Mexico,	Presence/absence surveys.	Harm, harass	Renew.
TE819477	Parametrix; Albuquerque, New Mexico.	Southwestern willow flycatcher (*Empidonax traillii extimus*).	Arizona, New Mexico	Presence/absence surveys.	Harm, harass	Renew.

Authority: We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*).

Amy L. Lueders,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2021–00968 Filed 1–15–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[212.LLAK941000 L14100000.ET0000; F–86061, F–16298, F–16299, F–16301, AA–61299, F–16304, F–85667, AA–61005, F–86064, F–85702, AA–66614]

Public Land Order No. 7899; Partial Revocation of Public Land Orders No. 5169, 5170, 5171, 5173, 5179, 5180, 5184, 5186, 5187, 5188, 5353, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order partially revokes 11 Public Land Orders (PLO) insofar as they affect approximately 9,727,730.01 acres of public lands reserved for study and classification, as appropriate, by the Department of the Interior and supersedes PLO Nos. 6477 and 6559. The purposes for which these lands were withdrawn no longer exist as described in the analysis and decisions made through the Kobuk-Seward Peninsula Record of Decision and Approved Resource Management Plan of 2008 (Kobuk-Seward Pen RMP).

DATES: This Public Land Order takes effect on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: David V. Mushovic, Bureau of Land Management (BLM) Alaska State Office, 222 West Seventh Avenue, Mailstop #13, Anchorage, AK 99513–7504, 907–271–4682, or *dmushovi@blm.gov.* People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This Order implements the recommendations made in the BLM's Kobuk-Seward Pen RMP that serves as the detailed statement required under the National Environmental Policy Act Section 102(2)(C). PLO Nos. 5169, 5170, 5171, and 5173, as amended, modified or corrected, withdrew lands for selection by Village and Regional Corporations under Sec. 11(a)(3) of Alaska Native Claims Settlement Act (ANCSA), and for classification. Sec. 22(h)(4) of ANCSA states ''the Secretary is authorized to terminate any withdrawal . . . whenever he determines the withdrawal is no longer necessary.'' The purposes for which these lands were withdrawn were satisfied by the analysis conducted during the development of the BLM's Kobuk-Seward Pen RMP. PLO No. 5179, as amended, modified or corrected, withdrew lands in aid of legislation concerning addition to, or creation of, units of the National Park, National Forest, Wildlife Refuge, and Wild and Scenic Rivers systems, and to allow for classification of the lands. Any additions to or creation of new units of National Parks, National Forests, Wildlife Refuges or Wild and Scenic Rivers from the land withdrawn by PLO No. 5179 were met by the Alaska National Interest Lands Conservation Act (ANILCA). The classification of the lands withdrawn by PLO No. 5179 was satisfied by the analysis conducted during the development of the Kobuk-Seward Pen RMP. PLO No. 5180, as amended, modified or corrected, withdrew lands to allow for classification and for the protection of the public interest in these lands. The classification and protection of the public interest in the lands withdrawn by PLO No. 5180 has been satisfied by the analysis conducted during the development of the Kobuk-Seward Pen RMP. PLO No. 5184, as amended, modified or corrected, withdrew lands to allow for classification or reclassification of some of areas withdrawn by ANCSA Sec. 11. These purposes were satisfied by the analysis conducted during the development of the Kobuk-Seward Pen RMP. PLO No. 5186, as amended, modified, or corrected, withdrew lands for classification and protection of the public interest in lands not selected by the State of Alaska. The classification of the lands withdrawn by PLO No. 5186 has been satisfied by the analysis conducted during the development of the Kobuk-Seward Pen RMP. PLO No. 5187, as amended, modified or corrected, withdrew lands for classification and protection of the public interest in lands in military reservations. The classification of the lands withdrawn by PLO No. 5187 has been satisfied by the analysis conducted

during the development of the Kobuk-Seward Pen RMP. PLO No. 5188, as amended, modified, or corrected, withdrew the lands in former reservations for classification and protection of the public interest for the use and benefit of Alaska Natives pursuant to Section 17(d)(1) of the Alaska Native Claims Settlement Act. The purposes of PLO No. 5188 were satisfied by the analysis conducted during the development of the BLM's Kobuk-Seward Pen RMP. PLO No. 5353, as amended, modified, or corrected, withdrew lands under the authority of ANCSA Sec. 17(d)(1), pending determination of eligibility of certain Native communities under ANCSA Sec. 11(b)(3), and classification of lands not conveyed pursuant to ANCSA Sec. 14. In the Kobuk-Seward Peninsula area, the Native Village of Council, Alaska, was determined eligible February 11, 1974, as well as the analysis conducted during the development of the Kobuk-Seward Pen RMP; therefore, the purpose for which PLO No. 5353 was withdrawn has been satisfied. Some lands covered by the revocation of the above listed withdrawals have been top filed by the State of Alaska per the Alaska Statehood Act. Upon revocation of the above listed withdrawals, the top filings will convert to selections, subject to valid existing rights. Lands validly selected by or conveyed to the State of Alaska are not subject to ANILCA Sec. 810, as they no longer fit the definition of public lands. The Sec. 810 analysis for the approved Kobuk-Seward Pen RMP found no significant restriction on subsistence uses due to this action.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, and Section 22(h)(4) of the Alaska Native Claims Settlement Act of 1971, 43 U.S.C. 1621(h)(4), it is ordered as follows:

1. Subject to valid existing rights, Public Land Orders No. 5169 (37 FR 4472 (1972)); 5170 (37 FR 5573 (1972)); 5171 (37 FR 5573 (1972)); 5173 (37 FR 5575 (1972)); 5179 (37 FR 5579 (1972)); 5180 (37 FR 5583 (1972)); 5184 (37 FR 5588 (1972)); 5186 (37 FR 5589 (1972)); 5187 (37 FR 5591 (1972)); 5188 (37 FR 5591 (1972)); and 5353 (38 FR 19825 (1973)) and any amendments, modifications or corrections to these Orders, if any, are hereby revoked insofar as they affect the following described Federal lands:

Kateel River Meridian, Alaska

T. 21 N., R. 3 E.,
Sec. 3, that portion outside the boundary of the Kobuk Valley National Park;
Secs. 4 thru 9;
Secs. 10 and 11, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 13 thru 24 and secs. 28 thru 33.
T. 10 N., R. 4 E., unsurveyed,
Secs. 1 thru 5;
Sec. 6, excepting lot 2, U.S. Survey No. 12331;
Sec. 7, excepting lots 1 and 2, U.S. Survey No. 12331;
Sec. 8, excepting U.S. Survey No. 13970;
Sec. 9, excepting U.S. Survey Nos. 12313 and 13970;
Secs. 10 thru 15;
Secs. 16 and 17, excepting U.S. Survey No. 13970;
Secs. 18 and 19;
Secs. 20 and 21, those portions outside the boundary of the Koyukuk National Wildlife Refuge;
Secs. 22 thru 26;
Secs. 27 thru 31 and sec. 34, those portions outside the boundary of the Koyukuk National Wildlife Refuge;
Secs. 35 and 36.
T. 11 N., R 4 E., unsurveyed,
Secs. 19 thru 36.
T. 19 N., R. 4 E.,
Secs. 19 thru 36.
T. 22 N., R. 4 E., unsurveyed,
Sec. 1;
Secs. 2 and 11, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 12 and 13;
Secs. 14 and 23, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 24 and 25;
Secs. 26, 27, and 33, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 34, 35, and 36.
T. 10 N., R. 5 E., unsurveyed,
Secs. 3 thru 10, secs. 15 thru 20, and sec. 30.
T. 11 N., R. 5 E., unsurveyed,
Secs. 1 thru 8;
Sec. 9, excepting U.S. Survey No. 12315;
Secs. 10 thru 15;
Sec. 16, excepting U.S. Survey No. 12315;
Secs. 17 thru 36.
T. 12 N., R. 5 E., unsurveyed,
Secs. 25 thru 36.
T. 13 N., R. 5 E., unsurveyed,
Secs. 1 thru 12.
Tps. 14 thru 17 N., R. 5 E., unsurveyed.
T. 18 N., R. 5 E.,
Secs. 4 thru 9 and secs. 16 thru 21;
Sec. 22, lot 1;
Sec. 23, lot 1;
Secs. 24 thru 36.
T. 22 N., R. 5 E.,
Secs. 4 thru 9, secs. 16 thru 21, sec. 26, secs. 28 thru 33, and sec. 35.
T. 13 N., R. 6 E., unsurveyed,
Secs. 1 thru 12.
Tps. 14, 15, and 16 N., R. 6 E., unsurveyed.
T. 17 N., R. 6 E.,
Secs. 1 thru 23;
Sec. 24, lots 1 and 2;
Sec. 25, lots 1 and 2;
Secs. 26 thru 32.
T. 19 N., R. 6 E.,
Secs. 1 thru 26 and secs. 35 and 36.
T. 20 N., R. 6 E.,
Secs. 13 thru 16 and secs. 19 thru 36.
T. 21 N., R. 6 E.,
Secs. 10 thru 15, secs. 22 thru 27, and secs. 34, 35, and 36.
T. 13 N., R. 7 E., unsurveyed,
Secs. 1 thru 12.
T. 14 N., R. 7 E., unsurveyed.
T. 15 N., R. 7 E.,
Sec. 1;
Secs. 2 thru 36, unsurveyed.
T. 16 N., R. 7 E.,
Secs. 14, 15, and 16, secs. 19 thru 23, and secs. 25 thru 36.
T. 20 N., R. 7 E.,
Secs. 1, 2, and 3 and secs. 10 thru 32;
Sec. 33, lot 1;
Secs. 34, 35, and 36.
T. 13 N., R. 8 E., unsurveyed,
Secs. 1 thru 12.
T. 14 N., R. 8 E., unsurveyed.
T. 15 N., R. 8 E.,
Secs. 1 thru 4, unsurveyed;
Secs. 5 and 6;
Secs. 7 thru 36, unsurveyed.
T. 16 N., R. 8 E.,
Secs. 1 thru 5, secs. 7 thru 17, and secs. 20 thru 36.
T. 20 N., R. 8 E.,
Secs. 1 thru 22 and secs. 29, 30, and 31.
T. 24 N., R. 8 E., unsurveyed,
Secs. 1, 2, and 3, secs. 10 thru 15, secs. 22 thru 27, and secs. 34, 35, and 36.
T. 11 N., R. 9 E., unsurveyed.
T. 12 N., R. 9 E., unsurveyed,
Secs. 25 thru 36.
Tps. 14 and 15 N., R. 9 E., unsurveyed.
T. 16 N., R. 9 E.,
Secs. 1 thru 4, unsurveyed;
Sec. 7;
Secs. 10 thru 15, unsurveyed;
Secs. 17 thru 20;
Secs. 22 thru 27 and secs. 30 thru 36, unsurveyed.
T. 20 N., R. 9 E.,
Sec. 1, secs. 3 thru 9, sec. 12, and secs. 15 thru 18.
T. 11 N., R. 10 E., unsurveyed,
Secs. 13, 14, and 15;
Sec. 16, excepting U.S. Survey No. 10040;
Secs. 17 thru 36.
T. 13 N., R. 10 E., unsurveyed,
Secs. 1, 2, and 3.
Tps. 14, 15, and 16 N., R. 10 E., unsurveyed.
T. 17 N., R. 10 E.,
Secs. 21 thru 36.
T. 13 N., R. 11 E., unsurveyed,
Secs. 1 thru 6, secs. 9 thru 16, secs. 21 thru 27, and secs. 34, 35, and 36.
Tps. 14 and 15 N., R. 11 E., unsurveyed.
T. 16 N., R. 11 E.,
Secs. 1 and 2, unsurveyed;
Secs. 3 thru 6;
Secs. 7 thru 36, unsurveyed.
T. 19 N., R. 11 E.,
Secs. 1 thru 4 and secs. 9 thru 14;
Sec. 15, lot 4;
Sec. 16, secs. 23 thru 26, and secs. 35 and 36.
T. 13 N., R. 12 E., unsurveyed.
Tps. 12 and 13 N., R. 13 E., unsurveyed.
T. 11 N., R. 14 E., unsurveyed,
Secs. 1 thru 27 and sec. 36.
T. 12 N., R. 14 E., unsurveyed,

Secs. 1 thru 7;
Sec. 8, excepting U.S. Survey No. 6337;
Secs. 9 thru 36.
T. 13 N., R. 14 E., unsurveyed.
Tps. 11, 12, and 13 N., R. 15 E., unsurveyed.
T. 7 N., R. 2 W., unsurveyed,
Secs. 25 thru 36.
T. 7 N., R. 3 W., unsurveyed,
Secs. 25 thru 36.
Tps. 1, 7 and 8 N., R. 4 W., unsurveyed.
Tps. 1 thru 8 N., R. 5 W., unsurveyed.
T. 9 N., R. 5 W., unsurveyed,
Sec. 1;
Sec. 2, excepting U.S. Survey No. 12311;
Secs. 3 thru 11;
Sec. 12, excepting U.S. Survey No. 12312;
Secs. 13 thru 36.
Tps. 1 and 2 N., R. 6 W., unsurveyed.
T. 3 N., R. 6 W., unsurveyed,
Sec. 1, excepting lot 2, U.S. Survey No. 11327;
Secs. 2 thru 10;
Sec. 11, excepting lots 1 and 3, U.S. Survey No. 11327;
Sec. 12, excepting lot 1, U.S. Survey No. 11327;
Secs. 13 thru 36.
T. 4 N., R. 6 W., unsurveyed,
Secs. 1 thru 17;
Sec. 18, excepting lot 2, U.S. Survey No. 11329;
Sec. 19, excepting lots 1 and 2, U.S. Survey No. 11329;
Secs. 20 thru 32;
Sec. 33, excepting U.S. Survey No. 11328;
Secs. 34, 35, and 36.
Tps. 5 thru 9 N., R. 6 W., unsurveyed.
T. 19 N., R. 6 W.,
Secs. 13 thru 20 and secs. 29 and 30.
Tps. 1 thru 9 N., R. 7 W., unsurveyed.
T. 19 N., R. 7 W.,
Secs. 13 thru 28;
Secs. 29, 30, and 31, excepting U.S. Survey No. 13879;
Secs. 32 thru 36.
T. 20 N., R. 7 W.,
Secs. 22, 23, and 24.
T. 23 N., R. 7 W., unsurveyed,
Secs. 4 and 5, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 6 and 7;
Secs. 8 and 17, those portions outside the boundary of the Kobuk Valley National Park;
Sec. 18;
Secs. 20, 21, 27, and 28, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 29, 31, 32, and 33;
Sec. 34, that portion outside the boundary of the Kobuk Valley National Park.
T. 24 N., R. 7 W., unsurveyed,
Secs. 2 and 3, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 4 thru 8;
Secs. 9, 10, 11, 16, and 17, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 18 and 19;
Secs. 20, 28, and 29, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 30, 31, and 32;
Sec. 33, that portion outside the boundary of the Kobuk Valley National Park.
T. 25 N., R. 7 W., unsurveyed,
Sec. 7, that portion outside the boundary of the Noatak National Preserve and Wilderness;
Sec. 8, that portion outside the boundaries of the Noatak National Preserve and Wilderness and the Kobuk Valley National Park;
Secs. 16 and 17, those portions outside the boundary of the Kobuk Valley National Park;
Sec. 18, that portion outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 19 and 20;
Secs. 21, 22, 27, and 28, those portions outside the boundary of the Kobuk Valley National Park;
Secs. 29 thru 33;
Secs. 34 and 35, those portions outside the boundary of the Kobuk Valley National Park.
Tps. 1 thru 4 N., R. 8 W., unsurveyed.
T. 5 N., R. 8 W., unsurveyed,
Secs. 1 thru 22;
Secs. 23 and 24, excepting U.S. Survey No. 11330;
Secs. 25 thru 36.
Tps. 6 thru 10 N., R. 8 W., unsurveyed.
T. 11 N., R. 8 W., unsurveyed,
Sec. 8;
Sec. 9, excepting lot 2, U.S. Survey No. 14141 and U.S. Survey No. 11994;
Sec. 10, excepting lot 1, U.S. Survey No. 14141 and U.S. Survey No. 11994;
Secs. 11 thru 36; lots 1 and 2, U.S. Survey No. 14141.
T. 23 N. R. 8 W., unsurveyed,
Secs. 1 thru 23 and secs. 26 thru 35.
T. 24 N., R. 8 W., unsurveyed.
T. 25 N., R. 8 W., unsurveyed,
Secs. 2 and 3, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 4 thru 10;
Secs. 11, 13, and 14, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 15 thru 36.
T. 26 N., R. 8 W., unsurveyed,
Secs. 16, 17, and 18, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 19 and 20;
Secs. 21, 22, 26, and 27, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 28 thru 33;
Sec. 34, that portion outside the boundary of the Noatak National Preserve and Wilderness.
Tps. 1 and 2 N., R. 9 W., unsurveyed.
T. 3 N., R. 9 W., unsurveyed,
Secs. 1 thru 5;
Sec. 6, excepting lots 1 and 2, U.S. Survey No. 11332;
Sec. 7, excepting lots 1 thru 5, U.S. Survey No. 11332;
Sec. 8, excepting lot 6, U.S. Survey No. 11332;
Secs. 9 thru 16;
Sec. 17, excepting lots 6, 7, and 8, U.S. Survey No. 11332;
Secs. 18 thru 36.
T. 4 N., R. 9 W., unsurveyed.
T. 5 N., R. 9 W., unsurveyed,
Secs. 1 thru 18;
Sec. 19, excepting lots 1 and 2, U.S. Survey No. 11335;
Sec. 20, excepting lots 1 and 6, U.S. Survey No. 11335;
Secs. 21 thru 28;
Sec. 29, excepting U.S. Survey No. 2018 and lots 1 thru 5 and lots 8 and 9, U.S. Survey No. 11335;
Sec. 30, excepting lots 1, 2, and 4, U.S. Survey No. 11335;
Secs. 31 thru 36; lot 9, U.S. Survey No. 11335.
Tps. 6 thru 9 N., R. 9 W., unsurveyed.
T. 10 N., R. 9 W., unsurveyed,
Secs. 1 thru 4;
Sec. 5, excepting U.S. Survey No. 12015;
Secs. 6 thru 36.
T. 11 N., R. 9 W., unsurveyed,
Sec. 13 and secs. 19 thru 36.
T. 18 N., R. 9 W.,
Secs. 4 thru 9 and secs. 16 thru 20.
T. 19 N., R. 9 W.,
Sec. 1, lots 1, 3, and 4;
Secs. 2 thru 36.
T. 20 N., R. 9 W.,
Secs. 1, 2, and 3.
T. 21 N., R. 9 W., unsurveyed,
Secs. 1 thru 18;
Sec. 19, excepting U.S. Survey No. 13978;
Secs. 20 thru 36.
T. 22 N., R. 9 W., unsurveyed,
Secs. 3 and 4, secs. 9 thru 17, and secs. 20 thru 36.
T. 23 N., R. 9 W., unsurveyed,
Secs. 33 and 34.
T. 26 N., R. 9 W., unsurveyed,
Secs. 13, 14, 22, and 23, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 24, 25, and 26;
Secs. 27, 34, and 35, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Sec. 36.
Tps. 6, 7, 8, and 10 N., R. 10 W., unsurveyed.
T. 11 N., R. 10 W., unsurveyed,
Secs. 6, 7, and 8 and secs. 13 thru 36.
T. 18 N., R. 10 W.,
Secs. 1 thru 24;
Sec. 25, lot 1;
Sec. 26;
Sec. 27, lot 1;
Sec. 28, lot 1;
Sec. 29, lot 1;
Sec. 30;
Sec. 31, lot 1;
Sec. 32, lot 2;
Sec. 34, lot 1;
Sec. 35, lot 2.
T. 19 N., R. 10 W.,
Secs. 7 and 8 and secs. 13 thru 36.
T. 21 N., R. 10 W., unsurveyed,
Secs. 1, 5, 6, and 7, secs. 11 thru 15, secs. 21 thru 28, and secs. 32 thru 36.
T. 22 N., R. 10 W., unsurveyed,
Secs. 2 thru 11, secs. 14 thru 22, and secs. 28 thru 32.
T. 23 N., R. 10 W., unsurveyed,
Secs. 31 thru 36.
T. 25 N., R. 10 W., unsurveyed,
Secs. 2 and 12, those portions outside the boundary of the Noatak National Preserve and Wilderness.
T. 26 N., R. 10 W., unsurveyed,
Secs. 19, 20, and 21 and secs. 27 thru 30, those portions outside the boundary of

the Noatak National Preserve and Wilderness;
Secs. 31, 32, and 33;
Sec. 34, that portion outside the boundary of the Noatak National Preserve and Wilderness.
T. 5 N., R. 11 W.,
Sec. 1, secs. 5 thru 9, sec. 12, secs. 16 thru 21, sec. 25, and secs. 27 thru 36.
T. 6 N., R. 11 W.,
Sec. 1, secs. 9 thru 15, secs. 22 thru 27, and secs. 35 and 36.
T. 7 N., R. 11 W.,
Secs. 1 thru 25 and sec. 36.
T. 8 N., R. 11 W.,
Secs. 1 thru 4, secs. 8 thru 17, and secs. 19 thru 36.
T. 10 N., R. 11 W., unsurveyed,
Secs. 1, 2, and 3, secs. 9 thru 15, secs. 23 thru 26, and secs. 35 and 36.
T. 11 N., R. 11 W., unsurveyed,
Secs. 1 thru 29 and secs. 33 thru 36.
T. 12 N., R. 11 W., unsurveyed,
Secs. 6, 7, and 8 and secs. 16 thru 21;
Sec. 26, excepting U.S. Survey No. 12326;
Secs. 27 thru 36.
T. 18 N., R. 11 W.,
Secs. 1 thru 24.
T. 19 N., R. 11 W.
T. 20 N., R. 11 W., unsurveyed,
Secs. 4, 12, and 19 and secs. 29 thru 34.
T. 21 N., R. 11 W., unsurveyed,
Sec. 1;
Secs. 2 and 3, excepting U.S. Survey No. 9139;
Secs. 9 thru 16;
Sec. 17, E½ and those lands west of the easterly bank of the Squirrel River, excepting U.S. Survey No. 6711;
Secs. 18 and 19, those lands west of the easterly bank of the Squirrel River, excepting U.S. Survey No. 6711;
Secs. 21 thru 24 and secs. 26, 27, 28, and 34.
T. 22 N., R. 11 W., unsurveyed,
Sec. 1 and secs. 3 thru 9;
Sec. 10, NW¼;
Sec. 11, E½;
Secs. 12, 13, and 14, secs. 17 thru 27, secs. 29 thru 32, and secs. 34, 35, and 36.
T. 23 N., R. 11 W., unsurveyed,
Secs. 3 thru 10, secs. 15 thru 22, and secs. 27 thru 34.
T. 24 N., R. 11 W., unsurveyed,
Secs. 1 thru 11;
Secs. 12 and 13, excepting U.S. Survey No. 13860;
Secs. 14 thru 24 and secs. 27 thru 34.
T. 25 N., R. 11 W., unsurveyed.
T. 26 N., R. 11 W., unsurveyed,
Secs. 17 and 18, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Sec. 19;
Secs. 20 thru 24, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 25 thru 29;
Secs. 30 and 31, those portions outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 32 thru 36.
T. 5 N., R. 12 W.
T. 9 N., R. 12 W.,
Secs. 15 thru 22 and secs. 27 thru 34.
T. 11 N., R. 12 W., unsurveyed,
Secs. 1 thru 6 and secs. 9 thru 14.
T. 12 N., R. 12 W., unsurveyed.
T. 13 N., R. 12 W., unsurveyed,
Sec. 23, excepting lot 6, U.S. Survey No. 6249;
Secs. 26, 27, 33, 34, and 35.
Tps. 18 and 19 N., R. 12 W.
T. 20 N., R. 12 W., unsurveyed,
Secs. 6 thru 9 and secs. 14 thru 36.
T. 21 N., R. 12 W., unsurveyed,
Secs. 4 thru 11;
Sec. 12, those lands right of the left bank of the Squirrel River;
Secs. 13 thru 27, secs. 29 thru 32, and sec. 36.
T. 22 N., R. 12 W., unsurveyed,
Secs. 1 and 2, secs. 4 thru 8, secs. 11 thru 14, secs. 17 thru 20, and secs. 23 thru 26;
Sec. 29, those lands right of the left bank of the Squirrel River;
Sec. 30, those lands within the left and right banks of the Squirrel River;
Sec. 31;
Sec. 32, those lands right of the left bank of the Squirrel River;
Sec. 33, those lands within the left and right banks of the Squirrel River;
Secs. 35 and 36.
Tps. 23 and 24 N., R. 12 W., unsurveyed.
T. 25 N., R. 12 W., unsurveyed,
Secs. 1, 2, 3, 9, and 10, those portions outside the boundary of the Noatak National Preserve;
Sec. 11;
Sec. 12, that portion outside the boundary of the Noatak National Preserve;
Secs. 13, 14, and 15;
Secs. 16, 17, 19, and 20, those portions outside the boundary of the Noatak National Preserve;
Secs. 21 thru 29;
Sec. 30, that portion outside the boundary of the Noatak National Preserve;
Secs. 31 thru 36.
T. 26 N., R. 12 W., unsurveyed,
Sec. 13, that portion outside the boundary of the Noatak National Preserve and Wilderness;
Secs. 24, 25, and 36, those portions outside the boundary of the Noatak National Preserve.
T. 5 N., R. 13 W.
T. 6 N., R. 13 W.,
Secs. 3 thru 10 and secs. 14 thru 36.
T. 7 N., R. 13 W.,
Secs. 1 thru 23 and secs. 27 thru 34.
T. 8 N., R. 13 W.
T. 9 N., R. 13 W., unsurveyed.
T. 10 N., R. 13 W., unsurveyed,
Secs. 26 thru 29 and secs. 31 thru 35.
T. 12 N., R. 13 W., unsurveyed,
Sec. 11, excepting lots 1 and 5, U.S. Survey No. 12324;
Sec. 12, excepting lot 5, U.S. Survey No. 12324;
Secs. 13 thru 16, secs. 19 thru 30, and secs. 33 thru 36.
T. 19 N., R. 13 W.,
Secs. 1 thru 30 and secs. 32 thru 36.
T. 20 N., R. 13 W., unsurveyed,
Secs. 1, 2, and 3;
Secs. 4 and 5, excepting U.S. Survey No. 8795;
Secs. 6 and 7;
Secs. 8 and 9, excepting U.S. Survey No. 8794;
Secs. 10 thru 15;
Secs. 16 and 17, excepting U.S. Survey No. 8794;
Secs. 18 thru 36.
T. 21 N., R. 13 W., unsurveyed,
Sec. 1, secs. 4 thru 9, and secs. 12 thru 36.
T. 22 N., R. 13 W., unsurveyed,
Secs. 1 thru 18;
Sec. 20, N½;
Secs. 22 and 27 and secs. 31 thru 36.
T. 23 N., R. 13 W., unsurveyed.
T. 24 N., R. 13 W., unsurveyed,
Sec. 1;
Secs. 2, 3, 8, 9, and 10, those portions outside the boundary of the Noatak National Preserve;
Secs. 11 thru 16;
Secs. 17 and 18, those portions outside the boundary of the Noatak National Preserve;
Secs. 19 thru 36.
T. 25 N., R. 13 W., unsurveyed,
Secs. 25 and 36, those portions outside the boundary of the Noatak National Preserve.
Tps. 5, 6, and 7 N., R. 14 W.
T. 8 N., R. 14 W.,
Secs. 1 thru 4, secs. 9 thru 16, secs. 21 thru 28, and secs. 32 thru 36.
T. 9 N., R. 14 W., unsurveyed,
Secs. 12 and 13, secs. 23 thru 26, and secs. 35 and 36.
T. 12 N., R. 14 W., unsurveyed,
Secs. 5 thru 8 and secs. 15 thru 30.
T. 13 N., R. 14 W., unsurveyed,
Sec. 31.
T. 19 N., R. 14 W.,
Secs. 1 thru 5, unsurveyed;
Sec. 6, unsurveyed, excepting U.S. Survey No. 10933;
Secs. 7 and 8;
Sec. 9, unsurveyed, excepting lot 2, U.S. Survey No. 10927;
Secs. 10 thru 14, unsurveyed;
Sec. 15, unsurveyed, excepting lots 1 and 2, U.S. Survey No. 10927;
Sec. 16;
Sec. 24, unsurveyed, excepting lot 1, U.S. Survey No. 10891.
T. 20 N., R. 14 W., unsurveyed.
T. 21 N., R. 14 W., unsurveyed,
Secs. 1 thru 29;
Secs. 30 and 31, those portions outside the boundary of the Noatak National Preserve;
Secs. 32 thru 36.
T. 22 N., R. 14 W., unsurveyed,
Secs. 1 thru 9, secs. 11 thru 14, secs. 16 thru 20, secs. 23 and 26, and secs. 29 thru 36.
T. 23 N., R. 14 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5, 7, 8, and 9, those portions outside the boundary of the Noatak National Preserve;
Secs. 10 thru 17;
Sec. 18, that portion outside the boundary of the Noatak National Preserve;
Secs. 19 thru 36.
T. 24 N., R. 14 W., unsurveyed,
Secs. 13, 14, 21, 22, and 23, those portions outside the boundary of the Noatak National Preserve;
Secs. 24 and 25;
Secs. 26 thru 29 and secs. 31 and 32, those portions outside the boundary of the Noatak National Preserve;

Secs. 33 thru 36.
T. 11 N., R. 15 W., unsurveyed,
Secs. 2 and 3.
T. 12 N., R. 15 W., unsurveyed,
Secs. 1 and 2;
Sec. 3, excepting lot 1, U.S. Survey No. 11667;
Sec. 10, excepting lots 1 and 2, U.S. Survey No. 11667;
Secs. 11 thru 15;
Sec. 22, excepting lot 1, U.S. Survey No. 12330;
Secs. 23 thru 27;
Secs. 34, 35, and 36.
T. 13 N., R. 15 W., unsurveyed,
Secs. 26 and 36.
T. 19 N., R. 15 W.,
Secs. 1, 2, and 3.
T. 20 N., R. 15 W., unsurveyed,
Secs. 1, 2, 9, 10, and 11, those portions outside the boundary of the Noatak National Preserve;
Secs. 12 thru 15;
Secs. 16 and 17, those portions outside the boundary of the Noatak National Preserve;
Secs. 20 thru 29 and secs. 31 thru 36.
T. 21 N., R. 15 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5, 8, and 9, those portions outside the boundary of the Noatak National Preserve;
Secs. 10 thru 14;
Secs. 15, 16, 17, 22, and 23, those portions outside the boundary of the Noatak National Preserve;
Sec. 24;
Secs. 25 and 26, those portions outside the boundary of the Noatak National Preserve.
T. 22 N., R. 15 W., unsurveyed,
Secs. 1 thru 18;
Secs. 19 and 20, those portions outside the boundary of the Noatak National Preserve;
Secs. 21 thru 27;
Secs. 28, 29, 32, and 33, those portions outside the boundary of the Noatak National Preserve;
Secs. 34, 35, and 36.
T. 23 N., R. 15 W., unsurveyed,
Secs. 6 thru 12, those portions outside the boundary of the Noatak National Preserve;
Secs. 13 thru 36.
T. 15 N., R. 16 W.,
Secs. 2 thru 6 and secs. 8, 9, 10, 15, 16, 22, and 27.
T. 16 N., R. 16 W.,
Secs. 29, 31, and 32.
T. 19 N., R. 16 W.,
Sec. 9, excepting Interim Conveyance Nos. 2150 and 2151;
Sec. 27, lots 1 and 2.
T. 22 N., R. 16 W., unsurveyed,
Secs. 1 and 2;
Secs. 3, 4, and 5, and secs. 8 thru 11, those portions outside the boundary of the Noatak National Preserve;
Sec. 12;
Secs. 13, 14, and 24, those portions outside the boundary of the Noatak National Preserve.
T. 23 N., R. 16 W., unsurveyed,
Secs. 1, 11, and 12, those portions outside the boundary of the Noatak National Preserve;
Sec. 13;
Secs. 14 and 23, those portions outside the boundary of the Noatak National Preserve;
Secs. 24 and 25;
Secs. 26, 27, 33, and 34, those portions outside the boundary of the Noatak National Preserve;
Secs. 35 and 36.
T. 15 N., R. 17 W.,
Secs. 1, 4, and 5.
T. 20 N., R. 17 W.,
Secs. 16, 17, 19, 20, and 23 and secs. 29 thru 32.
T. 26 N., R. 17 W.,
Secs. 5, 6, and 7.
T. 27 N., R. 17 W.,
Secs. 32 and 33.
T. 17 N., R. 18 W.,
Sec. 14, NW¼, excepting Patent No. 50–97–0162; tract 37.
T. 18 N., R. 18 W.,
Sec. 25, lot 6.
T. 20 N., R. 18 W.,
Secs. 5 thru 8 and secs. 16 thru 30.
T. 21 N., R. 18 W.,
Secs. 7 thru 11, secs. 13 thru 24, and secs. 26 thru 34.
T. 22 N., R. 18 W.,
Secs. 6 and 7, secs. 17 thru 21, and secs. 28, 29, and 30.
T. 23 N., R. 18 W.,
Secs. 1, 2, and 3, secs. 10 thru 15, secs. 22, 23, 24, and 27, and secs. 31 thru 34.
T. 24 N., R. 18 W.,
Secs. 25, 26, 34, 35, and 36.
T. 25 N., R. 18 W.,
Sec. 5, lot 1;
Secs. 8 and 17;
Sec. 19, lots 1 thru 4;
Secs. 30 and 31.
T. 26 N., R. 18 W.,
Secs. 12 thru 15 and sec. 21.
T. 27 N., R. 18 W.,
Sec. 33.
T. 32 N., R. 18 W., tract A.
T. 33 N., R. 18 W., tract A.
T. 6 N., R. 19 W.,
Sec. 19 and secs. 29 thru 32.
T. 20 N., R. 19 W., unsurveyed,
Sec. 1, that portion outside the boundary of the Cape Krusenstern National Monument.
T. 21 N., R. 19 W.,
Secs. 1 thru 17;
Secs. 18, 21, and 22, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 23, 24, and 25;
Secs. 26, 27, and 36, those portions outside the boundary of the Cape Krusenstern National Monument.
T. 22 N., R. 19 W.,
Secs. 1 thru 29 and secs. 31 thru 36.
T. 25 N., R. 19 W.,
lot 3, U.S. Survey No. 3778.
T. 33 N., R. 19 W.,
tract C.
T. 21 N., R. 20 W., unsurveyed,
Secs. 1, 2, and 3;
Secs. 4, 9, 10, and 11, those portions outside the boundary of the Cape Krusenstern National Monument;
Sec. 12;
Secs. 13 and 14, those portions outside the boundary of the Cape Krusenstern National Monument.
T. 22 N., R. 20 W.,
Secs. 1 thru 4, secs. 10 thru 14, secs. 18, 19, 20, and 24, and secs. 28 thru 35.
T. 24 N., R. 20 W.,
Secs. 7, 21, and 28.
T. 25 N., R. 20 W.,
Sec. 1, secs. 5 thru 8, secs. 17 thru 20, secs. 29 thru 32, and sec. 35.
T. 26 N., R. 20 W.,
Secs. 3, 4, and 5;
Secs. 6 and 7, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 8 thru 17;
Secs. 18 and 19, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 20 thru 36.
T. 27 N., R. 20 W., unsurveyed,
Secs. 1, 2, and 3;
Secs. 4 thru 7, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 8, 9, 10, 15, 16, and 17;
Secs. 18 and 19, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 20, 21, and 22;
Secs. 23, 24, and 25, excepting lot 1, U.S. Survey No. 6734;
Sec. 26, excepting lots 1 and 2, U.S. Survey No. 6734;
Sec. 27;
Sec. 28, excepting U.S. Survey No. 6733;
Secs. 29 thru 32;
Sec. 33, excepting U.S. Survey No. 6733;
Sec. 34;
Sec. 35, excepting lot 2, U.S. Survey No. 6734;
Sec. 36.
T. 33 N., R. 20 W., that portion of tract A, within secs. 13 thru 36.
T. 24 N., R. 21 W., unsurveyed,
Secs. 1 thru 3;
Secs. 4, 9, and 10, those portions outside the boundary of the Cape Krusenstern National Monument;
Secs. 11 thru 14;
Secs. 15, 22, and 23, those portions outside the boundary of the Cape Krusenstern National Monument;
Sec. 24;
Sec. 26, those portions outside the boundary of the Cape Krusenstern National Monument, excepting U.S. Survey No. 13923.
T. 25 N., R. 21 W., unsurveyed,
Secs. 1, 12, 13, 24, 25, 26, and 35, those portions outside the boundary of the Cape Krusenstern National Monument;
Sec. 36.
T. 26 N., R. 21 W., unsurveyed,
Secs. 1, 24, 25, and 36, those portions outside the boundary of the Cape Krusenstern National Monument.
T. 27 N., R. 21 W., unsurveyed,
Secs. 4, 5, 6, 13, 24, 25, and 36, those portions outside the boundary of the Cape Krusenstern National Monument.
T. 28 N., R. 21 W., unsurveyed,
Secs. 35 and 36, those portions outside the boundary of the Cape Krusenstern National Monument.
T. 30 N., R. 21 W., unsurveyed,
Secs. 27 and 34.
T. 33 N., R. 21 W.,

that portion of tract A, within secs. 25 thru 36.
T. 34 N., R. 21 W.,
tracts A, B, D, and E.
T. 30 N., R. 22 W., unsurveyed.
T. 31 N., R. 22 W., unsurveyed,
Secs. 19 thru 36.
T. 33 N., R. 22 W., unsurveyed,
Secs. 1 thru 12 and secs. 15 thru 19.
T. 34 N., R. 22 W., unsurveyed,
Sec. 13, secs. 24 thru 28, and secs. 33 thru 36.
T. 30 N., R. 23 W., unsurveyed.
T. 31 N., R. 23 W., unsurveyed,
Secs. 4 thru 9 and secs. 16 thru 36.
T. 32 N., R. 23 W., unsurveyed,
Secs. 4 thru 9, secs. 16 thru 21, and secs. 28 thru 33.
T. 33 N., R. 23 W., unsurveyed,
Secs. 6 and 13, secs. 23 thru 28, and secs. 30 thru 36.
T. 34 N., R. 23 W., unsurveyed,
Secs. 7 thru 24 and secs. 27 thru 33.
T. 27 N., R. 24 W.,
Secs. 1 thru 10, secs. 16 thru 21, and secs. 30 and 31.
T. 28 N., R. 24 W.,
Secs. 1 thru 12 and secs. 25, 35, and 36.
T. 29 N., R. 24 W.,
Secs. 1, 2, 11, and 12, secs. 24 thru 27, and secs. 34, 35, and 36.
T. 30 N., R. 24 W., unsurveyed,
Sec. 1;
Secs. 2 and 3, excepting U.S. Survey No. 13179;
Secs. 4 thru 16;
Secs. 17 and 18, excepting U.S. Survey No. 11923;
Secs. 19 thru 36.
T. 31 N., R. 24 W., unsurveyed.
T. 32 N., R. 24 W., unsurveyed,
Secs. 5 thru 8 and secs. 15 thru 36.
T. 33 N., R. 24 W., unsurveyed,
Secs. 1 thru 24 and secs. 26 thru 34.
T. 34 N., R. 24 W., unsurveyed.
T. 26 N., R. 25 W.,
Secs. 1, 2, 3, 11, and 12.
T. 27 N., R. 25 W.,
Secs. 1 thru 5, secs. 8 thru 30, and secs. 32 thru 36.
T. 28 N., R. 25 W.,
Secs. 1, 2, 11, 12, 14, 15, 16, 21, 22, and 23.
T. 29 N., R. 25 W.,
Secs. 1 thru 11, secs. 14 thru 22, and sec. 30.
Tps. 30 thru 34 N., R. 25 W., unsurveyed.
T. 29 N., R. 26 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5 and 6, excepting U.S. Survey No. 6852;
Secs. 7, 8, and 9;
Sec. 10, excepting U.S. Survey No. 6819;
Secs. 11 thru 36.
T. 30 N., R. 26 W., unsurveyed,
Secs. 1 thru 26;
Sec. 27, excepting U.S. Survey No. 6827;
Sec. 28, excepting U.S. Survey Nos. 6827 and 6830;
Secs. 29 thru 32;
Sec. 33, excepting U.S. Survey No. 6830;
Secs. 34, 35, and 36.
Tps. 31 thru 34 N., R. 26 W., unsurveyed.
T. 1 N., R. 27 W., unsurveyed,
Sec. 1, excepting M.S. No. 2545;
Secs. 2 thru 36;
M.S. No. 2545.
T. 2 N., R. 27 W., unsurveyed,
Sec. 5, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 6, 7, and 8;
Secs. 9, 10, 11, and 14, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 15 thru 22;
Secs. 23 and 24, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 25 thru 36.
T. 3 N., R. 27 W., unsurveyed,
Secs. 7, 18, and 31, those portions outside the boundary of the Bering Land Bridge National Preserve.
T. 4 N., R. 27 W., unsurveyed,
Secs. 4, 5, and 6, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 7, 8, and 9;
Secs. 10 and 11, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 14 thru 21;
Secs. 22 and 23, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 29, 30, and 31;
Sec. 32, that portion outside the boundary of the Bering Land Bridge National Preserve.
Tps. 30 thru 34 N., R. 27 W., unsurveyed.
T. 29 N., R. 28 W., unsurveyed,
Secs. 1 and 2;
Secs. 3 and 11, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 12 and 13.
Tps. 31 thru 34 N., R. 28 W., unsurveyed.
T. 30 N., R. 29 W., unsurveyed,
Sec. 3, that portion outside the boundary of the Alaska Maritime National Wildlife Refuge;
Sec. 11.
T. 31 N., R. 29 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5 and 8, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 9 thru 14;
Secs. 15, 16, 17, and 22, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 23 thru 26;
Secs. 27 and 34, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge.
T. 32 N., R. 29 W., unsurveyed,
Secs. 1 thru 18;
Secs. 19 and 20, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 21 thru 27;
Secs. 28, 29, and 32, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 33 thru 36.
T. 32 N., R. 30 W., unsurveyed,
Secs. 1, 2, and 3;
Secs. 4 and 9, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 10, 11, and 12;
Secs. 13 thru 16 and secs. 23, 24, and 25, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge.
T. 34 N., R. 30 W., unsurveyed,
Secs. 10 thru 15, secs. 22 thru 27, and secs. 34, 35, and 36.
T. 8 N., R. 32 W.,
Secs. 23 thru 26 and secs. 35 and 36.
T. 9 N., R. 32 W.,
Secs. 2 thru 6 and secs. 8 thru 11.
T. 8 N., R. 33 W.,
Sec. 31.
T. 10 N., R. 33 W.,
Secs. 1 and 2, secs. 11 thru 14, secs. 23 thru 26, and sec. 36.
T. 11 N., R. 33 W.,
Secs. 25, 35, and 36.
T. 8 N., R. 34 W.,
Secs. 30 thru 36.
T. 8 N., R. 35 W.,
Secs. 24, 25, and 36.
T. 1 N., R. 36 W.
T. 8 N., R. 36 W.,
Secs. 2 and 3, secs. 7 thru 11, secs. 14 thru 23, and secs. 27 thru 34.
T. 8 N., R. 37 W.,
Secs. 10 thru 15 and secs. 19 thru 36.
T. 1 N., R. 38 W.,
tracts A and B.
T. 5 N., R. 38 W., unsurveyed,
Secs. 1 thru 5;
Sec. 6, excepting U.S. Survey No. 12266;
Secs. 7 thru 36.
T. 1 N., R. 39 W.,
Secs. 1, 2, and 3.
T. 5 N., R. 39 W., unsurveyed.
T. 4 N., R. 40 W., unsurveyed,
Secs. 1, 2, and 3, secs. 10 thru 15, and secs. 19 thru 36.
T. 2 N., R. 41 W.,
Secs. 5, 8, and 17.
T. 3 N., R. 41 W.,
Secs. 13 thru 16, secs. 21 thru 28, and secs. 32 thru 36.
T. 4 N., R. 41 W., unsurveyed,
Secs. 19 thru 36.
T. 2 N., R. 42 W.,
Secs. 4, 5, 6, 9, and 16, secs. 21 thru 24, and secs. 26 and 27.
T. 3 N., R. 42 W.,
Secs. 1 thru 18.
T. 4 N., R. 42 W., unsurveyed,
Secs. 1, 2, and 3, secs. 8 thru 16, and secs. 21 thru 26;
Sec. 27, excepting U.S. Survey No. 13902;
Sec. 28;
Sec. 29, excepting U.S. Survey No. 13183;
Secs. 31 thru 36.
T. 2 N., R. 43 W.,
Secs. 5, 6, and 7.
T. 3 N., R. 43 W.,
Secs. 31 and 32.
T. 2 N., R. 44 W.,
tract 37.
T. 3 N., R. 44 W.,
Secs. 25, 26, and 27 and secs. 33 thru 36.
T. 2 N., R. 45 W.,
tracts 37 and 38.
Tps. 1 and 2 S., R. 4 W., unsurveyed.
Tps. 1 thru 6 S., R. 5 W., unsurveyed.
Tps. 1 thru 5 S., R. 6 W., unsurveyed.
T. 6 S., R. 6 W., unsurveyed,
Secs. 1 thru 31;
Sec. 32, excepting U.S. Survey No. 13579;
Secs. 33 thru 36.

Tps. 7 and 8 S., R. 6 W., unsurveyed.
Tps. 1 thru 10 S., R. 7 W., unsurveyed.
T. 11 S., R. 7 W., unsurveyed,
Secs. 1 thru 28;
Sec. 29, excepting U.S. Survey No. 13578;
Secs. 30 thru 36.
Tps. 1 thru 13 S., R. 8 W., unsurveyed.
Tps. 1 thru 4 S., R. 9 W., unsurveyed.
T. 5 S., R. 9 W., unsurveyed,
Secs. 1 thru 30;
Sec. 31, excepting lot 1, U.S. Survey No. 12420;
Secs. 32 thru 36.
T. 6 S., R. 9 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5 and 6, excepting U.S. Survey No. 12420;
Secs. 7 thru 36.
Tps. 7, 8, and 9 S., R. 9 W., unsurveyed.
T. 10 S., R. 9 W., unsurveyed,
Secs. 1 thru 30 and secs. 32 thru 36.
T. 11 S., R. 9 W., unsurveyed,
Secs. 1 thru 5 and secs. 8 and 9;
Sec. 10, excepting U.S. Survey No. 13575;
Secs. 11 thru 36.
Tps. 12, 13, and 14 S., R. 9 W., unsurveyed.
Tps. 4, 5, and 6 S., R. 10 W., unsurveyed.
T. 7 S., R. 10 W.,
Secs. 1 thru 29 and secs. 34, 35, and 36.
T. 8 S., R. 10 W., unsurveyed,
Sec. 1, excepting U.S. Survey No. 12432;
Sec. 2 and secs. 6 thru 36.
T. 9 S., R. 10 W.,
Sec. 36;
tracts A thru T.
T. 10 S., R. 10 W.,
Secs. 1, 12, 13, 24, and 25;
tracts A thru U.
T. 11 S., R. 10 W., unsurveyed,
Secs. 3 thru 5;
Sec. 6, excepting U.S. Survey No. 13564;
Sec. 7, excepting M.S. Nos. 1245, 1894, 1895, 2331, and U.S. Survey No. 13564;
Sec. 8, excepting M.S. Nos. 1245, 1894, and U.S. Survey No. 13564;
Secs. 9 and 10 and secs. 13 thru 16;
Secs. 17 and 18, excepting M.S. No. 1894;
Secs. 19 thru 36.
T. 12 S., R. 10 W., unsurveyed.
T. 13 S., R. 10 W., unsurveyed,
Secs. 1 thru 5;
Secs. 6 and 7, excepting U.S. Survey No. 13903;
Secs. 8 thru 36.
Tps. 14 and 15 S., R. 10 W., unsurveyed.
T. 3 S., R. 11 W.
T. 4 S., R. 11 W.,
Secs. 1 thru 16, sec. 18, secs. 21 thru 28, and secs. 34, 35, and 36.
T. 5 S., R. 11 W.,
Secs. 1 thru 4, secs. 9 thru 15, sec. 19, secs. 22 thru 27, secs. 30, 31, 34, 35, and 36.
T. 6 S., R. 11 W.,
Secs. 1, 2, 6, and 7, secs. 11 thru 15, secs. 22 thru 28, and secs. 32 thru 36.
T. 7 S., R. 11 W.,
Secs. 1 thru 22, secs. 24, 27, and 28.
T. 8 S., R. 11 W., unsurveyed,
Secs. 13, 14, 24, and 25.
T. 10 S., R. 11 W., unsurveyed,
Sec. 24, excepting lot 1, U.S. Survey No. 12250;
Sec. 25;
Sec. 34, excepting lot 1, U.S. Survey No. 12265;
Secs. 35 and 36.
T. 11 S., R. 11 W.,
Sec. 12;
Secs. 29 thru 36;
M.S. No. 2331.
T. 12 S., R. 11 W., unsurveyed.
T. 13 S., R. 11 W.,
Secs. 19 thru 36.
T. 14 S., R. 11 W., unsurveyed,
Secs. 1 thru 28 and secs. 33 thru 36.
T. 15 S., R. 11 W.,
Secs. 1 thru 5 and secs. 8 thru 36.
T. 3 S., R. 12 W.,
Secs. 1, 2, 3, 6, and 7, secs. 10 thru 15, secs. 18 and 19, secs. 22 thru 27, secs. 30, 34, 35, and 36.
T. 4 S., R. 12 W.,
Secs. 1, 2, and 3 and secs. 10 thru 13.
T. 5 S., R. 12 W.,
Secs. 1 thru 5, secs. 8 thru 12, secs. 16, 17, 19, 20, 24, 25, and 26, and secs. 29 thru 36.
T. 12 S., R. 12 W.,
Secs. 1 thru 4, secs. 9 thru 16, and secs. 23 and 24.
T. 13 S., R. 12 W.,
Sec. 25;
U.S. Survey No. 2046.
T. 14 S., R. 12 W.,
Sec. 1.
T. 1 S., R. 13 W.,
that portion of tract A, within sec. 24, S½;
that portion of tract A, within sec. 25, N½;
U.S. Survey No. 13586.
T. 3 S., R. 13 W.
T. 4 S., R. 13 W.,
Secs. 5, 6, 7, 19, 27, and 28 and secs. 33 thru 36.
T. 5 S., R. 13 W.,
Secs. 1 thru 12, secs. 14 thru 23, and secs. 28 thru 36.
T. 6 S., R. 13 W.,
Secs. 1 thru 30.
T. 7 S., R. 13 W.,
Secs. 2 thru 10, secs. 15 thru 20, and secs. 29, 30, and 31.
T. 8 S., R. 13 W.,
Sec. 6.
Tps. 3 and 4 S., R. 14 W., unsurveyed.
T. 5 S., R. 14 W.,
Sec. 12;
tracts A, B, and C.
Tps. 6 and 7 S., R. 14 W.
T. 8 S., R. 14 W.,
Secs. 1 thru 4, secs. 9 thru 12, secs. 14, 15, and 16, and secs. 21 thru 24.
Tps. 3, 4, and 5 S., R. 15 W., unsurveyed.
T. 6 S., R. 15 W.,
Secs. 1 and 2.
Tps. 3, 4 and 5 S., R. 16 W., unsurveyed.
T. 6 S., R. 16 W.,
tract A.
T. 3 S., R. 17 W., unsurveyed,
Secs. 1, 2, 6, and 7, secs. 11 thru 15, sec. 18, secs. 22 thru 28, and secs. 33 thru 36.
T. 4 S., R. 17 W., unsurveyed,
Secs. 1 thru 29 and secs. 32 thru 36.
T. 5 S., R. 17 W.,
Secs. 1, 2, and 3, secs. 10 thru 15, and secs. 22 thru 36.
T. 6 S., R. 17 W.,
Sec. 35;
tract A.
T. 3 S., R. 18 W.,
Secs. 1 thru 6 and secs. 10 thru 13;
Sec. 25, S½, excepting U.S. Survey No. 13777;
Sec. 36, N½, excepting U.S. Survey No. 13777.
T. 6 S., R. 18 W., unsurveyed,
Secs. 1 thru 4, secs. 9 thru 16, secs. 21 thru 29, and secs. 32 thru 36.
T. 7 S., R. 18 W.,
that portion of tract A, within secs. 1 thru 5, secs. 7 thru 11, secs. 15 thru 21, and secs. 29 thru 32.
T. 8 S., R. 18 W.,
tract A.
T. 2 S., R. 19 W., unsurveyed.
T. 3 S., R. 19 W., unsurveyed,
Secs. 1 thru 10 and sec. 18.
T. 4 S., R. 19 W., unsurveyed,
Secs. 4 thru 9, secs. 15 thru 21, and secs. 29 and 30.
T. 7 S., R. 19 W., unsurveyed,
Secs. 24, 25, 35, and 36.
Tps. 8 and 9 S., R. 19 W.,
T. 2 S., R. 20 W., unsurveyed,
Secs. 1, 2, and 3 and secs. 10 thru 15;
Sec. 22, that portion outside the boundary of the Bering Land Bridge National Preserve;
Sec. 23 thru 26;
Secs. 27, 32, and 33, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 34, 35, and 36.
T. 3 S., R. 20 W., unsurveyed,
Secs. 1 thru 4;
Secs. 5 and 6, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 7 thru 24 and secs. 26 thru 34.
T. 4 S., R. 20 W., unsurveyed,
Secs. 4 thru 8, secs. 13 and 14, and secs. 22 thru 29;
Sec. 30, excepting U.S. Survey No. 13778;
Secs 31 thru 34.
T. 5 S. R. 20 W., unsurveyed,
Secs. 5 thru 8, secs. 16 thru 20, and secs. 28 thru 34.
T. 6 S., R. 20 W., unsurveyed,
Secs. 5 thru 10, secs. 15 thru 22, and secs. 27 thru 33;
Sec. 34, excepting U.S. Survey No. 9550.
T. 7 S., R. 20 W., unsurveyed,
Secs 3, 4, and 5;
Sec. 6, excepting U.S. Survey No. 13781;
Secs. 7 thru 10 and secs. 16 thru 19;
Secs. 20 and 21, excepting U.S. Survey No. 13780;
Sec. 26, W½;
Sec. 27, E½;
Secs. 28 thru 33.
T. 8 S., R. 20 W., unsurveyed,
Secs. 3 thru 10 and secs. 14 thru 17;
Sec. 18, excepting U.S. Survey No. 13785;
Secs. 19 thru 23 and secs. 25 thru 36.
T. 9 S., R. 20 W.,
Secs. 1, 12, 13, and 24;
tract A.
T. 10 S., R. 20 W.,
that portion of tract A, within secs. 6, 7, 18, and 19, and secs. 29 thru 32.
T. 11 S., R. 20 W.,
Secs. 4 thru 9, secs. 16 thru 21, and secs. 28 thru 33.
T. 12 S., R. 20 W.,
Sec. 4;
Sec. 5, excepting U.S. Survey No. 13782;
Secs. 6 thru 9 and secs. 16, 17, and 18.
T. 2 S., R. 21 W., unsurveyed,

Secs. 18, 19, 20, 27, 28, and 29, those portions outside of the Bering Land Bridge National Preserve;
Secs. 30 thru 33;
Secs. 34, 35, and 36, those portions outside the boundary of the Bering Land Bridge National Preserve.
T. 3 S., R. 21 W.,
Sec. 1, unsurveyed, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 2 thru 12, unsurveyed;
Sec. 13, unsurveyed, excepting lots 1 and 2, U.S. Survey No. 10284;
Sec. 14, unsurveyed, excepting lot 1, U.S. Survey No. 10284;
Secs. 15 thru 22, unsurveyed;
Sec. 24, unsurveyed, excepting tract 37, and lot 3, U.S. Survey No. 10284 and U.S. Survey No. 13775;
Sec. 25, unsurveyed, secs. 27 thru 34, and sec. 36;
tract 37.
T. 4 S., R. 21 W., unsurveyed,
Secs. 6, 22, 23, 25, 26, 27, 34, 35, and 36.
T. 5 S., R. 21 W., unsurveyed,
Secs. 1 thru 4, secs. 9 thru 16, secs. 21 thru 28, and secs. 33 thru 36.
T. 6 S., R. 21 W., unsurveyed,
Secs. 1 thru 4 and secs. 7 and 8;
Sec. 9, excepting U.S. Survey No. 9715;
Secs. 10 thru 15;
Sec. 16, excepting U.S. Survey No. 9715;
Secs. 17 thru 22;
Secs. 23, 24, and 25, excepting U.S. Survey No. 9714;
Secs. 26 thru 36.
T. 7 S., R. 21 W., unsurveyed,
Sec. 1, excepting U.S. Survey No. 13781;
Secs. 2 thru 33;
Secs. 34 and 35, excepting U.S. Survey No. 14002;
Sec. 36.
T. 8 S., R. 21 W., unsurveyed,
Sec. 1;
Secs. 2 and 3, excepting U.S. Survey No. 14002;
Secs. 4 thru 30;
Sec. 31, excepting U.S. Survey No. 10048;
Secs. 32 thru 36.
T. 9 S., R. 21 W.,
tract A.
T. 10 S., R. 21 W.,
tract A., excepting U.S. Survey No. 13783.
T. 11 S., R. 21 W.,
Secs. 1, 2, and 3;
Sec. 10, lot 1;
Sec. 11;
Secs 12 and 13, excepting U.S. Survey No. 13784.
T. 1 S., R. 22 W., unsurveyed,
Secs 32 and 33, those portions outside the boundary of the Bering Land Bridge National Preserve.
T. 2 S., R. 22 W., unsurveyed,
Secs. 3 thru 6, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 7, 8 and 9;
Secs. 10 thru 13, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 14 thru 36.
T. 3 S., R. 22 W., unsurveyed,
Secs. 1 thru 30 and secs. 32 thru 36.
T. 5 S., R. 22 W., unsurveyed,
Sec. 24, excepting lots 3 and 4, U.S. Survey No. 9706.
T. 6 S., R. 22 W., unsurveyed,
Secs. 7 and 8;
Sec. 9, excepting lot 1, U.S. Survey No. 9934;
Sec. 10, excepting lots 2 and 3, U.S. Survey No. 9931, lots 1 and 2, U.S. Survey No. 9934, and lots 1 thru 3, U.S. Survey No. 9935;
Secs. 11 thru 14;
Sec. 15, excepting lots 1 and 2, U.S. Survey 9930, lots 1 thru 3, U.S. Survey No. 9931, lots 1 thru 3, U.S. Survey No. 9932, lots 1 and 2, U.S. Survey No. 9933, and lot 2, U.S. Survey No. 9934.
Sec. 16, excepting lot 2, U.S. Survey No. 9930 and lot 2, U.S. Survey No. 9932;
Secs. 17, 18, and 19;
Sec. 20, excepting lot 1, U.S. Survey No. 14004;
Sec. 21, excepting lots 1 thru 3, U.S. Survey No. 14004;
Secs. 22 thru 27;
Sec. 28, excepting lots 1 and 2, U.S. Survey No. 14004;
Sec. 29, excepting U.S. Survey No. 13996 and lot 1, U.S. Survey No. 14004;
Secs. 30 thru 36.
T. 7 S., R. 22 W.,
tract B.
T. 8 S., R. 22 W.,
tracts A thru E.
T. 9 S., R. 22 W.,
Secs. 4 and 9;
tract B.
T. 12 S., R. 22 W.,
Secs. 6, 7, 18, 19, and 30.
T. 1 S., R. 23 W., unsurveyed,
Sec. 33, that portion outside the boundary of the Bering Land Bridge National Preserve.
T. 2 S., R. 23 W., unsurveyed,
Secs. 1 thru 6, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 7, 8, and 9;
Secs. 10 and 11, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 12 thru 36.
T. 3 S., R. 23 W., unsurveyed,
Secs. 1 thru 33.
T. 4 S., R. 23 W., unsurveyed,
Secs. 5 and 6.
T. 5 S., R. 23 W., unsurveyed,
Secs. 31 thru 34.
T. 6 S., R. 23 W.,
that portion of tract A, within secs. 2 thru 17, and 19 thru 36.
T. 7 S., R. 23 W.,
Sec. 1, excepting U.S. Survey No. 13861;
Secs. 2 thru 10, sec. 13, secs. 16 thru 20, secs. 23 thru 26, and secs. 35 and 36.
T. 8 S., R. 23 W.,
Secs. 1 and 2, secs. 11 thru 14, and sec. 25.
T. 11 S., R. 23 W.,
Secs. 17 thru 20 and secs. 27, 28, and 29;
Secs. 34 and 35.
T. 1 S., R. 24 W., unsurveyed,
Secs. 34 and 36, that portion outside the boundary of the Bering Land Bridge National Preserve.
T. 2 S., R. 24 W., unsurveyed,
Secs. 1, 2, 3, 9, and 10, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 11 thru 15;
Secs. 16, 17, 19, and 20, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 21 thru 29;
Sec. 30, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 31 thru 36.
T. 3 S., R. 24 W., unsurveyed.
T. 4 S., R. 24 W., unsurveyed,
Secs. 1 thru 22 and secs. 27 thru 33.
T. 5 S., R. 24 W.,
Secs. 19, 20, 29, and 30, and secs. 33 thru 36, unsurveyed;
tract A.
T. 6 S., R. 24 W.,
Secs. 1 thru 6, sec. 12, secs. 21 thru 28, and secs. 33 thru 36.
T. 7 S., R. 24 W.,
Secs. 4, 9, 22, 23, and 24;
tract U.
T. 8 S., R. 24 W.,
tract D.
T. 10 S., R. 24 W.,
Secs. 4 thru 9, secs. 16 thru 21, and secs. 28 thru 33.
T. 2 S., R. 25 W., unsurveyed,
Secs. 19, 25, 30, 31, 32, 35, and 36, those portions outside the boundary of the Bering Land Bridge National Preserve.
T. 3 S., R. 25 W. unsurveyed,
Sec. 1;
Secs. 2, 3, and 5, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 6 and 7;
Secs. 8, 9, and 10, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 11 thru 16;
Sec. 17, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 18 thru 36.
T. 4 S., R. 25 W., unsurveyed.
T. 6 S., R. 25 W.,
Sec. 22;
tracts D, E, F, P thru U, X, and Y;
that portion of tract Z, within secs. 16, 21, and 33;
tract B1.
T. 9 S., R. 25 W.,
Sec. 1, lot 2;
Secs. 2 and 3 and secs. 7 thru 24.
T. 10 S., R. 25 W.,
Secs. 1 thru 4, secs. 10 thru 15, secs. 22 thru 26, and secs. 35 and 36.
T. 1 S., R. 26 W., unsurveyed,
Secs. 7, 17 and 18, those portions outside the boundary of the Bering Land Bridge National Preserve;
Sec. 19,
Secs. 20, 21, 27, and 28, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 29 thru 33;
Secs. 34 and 35, those portions outside the boundary of the Bering Land Bridge National Preserve.
T. 2 S., R. 26 W., unsurveyed,
Sec. 2, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 3 thru 10;

Secs. 11, 12, and 13, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 14 thru 23;
Sec. 24, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 25 thru 36.
T. 3 S., R. 26 W., unsurveyed.
T. 4 S., R. 26 W., unsurveyed,
Secs. 1 thru 5;
Sec. 6, excepting U.S. Survey No. 13788;
Secs. 7 thru 36.
T. 5 S., R. 26 W., unsurveyed.
T. 1 S., R. 27 W., unsurveyed,
Secs. 1, 2 and 3, those portions outside the boundary of the Bering Land Bridge National Preserve;
Secs. 4 thru 11;
Sec. 12, that portion outside the boundary of the Bering Land Bridge National Preserve;
Secs. 13 thru 36.
Tps. 2, 3, and 4 S., R. 27 W., unsurveyed.
Tps. 1 thru 4 S., R. 28 W., unsurveyed.
T. 2 S., R. 29 W.,
Secs. 1, 2, and 3 and secs. 10 thru 14, unsurveyed;
Sec. 15, unsurveyed, excepting U.S. Survey No. 11133;
Sec. 21, unsurveyed, excepting M.S. 1144;
Secs. 22 thru 26, unsurveyed;
Sec. 27, unsurveyed, excepting M.S. 1144;
Secs. 31 thru 34, unsurveyed;
Secs. 35 and 36, unsurveyed, excepting U.S. Survey No. 14169;
tracts F and G.
T. 4 S., R. 29 W., unsurveyed,
Secs. 1 thru 18, secs. 21 thru 28, and secs. 33 thru 36.
T. 4 S., R. 30 W.,
that portion of tract E, within secs.7 thru 9, secs. 15 thru 22, and sec. 28;
tracts F, G, and H;
that portion of tract X, within sec. 28;
tracts Y and Z;
that portion of tract GG, within sec. 28.
T. 5 S., R. 30 W.,
tract A.
T. 1 S., R. 31 W., unsurveyed,
Secs. 1 thru 7;
Sec. 8, excepting lot 1, U.S. Survey No. 11602;
Secs. 9 thru 18;
Sec. 19, excepting lot 2, U.S. Survey No. 11602;
Secs. 20 thru 36.
T. 2 S., R. 31 W., unsurveyed.
T. 3 S., R. 31 W.,
tracts A, B, and C.
T. 5 S., R. 31 W.,
Secs. 19 thru 36, unsurveyed;
tract B, excepting U.S. Survey No. 13910;
U.S. Survey No. 13910.
T. 6 S., R, 31 W., unsurveyed,
Secs. 5 and 6.
T. 7 S., R. 31 W.,
lot 23, U.S. Survey No. 4212;
U.S. Survey No. 13719.
T. 9 S., R. 31 W., unsurveyed,
Sec. 6, excepting U.S. Survey No. 11462;
Sec. 7 and secs. 17 thru 21.
T. 10 S., R. 31 W.,
Sec. 32.
Tps. 1 and 2 S., R. 32 W., unsurveyed.
T. 3 S., R. 32 W.,
tract E.
T. 4 S., R. 32 W.,
Sec. 19;
Sec. 27, excepting U.S. Survey No. 13917;
Sec. 28;
Sec. 29, lot 2;
that portion of tract JJ, within Sec. 35;
tracts KK thru MM.
T. 5 S., R. 32 W., unsurveyed.
T. 6 S., R. 32 W., unsurveyed,
Secs. 1 thru 21;
Secs. 33, S½NE¼, SE¼NW¼, E½SW¼, and SE ¼;
Sec. 34, W½SW¼.
T. 1 S., R. 33 W., unsurveyed.
T. 2 S., R. 33 W., unsurveyed,
Secs. 1 thru 21;
Sec. 22, excepting U.S. Survey No. 11603;
Secs. 23 thru 36;
lot 2, U.S. Survey No. 11603.
T. 3 S., R. 33 W.,
tract V.
T. 4 S., R. 33 W.,
tract R;
that portion of tract DD, within secs. 27 and 32;
tract EE.
Tps. 5 and 6 S., R. 33 W., unsurveyed.
T. 1 S., R. 34 W., unsurveyed,
Secs. 1 thru 32, and secs. 34, 35, and 36.
T. 2 S., R. 34 W., unsurveyed,
Secs. 1, 2, 3, 5, and 6, secs. 10 thru 16, secs. 20 thru 29, and secs. 31 thru 36.
T. 3 S., R. 34 W., unsurveyed,
Secs. 1 thru 6, secs. 8 thru 14;
Sec. 15, excepting U.S. Survey Nos. 11194 and 11604;
Secs. 16, 23, 24 and 26.
T. 6 S., R. 34 W., unsurveyed,
Secs. 3 thru 10, secs. 15 thru 22, and secs. 27 thru 34.
T. 7 S., R. 34 W., unsurveyed,
Secs. 3 thru 10, secs. 15 thru 20, and sec. 30.
T. 1 S., R. 35 W., unsurveyed,
Secs. 1 and 2, excepting U.S. Survey No. 11198;
Secs. 3 thru 29, and secs. 32 thru 36.
T. 2 S., R. 35 W., unsurveyed,
Secs. 1 thru 5, secs. 8 thru 17, secs. 20, 21, 22, 28, 29, 31, 32, and 33.
T. 3 S., R. 35 W.,
Secs. 3 thru 10;
Sec. 11, excepting lot 2, U.S. Survey No. 14175;
Secs. 13 thru 30;
Sec. 33, excepting U.S. Survey Nos. 14113 and 14174;
Sec. 34;
Sec. 35;
Sec. 36.
T. 5 S., R. 35 W., unsurveyed,
Sec. 7, secs. 16 thru 23, and secs. 29, 30, and 31.
T. 6 S., R. 35 W., unsurveyed,
Sec. 1 and secs. 10 thru 36.
T. 7 S., R. 35 W., unsurveyed,
Secs. 1 thru 10, secs. 12 and 13, secs. 15 thru 22, secs. 24 and 25, and secs. 27 thru 33.
T. 1 S., R. 36 W., unsurveyed,
Secs. 1, 6, 12, and 13.
T. 2 S., R. 36 W.,
Sec. 10;
Sec. 15, lot 1;
that portion of tract A, within secs. 7, 8, 11, and 12;
tracts B and D.
T. 3 S., R. 36 W.,
Sec. 13.
T. 4 S., R. 36 W.,
tracts C and E.
T. 5 S., R. 36 W., unsurveyed,
Secs. 2, 3, 4, and 6, secs. 9 thru 17, secs. 20 thru 28, and secs. 34, 35, and 36.
T. 6 S., R. 36 W., unsurveyed,
Sec. 3 and secs. 23 thru 36.
T. 7 S., R. 36 W., unsurveyed.
T. 8 S., R. 36 W., unsurveyed,
Secs. 6, 7, and 8.
T. 9 S., R. 36 W.,
Secs. 19 and 20 and secs. 29 thru 32.
T. 10 S., R. 36 W., unsurveyed,
Secs. 5 and 6.
T. 1 S., R. 37 W., unsurveyed,
Secs. 1 thru 19 and secs. 21, 22, 23, and 30.
T. 5 S., R. 37 W.,
Sec. 1;
Sec. 2, lot 1.
T. 6 S., R. 37 W.,
that portion of tract A, within secs. 25, 26, 27, 34, 35, and 36.
T. 7 S., R. 37 W.,
tracts B thru G;
that portion of tract H within secs. 1, 2, 3, secs. 10 thru 15, secs. 22 thru 28, and secs. 33 thru 36.
T. 1 S., R. 38 W.,
Sec. 29;
tract A.
T. 4 S., R. 38 W.,
Sec. 31;
that portion of tract A, within secs. 1 and 2, 11 thru 14, 21 thru 24, 27, 28, 33, and 34.
T. 5 S., R. 38 W.,
that portion of tract B, within secs. 19 and 20;
that portion of tract D, within secs. 31, 32, and 33.
T. 6 S., R. 38 W.,
Secs. 4 thru 10, secs. 15 thru 18, and secs. 20, 21, 22, and 29.
T. 4 S., R. 39 W.,
Secs. 35 and 36.
T. 5 S., R. 39 W.,
that portion of tract D, within secs. 4, 5, 8, and 17;
that portion of tract E, within secs. 1, 2, and 3, secs. 9 thru 16, and secs. 20 thru 36.
T. 6 S., R. 39 W.,
Secs. 1 thru 5;
Sec. 9, lot 1;
Secs. 10, 11 and 12.

Umiat Meridian, Alaska

T. 4 S., R. 42 W.,
Secs. 18, 19, 30, and 31.
T. 3 S., R. 43 W.,
Secs. 13 thru 36.
T. 4 S., R. 43 W.,
Secs. 7 thru 36.
T. 6 S., R. 43 W.,
Sec. 7 and secs. 13 thru 31.
T. 9 S., R. 43 W.,
Sec. 1, that portion outside the boundary of the National Petroleum Reserve, Alaska;
Secs. 4 thru 11;
Secs. 12 and 13, those portions outside the boundary of the National Petroleum Reserve, Alaska;

Secs. 14 thru 23;
Secs. 24 and 25, those portions outside the boundary of the National Petroleum Reserve, Alaska;
Secs. 26 thru 35;
Sec. 36, that portion outside the boundary of the National Petroleum Reserve, Alaska.
T. 10 S., R. 43 W.,
Sec. 1, that portion outside the boundary of the National Petroleum Reserve, Alaska;
Secs. 2, 3, 10, and 11;
Secs. 12 and 13, those portions outside the boundary of the National Petroleum Reserve, Alaska;
Secs. 14 thru 17 and secs. 19 thru 23;
Secs. 24 and 25, those portions outside the boundary of the National Petroleum Reserve, Alaska;
Secs. 26 thru 35;
Sec. 36, that portion outside the boundary of the National Petroleum Reserve, Alaska.
T. 11 S., R. 43 W.,
Sec. 1, lots 1 and 2;
Sec. 2, that portion outside the boundary of the Noatak National Preserve;
Secs. 3 thru 6;
Sec. 7, that portion outside the boundary of the Noatak National Preserve;
Secs. 8 thru 11;
Secs. 12 and 13, those portions outside the boundary of the Noatak National Preserve;
Secs. 14, 15, and 16;
Secs. 17 and 18, secs. 20 thru 24, and sec. 27, those portions outside the boundary of the Noatak National Preserve;
Sec. 28, lots 1 and 2.
T. 2 S., R. 44 W.,
Secs. 31 thru 36.
T. 3 S., R. 44 W.,
Secs. 9 thru 14 and secs. 23 and 24.
T. 4 S., R. 44 W.,
Secs. 19 thru 36.
T. 5 S., R. 44 W.,
Secs. 1 thru 6.
T. 6 S., R. 44 W.
T. 9 S., R. 44 W.,
Secs. 19 thru 36.
T. 10 S., R. 44 W.,
Secs. 2 thru 10, secs. 24 and 25, and secs. 31 thru 36.
T. 11 S., R. 44 W.,
Secs. 1 thru 6;
Secs. 7 thru 14 and secs. 17 and 18, those portions outside the boundary of the Noatak National Preserve.
T. 6 S., R. 45 W.,
Secs. 1 thru 4 and secs. 7 thru 36.
T. 9 S., R. 45 W.,
Secs. 19 thru 36.
T. 10 S., R. 45 W.,
Secs. 1 thru 24, secs. 29 thru 32, and secs. 35 and 36.
T. 11 S., R. 45 W.,
Secs. 1 thru 12;
Sec. 13, that portion outside the boundary of the Noatak National Preserve;
Secs. 14 thru 22;
Secs. 23, 24, 26, 27, and 28, those portions outside the boundary of the Noatak National Preserve;
Secs. 29 thru 32;
Sec. 33, that portion outside the boundary of the Noatak National Preserve.
T. 12 S., R. 45 W.,
Secs. 4 and 5, those portions outside the boundary of the Noatak National Preserve;
Sec. 6;
Secs. 7, 8, 16, 17, and 18, those portions outside the boundary of the Noatak National Preserve.
T. 6 S., R. 46 W.,
Secs. 12 thru 15.
T. 9 S., R. 46 W.,
Secs. 19 thru 36.
T. 10 S., R. 46 W.
T. 11 S., R. 46 W.,
Secs. 1 thru 12, secs. 15 thru 20, and secs. 35 and 36.
T. 12 S., R. 46 W.,
Secs. 1, 2, and 3;
Secs. 12, 13, 14, 22, and 23, those portions outside the boundary of the Noatak National Preserve.
T. 10 S., R. 47 W.,
Secs. 19 thru 36.
T. 11 S., R. 47 W.
T. 12 S., R. 47 W.,
Secs. 3 thru 10 and secs. 13 thru 18.
T. 9 S., R. 48 W.,
Secs. 13 thru 36.
T. 10 S., R. 48 W.,
Secs. 3 thru 10, secs. 15 thru 30, and secs. 32 thru 36.
T. 11 S., R. 48 W.,
Secs. 1, 2, and 3, secs. 10 thru 15, secs. 18 and 19, secs. 23 thru 26, and secs. 29 thru 32;
Secs. 35 and 36.
T. 12 S., R. 48 W.,
Secs. 1, 5, 6, 12, and 13.
T. 9 S., R. 49 W.,
Secs. 13 and 14, secs. 23 thru 26, secs. 29 thru 32, and secs. 35 and 36.
T. 10 S., R. 49 W.,
Secs. 1 and 2, secs. 5 thru 8, secs. 11 thru 14, secs. 17 thru 20, secs. 24 and 25, and secs. 28 thru 32.
T. 11 S., R. 49 W.,
Secs. 5 thru 8, secs. 17, 18, and 19, and secs. 35 and 36.
T. 12 S., R. 49 W.,
Sec. 1.
T. 7 S., R. 50 W.
T. 9 S., R. 50 W.,
Secs. 25, 26, and 27 and secs. 31 thru 36.
T. 10 S., R. 50 W.
T. 11 S., R. 50 W.,
Secs. 1 thru 24 and secs. 26 thru 33.
T. 12 S., R. 50 W.,
Sec. 6 and secs. 25 thru 27.
Tps. 10 and 11 S., R. 51 W.
T. 12 S., R. 51 W.,
Secs. 1 thru 6, secs. 9 thru 12, and secs. 14, 15, 29, and 30.
Tps. 10 thru 12 S., Rs. 52 thru 55 W.
Tps. 11 and 12 S., R. 56 W.
T. 10 S., R. 57 W.,
Secs. 4 thru 9, secs. 16 thru 21, and secs. 28 thru 33.
T. 7 S., R. 58 W., unsurveyed,
Secs. 16 thru 21 and secs. 28 thru 33.
T. 8 S., R. 58 W., unsurveyed,
Secs. 4 thru 9 and secs. 16 thru 36.
Tps. 9 and 10 S., R. 58 W., unsurveyed.
T. 11 S., R. 58 W.,
Sec. 25 and secs. 33 thru 36.
T. 12 S., R. 58 W.,
tract A.
T. 9 S., R. 61 W.,
Sec. 36, unsurveyed, that portion outside the boundary of the Alaska Maritime National Wildlife Refuge.
T. 10 S., R. 61 W., unsurveyed,
Secs. 1 and 2, those portions outside the boundary of the Alaska Maritime National Wildlife Refuge;
Secs. 11 thru 14 and secs. 23 thru 26;
Sec. 35, that portion outside the boundary of the Alaska Maritime National Wildlife Refuge;
Sec. 36.
T. 11 S., R. 61 W., unsurveyed,
Secs. 1 and 2 and secs. 11 thru 14.

The areas described aggregate approximately 9,727,730.01 acres.

2. PLO No. 5418, effective March 1974, amends PLO No. 5180 to add all unreserved public lands in Alaska, or those lands that may become unreserved unless specified by order at that time. Upon revocation, the lands in this order will not be subject to the terms and conditions of PLO No. 5418, which amended PLO No. 5180, but will continue to be subject to the terms and conditions of any other withdrawal, application, segregation of record, and other applicable law. In 1983, PLO No. 6477 modified the segregation of PLO Nos. 5170, 5179, 5180, and 5184. In 1984, PLO No. 6559 further modified the segregation of PLO No. 5180. PLO Nos. 6477 and 6559 will be superseded by this Order.

3. At 8 a.m. AKST on February 18, 2021, the lands described in Paragraph 1 shall be open to all forms of appropriation under the general public land laws, including location and entry under the mining laws, leasing under the Mineral Leasing Act of February 25, 1920, as amended, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8 a.m. AKST on February 18, 2021, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing. Appropriation of any of the lands referenced in this PLO under the general mining laws prior to the date and time of revocation remain unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. State law governs acts required to establish a location and to initiate a right of possession where not in conflict with Federal law. The BLM will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: January 11, 2021.

David L. Bernhardt,

Secretary of the Interior.

[FR Doc. 2021–01111 Filed 1–15–21; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW01000.L51100000.GN0000. LVEMF1907180.19XMO#4500150554]

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Gold Acquisition Corporation Relief Canyon Gold Mine Phase II Mine Expansion Amendment, Pershing County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Humboldt River Field Office, Winnemucca, Nevada has prepared a Draft Environmental Impact Statement (EIS) to analyze the potential impacts of approving the proposed expansion to the Relief Canyon gold mining operation in Pershing County, Nevada. This notice announces the beginning of the public comment period to solicit public comments on the Draft EIS.

DATES: To ensure comments will be considered, BLM must receive written comments on the Draft EIS no later than 45 days after the Environmental Protection Agency publishes its notice of availability of the Relief Canyon Mine Expansion Project Draft EIS DOI–BLM–NV–W010–2020–0030–EIS in the **Federal Register**. The BLM will announce the dates and locations of any future meetings or hearings and any other public involvement activities at least 15 days in advance through local media, newspapers and the BLM website at: *https://www.blm.gov/office/winnemucca-district-office.*

ADDRESSES: You may submit comments related to the Project by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2000567/510.*
- *Email: wfoweb@blm.gov,* include ''Relief Canyon Mine Expansion'' in the subject line.
- *Fax:* (775) 623–1740, please mark ''Attn: Relief Canyon Mine Expansion''.
- *Mail:* Bureau of Land Management, Attn: Relief Canyon Mine Expansion, 5100 East Winnemucca Boulevard, Winnemucca, NV 89445.

FOR FURTHER INFORMATION CONTACT: For questions about the proposed Project contact Ms. Jeanette ''Jean'' Black, telephone: (775) 623–1500, address: 5100 EastWinnemuccaBoulevard, Winnemucca, NV 89445. Contact Ms. Black to have your name added to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24-hours a day, 7-days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Gold Acquisition Corporation (GAC), a wholly-owned subsidiary of Pershing Gold Corporation, itself a wholly-owned subsidiary of Americas Gold and Silver Corporation, proposes an expansion to the existing Relief Canyon Gold Mine. The mine is located in Pershing County, Nevada, approximately 16 miles east-northeast of Lovelock, Nevada. The proposed expansion is located within GAC's authorized Plan of Operations boundary and proposes to modify the existing Plan of Operations as follows:

- Create roughly 576 acres of new surface disturbance on public and private land including re-disturbance of about 137 acres of previously disturbed vegetation communities.
- Expand the footprint of the existing approved pit area by approximately 84 acres (68 acres of public land and 16 acres of private land) with resultant elimination of a portion of existing Waste Rock Storage Facility (WRSF) 4.
- Mine to final pit bottom elevation of 4,420 feet above mean sea level (ft amsl), which will involve continued mining below the water table, and result in a post-mining pit lake that is predicted to reach an equilibrium elevation of 4,887 ft amsl roughly 50 years after completion of mining.
- Construct a dewatering conveyance pipeline and Rapid Infiltration to re-infiltrate up to 900 gallons per minute of mine dewatering water during the last three months of proposed Phase II mining.
- Install up to 50 vertical and horizontal drains in the pit wall to ensure pit slope stability and supplement pit dewatering operations.
- Convert up to 50 exploration drill holes located in and adjacent to the pit as vertical or near vertical drains and/or piezometer to monitor water levels to ensure pit slope stability and supplement pit dewatering operations.
- Expand WRSFs, heap leach pads, and construct process ponds, new growth media stockpiles, diversion ditches for stormwater control, and ancillary facilities.
- Expand yard and crusher-conveyor areas, roads, and fences.
- Close and reclaim all project facilities at the completion of Phase II.

Draft EIS Analysis Process

The purpose of the comment period is for the public to comment on the Draft EIS. The Draft EIS, through scoping, has identified and analyzed impacts to the following resources: Air and atmospheric resources, migratory birds and special status species, golden eagles, water quality (creation of a pit lake), and groundwater quantity. The Draft EIS describes and analyzes the proposed Project's direct, indirect, and cumulative impacts on all affected resources.

The BLM has consulted and continues to consult with Native American tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration.

Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed project that the BLM is evaluating, are invited to participate in the comment process.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request in your comment that your personal identifying information be withheld from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7.

Ester M. McCullough,

District Manager, Winnemucca District Office.

[FR Doc. 2021–00962 Filed 1–15–21; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–IEV–NPS0031130; PPWOIEADC0, PPMVSIE1Y.Y00000 (211); OMB Control Number 1024–NEW]

Agency Information Collection Activities; Education Reservation Request Form

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, we, the National Park Service (NPS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 22, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, NPS Information Collection Clearance Officer, 1201 Oakridge Drive Fort Collins, CO 80525; or by email to *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Linda Rosenblum, Education Program Manager, by email at *linda_rosenblum@nps.gov,* or by telephone at (202) 577–6469.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: NPS is authorized by 54 U.S.C. 100701, Protection, interpretation, and research in System, to administer education programs for education audiences including but not limited to school groups, scouting groups, extracurricular groups, and home school groups. To effectively manage requests received for NPS educational programs, the NPS Washington Support Office Division of Interpretation, Education, and Volunteers seeks approval for the use of a new Service-wide form, the Education Reservation Request Form.

The proposed form would collect necessary reservation information, including: (1) Person(s) or organization(s) requesting education program services, (2) type of program requested, (3) logistical details including, date, time, grade level, number of students, (4) technology available to group for distance learning programming, and (5) criteria for academic fee waiver eligibility.

This information will facilitate operational aspects of scheduling groups for in-park education programs, ranger in classroom programs, and/or online distance learning programs. The form will be fully electronic and available on participating parks websites for the purpose of making school group reservations and accommodating public requests for group education programming.

Title of Collection: Education Reservation Request Form.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Educators at public and private schools, homeschool groups, school-age clubs.

Total Estimated Number of Annual Respondents: 62,000.

Total Estimated Number of Annual Responses: 62,000.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 5,167.

Respondent's Obligation: Required to obtain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2021–01072 Filed 1–15–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–662 and 731–TA–1554 (Preliminary)]

R–125 (Pentafluoroethane) From China; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–662 and 731–TA–1554 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of R–125 (Pentafluoroethane)

from China, provided for in subheading 2903.39.20 of the Harmonized Tariff Schedule of the United States, and merchandise including certain mixtures containing R–125 provided for in subheading 3824.78.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by February 26, 2021. The Commission's views must be transmitted to Commerce within five business days thereafter, or by March 5, 2021.

DATES: January 12, 2021.

FOR FURTHER INFORMATION CONTACT: Ahdia Bavari ((202) 205–3191) and Andres Andrade ((202) 205–2078), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on January 12, 2021, by Honeywell International, Inc., Charlotte, North Carolina.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.— In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on Tuesday, February 2, 2021. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before January 29, 2021. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before February 5, 2021, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: January 13, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–01055 Filed 1–15–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1153]

Certain Bone Cements, Components Thereof and Products Containing the Same; Notice of Commission Determination Finding No Violation of Section 337; Termination of the Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to affirm in part, reverse in part, and vacate in part the final initial determination's (''ID'') finding that no violation of section 337 has occurred. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 10, 2019, based on a complaint filed by Heraeus Medical LLC of Yardley, Pennsylvania, and Heraeus Medical GmbH of Wehrheim, Germany (collectively, ''Complainants''). 84 FR 14394–95 (Apr. 10, 2019). The complaint alleges a violation of section 337 of the Tariff Act of 1930, as amended, by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States or to prevent the establishment of such an industry. The complaint named the following respondents: Zimmer Biomet Holdings, Inc. of Warsaw, Indiana; Biomet, Inc. of Warsaw, Indiana; Zimmer Orthopaedic Surgical Products, Inc. of Dover, Ohio; Zimmer Surgical, Inc. of Dover, Ohio; Biomet France S.A.R.L. of Valence, France; Biomet Deutschland GmbH of Berlin, Germany; Zimmer Biomet Deutschland GmbH of Freiburg im Breisgau, Germany; Biomet Europe B.V. of Dordrecht, Netherlands; Biomet Global Supply Chain Center B.V. of Dordrecht, Netherlands; Zimmer Biomet Nederland B.V. of Dordrecht, Netherlands; Biomet Orthopedics, LLC of Warsaw, Indiana; and Biomet Orthopaedics Switzerland GmbH of Dietikon, Switzerland. The Commission's Office of Unfair Import Investigations (''OUII'') also was named as a party.

The investigation has terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V., Order No. 10 (May 23, 2019), *unreviewed,* Notice (June 14, 2019), and as to certain accused products, Order No. 30 (Nov. 24, 2019), *unreviewed,* Notice (Dec. 10, 2019). Also, the first amended complaint and notice of investigation were amended to add three entities as respondents: Zimmer US, Inc.; Zimmer, GmbH; and Biomet Manufacturing, LLC. Order No. 18 (June 26, 2019), *unreviewed,* 84 FR 35884–85 (July 25, 2019). The remaining respondents are referred to collectively herein as ''Zimmer Biomet.''

On May 6, 2020, the presiding administrative law judge (''ALJ'') issued the final ID, which found that Zimmer Biomet did not violate section 337. On May 18, 2020, the parties filed petitions for review of the final ID.

On July 13, 2020, the Commission determined to review in part the final ID and requested briefing from the parties on the issues under review. In particular, the Commission determined to review the following: (1) The ALJ's findings and conclusions as to TS 1–35 and 121–23; and (2) the ALJ's domestic industry findings, including whether there has been a substantial injury to the alleged domestic industry. The Commission also sought briefing from the parties, interested government agencies, and any other interested parties on remedy, bonding, and the public interest.

Having examined the record of this investigation, including the final ID, the petitions for review, the responses thereto, and the written submissions in response to the Commission's request for briefing, the Commission finds that no violation of section 337 has occurred. Specifically, the Commission finds that the Complainants did not establish that an industry in the United States exists as required by section 337(a)(1)(A)(i) and therefore did not establish injury to a domestic industry. The investigation is hereby terminated.

The Commission vote for this determination took place on January 12, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 12, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–00996 Filed 1–15–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1200]

Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof; Notice of a Commission Determination Not To Review an Initial Determination Correcting the Notice of Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 33), granting the parties' joint motion to amend the notice of institution of the investigation by clarifying that claims 2 and 4–5 of U.S. Patent No. 10,593,196 (''the '196 patent'') are among the domestic industry claims but are not being asserted against any respondent for purposes of infringement. The notice of investigation is amended accordingly.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 22, 2020, based on a complaint

filed by Universal Electronics, Inc. (''UEI'') of Scottsdale, Arizona. 85 FR 31211–212 (May 22, 2020). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''Section 337''), in the importation into the United States, sale for importation, or sale in the United States after importation of certain electronic devices, including streaming players, televisions, set top boxes, remote controllers, and components thereof, by reason of infringement of one of more of the asserted claims of the '196 patent and U.S. Patent No. 7,696,514 (''the '514 patent''); 9,911,325 (''the '325 patent''); 7,589,642 (''the '642 patent''); 10,600,317 (''the '317 patent''); and 9,716,853 (''the '853 patent''). *Id.* The complaint also alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named the following respondents: Roku Inc. of Los Gatos, California; TCL Electronics Holdings Ltd. of New Territories, Hong Kong; Shenzhen TCL New Technology Co. Ltd. of Shenzhen, China; TCL King Electrical Appliances Co. Ltd., Huizhou, China; TTE Technology Inc. of Corona, California; TCL Corp. of Huizhou City, China; TCL Moka Int'l Ltd. of New Territories, Hong Kong; TCL Overseas Marketing Ltd. of New Territories, Hong Kong; TCL Industries Holdings Co., Ltd. of New Territories, Hong Kong; TCL Smart Device Co. of Bac Tan Uyen District, Vietnam; Hisense Co. Ltd. of Qingdao, China; Hisense Electronics Manufacturing Co. of America Corp. of Suwanee, Georgia; Hisense Import & Export Co. Ltd. of Qingdao, China; Qingdao Hisense Electric Co., Ltd. of Qingdao, China; Hisense International Co., Ltd. of Shen Wang, Hong Kong; Funai Electric Co., Ltd. of Osaka, Japan; Funai Corp. Inc. of Rutherford, New Jersey; and Funai Co., Ltd. of Nakhon Ratchasima, Thailand (collectively, ''Respondents''). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

The Commission previously terminated the investigation with respect to the '853 patent, claims 19 and 20 of the '196 patent, and claims 14 and 20 of the '642 patent due to the withdrawal of those patent claims. Order No. 27 at 1 (Dec. 2, 2020), *unreviewed by* Comm'n Notice (Dec. 23, 2020). The Commission subsequently terminated the investigation with respect to claim 20 of the '514 patent. Order No. 32 (Dec. 21, 2020), *unreviewed by* Comm'n Notice (Jan. 5, 2021).

On December 29, 2020, the presiding administrative law judge issued the subject ID (Order No. 33), granting a joint motion by UEI and Respondents to correct the notice of institution of the investigation by clarifying that claims 2 and 4–5 of the '196 patent are domestic industry claims only and are not being asserted against any Respondent for purposes of infringement.

No petition for review of the subject ID was filed.

The Commission has determined not to review the subject ID. The notice of institution of the investigation is corrected accordingly.

The Commission vote for this determination took place on January 13, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 13, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–01083 Filed 1–15–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Medical CBRN Defense Consortium

Notice is hereby given that, on January 8, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Medical CBRN Defense Consortium (''MCDC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Aldevron, LLC, Fargo, ND; Applied Nanotech, Inc., Austin, TX; Clark Street Associates, Los Altos, CA; Encryptor, Inc., Plano, TX; Entasis Therapeutics, Waltham, MA; ImmunityBio, Inc., El Segundo, CA; Polaris Sensor Technologies, Huntsville, AL; Qorvo Biotechnologies, LLC, Bend, OR; Rigel Pharmaceuticals, San Francisco, CA; SafetySpect, Inc., Los Angeles, CA; and Somnio Global, LLC, Novi, MI have been added as parties to this venture.

Also, 7 Hills Pharma, LLC, Houston, TX; ARMSTEL, Inc., Plano, TX; Captura Biopharma, Inc., Little Rock, AR; Chenega Reliable Services, LLC, San Antonio, TX; Data Intelligence Technologies, Inc., Arlington, VA; DEFTEC Corporation, Huntsville, AL; HDT Bio Corporation, Seattle, WA; MAE Group, LLC, Deerfield, NH; Metabiota, Inc., San Francisco, CA; Microscale Devices, LLC, Apex, NC; One Health Group, LLC, Chantilly, VA; Pathology Assist-Temp, Inc., Chantilly, VA; Peregrine Technical Solutions, LLC, Yorktown, VA; Profectus BioSciences, Inc., Baltimore, MD; TensorX, Inc., Vienna, VA and the University of Michigan, Ann Arbor, MI have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and MCDC intends to file additional written notifications disclosing all changes in membership.

On November 13, 2015, MCDC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on January 6, 2016 (81 FR 513).

The last notification was filed with the Department on October 20, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 20, 2020 (85 FR 74386).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–01051 Filed 1–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Countering Weapons of Mass Destruction

Notice is hereby given that, on January 7, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Countering Weapons of Mass Destruction (''CWMD'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, AimLock dba Dev-Lock Systems, Inc., Littleton, CO; Cahaba Micro, LLC, Pelham, AL; Consolidated Cordage Corporation, Boca Raton, FL; Encryptor, Inc., Plano, TX; Florida Institute for Human & Machine Cognition, Pensacola, FL; Intellisense Systems, Inc., Torrance, CA; INTERFUZE Corporation, Huntsville, AL; Pacific Advanced Technology, Inc., Los Olivos, CA; SciTec, Inc., Princeton, NJ; Shield AI, Inc., San Diego, CA; Technology In Images, Inc. (Ti2Inc), Pittsburgh, PA; University of Southern California, Los Angeles, CA have been added as parties to this venture.

Also, BAE Systems, Greenland, NY; Bill Baugh Associates, LLC, Millersville, MD; Bohemia Interactive Simulations, Inc. (BISim), Orlando, FL; Chenega Reliable Services, LLC, San Antonio, TX; Citadel Defense Company, National City, CA; CogniTech Corporation, Salt Lake City, UT; Continuum Dynamics, Inc., Ewing, NJ; Eirene Technologies, Inc., La Mesa, CA; GenScript USA, Inc., Knight Aerospace Medical Systems, LLC, San Antonio, TX; Military Battery Systems, Inc., Denver, CO; Morphix Technologies, Inc., Virginia Beach, VA; Nucsafe, Inc., Oak Ridge, TN; QinetiQ North America, Waltham, MA; VITNI Corporation, Hilo, HI; Women Veterans Contracting, Inc. (WVC), San Diego, CA have withdrawn from this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CWMD intends to file additional written notifications disclosing all changes in membership.

On January 31, 2018, CWMD filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 12, 2018 (83 FR 10750).

The last notification was filed with the Department on October 28, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on November 20, 2020 (85 FR 74386).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–01049 Filed 1–15–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—CHEDE–8

Notice is hereby given that, on January 7, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), CHEDE–8 (''CHEDE–8'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Mahle Engine Components USA, Inc., Farmington Hills, MI, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CHEDE–8 intends to file additional written notifications disclosing all changes in membership.

On December 4, 2019, CHEDE–8 filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 30, 2019 (84 FR 71977).

The last notification was filed with the Department on December 1, 2020. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on December 22, 2020 (85 FR 83613).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–01045 Filed 1–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Armaments Consortium

Notice is hereby given that, on January 12, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Armaments Consortium (''NAC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Acutronic USA Inc., Pittsburgh, PA; Applied Nanotech Inc., Austin, TX; Arquimea USA, Inc., Torrance, CA; Belcan Engineering Group, LLC, Cincinnati, OH; Capstone Research Corporation, Madison, AL; Cohere Solutions, LLC, Reston, VA; Del Sigma Technologies LLC, Rockford, MI; Epirus Inc., Hawthorne, CA; HII Technical Solutions Corporation, Virginia Beach, VA; Hydraulics International, Inc., Chatsworth, CA; Iowa State University of Science and Technology, Ames, IA; KMS Solutions, LLC, Alexandria, VA; Kowalski Heat Treating, Cleveland, OH; L3Harris Technologies Power Paragon, Inc., Anaheim, CA; Onodi Tool & Engineering, Melvindale, MI; Phased n Research, Inc., Huntsville, AL; Prasad, Sarita dba IMS-Pro LLC (Innovative Microwave System Prototypes), Albuquerque, NM; ProSync Technology Group, Inc., Ellicott City, MD; Reheat, LLC, Marquette, MI; Rocal Corp. dba Rebling Plastics, Warrington, PA; Starwin Industries LLC, Dayton, OH; Synthetik Applied Technologies, LLC, Pierre, SD; Telesis a Belcan Company, McLean, VA; Testek Solutions, Wixom, MI; Trusted Science and Technology, Inc., Bethesda, MD; Universal Technology Professional, LLC, Laurel, MD; University of South Carolina, Columbia, SC; Venturi, LLC, Huntsville, AL; VetAble Technologies, LLC, Brandon, FL; Veth Research Associates, LLC, Niceville, FL have been added as parties to this venture.

Also, AAI Corporation Inc., Hunt Valley, MD; Anthem Engineering, LLC, Elkridge, MD; Black River Systems Company, Utica, NY; Continuum Dynamics, Inc., Ewing, NJ; Cummings Aerospace, Inc., Huntsville, AL; Keystone Automation, Duryea, PA; Lancer Systems, LP, Quakertown, PA; ODAT Machine Inc., Gorham, ME; Optimax Systems, Inc., Ontario, NY; Remington Arms Company, LLC, Madison, NC; SemQuest Incorporated, Colorado Springs, CO; Syntek Technologies, Inc., Fairfax, VA; The University of Southern Mississippi, Hattiesburg, MS; Trijicon Inc., Wixom, MI have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NAC intends

to file additional written notifications disclosing all changes in membership.

On May 2, 2000, NAC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 30, 2000 (65 FR 40693).

The last notification was filed with the Department on October 9, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 30, 2020 (85 FR 68916).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–01071 Filed 1–15–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—MLCommons Association

Notice is hereby given that on January 5, 2021 pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. Section 4301 et seq (the ''Act''), MLCommons Association (''MLCommons'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Landing AI, Palo Alto, CA; Lingjie Xu (individual member), San Jose, CA; Neuchips Corporation, Hsinchu, TAIWAN; VerifAI Inc., Palo Alto, CA; CTUNING FOUNDATION, Cachan, FRANCE; VMind Technologies, Inc., San Francisco, CA; Poonam Yadav (individual member), York, UNITED KINGDOM; Relja Markovic (individual member), Bothell, WA; Emily Potyraj (individual member), Houston, TX; Tom St. John (individual member), Mountain View, CA; Debojyoti Dutta (individual member), Santa Clara, CA; Hanlin Tang (individual member), San Francisco, CA; and LSDTech, Seoul, KOREA have joined as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open and MLCommons intends to file additional written notifications disclosing all changes in membership.

On September 15, 2020, MLCommons filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 29, 2020 (85 FR 61032).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–01043 Filed 1–15–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Refuse Piles and Impoundment Structures, Recordkeeping and Reporting Requirements

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mining Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811, authorizes the Secretary of Labor to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines. Title 30 CFR part 77, subpart C, sets forth standards for surface installations to prevent accidents and injuries to miners. More specifically, section 77.215 addresses refuse piles and section 77.216 addresses impoundments. Refuse piles are deposits of coal mine waste (other than overburden or spoil) that are removed during mining operations or separated from mined coal and deposited on the surface. Impoundments are structures that can impound water, sediment, or slurry or any combination of materials. The failure of these structures can have a devastating effect on mine employees, communities, and nearby areas. To avoid or minimize such failures, MSHA has promulgated standards for the design, construction, and maintenance of these structures; for annual certifications; for certification for hazardous refuse piles; for the frequency of inspections; and the methods of abandonment for impoundments and impounding structures. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 6, 2020 (85 FR 63144).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years

without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Refuse Piles and Impoundment Structures, Recordkeeping and Reporting Requirements.

OMB Control Number: 1219–0015.

Affected Public: Businesses or other for-profits institutions.

Total Estimated Number of Respondents: 548.

Total Estimated Number of Responses: 28,047.

Total Estimated Annual Time Burden: 68,692 hours.

Total Estimated Annual Other Costs Burden: $1,509,202.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: January 12, 2021.

Anthony May,

Management and Program Analyst.

[FR Doc. 2021–00937 Filed 1–15–21; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Division of Energy Employees Occupational Illness (DEEOIC) Authorization Forms

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of the Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before February 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Office of Workers' Compensation Programs (OWCP) is the primary agency responsible for administration of the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA), 42 U.S.C. 7384 *et seq.* EEOICPA provides for the payment of compensation to covered employees and, where applicable, survivors of deceased employees, who sustained either an ''occupational illness'' or a ''covered illness'' in the performance of duty for the Department of Energy and certain of its contractors and subcontractors. One element of the compensation provided to covered employees is medical benefits for the treatment of their occupational or covered illnesses that are accepted as compensable. OWCP contracts with a private sector bill processing agent that handles many of the tasks associated with paying bills for medical treatment provided to covered employees under EEOICPA. This bill processing agent uses an automated system that matches incoming bills with the authorized medical treatment of covered employees before it issues payments, and a provider of medical treatment, supplies or services to covered employees must provide the bill processing agent with information necessary for creation of an authorization within the agent's automated system before a bill can be paid. The collection of this information is authorized by 20 CFR 30.400(a) and (c), 30.403, 30.404(b) and 30.700. The information collections in this ICR collect demographic, factual and medical information that OWCP and/or its bill processing agent needs to process bills for medical treatment, supplies or services. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 2, 2020 (85 FR 62327).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Division of Energy Employees Occupational Illness (DEEOIC) Authorization Forms.

OMB Control Number: 1240–0NEW.

Affected Public: Businesses or other for-profits institutions; individuals and households.

Total Estimated Number of Respondents: 12,890.

Total Estimated Number of Responses: 66,770.

Total Estimated Annual Time Burden: 11,129 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: January 12, 2021.

Anthony May,

Management and Program Analyst.

[FR Doc. 2021–01098 Filed 1–15–21; 8:45 am]

BILLING CODE 4510–CR–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2019–0008]

Ballard Marine Construction; Application for Permanent Variance and Interim Order; Grant of Interim Order

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice; request for comments.

SUMMARY: In this notice, OSHA announces Ballard Marine Construction's application for a Permanent Variance and Interim Order

from provisions of OSHA standards that regulate work in compressed air environments and presents the agency's preliminary finding to grant the Permanent Variance. OSHA also announces the granting of an Interim Order. OSHA invites the public to submit comments on the variance application to assist the agency in determining whether to grant the applicant a Permanent Variance based on the conditions specified in this application.

DATES: Submit comments, information, documents in response to this notice, and request for a hearing on or before February 18, 2021. The Interim Order described in this notice will become effective on January 19, 2021, and shall remain in effect until the completion of the Suffolk County Outfall Tunnel, in West Babylon, New York or the Interim Order is modified or revoked.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at: *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2019–0008, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone (202) 693–2350. OSHA's TTY number is (877) 889–5627. Please note: While OSHA's docket office is continuing to accept and process submissions by regular mail, due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the rulemaking record by express delivery, hand delivery and messenger service.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2019–0008). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.*

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. You may also contact Kevin Robinson, Director Office of Technical Programs and Coordination Activities (OTPCA) at the below address.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.*

Copies of this **Federal Register** *notice.* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at *http://www.osha.gov.*

Hearing Requests. According to 29 CFR 1905.15, hearing requests must include: (1) A short and plain statement detailing how the permanent variance would affect the requesting party; (2) a specification of any statement or representation in the variance application that the commenter denies, and a concise summary of the evidence offered in support of each denial; and (3) any views or arguments on any issue of fact or law presented in the variance application.

SUPPLEMENTARY INFORMATION:

I. Notice of Application

OSHA's standards in subpart S of 29 CFR part 1926 govern underground construction, caissons, cofferdams, and compressed air. On January 2, 2019, Ballard Marine Construction (''Ballard'' or ''the applicant''), 727 S. 27th Street, Washougal, Washington 98761, submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 (the ''Act''), 29 U.S.C. 655, and 29 CFR 1905.11 an application for a Permanent Variance from several provisions of the OSHA standard that regulates work in compressed air, 1926.803 of subpart S, and an Interim Order allowing it to proceed while OSHA considers the request for a Permanent Variance (OSHA–2019–0008–0001). This notice addresses Ballard's application for a Permanent Variance and Interim Order for construction of the Suffolk County Outfall Tunnel Project in West Babylon, New York only and is not applicable to future Ballard tunneling projects.

Specifically, this notice addresses Ballard's application for a Permanent Variance and Interim Order from the provisions of the standard that: (1) Require the use of the decompression values specified in decompression tables in Appendix A of subpart S (29 CFR 1926.803(f)(1)); and (2) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and (xvii), respectively).

OSHA has previously approved nearly identical provisions when granting several other very similar variances, as discussed in more detail in Section II. OSHA preliminarily concludes that the proposed variance is appropriate, grants an Interim Order temporarily allowing the proposed activity, and seeks comment on the proposed variance.

A. Background

Ballard is a contractor that works on complex tunnel projects using innovations in tunnel-excavation methods. The applicant's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balanced micro-tunnel boring machine (EPBMTBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, EPBMTBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies, and isolate that pressure to the forward section (the excavation working chamber) of the EPBMTBM.

Ballard asserts that generally it bores tunnels using an EPBMTBM at levels below the water table through soft soils. EPBMTBMs are capable of maintaining pressure at the tunnel face and stabilizing existing geological conditions through the controlled use of propel cylinders, a mechanically driven cutter head, bulkheads within a protective shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the EPBMTBM is the working chamber, and this chamber is the only pressurized segment of the EPBMTBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is

immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the manlock door and the entry door to the forward working chamber.

The EPBMTBM has twin manlocks located between the pressurized working chamber and the non-pressurized portion of the machine. Each manlock has two compartments. This configuration allows workers to access the manlocks for compression and decompression, and medical personnel to access the manlocks if required in an emergency.

The applicant will pressurize the working chamber to the level required to maintain a stable tunnel face, which for this project Ballard estimates will be up to a pressure not exceeding 30 pounds per square in gauge (p.s.i.g.). Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the forward excavation working chamber.

Ballard employs specially trained personnel for the construction of the tunnel. Ballard asserts that to keep the machinery working effectively, these workers must periodically enter the excavation working chamber of the EPBMTBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 30 p.s.i.g., which does not exceed the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the EPBMTBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head. These interventions are the only time that workers are exposed to compressed air. Interventions in the excavation working chamber (the pressurized portion of the EPBMTBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the excavation working chamber through one of the twin manlocks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward excavation working chamber. The manlocks and the excavation working chamber are designed to accommodate three people, which is the maximum crew size allowed under the proposed variance (Ballard only plans to employ a crew of two people for these activities). When the required decompression times are greater than work times, the twin manlocks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied manlock available for use.

Ballard asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and thereby reduced the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology have substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work that was typical when OSHA adopted the compressed-air standard for construction, 29 CFR 1926.803.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, Ballard asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. These procedures, however, would deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(f)(1) and the decompression tables in Appendix A of 29 CFR part 1926, subpart S. Nevertheless, according to Ballard, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

Ballard therefore believes its workers will be at least as safe under its proposed alternatives as they would be under OSHA's existing standard because of the reduction in the number of workers and duration of hyperbaric exposures, improved application of hyperbaric medicine, and the development of a project-specific Hyperbaric Operations Manual (HOM) (OSHA–2019–0008–0002) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained manlock attendants and hyperbaric or compressed-air workers (CAWs).

Based on an initial review of Ballard's application for a Permanent Variance and Interim Order for the construction of the Suffolk County Outfall Tunnel in West Babylon, New York, OSHA has preliminarily determined that Ballard has proposed an alternative that would provide a workplace at least as safe and healthful as that provided by OSHA's existing standard.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations, the applicant certifies that it provided employee representatives of affected workers with a copy of the variance application.[1] The applicant also certifies that it notified its workers of the variance application by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant informed its workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

A. OSHA History of Approval of Nearly Identical Variance Requests

OSHA previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects. OSHA notes that it granted four subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the completion of the Anacostia River Tunnel in Washington, DC, 80 FR 50652 (Aug. 20, 2015); (2) Traylor JV for the completion of the Blue Plains Tunnel in Washington, DC, 80 FR 16440 (March 27, 2015); (3) Tully/OHL USA Joint Venture for the completion of the New York Economic Development Corporation's New York Siphon Tunnel project, 79 FR 29809 (May 23, 2014); and (4) Salini-Impregilo Joint Venture in Washington, DC, 85 FR 27767 (May 11, 2020). The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous Permanent Variances.[2] OSHA is not aware of any injuries or other safety issues that arose from work

[1] See the definition of ''Affected employee or worker'' in section VI. D.

[2] Most of the other subaqueous tunnel construction variances allowed further deviation from OSHA standards by permitting employee exposures above 50 p.s.i.g. based on the composition of the soil and the amount of water above the tunnel for various sections of those projects. The current proposed variance includes substantively the same safeguards as the variances that OSHA granted previously, even though employees will only be exposed to pressures up to 30 p.s.i.g.

performed under these conditions in accordance with the previous variances.

B. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement to Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression according to the decompression tables in Appendix A of 29 CFR part 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables), which rely on staged decompression, and to supplement breathing air used during decompression with air or oxygen (as appropriate).[3] The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Suffolk County Outfall Tunnel-specific HOM are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR part 1926, subpart S. Accordingly, the applicant would commit to following the decompression procedures described in its HOM, which would require it to follow the 1992 French Decompression Tables to decompress compressed-air workers (CAWs) after they exit the hyperbaric conditions in the excavation working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. Ballard asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) maintaining appropriate levels of external pressure to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops to diminish worker fatigue and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, Ballard has stated that a physician certified in hyperbaric medicine will be required to manage the medical condition of CAWs during hyperbaric exposures and decompression. The project-specific HOM also requires a trained and experienced manlock attendant to be present during hyperbaric exposures and decompression. This manlock attendant, who will be a competent person with respect to hyperbaric systems, is to operate the hyperbaric system to ensure compliance with the specified decompression table. A intervention supervisor (competent person), who is trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

C. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

The applicant is applying for a Permanent Variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained manlock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (''DCI''), commonly referred to as ''the bends.'' This description of the etiology of DCI is consistent with current scientific theory and research on the issue.[4]

The 1992 French Decompression Tables proposed for use by the applicant provide for stops during worker decompression (*i.e.,* staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.[5] In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM includes an intervention supervisor (a competent person experienced and trained in hyperbaric operations, procedures, and safety) who directly supervises all hyperbaric interventions and ensures that the manlock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

D. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

[3] In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) Staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time). Source: J.C. Le Pechon, P. Barre, J.P. Baudi, F. Olivier, *Compressed Air Work—French Tables 1992—Operational Results.* JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS, pp. 1–5 (September 1996) (see Ex. OSHA–2012–0036–0005).

[4] See infra note 6, discussing a 1985 NIOSH report on DCI.

[5] See, *e.g.,* Eric Kindwall, *Compressed Air Tunneling and Caisson Work Decompression Procedures: Development, Problems, and Solutions,* 24(4) Undersea and Hyperbaric Medicine 337, 337–45 (1997). This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, ''Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . ., which provides less and less meaningful bubble suppression . . . .'' In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that ''[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control.''

The applicant proposes that it be permitted to rely on the manlocks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the manlocks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all of the exposed workers during decompression. The applicant uses the existing manlocks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. Under Ballard's application, only two crew members would have to decompress at the same time. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each manlock (during decompression stops) or exit the manlock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is at least as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

III. Agency Preliminary Determinations

After reviewing the proposed alternatives OSHA has preliminarily determined that collectively the applicant's proposed alternatives, subject to the conditions in the request and imposed by this Interim Order, provide measures that are as safe and healthful as those required by the cited OSHA standard addressed in section II of this document.

In addition, OSHA has preliminarily determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

29 CFR 1926.803(f)(1), Requirement to Use OSHA Decompression Tables.

Ballard has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the use of the 1992 French Decompression Tables. Depending on the maximum working pressure and exposure times during the interventions, these tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.,* staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced manlock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor (competent person), trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

As it did when granting the four previous variances to IHP JV, Traylor JV, Tully JV, and Salini-Impregilo, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.,* the 1992 French Decompression Tables) Ballard proposes would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions that would be imposed by the proposed variance.

Some of the literature concluded that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard.[6] For example, H. L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).[7] This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events, and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.[8]

OSHA's experience with the previous four variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provides evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans[9] that either granted variances (Nevada, Oregon and Washington)[10] or promulgated a standard (California)[11] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, provide additional evidence of the effectiveness of this alternative procedure.

29 CFR 1926.803(g)(1)(iii), Automatically Regulated Continuous Decompression

Ballard developed, and has proposed to implement, an equally effective alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine, to oversee all hyperbaric operations.

In reaching this preliminary conclusion, OSHA again notes the experience of previous, nearly identical

[6] In 1985, the National Institute for Occupational Safety and Health (NIOSH) published a report entitled ''Criteria for Interim Decompression Tables for Caisson and Tunnel Workers''; this report reviewed studies of DCI and other hyperbaric-related injuries resulting from use of OSHA's tables. This report is available on NIOSH's website: *http://www.cdc.gov/niosh/topics/decompression/default.html.*

[7] H.L. Anderson HL, *Decompression sickness during construction of the Great Belt tunnel, Denmark,* 29(3) Undersea and Hyperbaric Medicine 172, 172–88 (2002).

[8] J.C. Le Péchon, P. Barre, J.P. Baud, F. Ollivier, *Compressed Air Work—French Tables 1992—Operational Results,* JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS, pp. 1–5 (September 1996) (see Ex. OSHA–2012–0036–0005).

[9] Under Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as ''State Plan States.'' Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. See 29 U.S.C. 667.

[10] These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

[11] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

approved tunneling variances, the experiences of State Plan states, and a review of the literature and other information noted earlier.

29 CFR 1926.803(g)(1)(xvii), Requirement of Special Decompression Chamber

Ballard developed, and proposed to implement, an alternative that is at least as effective as the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The EPBMTBM's manlock and excavation working chamber appear to satisfy most of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around. While the alternative does not indicate that their chambers would be able to safely accommodate decompression times up to 360 minutes, Ballard addressed this issue in correspondence with OSHA and explained how their process is at least as effective as OSHA's requirement, which was designed to accommodate a different process:

With the relatively low pressure expected during hyperbaric interventions, the decompression process with oxygen (French tables) proposed could never reach this [360 minute] duration. The maximum decompression duration at 30 psi (2.07 bar) is 121 minutes.

(Justin Costello email August 11, 2020) (OSHA–2019–0008–0003). Ballard later added that their decompression chamber is fully capable of operating for much longer than the necessary 121 minutes:

The manlock where decompression occurs is capable of continuous operation, 24 hours per day for multiple days at a time. Operators of the manlock change shifts at the control station.

(Justin Costello email November 25, 2020) (OSHA–2019–0008–0004). Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the EPBMTBM's manlock and working chamber function at least as effectively as the special decompression chamber required by the standard.

Pursuant to section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the agency preliminarily finds that when the employer complies with the conditions of this Interim Order, the working conditions of the employer's workers would be at least as safe and healthful as if the employer complied with the working conditions specified by paragraphs 29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii).

IV. Grant of Interim Order, Proposal for Permanent Variance, and Request for Comment

OSHA announces the decision to grant an Interim Order allowing Ballard's CAWs to perform interventions in hyperbaric conditions not exceeding 30 p.s.i.g. during the Suffolk County Outfall Tunnel, subject to the conditions that follow in this document. This Interim Order will remain in effect until completion of the Suffolk County Outfall Tunnel or until the agency modifies or revokes the Interim Order or makes a decision on Ballard's application for a Permanent Variance. During the period starting with the publication of this notice until completion of the Suffolk County Outfall Tunnel, or until the agency modifies or revokes the Interim Order or makes a decision on its application for a Permanent Variance, the applicant is required to comply fully with the conditions of the Interim Order as an alternative to complying with the following requirements of 29 CFR 1926.803 (''the standard'') that:

1. Require the use of decompression values specified by the decompression tables in Appendix A of the compressed-air standard (29 CFR 1926.803(f)(1));
2. Require the use of automated operational controls (29 CFR 1926.803(g)(1)(iii)); and
3. Require the use of a special decompression chamber (29 CFR 1926.803(g)(1)(xvii)).

In order to avail itself of the Interim Order, Ballard must: (1) comply with the conditions listed in the Interim Order for the period starting with the grant of the Interim Order and ending with Ballard's completion of the Suffolk County Outfall Tunnel (or until the agency modifies or revokes the Interim Order or makes a decision on its application for a Permanent Variance); (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the proposed conditions, including the affected employees of other employers, using the same means it used to inform these employees of its application for a Permanent Variance.

OSHA is also proposing that the same requirements (see above section IV, parts A through C) would apply to a Permanent Variance if OSHA ultimately issues one for this project. OSHA requests comment on those conditions as well as OSHA's preliminary determination that the specified alternatives and conditions would provide a workplace as safe and healthful as those required by the standard from which a variance is sought. After reviewing comments, OSHA will publish in the **Federal Register** the agency's final decision approving or rejecting the request for a Permanent Variance.

V. Description of the Specified Conditions of the Interim Order and the Application for a Permanent Variance

This section describes the alternative means of compliance with 29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii) and provides additional detail regarding the proposed conditions that form the basis of Ballard's application for an Interim Order and for a Permanent Variance. The conditions are listed in Section VI. For brevity, the discussion that follows refers only to the Permanent Variance, but the same conditions apply to the Interim Order.

Proposed Condition A: Scope

The scope of the proposed Permanent Variance would limit coverage to the work situations specified. Clearly defining the scope of the proposed Permanent Variance provides Ballard, Ballard's employees, potential future applicants, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the proposed Permanent Variance would apply. To the extent that Ballard exceeds the defined scope of this variance, it would be required to comply with OSHA's standards.

Pursuant to 29 CFR 1905.11, an employer (or class or group of employers) [12] may request a Permanent Variance for a specific workplace or workplaces. If OSHA approves a Permanent Variance, it would apply only to the specific employer(s) that submitted the application and only to the specific workplace or workplaces designated as part of the project. In this instance, if OSHA were to grant a Permanent Variance, it would apply to only the applicant, Ballard Marine Construction, and only to the Suffolk County Outfall Tunnel. As a result, it is important to understand that if OSHA were to grant Ballard a Permanent Variance, it would not apply to any other employers or projects the

[12] A class or group of employers (such as members of a trade alliance or association) may apply jointly for a Variance provided an authorized representative for each employer signs the application and the application identifies each employer's affected facilities.

applicant may undertake in the future. However, 29 CFR 1905.13 does contain provisions for future modification of Permanent Variances to add or include additional employers if future joint ventures are established.

Proposed Condition B: Duration

The Interim Order is only intended as a temporary measure pending OSHA's decision on the Permanent Variance, so this condition specifies the duration of the Order. If OSHA approves a Permanent Variance, it would specify the duration of the Permanent Variance as the remainder of the Suffolk County Outfall Tunnel.

Proposed Condition C: List of Abbreviations

Proposed condition C defines a number of abbreviations used in the proposed Permanent Variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the proposed Permanent Variance.

Proposed Condition D: Definitions

The proposed condition defines a series of terms, mostly technical terms, used in the proposed Permanent Variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the proposed Permanent Variance.

Proposed Condition E: Safety and Health Practices

This proposed condition requires the applicant to develop and submit to OSHA an HOM specific to the Suffolk County Outfall Tunnel at least six months before using the EPBMTBM for tunneling operations. The applicant must also submit, at least six months before using the EPBMTBM, proof that the EPBMTBM's hyperbaric chambers have been designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or the most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM to OSHA, which Ballard has already completed, enables OSHA to determine whether the safety and health instructions and measures Ballard specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO–1.2019 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure.

Additionally, the proposed condition includes a series of related hazard prevention and control requirements and methods (*e.g.,* decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Proposed Condition F: Communication

This proposed condition requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication are intended to ensure that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The proposed condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications would enable affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during EPBMTBM operations.

Proposed Condition G: Worker Qualification and Training

This proposed condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The proposed condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work is intended to ensure that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this proposed condition requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if the workers believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Proposed Condition H: Inspections, Tests, and Accident Prevention

Proposed Condition H requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the EPBMTBM's hyperbaric equipment and support systems, and associated work areas. This condition would help to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition would also enhance worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this proposed condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the EPBMTBM, and maintain these documents at the jobsite for the duration of the job. This requirement would provide the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Proposed Condition I: Compression and Decompression

This proposed condition would require the applicant to consult with the designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical consultant. This proposed provision would ensure that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered

during EPBMTBM operations. Accordingly, CAWs requiring acclimation would have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition would prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the EPBMTBM.

Proposed Condition J: Recordkeeping

Under OSHA's existing recordkeeping requirements in 29 CFR part 1904 regarding Recording and Reporting Occupational Injuries and Illnesses, Ballard must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions by completing the OSHA's Form 301 Injury and Illness Incident Report and OSHA's Form 300 Log of Work-Related Injuries and Illnesses. The applicant did not seek a variance from this standard, and therefore must comply fully with those requirements.

Examples of important information to include on the OSHA's Form 301 Injury and Illness Incident Report (along with the corresponding question on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (*e.g.,* air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments; and
- unusual occurrences, if any, during the task or decompression.

Q15

- time of symptom onset; and
- duration between decompression and onset of symptoms.

Q16

- type and duration of symptoms; and
- a medical summary of the illness or injury.

Q17

- duration of the hyperbaric intervention;
- possible contributing factors; and
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.[13]

Proposed Condition J would add additional reporting responsibilities, beyond those already required by the OSHA standard. The applicant would be required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under proposed Condition K (using OSHA's Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, 1904.8–.12), would enable the applicant and OSHA to assess the effectiveness of the Permanent Variance in preventing DCI and other hyperbaric-related effects.

Proposed Condition K: Notifications

Under the proposed condition, the applicant is required, within specified periods of time, to: (1) Notify OSHA of any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during EPBMTBM operations; (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA's Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA's Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the Long Island New York OSHA Area Office (LIAO) within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect Ballard's ability to comply with the conditions of the proposed Permanent Variance; and (6) provide OTPCA and the LIAO, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA's Form 301 Injury and Illness Incident Report) is more restrictive than the existing recordkeeping requirement of completing OSHA's Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the Permanent Variance in providing the requisite level of safety to the applicant's workers and, based on this assessment, whether to revise or revoke the conditions of the proposed Permanent Variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this proposed condition requires the applicant to notify OSHA if it ceases to do business, has a new address or location for the main office, or transfers the operations covered by the proposed Permanent Variance to a successor company. In addition, the condition specifies that the transfer of the Permanent Variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the proposed Permanent Variance, and expedite the agency's administration and enforcement of the Permanent Variance. Stipulating that an applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by proposed Permanent Variance, thereby ensuring the safety of workers involved in performing the operations covered by the proposed Permanent Variance.

VI. Specific Conditions of the Interim Order and the Proposed Permanent Variance

The following conditions apply to the Interim Order OSHA is granting to Ballard. These conditions specify the alternative means of compliance with the requirements of paragraphs 29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii). In addition, these conditions are specific to the alternative means of

[13] See 29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses *(http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631);* recordkeeping forms and instructions *(http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf)*; and OSHA Recordkeeping Handbook *(http://www.osha.gov/recordkeeping/handbook/index.html)*.

compliance with the requirements of paragraphs 29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii) that OSHA is proposing for Ballard's Permanent Variance. To simplify the presentation of the conditions, OSHA generally refers only to the conditions of the proposed Permanent Variance, but the same conditions apply to the Interim Order except where otherwise noted.[14]

The conditions would apply with respect to all employees of Ballard exposed to hyperbaric conditions. These conditions are outlined in this Section:

Scope

The Interim Order applies, and the Permanent Variance would apply, only when Ballard stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.,* inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The Interim Order and Proposed Variance apply only to work:

1. That occurs in conjunction with construction of the Suffolk County Outfall Tunnel, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an EPBMTBM;
2. In the EPBMTBM's forward section (the excavation working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and
3. Performed in compliance with all applicable provisions of 29 CFR part 1926 except for the requirements specified by 29 CFR 1926.803(f)(1), (g)(1)(iii), and (g)(1)(xvii).

Duration

The Interim Order granted to Ballard will remain in effect until OSHA modifies or revokes this Interim Order or grants Ballard's request for a Permanent Variance in accordance with 29 CFR 1905.13. The proposed Permanent Variance, if granted, would remain in effect until the completion of Ballard's Suffolk County Outfall Tunnel.

List of Abbreviations

Abbreviations used throughout this proposed Permanent Variance would include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression illness
4. DMT—Diver medical technician
5. EPBMTBM—Earth pressure balanced micro-tunnel boring machine
6. HOM—Hyperbaric operations manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

Definitions

The following definitions would apply to this proposed Permanent Variance. These definitions would supplement the definitions in Ballard's project-specific HOM.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this proposed Permanent Variance, or any one of his or her authorized representatives. The term ''employee'' has the meaning defined by and used under the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*
2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 pounds per square inch absolute (p.s.i.a.), 1 atmosphere absolute, or 0 p.s.i.g.
3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 30 p.s.i.g.
4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[15]
5. *Decompression illness*—an illness (also called decompression sickness or ''the bends'') caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include, but are not limited to: Joint pain (also known as the ''bends'' for agonizing pain or the ''niggles'' for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).[16]

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: Barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O_2) at elevated partial pressures).

6. *Diver Medical Technician*—member of the dive team who is experienced in first aid.
7. *Earth Pressure Balanced Micro-Tunnel Boring Machine*—the machinery used by Ballard to excavate the tunnel in the Suffolk County Outfall Tunnel Project in West Babylon, New York.
8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.[17]
9. *Hyperbaric*—at a higher pressure than atmospheric pressure.
10. *Hyperbaric intervention*—a term that describes the process of stopping the EPBMTBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.
11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by Ballard for working in compressed air during the Suffolk County Outfall Tunnel.
12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.
13. *Manlock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into, or out of, a working chamber.
14. *Pressure*—a force acting on a unit area, usually expressed as pounds per square inch (p.s.i.).
15. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.
16. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure;

[14] In these conditions, OSHA is using the future conditional form of the verb (*e.g.,* ''would''), which pertains to the application for a Permanent Variance (designated as ''Permanent Variance'') but the conditions are mandatory for purposes of the Interim Order.

[15] Adapted from 29 CFR 1926.32(f).

[16] *See* U.K. Health & Safety Executive, A Guide to the Work in Compressed-Air Regulations 1996, 69 (2002), *available at http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf (Appendix 10).*

[17] See also 29 CFR 1910.146(b).

pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g. At sea level the gauge pressure is 0 p.s.i.g.

17. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[18]

18. *Working chamber*—an enclosed space in the EPBMTBM in which CAWs perform interventions, and which is accessible only through a manlock.

Safety and Health Practices

1. Ballard would have to adhere to the project-specific HOM submitted to OSHA as part of the application (see OSHA–2019–0018–0002). The HOM provides the minimum requirements regarding protections from expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. Ballard would have to demonstrate that the EPBMTBM on the project is designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*) for the EPBMTBM's hyperbaric chambers.

3. Ballard would have to implement the safety and health instructions included in the manufacturer's operations manuals for the EPBMTBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. The decompression chamber must be capable of providing a minimum decompression duration of 121 minutes.

5. Ballard would have to ensure that air or oxygen is the only breathing gas in the working chamber.

6. Ballard would have to follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM; specifically, the extracted portions of the 1992 French Decompression tables titled, ''French Regulation Air Standard Tables.''

7. Ballard would have to equip manlocks used by employees with an air or oxygen delivery system, as specified by the HOM, for the project. Ballard would be required not to store in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions would have to use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, Ballard would have to maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. Ballard would have to develop and implement one or more JHA(s) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.,* after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs would have to include all the job functions that the risk assessment [19] indicates are essential to prevent injury or illness.

11. A qualified person must perform a post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity, or other health effects associated with work in compressed air for each hyperbaric intervention.

12. Ballard would have to develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by the proposed Permanent Variance and this Interim Order (including all procedures required by the HOM approved by OSHA for the project, which this proposed Permanent Variance would incorporate by reference). The checklists would have to include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

Ballard would have to ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.

Communication

Ballard would have to:

1. Prior to beginning each shift, implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rock slides, cave-ins, flooding, fires, or explosions.

2. Provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) Use an independent power supply for powered communication systems, and these systems would have to operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) Test communication systems at the start of each shift and as necessary thereafter during each shift to ensure proper operation.

Worker Qualifications and Training

Ballard would have to:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction on hyperbaric conditions, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, and document this instruction. The instruction would need to include:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (*e.g.,* barotrauma, nitrogen narcosis, and oxygen toxicity);

(d) How to avoid discomfort during compression and decompression;

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (G)(2) of this proposed condition periodically and as necessary (*e.g.,* after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's nearest affected Area Office before the training takes place.

Inspections, Tests, and Accident Prevention

1. Ballard would have to initiate and maintain a program of frequent and

[18] Adapted from 29 CFR 1926.32(m).

[19] See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

regular inspections of the EPBMTBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the EPBMTBM.

2. Remove from service any equipment that constitutes a safety hazard until it corrects the hazardous condition and has the correction approved by a qualified person.

3. Ballard would have to maintain records of all tests and inspections of the EPBMTBM, as well as associated corrective actions and repairs, at the job site for the duration of the job.

Compression and Decompression

Ballard would have to consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

Recordkeeping

In addition to completing OSHA's Form 301 Injury and Illness Incident Report and OSHA's Form 300 Log of Work-Related Injuries and Illnesses, Ballard would have to maintain records of:

1. The date, times (*e.g.,* time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity, or other health effects associated with work in compressed air for each hyperbaric intervention.

Notifications

1. To assist OSHA in administering the conditions specified herein, Ballard would have to:

(a) Notify the OTPCA and the LIAO of any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during EPBMTBM operations, including those that do not require recompression treatment (*e.g.,* nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The notification would have to be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality; a copy of the incident investigation (OSHA's Form 301 Injury and Illness Incident Report) must be submitted to OSHA within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by OSHA's Form 301 Injury and Illness Incident Report, the incident-investigation report would have to include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification to the LIAO within 15 working days of the incident that Ballard informed affected workers of the incident and the results of the incident investigation (including the root-cause determination as well as the preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the LIAO within 15 working days and in writing, of any change in the compressed-air operations that affects Ballard's ability to comply with the proposed conditions specified herein.

(d) Upon completion of the Suffolk County Outfall Tunnel, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the LIAO.

Note: The evaluation report would have to contain summaries of (1) the number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures, air, and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA's Form 301 Injury and Illness Incident Report and OSHA's Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses, and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the proposed conditions specified herein, inform the OTPCA and the LIAO as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

(i) Cease doing business;

(ii) Change the location and address of the main office for managing the tunneling operations specified herein; or

(iii) Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this proposed Permanent Variance by the same means required to inform them of its application for a Variance.

2. OSHA would have to approve the transfer of the proposed Permanent Variance to a successor company.

VII. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to Section 29 U.S.C. 655(6)(d), Secretary of Labor's Order No. 8–2020 (85 FR 58393; Sept. 18, 2020), and 29 CFR 1905.11.

Signed at Washington, DC, on January 13, 2021.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–01110 Filed 1–15–21; 8:45 am]

BILLING CODE 4510–26–P

OFFICE OF MANAGEMENT AND BUDGET

Recommendations From the Metropolitan and Micropolitan Statistical Area Standards Review Committee to the Office of Management and Budget Concerning Changes to the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice and request for comment.

SUMMARY: The Office of Management and Budget (OMB) requests public comment on the recommendations it has received from the Metropolitan and Micropolitan Statistical Area Standards Review Committee for changes to OMB's metropolitan and micropolitan statistical area standards. These standards determine the procedures for delineating and updating the statistical areas as new data become available, and responses to this request will be

carefully considered by OMB in establishing revised standards.

DATES: Comments must be submitted in writing. To ensure consideration of comments, they must be received no later than 60 days from the publication of this notice. Because of delays in the receipt of regular mail related to security screening, respondents are encouraged to send comments electronically (see **ADDRESSES**, below).

ADDRESSES: Comments may be sent electronically via *www.regulations.gov*—a Federal E-Government website that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type ''OMB–2021–0001'' (including quotation marks) in the Comment or Submission search box, click ''Go,'' and follow the instructions for submitting comments. Comments received by the date specified above will be included as part of the official record.

Comments submitted in response to this notice may be made available to the public. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

Electronic Availability: This notice is available on the internet on the OMB website at *https://www.whitehouse.gov/omb/.* **Federal Register** notices are also available electronically at *https://www.federalregister.gov/.*

FOR FURTHER INFORMATION CONTACT: James D. Fitzsimmons, Chair, Metropolitan and Micropolitan Statistical Area Standards Review Committee, telephone (301) 763–1465; or Email *statistical_directives@omb.eop.gov.*

SUPPLEMENTARY INFORMATION:

Outline of Notice

1. Background
2. Review Process
3. Overview of Recommendations From the Metropolitan and Micropolitan Statistical Area Standards Review Committee
4. Issues for Comment

1. Background

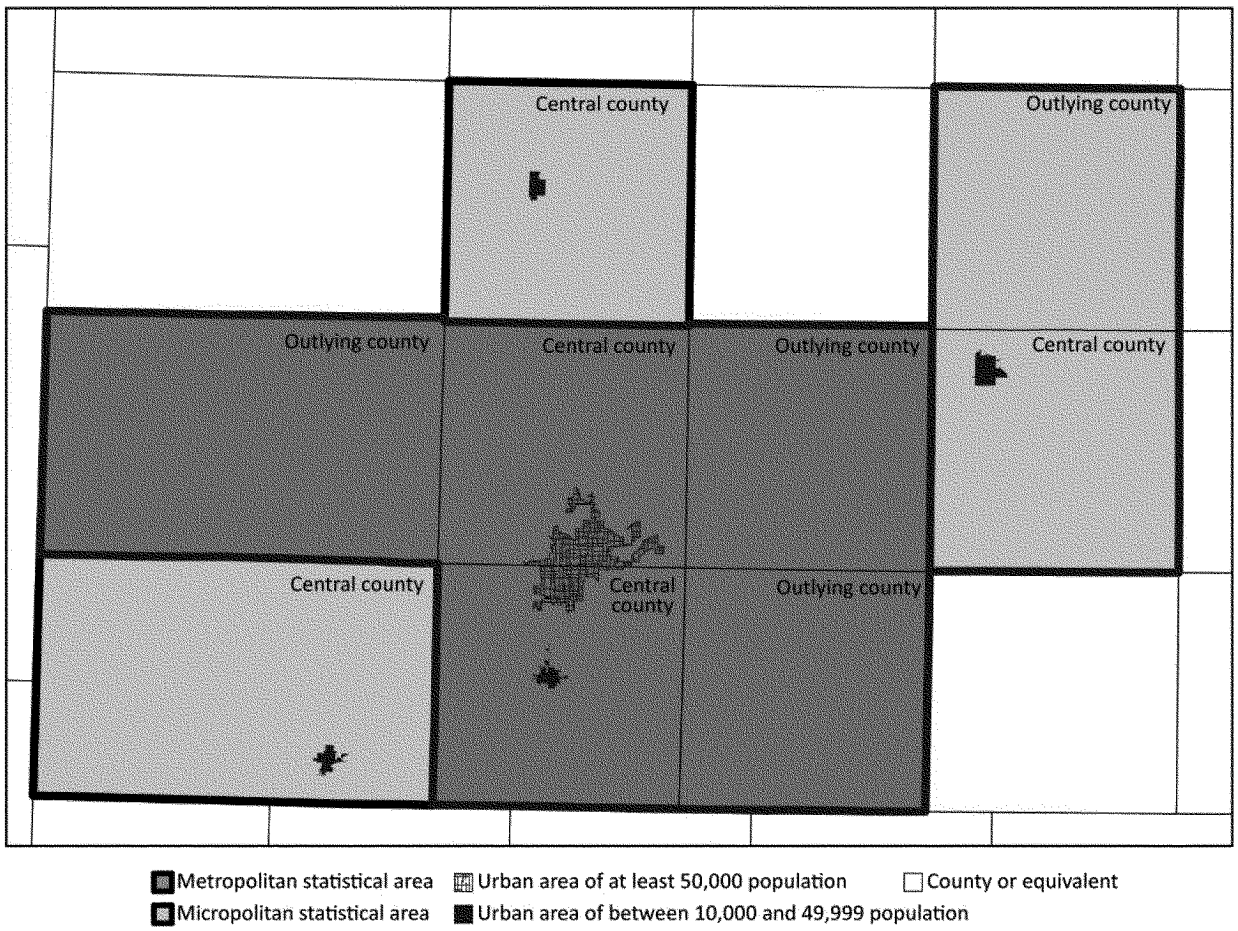
The metropolitan area program has provided standard statistical area delineations for approximately 70 years. In the 1940s, it became clear that the value of statistics produced by Federal agencies would be greatly enhanced if agencies used a single set of geographic delineations for the Nation's largest centers of population and activity. OMB's predecessor, the Bureau of the Budget, led the effort to develop what were then called ''standard metropolitan areas'' in time for their use in 1950 census publications. Since then, comparable data products for metropolitan areas have been available.

The general concept of a metropolitan statistical area is that of an area containing a large population nucleus and adjacent communities that have a high degree of integration with that nucleus. The concept of a micropolitan statistical area closely parallels that of the metropolitan statistical area, but a micropolitan statistical area features a smaller nucleus.

As currently operationalized, a metropolitan statistical area must contain a Census Bureau-delineated urban area with a population of 50,000 or more, while a micropolitan statistical area must contain a Census Bureau-delineated urban area with a population of 10,000 to 49,999. (Areas delineated in annual updates based on Census Bureau place population estimates are excepted from this requirement until the following decade.)

Both metropolitan and micropolitan statistical areas are composed of entire counties (Figure 1). ''Central counties'' are those that have substantial population residing in the largest urban area of the metropolitan or micropolitan statistical area. ''Outlying counties'' qualify based on having sufficient commuting with the central county or counties of the area. Counties that do not fall within metropolitan or micropolitan statistical areas are termed ''outside core based statistical area.''

Figure 1. Representative Metropolitan and Micropolitan Statistical Areas with Urban Areas



The purpose of these statistical areas is unchanged from when standard metropolitan areas were first delineated: The classification provides a nationally consistent set of delineations for collecting, tabulating, and publishing Federal statistics for geographic areas.

OMB establishes and maintains these areas solely for statistical purposes. *In reviewing and revising these areas, OMB does not take into account or attempt to anticipate any public or private sector nonstatistical uses that may be made of the delineations. These areas are not designed to serve as a general-purpose geographic framework applicable for nonstatistical activities or for use in program funding formulas.*

2. Review Process

Periodic review of the standards is necessary to ensure their continued usefulness and relevance. OMB reviews the statistical area standards and, if warranted, revises them prior to their application to new decennial census data. The current review of the metropolitan and micropolitan statistical area standards is the seventh such review. In 2018, OMB charged the Metropolitan and Micropolitan Statistical Area Standards Review Committee with examining the 2010 metropolitan and micropolitan statistical area standards and providing recommendations on the standards scheduled to be issued no later than December 2020. Agencies represented on the review committee include the U.S. Census Bureau (Chair), Bureau of Economic Analysis, Bureau of Justice Statistics, Bureau of Labor Statistics, Bureau of Transportation Statistics, Economic Research Service, National Center for Health Statistics, Statistics of Income, and *ex officio,* OMB. The Census Bureau provided research support to the committee.

This notice is the first of two anticipated notices related to the review of the 2010 standards. After OMB considers the recommendations of the review committee and the comments received through this notice, any revisions to the standards will be announced in a final notice.

3. Overview of Recommendations From the Metropolitan and Micropolitan Statistical Area Standards Review Committee

The committee noted that the 2010 standards have served the Federal statistical community well over the past decade. There are aspects of the standards, however, that require evaluation in light of experiences from the implementation of the 2010 standards and continuing change in U.S. population and activity patterns.

The committee made the following recommendations in their report to OMB, available as a supplemental document to this Notice at *www.regulations.gov:*

(1) The minimum urban area population to qualify a metropolitan statistical area should be increased from 50,000 to 100,000 (see Appendix, Part A: Table 1 for a list of current metropolitan statistical areas likely to be among those that would be affected by this recommendation).

(2) The delineation of New England city and town areas (NECTAs), NECTA

divisions, and combined NECTAs should be discontinued.

(3) Research should be undertaken on an additional, territorially exhaustive classification that covers all of the United States and Puerto Rico.

(4) The first annual delineation update of the coming decade should be combined with the decennial-based delineations.

(5) OMB should make publicly available a schedule for updates to the core based statistical areas (see proposed update schedule below).

(6) OMB should continue use of American Community Survey commuting data in measurement of intercounty connectivity, though changing societal and economic trends may warrant considering changes in the 2030 standards.

Under the recommendations of the committee, OMB would release three different types of updates, subject to the proposed standards.

(1) Annual Updates—These updates would address qualification of new metropolitan and micropolitan statistical areas and typically would affect a small number of counties. (In some years, there may be no updates warranted by the data.)

(2) Five-Year (''mid-decade'') Update—This broader update would include: Qualification of metropolitan and micropolitan statistical areas, qualification of outlying counties, merging of adjacent metropolitan or micropolitan statistical areas, qualification of principal cities, categorization of metropolitan and micropolitan statistical areas, qualification of metropolitan divisions, qualification of combined statistical areas, and titling of metropolitan and micropolitan statistical areas, metropolitan divisions, and combined statistical areas.

(3) Decennial Delineation—The initial re-delineation following adoption of revised standards would include all of the changes listed for the five-year update, plus the qualification of central counties.

The schedule for these updates as described in the attached proposed standards is as follows:

Update type	Release date
Decennial Delineation	June 2023.
Annual Update	December 2024.
Annual Update	December 2025.
Annual Update	December 2026.
Annual Update	December 2027.
Five-Year Update	December 2028.
Annual Update	December 2029.

4. Issues for Comment

OMB is seeking comments on the specific recommendations of the committee for revising the 2010 standards and their potential effects on the statistical area delineations (see Section 3 above). Comments are also sought on any other aspect of the current 2010 Standards that are of interest to reviewers, including topics such as commuting thresholds, alternative sources of data, stakeholder engagement, and procedures for OMB dissemination of updates to the delineations, as well as editorial suggestions to help improve the clarity of the standards.

Dominic J. Mancini,

Deputy Administrator.

[FR Doc. 2021–00988 Filed 1–15–21; 8:45 am]

BILLING CODE 3110–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0153]

Updated Aging Management Criteria for Reactor Vessel Internal Components for Pressurized-Water Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) SLR–ISG–2021–01–PWRVI, ''Updated Aging Management Criteria for Reactor Vessel Internal Components for Pressurized-Water Reactors.'' This ISG updates the aging management criteria for pressurized-water reactor (PWR) vessel internals components in the NRC's subsequent license renewal (SLR) guidance documents. Specifically, the ISG revises guidance contained in NUREG–2191, ''Generic Aging Lessons Learned for Subsequent License Renewal (GALL–SLR) Report,'' and NUREG–2192, ''Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants.'' This ISG is intended to facilitate preparation of SLR applications by clarifying existing guidance for aging management and adding new guidance, which also will facilitate the NRC staff's review of SLR applications.

DATES: This guidance is effective on February 18, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0153 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0153. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jeffrey Mitchell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0833; email: *jeffrey.mitchell2@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 3, 2020 (85 FR 46735), the staff requested public comments on draft SLR–ISG–PWRVI–2020–XX, ''Updated Aging Management Criteria for Reactor Vessel Internal Components for Pressurized-Water Reactors.'' The NRC received comments from the Electric Power Research Institute, Materials Reliability Program (EPRI MRP) by letter dated September 1, 2020 (ADAMS Accession No. ML20245E539), and from the Nuclear Energy Institute by letter dated September 2, 2020 (ADAMS Accession No. ML20246G654). No other comments were submitted. The NRC staff considered those comments in developing the final version of the ISG. The staff's responses to the comments are provided in

Appendix H, ''Disposition of Public Comments,'' of the final ISG.

This ISG updates NUREG–2191, ''Generic Aging Lessons Learned for Subsequent License Renewal (GALL–SLR) Report,'' and NUREG–2192, ''Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants.'' NUREG–2191 and NUREG–2192 were published in July 2017, and a full review and revision to these documents is not scheduled to be performed for several years. The staff has reviewed the first three subsequent license renewal applications (SLRAs) that were based on the above guidance documents. During these reviews, the staff and applicants identified improvements to the guidance that would assist in preparing and reviewing future SLRAs more effectively and efficiently. This ISG provides an interim update to NUREG–2191 and NUREG–2192 to implement these improvements.

This ISG is not intended for standalone use. It provides revisions to NUREG–2191 and NUREG–2192 sections and tables that supersede the content in the NUREGs and is intended to be used within the context of the NUREGs. The revisions captured in this ISG include:

- Updates to GALL–SLR Report aging management program XI.M16A, ''PWR Vessel Internals'';
- changes to aging management review items in NUREG–2191 tables and corresponding summary tables in NUREG–2192;
- new aging management review items in NUREG–2191 tables and corresponding summary tables in NUREG–2192;
- changes to NUREG–2192 ''further evaluation'' guidance sections;
- updates to references listed in affected NUREG–2191 sections; and
- editorial corrections to relevant sections.

II. Availability of Documents

The documents identified in the following table are available to interested persons in ADAMS, as indicated.

Document	ADAMS accession No.
NUREG–2191, ''Generic Aging Lessons Learned for Subsequent License Renewal (GALL–SLR) Report''	ML16274A389 (Vol. 1) ML16274A399 (Vol. 2).
NUREG–2192, ''Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants''.	ML16274A402.
Draft SLR–ISG–PWRVI–2020–XX, ''Updated Aging Management Criteria for Reactor Vessel Internal Components for Pressurized-Water Reactors''.	ML20156A343.
Final SLR–ISG–2021–01–PWRVI, ''Updated Aging Management Criteria for Reactor Vessel Internal Components for Pressurized-Water Reactors''.	ML20217L203.
March 28, 2019, Summary of Category 2 Public Meeting on Lessons Learned from the Review of the First Subsequent License Renewal Applications.	ML19112A206.
Summary of December 12, 2019, Category 2 Public Meeting on Lessons Learned from the Review of the First Subsequent License Renewal Applications.	ML20016A347.
February 20, 2020, Summary of Category 2 Public Meeting on Lessons Learned from the Review of the First Subsequent License Renewal Applications.	ML20076E074.
Summary of March 25, 2020 Meeting with Industry Related to Revisions to Subsequent License Renewal Guidance Documents.	ML20107F702.
Summary of April 3, 2020, Meeting with Industry Regarding Changes to Subsequent License Renewal Guidance Documents.	ML20107F733.
Summary of April 7, 2020, Meeting with Industry Regarding Revisions to the Subsequent License Renewal Guidance Documents.	ML20107F699.
Comment Letter (1) of Christopher Koehler and Brian Burgos, on behalf of the Electric Power Research Institute, Subject: ''Industry Comments to Draft Interim Staff Guidance (ISG)–SLR–ISG–PWRVI–2020–XX''.	ML20245E539.
Comment Letter (2) of Peter W. Kissinger, on behalf of Nuclear Energy Institute, Subject: ''Comments on the proposed changes to subsequent license renewal document SLR–ISG–PWRVI–2020–XX''.	ML20246G654.

III. Backfit Discussion

This ISG intends to revise guidance for the NRC staff reviewing SLRAs and for prospective applicants in preparing SLRAs. Issuance of this ISG does not constitute a backfit as defined in section 50.109(a)(1) of title 10 of the *Code of Federal Regulations* (10 CFR) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the ''Backfitting'' section of the final ISG, the ISG positions do not constitute backfitting inasmuch as the ISG is guidance directed to the NRC staff with respect to its regulatory responsibilities and to applicants who choose to follow the guidance. Applicants and potential applicants are not, with certain exceptions, the subject of either the backfit rule or any issue finality provisions under 10 CFR part 52. The NRC staff has no intention to impose the ISG positions on existing nuclear power plant licensees either now or in the future (absent a voluntary request for a change from the licensee).

IV. Congressional Review Act

This ISG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

Dated: January 13, 2021.

For the Nuclear Regulatory Commission.

Robert Caldwell,

Deputy Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–01041 Filed 1–15–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0279]

Application and Testing of Safety-Related Diesel Generators in Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG–1303, ''Application and Testing of Safety-Related Diesel Generators in Nuclear Power.'' This draft guide is proposed revision 5 of Regularity Guide (RG) 1.9. DG–1303 provides updated guidance that the staff of the NRC considers acceptable to demonstrate

compliance with the NRC regulations for safety-related alternating current (AC) power supplies intended for use as onsite emergency power sources in nuclear power plants. This revision of RG 1.9 would endorse, with supplements and clarifications, Institute of Electrical and Electronics Engineers (IEEE) Std 387–2017, ''IEEE Standard for Criteria for Diesel Generator Units Applied as Standby Power Supplies for Nuclear Power Generating Stations'' and IEEE Std 2420–2019, ''IEEE Standard for Combustion Turbine Generator Units Applied as Standby Power Supplies for Nuclear Power Generating Stations.'' This guidance would help ensure that the standby emergency power supplies are qualified, have sufficient capacity, and have the necessary reliability and availability for design-basis events.

DATES: Submit comments by February 18, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0279. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on accessing information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lilianna Ramadan, telephone: 301–415–2463, email: *Liliana.Ramadan@nrc.gov,* and Stanley Gardocki, telephone: 301–415–1067, email: *Stanley.Gardocki@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0279 when contacting the NRC about the availability of information regarding this action. You may obtain publicly available information related to this action, by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0279.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0279 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *https://www.regulations.gov/* as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is issuing for public comment a draft regulatory guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

This DG titled, ''Application and Testing of Safety-Related Diesel Generators in Nuclear Power Plants,'' is identified by its temporary task number, DG–1303. The draft guide is proposed revision 5 of RG 1.9 of the same name (ADAMS Accession No. ML14281A071). This DG provides updated guidance for actions and information that is needed for licensees, applicants, and combined operating license (COL) holders to meet the NRC regulations for safety-related standby AC power supplies intended for use as onsite emergency power sources in nuclear power plants. Information provided in this DG may be used by NRC staff, applicants, COLs holders, and licensees. This guidance helps ensure that the emergency standby AC power supplies are qualified, have sufficient capacity, and have the necessary reliability and availability for design-basis events.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML14297A097). The staff develops a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

III. Backfitting, Forward Fitting, and Issue Finality

DG–1303, if finalized, would revise RG 1.9, revision 4, which describes methods acceptable to the NRC staff for complying with the NRC's regulations for safety-related standby AC power supplies intended for use as onsite emergency power sources in nuclear power plants.

Issuance of DG–1303, if finalized, would not constitute backfitting as defined in section 50.109 of title 10 of the Code of Federal Regulations (10 CFR) 50.109, ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in MD 8.4; or affect the

issue finality of any approval issued under 10 CFR part 52. As explained in DG–1303, applicants and licensees would not be required to comply with the positions set forth in DG–1303.

Dated: January 12, 2021.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–00940 Filed 1–15–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–334, 50–412, 50–456, 50–457, 50–259, 50–260, 50–296, 50–325, 50–324, 50–454, 50–455, 50–317, 50–318, 50–413, 50–414, 50–461, 50–397, 50–445, 50–446, 50–298, 50–346, 50–275, 50–323, 50–315, 50–316, 50–237, 50–249, 50–321, 50–366, 50–341, 50–354, 50–272, 50–311, 50–003, 50–247, 50–286, 50–333, 50–348, 50–364, 50–261, 50–373, 50–374, 50–352, 50–353, 50–369, 50–370, 50–245, 50–336, 50–423, 50–263, 50–220, 50–410, 50–338, 50–339, 50–269, 50–270, 50–287, 50–243, 50–255, 50–528, 50–529, 50–530, 50–277, 50–278, 50–440, 50–266, 50–301, 50–282, 50–306, 50–254, 50–265, 50–244, 50–458, 50–335, 50–389, 50–443, 50–400, 50–498, 50–499, 50–280, 50–281, 50–387, 50–388, 50–395, 50–424, 50–425, 50–382, 50–390, 50–391; NRC–2020–0110]

Issuance of Multiple Exemptions in Response to COVID–19 Public Health Emergency

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemptions; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued 68 exemptions in response to requests from 26 licensees. The exemptions afford these licensees temporary or permanent relief from certain requirements under NRC regulations. The exemptions are in response to the licensees' requests for relief due to the coronavirus disease 2019 (COVID–19) public health emergency (PHE). The NRC is issuing a single notice to announce the issuance of the exemptions.

DATES: During the period from December 1, 2020, to December 28, 2020, the NRC granted 68 exemptions in response to requests submitted by licensees from September 30, 2020, to December 23, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0110 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0110. Address questions about NRC Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

FOR FURTHER INFORMATION CONTACT: James Danna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–7422, email: *James.Danna@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

During the period from December 1, 2020, to December 28, 2020, the NRC granted 68 exemptions in response to requests submitted by licensees from September 30, 2020, to December 23, 2020. These exemptions allow the licensees to deviate from certain requirements (as cited in this notice) of various parts of chapter I of title 10 of the *Code of Federal Regulations* (10 CFR).

The exemptions from certain requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' for Exelon Generation Company, LLC (for Braidwood Station, Units 1 and 2; Byron Station, Unit Nos. 1 and 2; Clinton Power Station, Unit No. 1; LaSalle County Station, Units 1 and 2; and Quad Cities Nuclear Power Station, Units 1 and 2); for Vistra Operations Company LLC (for Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2); for Arizona Public Service Company (for Palo Verde Nuclear Generating Station, Units 1, 2, and 3); for PSEG Nuclear LLC (for Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2); and for Indiana Michigan Power Company (for Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2), afford these licensees temporary relief from the work-hour controls under 10 CFR 26.205(d)(1) through (d)(7). The exemptions from 10 CFR 26.205(d)(1) through (d)(7) ensure that the control of work hours and management of worker fatigue do not unduly limit licensee flexibility in using personnel resources to most effectively manage the impacts of the COVID–19 PHE on maintaining the safe operation of these facilities. Specifically, these licensees have stated that their staffing levels are affected or are expected to be affected by the COVID–19 PHE, and they can no longer meet or likely will not meet the work-hour controls of 10 CFR 26.205(d)(1) through (d)(7). These licensees have committed to effecting site-specific administrative controls for COVID–19 PHE fatigue management for personnel specified in 10 CFR 26.4(a).

The exemptions from certain requirements of 10 CFR part 50, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' section IV.F., ''Training,'' for Energy Northwest (for Columbia Generating Station); for DTE Electric Company (for Fermi-2); for PSEG Nuclear LLC (for Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2); for Entergy Nuclear Operations, Inc. (for Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3; and Palisades Nuclear Plant); for Virginia Electric and Power Company (for North Anna Power Station, Unit Nos. 1 and 2); for Exelon Generation Company, LLC (for LaSalle County Station, Units 1 and 2); for Oregon State University (for the Oregon State TRIGA Reactor); for Entergy Operations, Inc. (for River Bend Station, Unit 1); for NextEra Energy Seabrook, LLC (for Seabrook Station, Unit No. 1), grant temporary exemptions from the biennial emergency preparedness exercise requirement. The exemptions allow a temporary exemption from the requirements of 10 CFR part 50, appendix E, regarding the conduct of the biennial emergency preparedness exercise. These exemptions will not adversely affect the emergency response capability of the facilities because affected licensee

personnel are currently qualified, and the licensees' proposed compensatory measures will enable their staff to maintain their knowledge, skills, and abilities without the conduct of the biennial emergency preparedness exercise during the exemption term.

The exemptions from certain requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' section VI, ''Nuclear Power Reactor Training and Qualification Plan for Personnel Performing Security Program Duties,'' for Energy Harbor Nuclear Corp. (for Beaver Valley Power Station, Units 1 and 2; Davis-Besse Nuclear Power Station, Unit No. 1; and Perry Nuclear Power Plant, Unit No. 1); for Exelon Generation Company, LLC (for Braidwood Station, Units 1 and 2; Byron Station, Unit Nos. 1 and 2; Calvert Cliffs Nuclear Power Plant, Units 1 and 2; Clinton Power Station, Unit No. 1; Dresden Nuclear Power Station, Units 2 and 3; James A. FitzPatrick Nuclear Power Plant; LaSalle County Station, Units 1 and 2; Limerick Generating Station, Units 1 and 2; Nine Mile Point Nuclear Station, Units 1 and 2; Peach Bottom Atomic Power Station, Units 2 and 3; Quad Cities Nuclear Power Station, Units 1 and 2; and R. E. Ginna Nuclear Power Plant); for Tennessee Valley Authority (for Browns Ferry Nuclear Plant, Units 1, 2, and 3; and Watts Bar Nuclear Plant, Units 1 and 2); for Duke Energy Progress, LLC (for Brunswick Steam Electric Plant, Units 1 and 2; Shearon Harris Nuclear Power Plant, Unit 1; and H. B. Robinson Steam Electric Plant, Unit No. 2); for Nebraska Public Power District (for Cooper Nuclear Station); for Duke Energy Carolinas, LLC (for Catawba Nuclear Station, Units 1 and 2; McGuire Nuclear Station, Unit Nos. 1 and 2; and Oconee Nuclear Station, Units 1, 2, and 3); for Energy Northwest (for Columbia Generating Station); for Vistra Operations Company LLC (for Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2); for Pacific Gas and Electric Company (for Diablo Canyon Nuclear Power Plant, Units 1 and 2); for Indiana Michigan Power Company (for Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2); for Southern Nuclear Operating Co., Inc. (for Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2; Joseph M. Farley Nuclear Plant, Units 1 and 2; and Vogtle Electric Generating Plant, Units 1 and 2); for DTE Electric Company (for Fermi-2); for Entergy Nuclear Operations, Inc. (for Indian Point Nuclear Generating Unit Nos. 2 and 3; and Palisades Nuclear Plant); for Dominion Energy Nuclear Connecticut, Inc. (for Millstone Power Station, Unit Nos. 1, 2, and 3); for Northern States Power Company (for Monticello Nuclear Generating Plant and Prairie Island Nuclear Generating Plant, Units 1 and 2); for Virginia Electric and Power Company (for North Anna Power Station, Unit Nos. 1 and 2; and Surry Power Station, Unit Nos. 1 and 2); for NextEra Energy Point Beach, LLC (for Point Beach Nuclear Plant, Units 1 and 2); for Florida Power & Light Company (for St. Lucie Plant, Unit Nos. 1 and 2); for NextEra Energy Seabrook, LLC (for Seabrook Station, Unit No. 1); STP Nuclear Operating Company (for South Texas Project, Units 1 and 2); for Susquehanna Nuclear LLC (for Susquehanna Steam Electric Station, Units 1 and 2), for Dominion Energy South Carolina, Inc. (for Virgil C. Summer Nuclear Station, Unit No. 1); and Entergy Operations, Inc. (for Waterford Steam Electric Station, Unit 3), will help to ensure that these regulatory requirements do not unduly limit licensee flexibility in using personnel resources in a manner that most effectively manages the impacts of the COVID–19 PHE on maintaining the safe and secure operation of these facilities and the implementation of the licensees' NRC approved security plans, protective strategy, and implementing procedures. These licensees have committed to certain security measures to ensure response readiness and for their security personnel to maintain performance capability.

The NRC is providing compiled tables of exemptions using a single **Federal Register** notice for COVID–19 related exemptions instead of issuing individual **Federal Register** notices for each exemption. The compiled tables in this notice provide transparency regarding the number and type of exemptions the NRC has issued. Additionally, the NRC publishes tables of approved regulatory actions related to the COVID–19 PHE on its public website at *https://www.nrc.gov/about-nrc/covid-19/reactors/licensing-actions.html.*

II. Availability of Documents

The tables in this notice provide the facility name, docket number, document description, and ADAMS accession number for each exemption issued. Additional details on each exemption issued, including the exemption request submitted by the respective licensee and the NRC's decision, are provided in each exemption approval listed in the tables in this notice. For additional directions on accessing information in ADAMS, see the **ADDRESSES** section of this document.

Document description	ADAMS accession No.
Beaver Valley Power Station, Units 1 and 2 Docket Nos. 50–334 and 50–412	
Beaver Valley Power Station, Units 1 and 2 -Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 28, 2020.	ML20303A213.
Beaver Valley Power Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0171 [COVID–19]), dated December 15, 2020.	ML20324A089.
Braidwood Station, Units 1 and 2 Docket Nos. 50–456 and 50–457	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Braidwood Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0198) [COVID–19], dated December 10, 2020.	ML20322A338.

Document description	ADAMS accession No.
Braidwood Station, Units 1 and 2 Docket Nos. 50–456 and 50–457	
Braidwood Station, Units 1 and 2—COVID–19 Related Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated November 17, 2020.	ML20323A008.
Braidwood Station, Units 1 and 2—Response to Request for Additional Information Related to Exemption from 10 CFR part 26 Requirements, dated November 23, 2020.	ML20328A215.
Braidwood Station, Units 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0207 [COVID–19]), dated December 1, 2020.	ML20324A002.
Browns Ferry Nuclear Plant, Units 1, 2, and 3 Docket Nos. 50–259, 50–260, and 50–296	
Browns Ferry Nuclear Power Plant, Units 1, 2, and 3—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 8, 2020.	ML20343A214.
Browns Ferry Nuclear Plant, Units 1, 2, and 3—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0233 [COVID–19]), dated December 15, 2020.	ML20343A363.
Brunswick Steam Electric Plant, Units 1 and 2 Docket Nos. 50–325 and 50–324	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Brunswick Steam Electric Plant, Units 1 and 2 Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0180 [COVID–19]), dated December 17, 2020.	ML20338A329.
Byron Station, Unit Nos. 1 and 2 Docket Nos. 50–454 and 50–455	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Byron Station, Unit Nos. 1 and 2—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(I)(1) (EPID L–2020–LLE–0199) [COVID–19], dated December 10, 2020.	ML20323A393.
Byron Station, Unit Nos. 1 and 2 Docket Nos. 50–454 and 50–455	
Byron Station, Unit Nos. 1 and 2—Subsequent Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated November 24, 2020.	ML20329A533.
Byron Station, Unit Nos. 1 and 2—Response to Request for Additional Information Related to Subsequent Exemption from 10 CFR part 26 Requirements, dated December 1, 2020.	ML20336A341.
Byron Station, Unit Nos. 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0218 [COVID–19]), dated December 2, 2020.	ML20332A017.
Calvert Cliffs Nuclear Power Plant, Units 1 and 2 Docket Nos. 50–317 and 50–318	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A288.
Calvert Cliffs Nuclear Power Plant, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(I)(1) (EPID L–2020–LLE–0194 [COVID–19]), dated December 11, 2020.	ML20321A243.
Catawba Nuclear Station, Units 1 and 2 Docket Nos. 50–413 and 50–414	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1), Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Catawba Nuclear Station, Units 1 and 2—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0180 [COVID–19]), dated December 17, 2020.	ML20337A128.

Document description	ADAMS accession No.
Clinton Power Station, Unit No. 1 Docket No. 50–461	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Clinton Power Station, Unit No. 1—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(l)(1) (EPID L–2020–LLE–0200 [COVID–19]), dated December 11, 2020.	ML20323A434.
Clinton Power Station, Unit No. 1 Docket No. 50–461	
Clinton Power Station, Unit No. 1—COVID–19 Related Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated December 3, 2020.	ML20339A318.
Clinton Power Station, Unit No. 1—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0232 [COVID–19]), dated December 16, 2020.	ML20339A538.
Columbia Generating Station Docket No. 50–397	
Columbia Generating Station—Exemption Request from 10 CFR part 50, appendix E due to COVID–19 Pandemic, dated October 29, 2020.	ML20303A348.
Columbia Generating Station—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0173 [COVID–19]), dated December 17, 2020.	ML20336A183.
Columbia Generating Station Docket No. 50–397	
Columbia Generating Station—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated October 29, 2020.	ML20303A286.
Columbia Generating Station—Response to Request for Additional Information Related to Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-On-Force Exercises due to COVID–19, dated December 3, 2020.	ML20338A541.
Columbia Generating Station—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0172 [COVID–19]), dated December 17, 2020.	ML20342A211.
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 Docket Nos. 50–445 and 50–446	
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(l) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 10, 2020.	ML20345A341.
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2—Exemption from Annual Force-On-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0235 [COVID–19]), dated December 22, 2020.	ML20350B666.
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 Docket Nos. 50–445 and 50–446	
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2—Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated December 11, 2020.	ML20346A565.
Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2—Supplement to Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated December 15, 2020.	ML20350B830.
Comanche Peak, Unit Nos. 1 and 2—Exemption from Selection from Requirements of 10 CFR part 26 (EPID L–2020–LLE–0236 [COVID–19]), dated December 16, 2020.	ML20349A038.
Cooper Nuclear Station Docket No. 50–298	
Cooper Nuclear Station—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 27, 2020.	ML20309A663.
Cooper Nuclear Station—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0178 [COVID–19]), dated December 11, 2020.	ML20323A237.

Document description	ADAMS accession No.
Davis-Besse Nuclear Power Station, Unit No. 1 Docket No. 50–346	
Davis-Besse Nuclear Power Station, Unit No. 1—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 29, 2020.	ML20304A046.
Davis-Besse Nuclear Power Station, Unit No. 1—Response to Request for Additional Information Regarding Request for Exemption—10 CFR part 73 Force-on-Force Exercises (EPID L–2020–LLE–0175), dated December 7, 2020.	ML20342A199.
Davis-Besse Nuclear Power Station, Unit No. 1—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0175 [COVID–19]), dated December 15, 2020.	ML20345A205.
Diablo Canyon Nuclear Power Plant, Units 1 and 2 Docket Nos. 50–275 and 50–323	
Diablo Canyon Nuclear Power Plant, Units 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 14, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Diablo Canyon Nuclear Power Plant, Units 1 and 2—Response to Request for Additional Information Regarding Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Diablo Canyon Nuclear Power Plant, Units 1 and 2—Exemption from Annual Force-On-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0166 [COVID–19]), dated December 17, 2020.	ML20346A024.
Diablo Canyon Nuclear Power Plant, Units 1 and 2 Docket Nos. 50–275 and 50–323	
Diablo Canyon Power Plant, Units 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection F.5.(a) Regarding Firearms Requalification due to COVID–19 Pandemic, dated October 14, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Diablo Canyon Nuclear Power Plant, Units 1 and 2—Response to Request for Additional Information Regarding Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection F.5.(a) Regarding Firearms Requalification due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Diablo Canyon Nuclear Power Plant, Units 1 and 2—Exemption from Annual Firearms Tactical Qualification Course Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.F.5.(a) (EPID L–2020–LLE–0167 [COVID–19]), dated December 18, 2020.	ML20346A120.
Donald C. Cook Nuclear Plant, Units Nos. 1 and 2 Docket Nos. 50–315 and 50–316	
Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	ML20318A034.
Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2—Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' section VI (EPID L–2020–LLE–0182 [COVID–19]), dated December 8, 2020.	ML20324A003.
Donald C. Cook Nuclear Plant, Units Nos. 1 and 2 Docket Nos. 50–315 and 50–316	
Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR 26.205(d) due to COVID–19 Pandemic, dated November 30, 2020.	ML20338A324.
Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0221 [COVID–19]), dated December 3, 2020.	ML20336A111.
Dresden Nuclear Power Station, Units 2 and 3 Docket Nos. 50–237 and 50–249	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Dresden Nuclear Power Station, Units 2 and 3—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0203 [COVID–19]), dated December 14, 2020.	ML20322A303.
Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2 Docket Nos. 50–321 and 50–366	
Request for One-Time Exemptions from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 6, 2020.	ML20311A662.

Document description	ADAMS accession No.
Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0215 [COVID–19]), dated December 4, 2020.	ML20329A488.
Fermi-2 Docket No. 50–341	
Fermi-2—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated November 12, 2020.	ML20317A203.
Fermi-2—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0188 [COVID–19]), dated December 8, 2020.	ML20332A179.
Fermi-2 Docket No. 50–341	
Fermi-2—Request for Exemption from the Annual Force-on-Force Training Requirements of 10 CFR part 73, appendix B, section VI due to the COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A383.
Fermi-2—Response to Request for Additional Information Regarding Exemption from the Annual Force-on-Force Training Requirements of 10 CFR part 73, appendix B, section VI due to the COVID–19 Public Health Emergency, dated December 3, 2020.	ML20338A333.
Fermi-2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0204 [COVID–19]), dated December 18, 2020.	ML20343A350.
Hope Creek Generating Station Docket No. 50–354 Salem Nuclear Generating Station, Unit Nos. 1 and 2 Docket Nos. 50–272 and 50–311	
Hope Creek Generating Station and Salem Generating Station, Units Nos. 1 and 2—Exemption Request from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated October 13, 2020.	ML20287A628.
Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2—Temporary Exemption from the Exercise Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0164 [COVID–19]), dated December 7, 2020.	ML20315A434.
Hope Creek Generating Station Docket No. 50–354 Salem Nuclear Generating Station, Unit Nos. 1 and 2 Docket Nos. 50–272 and 50–311	
Hope Creek Generating Station and Salem Generating Station, Unit Nos. 1 and 2—Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated December 23, 2020.	ML20358A186.
Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0239 [COVID–19]), dated December 28, 2020.	ML20358A281.
Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3 Docket Nos. 50–003, 50–247, and 50–286	
Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3—One-time Scheduler Exemption Request from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Public Health Emergency, dated October 8, 2020.	ML20282A612.
Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3—Supplement to One-Time Exemption Request from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements'' (EPID L–2020–LLE–0160 [COVID–19]), dated November 12, 2020.	ML20317A344.
Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3—Temporary Exemption from Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F.2.B (EPID L–2020–LLE–0160 [COVID–19]), dated December 8, 2020.	ML20320A000.
Indian Point Nuclear Generating Unit Nos. 2 and 3 Docket Nos. 50–247 and 50–286	
Indian Point Nuclear Generating Unit Nos. and 3—Request for a One-Time Exemption from 10 CFR 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force (FOF) Exercises, Due to COVID 19 Pandemic, dated November 12, 2020.	ML20317A299.
Indian Point Nuclear Generating Unit Nos. 2 and 3—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0189 [COVID–19]), dated December 14, 2020.	ML20321A121.

Document description	ADAMS accession No.
James A. FitzPatrick Nuclear Power Plant Docket No. 50–333	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A288.
James A. Fitzpatrick Nuclear Power Plant—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0197 [COVID 19]), dated December 8, 2020.	ML20337A004.
Joseph M. Farley Nuclear Plant, Units 1 and 2 Docket Nos. 50–348 and 50–364	
Request for One-Time Exemptions from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 6, 2020.	ML20311A662.
Joseph M. Farley Nuclear Plant, Units 1 and 2—Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI C.3.(l)(1) (EPID L–2020–LLE–0183 [COVID–19]), dated December 4, 2020.	ML20315A374.
H. B. Robinson Steam Electric Plant, Unit No. 2 Docket No. 50–261	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
H. B. Robinson Steam Electric Plant, Unit No. 2—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1), dated December 17, 2020.	ML20339A521.
LaSalle County Station, Units 1 and 2 Docket Nos. 50–373 and 50–374	
LaSalle County Station, Units 1 and 2—Request for Exemption from the Biennial Emergency Preparedness Exercise Requirements in 10 CFR part 50, appendix E, section IV.F.2.b, dated November 23, 2020.	ML20328A292.
LaSalle County Station, Units 1 and 2—Supplemental Information Regarding Request for Exemption from the Biennial Emergency Preparedness Exercise Requirements of 10 CFR part 50, appendix E, section IV.F.2.b, dated December 7, 2020.	ML20342A259.
LaSalle County Station, Units 1 and 2—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F.2.b (EPID–L–2020–LLE–0223 [COVID–19]), dated December 18, 2020.	ML20346A014.
LaSalle County Station, Units 1 and 2 Docket Nos. 50–373 and 50–374	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
LaSalle County Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(l)(1) (EPID L–2020–LLE–0191 [COVID–19]), dated December 9, 2020.	ML20324A104.
LaSalle County Station, Units 1 and 2 Docket Nos. 50–373 and 50–374	
LaSalle County Station, Units 1 and 2- COVID–19 Related Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated November 24, 2020.	ML20329A301.
LaSalle County Station, Units 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0217 [COVID–19]), dated December 1, 2020.	ML20330A326.
Limerick Generating Station, Units 1 and 2 Docket Nos. 50–352 and 50–353	
Exelon Generation—Limerick Generating Station, Units 1 and 2—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A288.
Limerick Generating Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0201 [COVID–19]), dated December 10, 2020.	ML20330A295.

Document description	ADAMS accession No.
McGuire Nuclear Station, Unit Nos. 1 and 2 Docket Nos. 50–369 and 50–370	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
McGuire Nuclear Station, Unit Nos. 1 and 2—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0180) [COVID–19], dated December 9, 2020.	ML20330A321.
Millstone Power Station, Unit Nos. 1, 2, and 3 Docket Nos. 50–245, 50–336, and 50–423	
Millstone Power Station, Unit Nos. 1, 2, and 3—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Millstone Power Station, Unit Nos. 1, 2, and 3—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0227 [COVID–19]), dated December 16, 2020.	ML20338A552.
Monticello Nuclear Generating Plant Docket No. 50–263	
Monticello and Prairie Island—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 30, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Response to Request for Additional Information Regarding Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 14, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Monticello Nuclear Generating Plant—Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0174 [COVID–19]), dated December 22, 2020.	ML20317A136.
Nine Mile Point Nuclear Station, Units 1 and 2 Docket Nos. 50–220 and 50–410	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A288.
Nine Mile Point Nuclear Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0195 [COVID–19]), dated December 14, 2020.	ML20321A290.
North Anna Power Station, Unit Nos. 1 and 2 Docket Nos. 50–338 and 50–339	
North Anna Power Station, Unit Nos. 1 and 2—Request for One-Time Schedular Exemption from Offsite Biennial Emergency Preparedness Exercise Requirement in 10 CFR part 50, appendix E, section IV.F.2.c, dated November 10, 2020.	ML20317A162.
North Anna Power Station, Unit Nos. 1 and 2—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F.2.C (EPID L–2020–LLE–0184 [COVID–19]), dated December 8, 2020.	ML20324A222.
North Anna Power Station, Unit Nos. 1 and 2 Docket Nos. 50–338 and 50–339	
North Anna Power Station, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
North Anna Power Station, Units Nos. 1 and 2—Exemption from Annual Force-On Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0231 [COVID–19]), dated December 15, 2020.	ML20342A293.
Oconee Nuclear Station, Units 1, 2, and 3 Docket Nos. 50–269, 50–270, and 50–287	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.

Document description	ADAMS accession No.
Oconee Nuclear Station, Units 1, 2, and 3—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0180 [COVID–19]), dated December 17, 2020.	ML20344A004.
Oregon State University Docket No. 50–243	
Oregon State University—Extension of Timeframe Required to Complete Biennial Emergency Exercise per Oregon State TRIGA Reactor Emergency Response Plan, dated November 3, 2020.	ML20318A035.
Oregon State University—Extension of Timeframe required to Complete Biennial Emergency Exercise per Oregon State TRIGA Reactor Emergency Response Plan, dated December 10, 2020.	ML20350B726.
Oregon State University—Temporary Exemption from the Requirements of 10 CFR part 50, appendix E, section IV.F.2.b Related to Biennial Emergency Exercise [COVID–19], dated December 18, 2020.	ML20318A380.
Palisades Nuclear Plant Docket No. 50–255	
Palisades Nuclear Plant—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated September 30, 2020.	ML20275A110.
Palisades Nuclear Plant—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F (EPID L–2020–LLE–0155 [COVID–19]), dated December 9, 2020.	ML20308A607.
Palisades Nuclear Plant Docket No. 50–255	
Palisades Nuclear Plant—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 12, 2020.	ML20317A300.
Palisades Nuclear Plant—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0190 [COVID–19]), dated December 3, 2020.	ML20330A000.
Palo Verde Nuclear Generating Station, Units 1, 2, and 3 Docket Nos. 50–528, 50–529, 50–530	
Palo Verde Nuclear Generating Station, Units 1, 2, and 3, and Independent Spent Fuel Storage Installation—Subsequent Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated December 21, 2020.	ML20356A292.
Palo Verde Nuclear Generating Station, Units 1, 2, and 3—Subsequent Request for Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0238 [COVID–19]), dated December 23, 2020.	ML20357A055.
Peach Bottom Atomic Power Station, Units 2 and 3 Docket Nos. 50–277 and 50–278	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	ML20318A288.
Peach Bottom Atomic Power Station, Units 2 and 3—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0192 [COVID–19]), dated December 10, 2020.	ML20325A017.
Perry Nuclear Power Plant, Unit No. 1 Docket No. 50–440	
Perry Nuclear Power Plant, Unit No. 1—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 29, 2020.	ML20304A191.
Perry Nuclear Power Plant, Unit No. 1—Response to Request for Additional Information Regarding Request for Exemption—10 CFR part 73 Force-on-Force Exercises (EPID L–2020–LLE–0176), dated November 25, 2020.	ML20335A531.
Perry Nuclear Power Plant, Unit No. 1—Exemption from Certain Requirements of 10 CFR part 73, appendix B, section VI.C.3.(l)(1) Re: Annual Force-on-Force Exercise for CY 2020 (EPID L–2020–LLE–0176 [COVID–19]), dated December 14, 2020.	ML20309A135.
Point Beach Nuclear Plant, Units 1 and 2 Docket Nos. 50–266 and 50–301	
Point Beach Nuclear Plant, Units 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Point Beach Nuclear Plant, Units 1 and 2—Response to Request for Additional Information, Request for Exemption from 10 CFR part 73, appendix B, section VI Regarding Annual Force-On-Force Exercise, dated December 8, 2020.	non-public, withheld pursuant to 10 CFR 2.390.

Document description	ADAMS accession No.
Point Beach Nuclear Plant, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0210 [COVID–19]), dated December 15, 2020.	ML20345A000.
Prairie Island Nuclear Generating Plant, Units 1 and 2 Docket Nos. 50–282 and 50–306	
Monticello and Prairie Island—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3(l)(1) Re: Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated October 30, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Response to Request for Additional Information, Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 14, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Prairie Island Nuclear Generating Plant, Units 1 and 2—Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0177 [COVID–19]), dated December 21, 2020.	ML20317A259.
Quad Cities Nuclear Power Station, Units 1 and 2 Docket Nos. 50–254 and 50–265	
Exelon Generation—Request for Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding 2020 Annual Force-on-Force Exercises due to COVID–19 Public Health Emergency, dated November 13, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Quad Cities Nuclear Power Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0193 [COVID–19]), dated December 4, 2020.	ML20332A175.
Quad Cities Nuclear Power Station, Units 1 and 2 Docket Nos. 50–254 and 50–265	
Quad Cities Nuclear Power Station, Units 1 and 2—COVID–19 Related Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated December 4, 2020.	ML20339A474.
Quad Cities Nuclear Power Station, Units 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0228 [COVID–19]), dated December 17, 2020.	ML20343A027.
R. E. Ginna Nuclear Power Plant Docket No. 50–244	
Exelon Generation—Request for One-Time Exemptions from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 13, 2020.	ML20318A288.
R. E. Ginna Nuclear Power Plant—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0202 [COVID–19]), dated December 10, 2020.	ML20330A291.
River Bend Station, Unit 1 Docket No. 50–458	
River Bend Station, Unit 1—One-Time Schedular Exemption Request from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Public Health Emergency, dated December 3, 2020.	ML20338A539.
River Bend Station, Unit 1—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F.2.b (EPID–L–2020–LLE–0212 [COVID–19]), dated December 22, 2020.	ML20344A135.
St. Lucie Plant, Unit Nos. 1 and 2 Docket Nos. 50–335 and 50–389	
St. Lucie Plant, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 9, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
St. Lucie Plant, Unit Nos. 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0234) [COVID–19], dated December 18, 2020.	ML20352A118.
Seabrook Station, Unit No. 1 Docket No. 50–443	
Seabrook Station, Unit No. 1—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 23, 2020.	ML20329A205.
Seabrook Station, Unit No. 1—Response to Request for Additional Information in Response to One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated December 8, 2020.	ML20343A112.

Document description	ADAMS accession No.
Seabrook Station, Unit No. 1—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0219 [COVID–19]), dated December 16, 2020.	ML20336A006.
Seabrook Station, Unit No. 1 Docket No. 50–443	
Seabrook Station, Unit No. 1—One-Time Exemption Request for the Biennial Emergency Preparedness Exercise Requirements of 10 CFR part 50, appendix E, sections IV.F.2.b and IV.F.2.c, dated December 3, 2020.	ML20338A493.
Seabrook Station, Unit No. 1—Exemption from Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0229 and EPID L–2020–LLE–0230 [COVID–19]), dated December 21, 2020.	ML20345A119.
Shearon Harris Nuclear Power Plant, Unit 1 Docket No. 50–400	
Duke Energy—Request for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 4, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Duke Energy—Response to Request for Additional Information for One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 19, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Shearon Harris Nuclear Power Plant, Unit No. 1—Exemption from Annual Force-on-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(l)(1) (EPID L–2020–LLE–0180 [COVID–19]), dated December 17, 2020.	ML20330A301.
South Texas Project, Units 1 and 2 Docket Nos. 50–498 and 50–499	
South Texas Project, Units 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 16, 2020.	ML20321A331.
South Texas Project, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0205 [COVID–19]), dated December 10, 2020.	ML20330A312.
Surry Power Station, Unit Nos. 1 and 2 Docket Nos. 50–280 and 50–281	
Surry Power Station, Unit Nos. 1 and 2—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Surry Power Station, Unit Nos. 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0226 [COVID–19]), dated December 14, 2020.	ML20339A645.
Susquehanna Steam Electric Station, Units 1 and 2 Docket Nos. 50–387 and 50–388	
Susquehanna Steam Electric Station—Request for One-Time Exemption From 10 CFR part 73, appendix B, section VI, subsection C.3.(1)(1) Regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated November 24, 2020.	ML20329A335.
Susquehanna Steam Electric Station, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1) (EPID L–2020–LLE–0222), dated December 17, 2020.	ML20344A458.
Virgil C. Summer Nuclear Station, Unit No. 1 Docket No. 50–395	
Virgil C. Summer Nuclear Station, Unit No. 1—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-On-Force Exercises due to COVID–19 Pandemic, dated December 3, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Virgil C. Summer Nuclear Station, Unit No. 1—Exemption from Annual Force On-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(l)(1)l (EPID L–2020–LLE–0225 [COVID–19]), dated December 18, 2020.	ML20342A003.
Vogtle Electric Generating Plant, Units 1 and 2 Docket Nos. 50–424 and 50–425	
Request for One-Time Exemptions from 10 CFR part 73, appendix B, section VI, subsection C.3.(l)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 6, 2020.	ML20311A662.
Vogtle Electric Generating Plant, Units 1 and 2—Exemption from Annual Force-On-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI C.3.(l)(1) (EPID L–2020–LLE–0216 [COVID–19]), dated December 4, 2020.	ML20329A392.

Document description	ADAMS accession No.
Waterford Steam Electric Station, Unit 3 Docket No. 50–382	
Waterford Steam Electric Station, Unit 3—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force Exercises due to COVID–19 Pandemic, dated November 12, 2020.	ML20317A301.
Waterford Steam Electric Station, Unit 3—Exemption from Annual Force-On-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3.(I)(1) (EPID L–2020–LLE–0186 [COVID–19]), dated December 16, 2020.	ML20338A274.
Watts Bar Nuclear Plant, Units 1 and 2 Docket Nos. 50–390 and 50–391	
Watts Bar Nuclear Plant, Units 1 and 2—Request for Exemption Regarding Calendar Year 2020 Force-on-Force Exercise, dated November 4, 2020.	ML20309A695.
Watts Bar Nuclear Plant, Units 1 and 2—Exemption from Annual Force-on-Force Exercise Requirement of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI C.3(I)(1) (EPID L–2020–LLE–0179 [COVID–19]), dated December 8, 2020.	ML20318A036.

Dated: January 13, 2021.

For the Nuclear Regulatory Commission.

James G. Danna,

Chief, Plant Licensing Branch I, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–01091 Filed 1–15–21; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–438 and 50–439; NRC–2020–0273]

Tennessee Valley Authority Bellefonte, Units 1 and 2 Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering extending the completion dates for Construction Permit Nos. CPPR–122 and CPPR–123, issued to the Tennessee Valley Authority (TVA) for Bellefonte Nuclear Plant, Units 1 and 2 (BLN), located on the west shore of the Guntersville Reservoir at Tennessee River Mile (RM) 392 in Jackson County, Alabama. The NRC prepared this environmental assessment (EA) documenting the environmental review and finding of no significant impact (FONSI) for this proposed action.

DATES: The EA and FONSI are available January 13, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0273 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0273. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209 or 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Omid Tabatabai, Office of Nuclear Reactor Regulation, telephone: 301–415–6616; email: *Omid.Tabatabai@nrc.gov,* and Jeffrey Rikhoff, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–1090, email: *Jeffrey.Rikhoff@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering extending the completion dates specified in Construction Permit Nos. CPPR–122 and CPPR–123, issued to TVA for BLN, Units 1 and 2. The Bellefonte site is located on the west shore of the Guntersville Reservoir at Tennessee RM 392, near Hollywood, Alabama, in Jackson County, about 6 miles east-northeast of Scottsboro, Alabama.

As required by section 51.21 of the *Code of Federal Regulations* (10 CFR), ''Criteria for and identification of licensing and regulatory actions requiring environmental assessments,'' the NRC has conducted an environmental review and prepared an EA that evaluates the environmental effects of extending the construction permit completion dates (proposed action). Based on the results of the environmental review conducted for this EA, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an environmental impact statement and is issuing a FONSI.

Facility Site and Environs

The unfinished two-unit pressurized-water reactor nuclear power plant is situated on a peninsula between Town Creek and the Tennessee River at RM 392 on the west shore of Guntersville Reservoir in Jackson County near Hollywood, Alabama. Most of the 1,600-acre Bellefonte site has been impacted by the construction of BLN Unit 1 and 2.

The affected environment at the Bellefonte site is described in the June 1974 final environmental statement (FES) for the construction of BLN Units 1 and 2 (FES–CP) prepared by the U.S.

Atomic Energy Commission's (AEC; now the NRC); the NRC's January 2003 BLN Units 1 and 2 construction permit extension EA; and the NRC's September 2011 BLN Unit 1 construction permit extension EA. Also, TVA has issued several EAs that describe the environment at the Bellefonte site, including a January 2006 final EA and a May 2010 final supplemental Environmental Impact Statement. Environmental conditions at the Bellefonte site have not changed appreciably from the descriptions portrayed in these documents.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would extend the construction completion date of the BLN Unit 1 construction permit (CPPR–122) from October 1, 2020, to October 1, 2021, and the BLN Unit 2 construction permit (CPPR–123) from October 1, 2014, to October 1, 2021. TVA submitted the extension request for Unit 1 CPPR–122 on August 28, 2020, and the extension request for Unit 2 CPPR–123 on June 10, 2014, as supplemented on March 31, 2017. With respect to both construction permits, TVA submitted its requests at least 30 days before the expiration of the existing permits. Therefore, in accordance with 10 CFR 2.109(a), ''Effect of timely renewal application,'' the existing construction permits remain in effect until the NRC completes its review of the requests. The proposed extensions would not allow any work to be performed that is not already authorized under the existing construction permits; the extensions would merely grant the permittee additional time to complete the construction of both units.

Need for the Proposed Action

The proposed action is needed to provide time for the continued construction of BLN Units 1 and 2. The construction permits, both issued December 24, 1974, were originally set to expire on December 1, 1979 (Unit 1) and September 1, 1980 (Unit 2). At the request of TVA, the NRC has subsequently extended the completion dates of both BLN Units 1 and 2 several times. The BLN Unit 2 construction permit completion date was last extended to October 1, 2014. Most recently, the NRC extended the BLN Unit 1 construction completion date to October 1, 2020. In its March 31, 2017 and August 28, 2020 letters, TVA noted that it sold the Bellefonte property at auction, the sale of BLN Units 1 and 2 did not close, and the purchaser filed a lawsuit against TVA. TVA stated that an extension is needed to allow the parties additional time to obtain a decision in the lawsuit.

Environmental Impacts of the Proposed Action

The AEC evaluated the environmental impacts from constructing BLN Units 1 and 2 in the 1974 FES–CP. Subsequently, the NRC reevaluated the environmental impacts of completing the construction of BLN Units 1 and 2 in several EAs. These include the January 2003 and September 2011 construction permit extension EAs, both of which addressed environmental impact issues identified after the publication of the FES–CP. New issues included groundwater quality, public services, noise, socioeconomics, severe accident mitigation alternatives, cultural and historical resources, environmental justice, greenhouse gas emissions, and cumulative impacts. Additionally, these EAs evaluated changes to regional demography, natural resource use, meteorology, ecology, impacts to humans and the environment, severe accident mitigation design alternatives, and socioeconomic impacts, including environmental justice. Based on these reviews, NRC staff concluded that there were no significant differences in the environmental impacts previously addressed in the FES–CP. Further, the staff also did not identify any significant environmental impacts that have not already been addressed in the construction permit extension EAs. The NRC staff determined that the environmental impacts associated with completing the construction of BLN would be generally consistent with the impacts disclosed in the FES–CP and subsequent construction permit extension EAs. Specifically, in the 2011 EA, the NRC staff concluded that the environmental impacts of extending the BLN Unit 1 construction permit would not be significant, and the completion of BLN Unit 1 would not result in any disproportionately high and adverse human health and environmental effects on minority and low-income populations and communities residing near the Bellefonte site. The staff also determined that the environmental impacts from completing BLN Unit 1 would not be significant since the most environmentally disruptive construction activities have already been completed and any remaining construction activities would take place within completed structures at the Bellefonte site. Because of the conclusions reached in the January 2003 and September 2011 EAs, the NRC staff issued FONSIs extending the construction permit completion dates for both units.

In addition, extending the BLN Units 1 and 2 construction permit completion dates would have no effect on federally listed species or critical habitats protected under the Endangered Species Act of 1973, as amended, because all ground and river disturbances associated with construction have long since been completed. Federal agencies are not required to consult with the U.S. Fish and Wildlife Service or National Marine Fisheries Service if they determine that an action will not affect listed species or critical habitats. Thus, the Endangered Species Act does not require consultation for the proposed action, and the staff considers NRC's Section 7 obligations to be fulfilled.

Since the proposed action would only extend the period of construction activities described in the FES–CP and subsequent construction permit extension EAs, it would not create any new or different impacts or significantly change the impacts from those previously evaluated in these environmental documents. The NRC concludes that, based on this information, extending the construction completion date of the BLN Unit 1 construction permit (CPPR–122) from October 1, 2020, to October 1, 2021, and the BLN Unit 2 construction permit (CPPR–123) from October 1, 2014, to October 1, 2021, would have no significant environmental impacts.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative, the NRC considered denying the proposed action (*i.e.,* the ''no-action'' alternative). This alternative would result in expiration of the BLN Units 1 and 2 construction permits and, thus, would require the submittal of a new construction permit application in order to complete the nuclear facility with no significant environmental benefit. Therefore, the environmental impacts of the proposed action and the no-action alternative are similar.

Several alternatives to constructing and operating BLN Units 1 and 2 were considered in the FES–CP, including various sources of base load generation and alternative plant locations. Alternatives considered include not requiring new generating capacity and combinations of power generation.

Alternatives that could potentially replace new generating capacity include power purchases, repowering electrical generating plants, and energy conservation. Non-nuclear power generating alternatives include fossil fuel, wind, solar, biomass, and hydropower. Combining energy-generating alternatives could achieve an

energy profile similar to base load operation from BLN Units 1 and 2. Storage technology with wind or solar technology could augment the variability of wind and solar power with the dispatchability of fossil generation (coal and gas) or biomass generation.

Alternative Use of Resources

The proposed action does not involve any different environmental resources beyond those previously considered in the construction permit final environmental statement.

Agencies and Persons Consulted

The NRC staff did not consult with any other Federal agencies or with the State of Alabama regarding the environmental impacts of the proposed action. However, on December 1, 2020, the NRC notified the Alabama State official, Mr. David A. Turberville, Director, Office of Radiation Control of Alabama Department of Public Health, of the proposed action. Mr. Turberville had no comments.

III. Finding of No Significant Impact

The TVA has requested the NRC to extend the dates for completing the construction of BLN Units 1 and 2. The NRC is therefore considering extending the completion dates of Construction Permit Nos. CPPR–122 and CPPR–123, issued to TVA for BLN from October 1, 2020, to October 1, 2021 (Unit 1), and CPPR–123 from October 1, 2014, to October 1, 2021 (Unit 2). Based on the review of available information, the NRC determined that the proposed action would not affect safety, would not have a significant adverse effect on the probability of an accident, and would not have any significant radiological and non-radiological environmental impacts beyond what has been described in the FES–CP and subsequent construction permit extension EAs. The NRC also considered information provided in the licensee's application and related TVA environmental documents.

Consistent with 10 CFR 51.21, the NRC conducted an environmental review of the proposed action, and this FONSI incorporates Section II of the EA by reference in this notice. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined there is no need to prepare an environmental impact statement for the proposed action.

This FONSI and other related environmental documents are accessible online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by email to *pdr.resource@nrc.gov.*

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No.
AEC Final Environmental Statement Related to Construction of Bellefonte Nuclear Plant Units 1 and 2, June 1974	ML100570049
Letter from NRC to TVA, Regarding Issuance of Construction Permit Nos. CPPR–122 and CPPR-123, December 24, 1974	ML111110111
NRC Generic Letter 87–15, Commission Policy Statement on Deferred Plants, October 7, 1987	ML20236L426
NRC Environmental Assessment for Extension of Construction Permits, January 16, 2003	ML030170463
Letter from NRC to TVA, BLN Units 1 and 2—Extension of Construction Permit Expiration Dates, March 4, 2003	ML012290092
TVA Final Environmental Assessment for Bellefonte Nuclear Plant Redress, January 2006	ML061810465
Letter from NRC to TVA, BLN Units 1 and 2—Order Granting Reinstatement of Construction Permits Nos. CPPR–122 and CPPR–123, March 9, 2009	ML090610237
TVA Final Supplemental Environmental Impact Statement for Single Nuclear Unit at the Bellefonte Plant Site, May 2010	ML102870235
Letter from NRC to TVA, BLN Units 1 and 2—Regarding Key Assumptions for Reactivation, August 4, 2010	ML101880337
Letter from TVA to NRC, BLN Unit 1 Request for Extension of Construction Permit CPPR–122, October 8, 2010	ML102870233
NRC Environmental Assessment and Finding of No Significant Impact Related to the Request to Extend Construction Permit No. CPPR–122, September 9, 2011	ML103630202
Letter from NRC to TVA, BLN Unit 1—Extension of Construction Permit Expiration Date, September 30, 2011	ML11245A128
Letter from TVA to NRC, BLN Unit 2—Request for Extension of Construction Permit CPPR–123, June 10, 2014	ML14168A489
Letter from TVA to NRC, BLN Unit 2—Status Update Regarding Construction Permit CPPR–123, March 31, 2017	ML17090A388
Letter from ND to NRC, Application for Order Approving Construction Permit Transfers and Conforming Administrative Construction Permit Amendments, November 13, 2018	ML18318A428
Letter from NRC to TVA, BLN Units 1 and 2—Status Update and Request for Extension of Unit 1 Construction Permit CPPR–122, August 28, 2020	ML20244A305

Dated: January 13, 2021.

For the Nuclear Regulatory Commission.

Michael I. Dudek,

Chief, New Reactor Licensing Branch, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–01050 Filed 1–15–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of January 11, 18, 25, February 1, 8, 15, 22, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of January 11, 2021

Friday, January 15, 2021

10:00 a.m. Affirmation Session (Public Meeting) (Tentative)

a. Entergy Nuclear Operations, Inc. (Indian Point Nuclear Generating Station Units 1, 2, and 3 and ISFSI), Memorandum and Order Ruling on Petitions to Intervene (Tentative)

b. FirstEnergy Companies and TMI–2 Solutions, LLC (Three Mile Island Nuclear Station, Units 1 and 2), Petition to Intervene in License Transfer Proceeding (Tentative)

c. In the Matter of Joseph Shea (Order

Prohibiting Involvement in NRC-Licensed Activities Immediately Effective), Review of LBP–20–11 (Tentative)

(Contact: Wesley Held: 301–287–3591)

Additional Information: By a vote of 5–0 on January 13 and 14, 2021, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 of the Commission's rules that the above referenced Affirmation Session be held with less than one week notice to the public. The meeting will be held on January 15, 2021. Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live via teleconference. Details for joining the teleconference in listen only mode can be found at *https://www.nrc.gov/pmns/mtg.*

Week of January 18, 2021

There are no meetings scheduled for the week of January 18, 2021.

Week of January 25, 2021—Tentative

There are no meetings scheduled for the week of January 25, 2021.

Week of February 1, 2021—Tentative

There are no meetings scheduled for the week of February 1, 2021.

Week of February 8, 2021—Tentative

There are no meetings scheduled for the week of February 8, 2021.

Week of February 15, 2021—Tentative

Thursday, February 18, 2021

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting) (Contact: Nadim Khan: 301–415–1119)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of February 22, 2021—Tentative

There are no meetings scheduled for the week of February 22, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: January 14, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2021–01225 Filed 1–14–21; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34172; File No. 812–15178]

ActiveShares ETF Trust, et al.

January 12, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), and 22(d) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

Applicants: ActiveShares ETF Trust (the ''Trust''), Legg Mason Partners Fund Advisor, LLC (the ''Initial Adviser''), and Legg Mason Investor Services, LLC (the ''Distributor'').

Summary of Application: Applicants request an order (''Order'') that permits: (a) ActiveShares ETFs (as described in the Reference Order (as defined below)) to issue shares (''Shares'') redeemable in large aggregations only (''creation units''); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value; and (c) certain affiliated persons of an ActiveShares ETF to deposit securities into, and receive securities from, the ActiveShares ETF in connection with the purchase and redemption of creation units. The relief in the Order would incorporate by reference terms and conditions of the same relief of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

Filing Date: The application was filed on November 5, 2020 and amended on December 23, 2020.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on February 8, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: ActiveShares ETF Trust, Legg Mason Partners Fund Advisor, LLC, and Legg Mason Investor Services, LLC: c/o Marc De Oliveira, ActiveShares ETF Trust, *MADeoliveira@leggmason.com;* Laura E. Flores, Morgan, Lewis & Bockius LLP, *laura.flores@morganlewis.com.*

FOR FURTHER INFORMATION CONTACT: Kay M. Vobis, Senior Counsel, at (202) 551–6728 or Trace W. Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the

[1] Precidian ETFs Trust, *et al.,* Investment Company Act Release Nos. 33440 (April 8, 2019) (notice) and 33477 (May 20, 2019) (order). Applicants are not seeking relief under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act (the ''Section 12(d)(1) Relief''), and relief under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act relating to the Section 12(d)(1) Relief, as granted in the Reference Order. Accordingly, to the extent the terms and conditions of the Reference Order relate to such relief, they are not incorporated by reference into the Order.

application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants

1. The Trust is a statutory trust established under the laws of the State of Maryland and will consist of one or more series operating as ActiveShares ETFs. The Trust is registered as an open-end management investment company under the Act. Applicants seek relief with respect to Funds (as defined below), including an initial Fund (the ''Initial Fund''). The Funds will operate as ActiveShares ETFs as described in the Reference Order.[2]

2. The Initial Adviser, a Delaware limited liability company, will be the investment adviser to the Initial Fund. An Adviser (as defined below) will serve as investment adviser to each Fund. The Initial Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers with respect to the Funds (each a ''Sub-Adviser''). Any Sub-Adviser will be registered under the Advisers Act.

3. The Distributor is a Delaware limited liability company and a broker-dealer registered under the Securities Exchange Act of 1934, as amended, and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser and/or Sub-Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), and 22(d) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act. The requested Order would permit applicants to offer ActiveShares ETFs. Because the relief requested is the same as certain of the relief granted by the Commission under the Reference Order and because the Initial Adviser, or an affiliate thereof, has entered into a license agreement with Precidian Investments LLC, or an affiliate thereof, in order to offer ActiveShares ETFs,[3] the Order would incorporate by reference the terms and conditions of the same relief of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Initial Adviser or any entity controlling, controlled by, or under common control with the Initial Adviser (any such entity, along with the Initial Adviser, included in the term ''Adviser''); (b) operates as an ActiveShares ETF as described in the Reference Order; and (c) complies with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order (each such company or series and the Initial Fund, a ''Fund'').[4]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c) and 17(b) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–00960 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

[2] To facilitate arbitrage, an ActiveShares ETF disseminates a ''verified intraday indicative value'' or ''VIIV,'' reflecting the value of its portfolio holdings, calculated every second during the trading day. To protect the identity and weightings of its portfolio holdings, an ActiveShares ETF sells and redeems its Shares in creation units to authorized participants only through an unaffiliated broker-dealer acting on an agency basis.

[3] Aspects of the Funds are covered by intellectual property rights, including but not limited to those which are described in one or more patent applications.

[4] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90903; File No. SR–ISE–2020–43]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete the Exchange Membership Rules and Incorporate by Reference the Membership Rules of The Nasdaq Stock Market LLC

January 12, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 29, 2020, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete the Exchange's membership rules currently under the General 3 title, incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') rules in the General 3 Rule 1000 Series, and other related changes.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

General 3 of the Exchange's General Rules and Nasdaq's General 3, Rules 1000 Series prescribe the qualifications and procedures for applying for membership, respectively, on the Exchange and Nasdaq. The Exchange proposes to delete in their entirety the rules under its General 3 title, entitled ''Membership and Access,'' and incorporate by reference the Nasdaq General 3, Rules 1000 Series (the ''Nasdaq Rule 1000 Series'' or ''Nasdaq Membership Rules'') as described below.[3] The Exchange will also relocate the text under its rule General 3, Section 5(g) and place it under new Options 2A, Section 1(f) rule and General 3, Section 4(b) which will be placed under new Exchange General 2, Section 11, as further described below.

This proposal is part of the Exchange's plan to harmonize its membership rules with the membership rules of the Nasdaq and Nasdaq BX, Inc. (''BX'') exchanges.[4] The Exchange notes that Nasdaq GEMX, LLC, Nasdaq MRX, LLC, and Nasdaq Phlx, LLC (''Phlx'') (together with Nasdaq and BX, the ''Affiliated Exchanges'') each plan to propose similar rule changes that will render their membership rules substantially similar to those of Nasdaq and BX. To account for any differences that may exist, the proposed introductory paragraphs list instances in which cross references in the Nasdaq Series 1000 Rules to other Nasdaq rules shall be read to refer instead to the Exchange Rules, and references to Nasdaq terms (whether or not defined) shall be read to refer to the Exchange-related meanings of those terms. For instance, references to defined terms ''Exchange'' or ''Nasdaq'' shall be read to refer to the Nasdaq ISE Exchange; ''Rule'' or ''Exchange Rule'' shall be read to refer to the Exchange Rules; the defined term ''Applicant'' in the Nasdaq Rule 1000 Series shall be read to refer to an Applicant to the Nasdaq ISE Exchange; the defined terms ''Board'' or ''Exchange Board'' in the Nasdaq Rule 1000 Series shall be read to refer to the Nasdaq ISE Board of Directors; the defined term ''Director'' in the Nasdaq Rule 1000 Series shall be read to refer to a Director of the Board of the Nasdaq ISE Exchange; the defined term ''Exchange Review Council'' in the Nasdaq Rule 1000 Series shall be read to refer to the Nasdaq ISE Exchange Review Council; the defined term ''Subcommittee'' in the Nasdaq Rule 1000 Series shall be read to refer to a Subcommittee of the Nasdaq ISE Exchange Review Council; the defined term ''Interested Staff'' in the Nasdaq Rule 1000 Series shall be read to refer to Interested Staff of Nasdaq ISE; the defined term ''Member'' in the Nasdaq Rule 1000 Series shall be read to refer to a Nasdaq ISE Member who acts in its capacity as an Electronic Access Member, a Primary Market Maker, or a Competitive Market Maker (including a ''Foreign Member,'' as defined under Nasdaq General 9, Section 50); the defined term ''Associated Person'' shall be read to refer to a Nasdaq ISE Associated Person; the defined terms ''Exchange Membership Department'' or ''Membership Department'' shall be read to refer to the Nasdaq ISE Membership Department; and the defined term ''Exchange Regulation Department'' shall be read to refer to the Nasdaq ISE Regulation Department.

Additionally, cross references in the Nasdaq Rule 1000 Series to ''General 1 and Equity 1'' shall be read as references to Nasdaq ISE General 1, Section 1; cross references in the Nasdaq Rule 1000 Series to ''General 9, Section 20'' shall be read as references to Nasdaq ISE Options 10, Section 5(c)(2); cross references in the Nasdaq Rule 1000 Series to ''General 9, Section 37'' shall be read as references to Nasdaq ISE Options 9, Section 21; and cross references to the ''General 4, Rule 1200 Series'' shall be read as references to Nasdaq ISE General 4, Section 1.[5]

Finally, as explained below, the introductory paragraph will indicate that the Nasdaq Rule 1000 Series shall also apply to Nasdaq ISE Members who meet the requirements of a ''Foreign Member.''

As compared to the Exchange's existing General 3, by virtue of incorporating by reference the Nasdaq Membership Rules into the Exchange's rulebook, the Exchange's membership rules will be organized in a more logical order. The incorporated rules will eliminate unnecessary or vague provisions that exist under the current General 3 title, eliminate unnecessary complexity in the membership process, and otherwise streamline the Exchange's existing membership rules and their associated procedures.

Summary of Proposed Changes

A comparison between the Exchange's existing General 3 and the Nasdaq Membership Rules is summarized below. As a general matter, in comparison to the Exchange's existing membership rules, the Nasdaq Membership Rules provide for more specific membership procedures and due process. Moreover, as described below, some of the Nasdaq Rule 1000 Series rules have no analogue in the existing Exchange rules. Finally, as explained later, the Exchange will also relocate the text under its General 3, Section 5(g) rule and place it under new Options 2A, Section 1(f) rule and General 3, Section 4(b) which will be relocated under new Exchange General 2, Section 11.

Rule 1001

Nasdaq Rule 1001 states that Nasdaq and the Financial Industry Regulatory Authority (''FINRA'') are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions described in the Rule 1000 Series and the General 4, Rule 1200 Series on behalf of Nasdaq.[6] Moreover, Nasdaq Rule 1001 provides that Nasdaq rules that refer to Nasdaq's Regulation Department, Nasdaq Regulation Department staff, Nasdaq staff, and Nasdaq departments should be understood as also referring to FINRA staff and FINRA departments acting on behalf of Nasdaq pursuant to the Regulatory Contract.

Nasdaq Rule 1001 also provides that, notwithstanding the fact that Nasdaq has entered into the Regulatory Contract with FINRA to perform some of Nasdaq's functions, Nasdaq shall retain ultimate legal responsibility for, and control of, such functions. In addition, the rule informs that Nasdaq has incorporated by reference certain FINRA rules and that Nasdaq members shall comply with those rules and

[3] The Exchange will separately request an exemption from the rule filing requirements of Section 19(b) of the Act for changes to General 3 to the extent such rules are effected solely by virtue of a change to the Nasdaq Rule 1000 Series. The Exchange's proposed rule change will not become effective unless and until the Commission approves this exemption request.

[4] The BX membership rules were previously amended to incorporate by reference Nasdaq's membership rules. *See* Securities Exchange Act Release No. 34–86425 (July 22, 2019), 84 FR 36139 (July 26, 2019) (SR–BX–2019–022).

[5] The Exchange notes that its General 4 title (entitled ''Regulation'') currently incorporates by reference the rules contained in Nasdaq's General 4 title. *See* Securities Exchange Act Release No. 85728 (April 26, 2019), 84 FR 18892 (May 2, 2019) (SR–ISE–2019–12).

[6] Nasdaq's General 4, Section 1 (Registration, Qualification and Continuing Education) is currently incorporated by reference into the Exchange's General 4 title. *See supra* note 5.

interpretations as if such rules and interpretations were part of Nasdaq's Rules.

The Exchange is proposing to incorporate by reference Nasdaq Rule 1001, which currently has no analogue rule under its membership rules. The language of Nasdaq Rule 1001 is applicable to the Exchange, as the Exchange is, similarly, a signatory of a Regulatory Contract with FINRA, pursuant to which FINRA has agreed to perform certain membership functions on its behalf, and also retains the ultimate legal responsibility for the performance of said functions. The Exchange believes that the incorporation by reference to Nasdaq Rule 1001 is not a substantive amendment to the Exchange rules.

Rule 1002

Nasdaq Rule 1002, which will be incorporated by reference under the Exchange's General 3 title, describes the qualifications of Nasdaq members and associated persons, the registration of branch offices, and the designation of a Member's office of supervisory jurisdiction. The Exchange will adopt by incorporation the provisions of Nasdaq Rule 1002 and delete those under current General 3, Section 1. The Exchange believes that incorporating by reference this rule will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

Nasdaq Rule 1002(a) provides that any registered broker or dealer shall be eligible for membership in Nasdaq (except for those excluded under paragraph (b) of the rule); additionally, paragraph (a) provides that any person shall be eligible to become an Associated Person of a Member (except for those excluded under Rule 1002(b)). Rule 1002(a) is similar to General 3, Section 1(a) of the Exchange's membership rules to the extent that it describes that brokers or dealers may become Exchange members (''Members''). General 3, Section 1(a) provides that a Member may be a corporation, partnership, or limited liability company, and must be a registered broker-dealer and meet the qualifications for Exchange membership. The Exchange believes that incorporating by reference Nasdaq Rule 1002(a) expands upon Exchange General 3, Section 1(a) by including an associated person of a Member (''Associated Person'') under this threshold requirement.

The Exchange's General 3, Section 1(b) provides that a Member that does not maintain an office in the United States (''Foreign Member'') that is responsible for preparing and maintaining financial and other reports required to be filed with the Commission and with the Exchange must prepare such reports in English and in U.S. dollars, reimburse the Exchange for any expense incurred in examining the Member to the extent that such expense is in excess of the cost associated with examining a Member located within the continental United States, and ensure the availability of an individual who is fluent in English and knowledgeable in securities and financial matters to assist representatives of the Exchange during examinations. Nasdaq General 9, Section 50 is a Nasdaq rule substantially similar to the provisions in General 3, Section 1(b). In order to preserve the enumerated characteristics of a Foreign Member, which would otherwise be deleted from its Rulebook by incorporating by reference the Nasdaq Rule 1000 Series, the Exchange proposes to include the text of its General 3, Section 1(b) under the General 3's introductory paragraph and indicate that the Nasdaq Membership Rules will also apply to the members who meet the Foreign Member requirements.

Furthermore, General 3, Section 1(c) provides that every Member shall have as the principal purpose of being a Member the conduct of a public securities business, and that purpose shall be deemed to exist if and so long as: (1) The Member has qualified and acts in respect of its business on the Exchange in one or more of the following capacities: (i) An Electronic Access Member; (ii) a Primary Market Maker; or (iii) a Competitive Market Maker; and (2) all transactions effected by the Member are in compliance with Section 11(a) of the Exchange Act and the rules and regulations adopted thereunder. The Exchange believes that the membership qualifications described in this section are consistent with the eligibility criteria described in Nasdaq Rule 1002 and the disclosures and information provided by Applicant pursuant to Nasdaq Rule 1013. To account for the Exchange rights referenced in Section 1(c) (Electronic Access Member, Primary Market Maker, or Competitive Market Maker), as defined under the Exchange's Options 1, Section 1 provisions, the Exchange will also indicate in the proposed General 3 introductory paragraph that the defined term ''Member'' in the Nasdaq Rule 1000 Series shall be read to refer to a Nasdaq ISE Member who acts in its capacity as an Electronic Access Member, a Primary Market Maker, or a Competitive Market Maker. The Exchange notes that the rules related to a Primary Market Maker's and Competitive Market Maker's trading rights are not being impacted by this proposal. These rules are preserved and located in the Exchange's Options 2A title, ISE Market Maker Rights.

Nasdaq Rule 1002(b)(1) establishes that subject to such exceptions as may be explicitly provided elsewhere in the Nasdaq rules, no registered broker or dealer shall be admitted to membership, and no Member shall be continued in membership, if such broker, dealer, or Member fails or ceases to satisfy the qualification requirements established by Nasdaq rules, or if such broker, dealer, or Member is or becomes subject to a statutory disqualification, or if such broker, dealer, or Member fails to file such forms as may be required in accordance with such process as Nasdaq may prescribe. Nasdaq Rule 1002(b)(1) can be compared to the provision currently under Exchange's General 3, Section 2(b) that establishes that the Exchange may deny or condition the approval of a Member, or preclude or condition a person from becoming associated with a Member, for the same reasons that the Commission may deny or revoke a broker-dealer registration and for those reasons required or allowed under the Act. Furthermore, the requirement to comply with Nasdaq rules under Section (b)(1), is also consistent with the provision under Exchange General 3, Section 4(c) that states that every Member shall pledge to abide by the by-laws and rules of the Exchange, as amended from time to time, and by all Options Regulatory Alerts, notices, directives or decisions adopted pursuant to or made in accordance with the Exchange's by-laws and rules.

Nasdaq Rule 1002(b)(2) establishes that, subject to such exceptions as may be explicitly provided elsewhere in Nasdaq rules, no person shall become associated with a Member, continue to be associated with a Member, or transfer association to another Member, if such person fails or ceases to satisfy the qualification requirements established by Nasdaq rules, or if such person is or becomes subject to a statutory disqualification; and no broker or dealer shall be admitted to membership, and no Member shall be continued in membership, if any person associated with it is ineligible to be an Associated Person under Nasdaq Membership Rules. Nasdaq Rule 1002(b)(2) is similar to the requirement that applies to Associated Persons under General 3, Section 3(a) of the Exchange rules. The

Exchange's General 3, Section 3 rules enumerate conditions that apply to persons associated with Members of the Exchange. Exchange General 3, Section 3(a) provides that Associated Persons are bound by the Exchange's by-laws and rules and the rules of the Clearing Corporation and describes the circumstances concerning the barring of an Associated Person in such role. Exchange General 3, Sections 2(b), 3(a), and 4(c) are, substantially similar to the provisions of Nasdaq Rule 1002(b),[7] which the Exchange proposes be incorporated by reference into its membership rules. The Exchange notes that General 3, Section 3(b) requires that Members file and keep current a list of its associated persons who are its executive officers, directors, principals, shareholders, and general partners. A Member's obligation to maintain updated information for their registered representatives or principals is prescribed under Nasdaq's General 4 title which was previously incorporated by reference into the Exchange rules,[8] rendering Exchange General 3, Section 3(b) unnecessary.

Exchange General 3, Section 3(c) provides that a claim of any Associated Person described in the first sentence of General 3, Section 3(b) (*i.e.,* a Member's executive officers, directors, principal shareholders, and general partners) against a Member shall be subordinate in right of payment of customers and other Members. This subordination rule was approved as part of the Exchange's Form 1 filing on February 24, 2000.[9] At that time, Exchange members had equity ownership interest in the Exchange and the subordination language was relevant. In April of 2002, the Exchange demutualized, which ultimately resulted in Exchange members no longer having any equity ownership interest in ISE. As such, this language became obsolete.[10] The Exchange proposes to delete this provision in its entirety.

Nasdaq Rule 1002(c) establishes, as a condition to maintaining Nasdaq membership, that Members shall at all times maintain membership in a registered securities association or another registered exchange. Furthermore, the rule prescribes that Members that transact business with customers shall at all times be members of FINRA. The Exchange proposes to incorporate this rule by reference. Because the Exchange does not act in the capacity of a designated examining authority (''DEA''), like the Nasdaq and BX exchanges, it requires that all applicants for membership have an assigned DEA in place as a condition of its membership.

Nasdaq Rule 1002(d) states that Nasdaq members are deemed to comply with Nasdaq's branch office registration requirements to the extent that they keep current a Uniform Branch Office Registration Form (''Form BR''), which contains the requisite information and which is accessible electronically to Nasdaq. Members that are not FINRA members shall continue to submit to Nasdaq a Branch Office Disclosure Form, as they have done previously. The Exchange proposes to incorporate by reference this rule, which is consistent with the provisions under the Exchange's Options 10, Section 5, entitled Branch Offices. The Exchange proposes that the cross-reference in Nasdaq Rule 1002(d)(2) to General 9, Section 20 shall be read as a reference to Exchange Options 10, Section 5(c)(2).

Rule 1011

Nasdaq Rule 1011 contains definitions applicable to the Nasdaq Membership Rules. Nasdaq Rule 1011 has no analogue rule in the existing Exchange's General 3 title. By incorporating by reference the Nasdaq definitions under Rule 1011, the Exchange believes it will further harmonize its rules with respect to the membership rules of Nasdaq and BX. The Exchange notes that the defined terms in Nasdaq Rule 1011, to be incorporated by reference into the Exchange's rules, are self-contained and have no impact on ISE rules outside its membership rules. The terms ''Applicant,'' ''Department,'' ''Director,'' ''Interested Staff,'' ''Securities business,'' ''Exchange Board,'' ''principal place of business,'' ''registered broker or dealer,'' ''Representative,'' ''sales practice event,'' ''Subcommittee,'' and ''statutory disqualification'' have not been defined in the Exchange's rulebook. The Exchange notes that the term ''associated person'' as defined in the Exchange's rulebook[11] is substantially similar to the definition in Nasdaq General 1(b)(2). Relatedly, the term ''Proprietary Trading Firm'' as defined in Nasdaq Rule 1011(o) is substantially similar with the definition of ''proprietary trading'' as defined in the Exchange's rulebook.[12] The Exchange proposes to adopt by incorporation the text of Nasdaq Rule 1011 in its entirety. The Exchange believes that incorporating by reference this rule will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

Rule 1012

Nasdaq Rule 1012 (''General Application Provisions'') provides a detailed outline of the requirements that an Applicant must follow in order to file an application for membership with Nasdaq. In contrast, the Exchange membership rules contain vague provisions describing the manner in which an application shall be submitted or how service shall be performed. The Exchange believes that Nasdaq Rule 1012 provides a more detailed set of instructions for Applicants, Members, and Associated Persons to submit materials and the requirements for service of documents. The Exchange believes that incorporating Rule 1012 by reference will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

Nasdaq Rule 1012(a) provides that Applicants and Nasdaq Members may submit an application or other documents and information to Nasdaq by first-class mail, overnight courier, hand delivery, or by electronic means; this section also provides that Nasdaq shall serve a notice or decision issued under the Nasdaq Membership Rules by first-class mail or electronic means on the Applicant or Member or its counsel, unless a Nasdaq rule specifies a different method of service; finally, this section also details when service by Nasdaq or an Applicant shall be deemed complete. The Exchange membership rules contain no such provision. The Exchange believes that incorporating Nasdaq 1012(a) by reference improves its membership application process by adopting specific provisions regarding the manner of submission and service of documents.

Nasdaq Rule 1012(b) provides a definition of the term ''calendar days'' and describes the manner in which times under the Nasdaq Membership Rule shall be computed. The Exchange

[7] The Exchange notes that it will not relocate or carve-out this duplicative provision concerning The Options Clearing Corporation (''OCC''). Pursuant to the Exchange's Options 9, Section 2 (''Adherence to Law''), Members are required to abide by the Act, the Exchange's by-laws, the rules of the Exchange, and OCC rules.

[8] *See supra* note 5.

[9] *See* Securities Exchange Act Release No. 42455 (February 24, 2000), 65 FR 11401 (March 2, 2000) (Order Granting Registration as a National Securities Exchange).

[10] *See* Securities Exchange Act Release No. 45803 (April 23, 2002), 67 FR 21306 (April 30, 2002) (Order Approving Proposed Rule Change and Amendment No. 1 thereto by the International Securities Exchange LLC To Restructure From a Limited Liability Company to a Corporation).

[11] Exchange General 1, Section 1(a)(1).

[12] Exchange Options 1, Section 1(a)(41)

membership rules contain no such provision. The Exchange believes that adopting this rule by incorporation will provide further clarity to the calculation of times under its membership rules.

Nasdaq Rule 1012(c) describes a(n) Applicant's, Member's, and Associated Person's duty to ensure that the information they provide to Nasdaq at the time of the filing is accurate, complete, and current. Moreover, this provision requires that Applicant's, Member's, and Associated Person's shall ensure that membership applications and supporting materials filed with Nasdaq remain accurate, complete, and current at all times by filing supplementary amendments, which must be filed within 15 business days of their learning of the facts or circumstances giving rise to the need for an amendment. Furthermore, this section requires that Applicants, Members, and Associated Persons promptly notify Nasdaq, in writing, of any material adverse change in their financial condition. The Exchange membership rules contain no such provision. The Exchange believes that incorporating Nasdaq 1012(c) by reference improves its membership rules by adopting provisions concerning a Member's duty to ensure the accuracy, completeness, and current nature of membership information.

Exchange General 3, Section 4(b) states that every Member shall report to the Exchange all contact information required by the Exchange via the FINRA Contact System. Section 4(b) also requires Exchange Members to update their contact information promptly when necessary, but in no event later than 30 days following any change, and within 17 business days after the end of each calendar year; furthermore, it requires members to comply with any request for such information by the Exchange within 15 days or any longer period agreed upon with Exchange staff. The Exchange proposes the relocation of this provision, with minor lettering changes, to Exchange General 2 title (''Organization and Administration'') under new Section 11, entitled Contact Information Requirements. Exchange General 3, Section 4(b) is substantially similar to the rule text in both Nasdaq's and BX's General 2, Section 11.

As previously stated, the Exchange proposes to adopt by incorporation the text of Nasdaq Rule 1012 in its entirety, as the rule's provisions provide clear instructions concerning the submission of membership applications and other materials; the requirements for service of documents; and the Applicants', Members', and Associated Persons' duty to ensure that the information filed with the Exchange is up to date.

Rule 1013

Nasdaq Rule 1013 sets forth the procedure for filing applications for new membership on the Exchange. The Exchange proposes to incorporate Nasdaq Rule 1013 by reference under its General 3 title. The Exchange is adopting Nasdaq Rule 1013 as it expands upon and provides clarity to the procedure in the Exchange's General 3, Section 5. The Exchange believes that incorporating Rule 1013 by reference will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

Nasdaq Rule 1013(a) describes in detail the membership application process. Subsection (a)(1) (''Where to File; Contents''), provides that an application shall include (A) a copy of the Applicant's current Form BD, if not otherwise available to Nasdaq electronically through the Central Registration Depository (''CRD''); (B) an original Nasdaq-approved fingerprint card for each Associated Person who will be subject to SEC Rule 17f-2 and for whom a fingerprint card has not been filed with another self-regulatory organization (SRO), if such fingerprints are not otherwise available electronically to Nasdaq through CRD; (C) payment for such fee as may be required under the Rules; (D) a description of the Applicant's proposed trading activities on Nasdaq, such as the types of securities it will trade, whether it will be a market maker, or an order entry firm, and/or engage in block trading activities, and the extent to which the Applicant is conducting such activities as a member of other SROs; (E) a copy of the Applicant's most recent audited financial statements and a description of any material changes in the Applicant's financial condition since the date of the financial statements; (F) an organizational chart; (G) the intended location of the Applicant's principal place of business and all other branch offices, if any, and the names of the persons who will be in charge of each office; (H) a description of the communications and operational systems the Applicant will employ to conduct business and the plans and procedures the Applicant will employ to ensure business continuity, including: system capacity to handle the anticipated level of usage; contingency plans in the event of systems or other technological or communications problems or failures; system redundancies; disaster recovery plans; and system security; (I) a copy of any decision or order by a federal or state authority or SRO taking permanent or temporary adverse action with respect to a registration or licensing determination regarding the Applicant or an Associated Person; (J) a statement indicating whether the Applicant or any person listed on Schedule A of the Applicant's Form BD is currently, or has been in the last ten years, the subject of any investigation or disciplinary proceeding conducted by any SRO, the foreign equivalent of a SRO, a foreign or international securities exchange, a contract market designated pursuant to the Commodity Exchange Act (''CEA'') or any substantially equivalent foreign statute or regulation, a futures association registered under the CEA or any substantially similar foreign statute or regulation, the Commission or any other ''appropriate regulatory agency'' (as defined in the Act), the Commodity Futures Trading Commission, or any state financial regulatory agency regarding the Applicant's activities that has not been reported to the CRD, together with all relevant details, including any sanctions imposed; (K) a statement indicating whether any person listed on Schedule A of the Applicant's Form BD is currently, or has been in the last ten years, the subject of any investigation or disciplinary proceeding conducted by any SRO, the foreign equivalent of an SRO, a foreign or international securities exchange, a contract market designated pursuant to the CEA or any substantially equivalent foreign statute or regulation, a futures association registered under the CEA or any substantially similar foreign statute or regulation, the Commission or any other ''appropriate regulatory agency'', the CFTC, or any state financial regulatory agency regarding the Applicant's activities that has not been reported to the CRD, together with all relevant details, including any sanctions imposed; (L) a copy of any contract or agreement with another broker-dealer, a bank, a clearing entity, a service bureau or a similar entity to provide the Applicant with services regarding the execution or clearance and settlement of transactions effected on Nasdaq; (M) if the Applicant proposes to make markets on Nasdaq, a description of the source and amount of Applicant's capital to support its market making activities on Nasdaq, and the source of any additional capital that may become necessary; (N) a description of the financial controls to be employed by the Applicant with respect to anti-money laundering compliance rules as set forth in General 9, Section 37; (O) a copy of

the Applicant's written supervisory procedures with respect to the activities identified in paragraph (a)(1)(D); (P) a list of the persons conducting the Applicant's market making and other trading activities, and a list of the persons responsible for such persons' supervision, together with the CRD numbers; (R) a copy of the Applicant's most recent ''FOCUS Report'' (Form X–17A–5) filed with the SEC pursuant to SEC Rule 17a–5; (S) all examination reports and corresponding responses regarding the Applicant for the previous two years from the SROs of which it is a member; (T) a copy of Nasdaq's Membership Agreement, duly executed by the Applicant, which includes, among other things: (1) An agreement to comply with the federal securities laws, the rules and regulations thereunder, Nasdaq rules, and all rulings, orders, directions, and decisions issued and sanctions imposed under Nasdaq rules; (2) an agreement to pay such dues, assessments, and other charges in the manner and amount as from time to time shall be fixed pursuant to Nasdaq rules; and (U) such other reasonable information with respect to the Applicant as Nasdaq may require.

In contrast, current General 3, Section 2(a) states simply that to become a Member of the Exchange an Applicant must seek approval in the form and manner prescribed by the Exchange. Relatedly, General 3, Section 4(a) provides a short list of documents that Applicants and Members may submit with their application for membership with the Exchange. Section 4(a) states that Members and Applicants shall file with (and be subject to review by) the Exchange, at a minimum, their partnership agreements and any subsequent amendments, in the case of partnerships; articles of incorporation, by-laws and their amendments, in the case of corporations; the articles of organization and operating agreements and their respective amendments, in the case of limited liability companies; and any lease agreements that Members may be subject to.[13] The paragraph further provides that no action or failure by the Exchange to act shall be construed to mean that the Exchange has in any way passed on the investment merits of or approved the submitted document. The Exchange believes that deleting General 3, Section 4(a) is appropriate because the Exchange's current rule is ambiguous while Nasdaq Rule 1013(a)(1), which will be incorporated by reference, lists in detail all of the supplementary application materials required for submission by an Applicant. Incorporating this provision by reference will further standardize the Exchange's membership application process.

Exchange's General 3, Section 5(a) provides that to become a Member of the Exchange an Applicant shall file an application, which must be accompanied by a non-refundable application fee. The Exchange proposes to delete Section 5(a) because the provisions in this section are already included in Nasdaq Rule 1013, New Member Application which is being incorporated by reference.

The Exchange also believes that the provision under General 3, Section 5(c) that indicates that an applicant must be approved by the Exchange to perform in at least one of the recognized capacities of a Member as stated in General 3, Section 1(c) (discussed above when describing the incorporation by reference of Nasdaq Rule 1002) is substantially similar to the language contained in Nasdaq Rule 1013(a)(1)(D).

Nasdaq Rule 1013(a)(2) provides that the Membership Department will deem an application to be filed on the date when it is substantially complete, meaning the date on which the Membership Department receives from the Applicant all material documentation and information required under Rule 1013. This rule also provides that Nasdaq will notify the Applicant in writing when it deems the Applicant's application to be substantially complete. The Exchange's General 3, Section 5(d) contains a parallel, although brief, provision when describing the completion of the application process (''Upon completion of the application process, the Exchange shall consider whether to approve the application, unless there is just cause for delay'').

Nasdaq Rule 1013(a)(3) provides the procedure concerning incomplete applications (including the conditions necessary for the refund of application fees); and the request for additional documents or supporting information. Specifically, Nasdaq Rule 1013(a)(3)(A) (''Lapse of Applications that are not Substantially Complete'') provides that if an application that was initiated under 1013 is not deemed to be substantially complete by the Membership Department within 90 calendar days after an Applicant initiates it, then absent a showing of good cause by the Applicant, the Membership Department may, at its discretion, deem the application to have lapsed without filing, and the Membership Department will take no action in furtherance of the application. If the Membership Department deems an application to have lapsed, then the Membership Department shall serve a written notice of that determination on the Applicant. If an Applicant still wishes to apply for membership on Nasdaq after receiving notice of a lapse in its application, then the Applicant will be required to submit a new application pursuant to Nasdaq Membership Rules and pay a new application fee for doing so, if applicable. The Membership Department will refund fees that an Applicant has paid to the Nasdaq in connection with a lapsed application, in accordance with Nasdaq rules regarding fees, provided that the Nasdaq has not proceeded to process the application at the time it lapses. The rule also provides that, for purposes of Rule 1013(a)(3)(A), the Membership Department will deem an application to be not ''substantially complete'' if the Applicant fails to submit to the Membership Department materially important information or documentation that is required or requested under these Rules.

Nasdaq Rule 1013(a)(3)(B) (''Rejection of Filed Applications that Remain or Become Incomplete After Filing'') provides that if an application that was initiated under Rule 1013 is substantially complete and thus is deemed to be filed with Nasdaq under Rule 1013(a)(2), but the application nevertheless remains or becomes incomplete with respect to any required or requested information or documentation, then the Membership Department shall serve written notice to the Applicant of such incompleteness and describe the missing information or documentation. If the Applicant fails to submit to Nasdaq the missing information or documentation within a reasonable period after it receives a notice of incompleteness, then absent a showing of good cause by the Applicant, the Membership Department may, at its discretion, reject the application. If the Membership Department rejects an application on the basis of incompleteness, then the Membership Department shall serve a written notice on the Applicant of the Membership Department's determination and the reasons therefor. Nasdaq shall not refund the application fees that an Applicant has paid to Nasdaq in connection with an application that Nasdaq rejects. If the Applicant determines to continue to seek membership on Nasdaq, then the Applicant shall submit a new

[13] Concerning the lease agreements referenced in Section 4(a), the Exchange also believes it unnecessary to preserve this text for purposes of the General 3 amendments. The lease agreements are fully described in Options 2A, Section 4. (''Leasing Memberships'') in the Exchange's rulebook.

application and pay a new application fee in accordance with Nasdaq rules.

The Exchange currently contains two provisions related to the lapsing of its membership applications. Pursuant to General 3, Section 5(f), if the membership application process is not completed within six (6) months of the filing of the application form and payment of the appropriate fee, the application shall be deemed to be automatically withdrawn. The Exchange plans to replace General 3, Section 5(f) by incorporating by reference Rule 1013(a)(3) which provides well-defined processes for the treatment of applications that become stale or result in the Applicant's failure to pursue membership by not responding to requests for additional information.

The second rule describing the lapsing of an application is currently located under the Exchange's General 3, Section 5(g). Section 5(g) is specific to Applicants who are seeking approval as either a Competitive Market Maker or a Primary Market Maker on the Exchange, either of which require the Applicant to purchase or lease trading rights. This provision establishes that approved Applicants must become effective Members within 90 days of the date of approval by owning or leasing a membership or else the approval will expire (unless the Exchange grants an extension). Because this rule specifically relates to the requirement for Market Makers to promptly secure their trading rights, the Exchange believes that it will be better situated under the Options 2A, Section 1 (''Market Maker Rights'') title. The Exchange thus proposes to relocate the rule text in General 3, Section 5(g) and create new subsection Options 2A, Section 1(f) in the Exchange's rulebook (the Exchange will make some minor style changes to the rule text to facilitate its reading). The Exchange intends to preserve the rules related to Competitive Market Makers and Primary Market Makers in Options 2A due to the unique nature of this structure. As stated above, the Exchange is not amending this structure nor the process by which Exchange Members secure and exercise Market Maker trading rights.

Nasdaq Rule 1013(a)(4) (''Requests by the Department for Additional Documents or Information from the Applicant or from Third Parties'') establishes that (A) at any time before the Membership Department serves its decision as to an application for new membership in Nasdaq, the Membership Department may serve a written request for additional information or documentation, from the Applicant or from a third party, if the Membership Department deems such information or documentation to be necessary to clarify, verify, or supplement the application materials. The Membership Department may, at its discretion, request that the Applicant or the third party provide the requested information or documentation in writing or through an in-person or telephonic interview. In the written request, the Membership Department shall afford the Applicant or the third party a reasonable period of time within which to respond to the request; moreover, (B) in the event that the Membership Department obtains information or documentation about an Applicant from a third party that the Membership Department reasonably believes could adversely impact its decision on an application, then the Membership Department shall promptly inform the Applicant in writing and provide the Applicant with a description of the information or a copy of the documentation that the Membership Department obtained, where appropriate under the circumstances. Prior to rendering an application decision on the basis of information or documentation obtained from a third party source, the Membership Department shall afford the Applicant with a reasonable opportunity to discuss or to otherwise address the information or documentation that the Membership Department obtained from the third party.

The provisions under the Nasdaq Rule 1013(a)(4) are similar to the Exchange's General 3, Section 4(a), to the extent that they describe the Exchange's authority to request additional documents or information from the Applicant or Member. Relatedly, General 3, Section (d) also provides the Exchange with authority to request Associated Persons to provide additional information or testimony. The Exchange believes that incorporating by reference Nasdaq Rule 1013(a)(4) into its membership rules will provide a greater degree of detail concerning the Exchange's discretion and authority to request additional information.

Nasdaq Rule 1013(b)(1) sets forth the procedure that allows an Applicant who is a FINRA member to ''waive-in'' to become an Exchange Member and to register with the Exchange all persons associated with it whose registrations FINRA has approved (in categories recognized by the Exchange's rules). This section defines the term ''waive-in'' to mean that the Membership Department will rely substantially upon FINRA's prior determination to approve the Applicant for FINRA membership when the Membership Department evaluates the Applicant for Exchange membership. That is, the Membership Department will normally permit a FINRA member to waive-into Exchange membership without conducting an independent examination of the Applicant's qualifications for membership on the Exchange, provided that the Membership Department is not otherwise aware of any basis set forth in Nasdaq Rule 1014 to deny or condition approval of the application.

The second special application process, which is set forth in Nasdaq 1013(b)(2), permits Applicants for Nasdaq membership that are already approved members of one or more of the affiliated exchanges to waive-into Nasdaq. In this context, ''waive-in'' means that the Membership Department will rely substantially upon an affiliated exchange's prior determination to approve the Applicant for Nasdaq membership. The procedures in Nasdaq Rule 1013(b)(2) for an Applicant to submit a waive-in application under this provision and for the Membership Department to issue a decision based upon such an application are identical to the procedures described above for FINRA members that seek to waive-into Nasdaq membership. Applicants who meet the criteria for this waive-in review process have already demonstrated their ability to meet membership standards on one or more of the affiliated exchanges which eliminates the need for a full review.

Nasdaq Rule 1013(b) (''Special Application Procedures'') was adopted by Nasdaq to expedite the membership application process of Applicants who were already members of FINRA or members of one of the affiliated exchanges. The Special Application Procedures also include updated provisions requiring compliance with Nasdaq's anti-money laundering rules.[14] The Exchange proposes to adopt by incorporation these same provisions to facilitate Applicants who meet the rule requirements. The adoption of this rule will offer members of FINRA, Nasdaq, and BX the option to apply for membership on the Exchange through an expedited membership application process.

Current Exchange rules do not allow this expedited process. However, today, this concept does exist in both GEMX and MRX General 3, Section 5. Both GEMX and MRX rules afford an Exchange member in good standing the ability to become a GEMX or MRX

[14] *See* Securities Exchange Act Release No. 34–85513 (April 4, 2019), 84 FR 14429 (April 10, 2019) (SR–NASDAQ–2019–022).

member of the same category without application. The Exchange believes that incorporating by reference Nasdaq's waive-in provisions will further the Exchange's objective to provide uniformity and clarity to its rules by aligning its membership application process with the Nasdaq and BX exchanges.

Rule 1014

Nasdaq Rule 1014 (''Department Decision'') describes the Membership Department's process for the issuance of a decision. The Exchange proposes to incorporate by reference Nasdaq Rule 1014 in its entirety as it provides a more organized, detailed, and logical description of the procedure currently described in General 3, Section 2 (in addition to the grounds for approval or disapproval referenced in General 3, Section 5(d) and (e)). Incorporating Nasdaq Rule 1014 by reference in the Exchange's rules will improve the membership application and decision making process by better defining the Membership Department's authority and obligations, describing the basis for approval, conditional approval or denial of an application. Further, the Exchange believes that this proposed change provides consistency in the treatment of Exchange Applicants. Nasdaq Rule 1014(a) describes the Membership Department's authority to act on an application by approving it, denying it, or approving it subject to restrictions: (1) That are reasonably designed to address a specific (financial, operational, supervisory, disciplinary, investor protection, or other regulatory) concern; or (2) that mirror a restriction placed upon the Applicant by FINRA or an affiliated exchange.

Nasdaq Rule 1014(b), entitled ''Bases for Approval, Conditional Approval, or Denial,'' provides that the Membership Department will approve, grant conditional approval, or deny a membership application filed under Nasdaq Rules 1013 and 1017 by an Applicant that is not, and is not required to become, a FINRA member. Nasdaq Rule 1014(b)(1) indicates that the Membership Department may deny or condition membership approval for the same reasons that the Commission may deny or revoke a broker or dealer's registration; this Nasdaq Rule parallels existing General 3, Section 2(b), which describes the Exchange's authority to deny an application for the same reasons that the SEC may deny or revoke a broker-dealer registration and for those reasons required or allowed under the Act.

Nasdaq Rule 1014(b)(2) enumerates the reasons for denial or conditional approval of a membership application in the cases when the Applicant (A) is unable to satisfactorily demonstrate its capacity to adhere to the Exchange and Commission rules; (B) has previously violated, and there is a reasonable likelihood that such Applicant will again engage in violative acts or practices, of any Exchange or Commission policies, rules, and regulations; (C) has engaged in acts or practices inconsistent with just and equitable principles of trade, and there is a reasonable likelihood that such Applicant will again engage in violative acts or practices, of any Exchange or Commission policies, rules, and regulations; (D) is not in compliance with the Commission's net capital rule or has financial difficulties greater than 5% of their net worth; (E) has been itself, or is the successor to an entity subject to a bankruptcy, proceeding, receivership, or arrangement for the benefit of creditors within the past 3 years; (F) has engaged in an established pattern of failure to pay just debts; (G) does not hold required licenses or registrations; or (H) is unable to satisfactorily demonstrate reasonably adequate systems capacity and capability.

The Exchange notes that the basis for denial listed under its General 3, Section 2(c)(1), regarding an Applicant who has a negative net worth, has financial difficulties involving an amount that is more than five percent (5%) of the applicant's net worth, or has a pattern of failure to pay just debts (whether or not such debts have been the subject of a bankruptcy action), is parallel to Nasdaq Rule 1014(b)(2)(D). Similarly, the Exchange's basis for denial under General 3, Section 2(c)(2), regarding an Applicant unable satisfactorily to demonstrate a capacity to adhere to all applicable Exchange, SEC, the Clearing Corporation and Federal Reserve Board policies, rules and regulations, including those concerning record-keeping, reporting, finance and trading procedures, is parallel to Nasdaq Rule 1014(b)(2)(A). Finally, the provision under General 3, Section 2(c)(3), regarding an Applicant unable satisfactorily to demonstrate reasonably adequate systems capability and capacity, is parallel to Nasdaq Rule 1014(b)(2)(H).

Furthermore, the Exchange believes that the provisions under Nasdaq Rule 1014(b)(2)(A), (B), and (C), which describe the basis for a decision regarding the Applicant's inability to satisfy the Exchange and securities rules, previous violative conduct, and past or potential conduct inconsistent with just and equitable principles of trade, provide the Exchange with greater authority than the one described under General 3, Section 2(d), which provides that when an Applicant is a subject of an investigation conducted by any SRO or government agency involving its fitness for becoming a Member, the Exchange need not act on the application until the matter has been resolved.

The Exchange notes that current General 3, Section 2(e) and (f), which refer to the basis for membership denial as it relates to statutory disqualification, are substantially similar to Nasdaq Rule 1002(b)(1) and (2), which describe an Applicant's ineligibility of certain persons for membership or association due to statutory disqualification. As stated above, the Exchange proposes to incorporate Nasdaq Rule 1002 in its entirety.

Nasdaq Rule 1014(b)(3) provides that the Membership Department will not approve an Applicant unless the Applicant is a member of another registered securities exchange or association that is not registered solely under Section 6(g) or Section 15A(k) of the Act. This rule also provides that an Applicant that will transact business with the public must be a member of FINRA. This requirement exists in the Exchange's rulebook in Options 10, Section 1 (''Exchange Approval''); however, to maintain harmonization of the rules, the Exchange proposes to incorporate by reference this same parallel rule. There are no proposed changes to rule text found in Exchange Options 10, Section 1 at this time.

The Exchange proposes to incorporate by reference Nasdaq Rule 1014(c) to establish the time and content of a decision and the recourse available to an Applicant if the Membership Department fails to timely issue a decision on a membership application. Current Exchange General 3, Section 5(d), broadly prescribes that the Exchange will consider approval of the membership application, ''unless there is just cause for delay.'' Nasdaq Rule 1014(c) outlines this process in greater detail. The Nasdaq rule requires the Membership Department to serve a decision on the membership application within a reasonable time period, not to exceed 45 (calendar) days after the Applicant files and provides to the Exchange all required and requested information or documents in connection with the application. Additionally, the rule allows the Membership Department and the Applicant the ability to agree to further extensions of the decision deadlines. Nasdaq Rule 1014(c) also provides that the decision will detail the reason(s) for the denial of membership

or the approval of the application subject to restrictions. This provision is similar to General 3, Section 5(e), which currently establishes that the Exchange will inform the Applicant of the grounds for disapproval of a membership application. Moreover, if the Membership Department fails to timely issue a decision, the rule prescribes that the Applicant may request the Exchange Board to direct the Membership Department to issue a decision. The rule further provides that the Exchange Board, within seven days, will direct the Membership Department to serve its decision or to show good cause for a time extension. If the Membership Department shows good cause, the Exchange Board may grant the Membership Department up to 45 days to issue the decision.

Nasdaq Rule 1014(e) prescribes that service of the Membership Department's decision shall be made pursuant to Nasdaq Rule 1012. Further, the rule provides that the decision shall become effective upon service and shall remain in effect during the pendency of any review until a decision constituting final action of the Exchange is issued under Rule 1015 or 1016, unless otherwise directed by the Exchange Review Council, the Exchange Board, or the Commission. Current Exchange General 3, Section 5(e) prescribes that a notice of the Exchange's decision shall be provided to the Applicant but does not specify the manner of such notification. In addition, Exchange General 3, Section 5(h) indicates that once an Applicant's membership becomes effective, the Exchange will promptly notify the Applicant of such decision. The Exchange believes that incorporating this rule by reference clarifies the process for serving the Membership Department's decision on applications.

Nasdaq Rules 1014(f) and (g), respectively, provide for the effectiveness of restrictions on an approved application and what constitutes final action in the Membership Department's decision. Rule 1014(f) establishes that a restriction imposed under Rule 1014 shall remain in effect and bind the Applicant and all successors to the ownership or control of the Applicant unless (1) it is removed or modified by a decision constituting final action of the Exchange issued under Nasdaq Rules 1015, 1016, or 1017; or (2) stayed by the Exchange Review Council, the Exchange Board, or the Commission. Rule 1014(g) provides that unless the Applicant files a written request for a review under Rule 1015, the Membership Department's decision shall constitute final action by Nasdaq.

Rule 1015

The Exchange proposes to incorporate by reference Nasdaq Rule 1015 in its entirety under its General 3 title. Nasdaq Rule 1015, subsections (a) through (j) are substantially similar to the current provisions concerning a review by the Exchange Review Council detailed in Exchange General 3, Section 2(g).[15]

Current Exchange General 3, Section 2(g) (formerly Exchange Rule 302(g)) was amended in 2018 [16] to base the Exchange's procedures on those set forth in Nasdaq and BX Rules 1015 and 1016 (which were identical to Nasdaq's and now incorporate by reference the Nasdaq Membership rules [17]). The Exchange believes that incorporating by reference Nasdaq Rule 1015 it will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

The Exchange proposes also to incorporate by reference Nasdaq Rule 1015(k) and (l) (respectively, ''Ex Parte Communications'' and ''Recusal or Disqualification''). Both paragraphs (k) and (l) were, respectively, previously located under Nasdaq Rule 1012(c) and (d) but were moved to their current location in the Nasdaq rulebook as the two provisions logically fit within the section of the membership rules that govern appeals of membership decisions.[18] Nasdaq Rule 1015(k) prohibits *ex parte* communications involving membership decisions subject to review among certain Exchange staff, members of the Exchange Review Council, members of a Subcommittee of the Council, and the Board of Directors. Nasdaq Rule 1015(l) governs the recusal and disqualification of a member of the Exchange Review Council, a Subcommittee thereof, or the Board of Directors from participating in a review of a membership decision. The Exchange has no parallel provisions in its rulebook to Nasdaq Rule 1015(k) and (l). The Exchange believes that incorporating Rule 1015(k) and (l) by reference enhances the Exchange Review Council's procedures and is in line with the Exchange's goal of harmonizing its rules with those of the Nasdaq and BX exchanges.

Rule 1016

Aside from their respective internal cross-references, the text in Nasdaq Rule 1016 and Exchange General 3, Section 2(h) (both entitled ''Discretionary Review by the Exchange Board'') are identical. The Exchange proposes to incorporate by reference Nasdaq Rule 1016 under its General 3 title. The Exchange believes that incorporating by reference this rule will further the Exchange's objective to provide uniformity and clarity to its rules by aligning them with the membership rules of the Nasdaq and BX exchanges.

Rule 1017

Nasdaq Rule 1017, ''Application for Approval of Change in Ownership, Control, or Material Business Operations,'' has no analogue rule in the Exchange's current General 3 title. Incorporating Nasdaq Rule 1017 by reference in its entirety in the Exchange's rules will enhance the Exchange's ongoing regulatory oversight capabilities by clearly identifying events that would trigger the requirement for an approved Member to file an application with the Exchange. As stated below, Nasdaq Rule 1017 outlines in detail the circumstances that trigger the filing of an application pursuant to this rule. While the Exchange has no corresponding rule, it does have a similar process in place that it administers procedurally. For example, if an existing Electronic Access Member of the Exchange is seeking market maker status for the first time, the current Exchange process is to require that the Member submit an amended Exchange application along with relevant supplementary material. The Exchange believes that incorporating Nasdaq Rule 1017 by reference and harmonizing its process with that of Nasdaq and BX will improve its current practice by further streamlining its current practices. As stated previously, the objective is to eventually harmonize membership rules across all Affiliated Exchanges in order to advance uniformity within the membership rules and procedures.

Nasdaq Rule 1017(a) prescribes the events that require Members to file applications with the Exchange. Paragraph (a) provides that a Member shall file an application for approval prior to effecting the following changes: (1) A merger of the Member with another Member; (2) a direct or indirect

[15] The Exchange notes that, recently, Nasdaq adopted Rule 1015(f)(5) which provides for the Exchange Review Council to conduct its hearings via video conferencing. *See* Securities Exchange Act Release No. 34–90390 (November 10, 2020), 85 FR 73302 (November 17, 2020) (SR–NASDAQ–2020–076). The Exchange has adopted an identical provision under General 3, Section 2(g)(6)(E). *See* Securities Exchange Act Release No. 34–90756 (December 21, 2020), 85 FR 85817 (December 29, 2020) (SR–ISE–2020–42).

[16] *See* Securities Exchange Act Release No. 34–83703 (July 25, 2018), 83 FR 36992 (July 31, 2018) (SR–ISE–2018–59).

[17] *See supra* note 4.

[18] *See supra* note 14.

acquisition by the Member of another Member; (3) direct or indirect acquisitions or transfers of 25% or more in the aggregate of the Member's assets or any asset, business line or line of operations that generates revenues comprising 25% or more in the aggregate of the Member's earnings measured on a rolling 36 month basis; (4) a change in the equity ownership or partnership capital of the Member that results in one person or entity directly or indirectly owning or controlling 25% or more of the equity or partnership capital; or (5) a material change in business operations, which consist of (A) removing or modifying a membership restriction; (B) acting as a dealer or a market maker for the first time; (C) adding business activities that require a higher minimum net capital under SEC Rule 15c3–1; or (D) adding business activities that would cause a proprietary trading firm no longer to meet the definition of that term contained in the Rule 1000 Series.

Nasdaq Rule 1017(b), governs the filing and content of applications filed under Nasdaq Rule 1017. This Rule provides that the application should be filed with the Membership Department; if the Applicant seeks approval of change of ownership or control or a material change in the Member's business operations, the application should (A) provide a detailed description of the proposed change, (B) provide a business plan, pro forma financials, an organizational chart, and written supervisory procedures reflecting the proposed change; and (C) if the application requests approval of a change in ownership or control, the application also shall include the names of the new owners, their percentage of ownership, and the sources of their funding for the purchase and recapitalization of the member.

Furthermore, Nasdaq Rule 1017(b) provides that if the application requests the removal or modification of a membership restriction, the application also shall, (A) present facts showing that the circumstances that gave rise to the restriction have changed; and (B) state with specificity why the restriction should be modified or removed in light of the applicable bases for denial or standards for approval set forth in Nasdaq Rules 1014 or 1017 and the articulated rationale for the imposition of the restriction. Moreover, the Rule indicates that if the application requests approval of an increase in Associated Persons involved in sales, offices, or markets made, the application shall set forth the increases in such areas during the preceding 12 months.

Nasdaq Rule 1017(c) indicates when an application shall or may be filed. Specifically, the Rule provides that (1) an application for approval of a change in ownership or control shall be filed at least 30 days prior to such change; (2) that an application to remove or modify a membership restriction may be filed at any time (clarifying that an existing restriction shall remain in effect during the pendency of the proceeding); and that (3) an application for approval of a material change in business operations, other than the modification or removal of a restriction, may be filed at any time, but the Member may not effect such change until the conclusion of the proceeding, unless the Membership Department and the Member otherwise agree.

Nasdaq Rule 1017(d) prescribes that an application will be deemed to be filed on the date when it is substantially complete, meaning the date on which the Membership Department receives from the Applicant all material documentation and information required under this Rule, and that the Membership Department will notify the Applicant in writing when the Membership Department deems the Applicant's application to be substantially complete.

Nasdaq Rule 1017(e) indicates that, pursuant to Nasdaq Rule 1013(a)(3), the Membership Department may treat an application filed under this Rule as having lapsed or it may reject such an application, except that the Membership Department may treat an application as having lapsed if it is not substantially complete for 30 days or more after the Applicant initiates it.

Nasdaq Rule 1017(f) provides that the Membership Department, at any time before it serves its decision, may request additional information or documentation from the Applicant or from a third party in accordance with Nasdaq Rule 1013(a)(4).

Nasdaq Rule 1017(g) establishes that a Membership Department's decision shall be issued in accordance with Nasdaq Rule 1014, except that (1) In rendering a decision on an application submitted under the Rule that requests the modification or removal of a membership restriction, the Membership Department shall consider whether maintenance of the restriction is appropriate in light of: (A) The applicable bases for denial or standards for approval set forth in Nasdaq Rule 1014; (B) the circumstances that gave rise to the imposition of the restriction; (C) the Applicant's operations since the restriction was imposed; (D) any change in ownership or control or supervisors and principals; and (E) any new evidence submitted in connection with the application. Furthermore, this Rule provides that the Membership Department shall serve a written decision on an application filed under this Rule in accordance with Nasdaq Rule 1013(c). Moreover, the Rule provides that in the event that a proposed change in ownership, control, or business operations by a Member requires such Member to become a member of FINRA, the Membership Department shall not be required to serve a written decision under this Rule until 10 business days after the Member becomes a FINRA member.

Nasdaq Rule 1017(h) provides that service of the decision on the Applicant in accordance with Nasdaq Rule 1012. Moreover, the Rule indicates that the decision shall become effective upon service and shall remain in effect during the pendency of any review until a decision constituting final action of the Exchange is issued under Rules 1015 or 1016, unless otherwise directed by the Exchange Review Council, the Exchange Board, or the Commission.

Nasdaq Rule 1017(i) indicates that an Applicant may file a written request for review of the Membership Department's decision with the Exchange Review Council pursuant to Nasdaq Rule 1015, the rule further clarifies that the procedures set forth in Nasdaq Rule 1015 shall apply to such review, and the Exchange Review Council's decision shall be subject to discretionary review by the Exchange Board pursuant to Nasdaq Rule 1016. If the Applicant does not file a request for a review, the Membership Department's decision shall constitute final action by Nasdaq.

Nasdaq Rule 1017(j) prescribes that the Membership Department shall modify or remove a restriction on its own initiative if the Membership Department determines such action is appropriate in light of the considerations set forth in paragraph (g)(1) of the Rule. The Membership Department shall notify the member in writing of the Membership Department's determination and inform the member that it may apply for further modification or removal of a restriction by filing an application under paragraph Rule 1017(a).

Rule 1018

Nasdaq Rule 1018, ''Resignation, Reinstatement, Termination, and Transfer of Membership,'' has no analogue rule in the Exchange's current General 3 title. The Exchange proposes to incorporate the rule by reference under its General 3 title. Nasdaq Rule 1018 outlines the process for resignation, reinstatement, termination,

and transfers of memberships. Incorporating Nasdaq Rule 1018 by reference will eventually allow the Exchange to standardize the processing of these requests across all the Affiliated Exchanges.

Nasdaq Rule 1018(a) provides that membership in Nasdaq may be voluntarily terminated only by formal resignation. Resignations of Members must be filed via electronic process or such other process as the Exchange may prescribe. Any Member may resign from Nasdaq at any time. Such resignation shall not take effect until all indebtedness due to Nasdaq from such Member shall have been paid in full and so long as any complaint or action is pending against the Member under the Rules. Nasdaq, however, may in its discretion declare a resignation effective at any time.

Nasdaq Rule 1018(b) indicates that no Member may transfer its membership or any right arising therefrom; the membership of a corporation, partnership, or any other business organization that is a Member shall terminate upon its liquidation, dissolution, or winding up; and the membership of a sole proprietorship that is a Member shall terminate at death, provided that all obligations of membership under the Rules have been fulfilled. Moreover, the Rule provides that the consolidation, reorganization, merger, change of name, or similar change in any corporate Member shall not terminate the membership of such corporate Member, provided that the Exchange Member or surviving corporation, if any, shall be deemed a successor to the business of the corporate Member, and the Member or the surviving organization shall continue in the securities business, and shall possess the qualifications for membership in the Exchange. Furthermore, the death, change of name, withdrawal of any partner, the addition of any new partner, reorganization, consolidation, or any change in the legal structure of a partnership Member shall not terminate the membership of such partnership Member, provided that the Member or surviving organization, if any, shall be deemed a successor to the business of the partnership Member, and the Member or surviving organization shall possess the qualifications for membership in the Exchange. If the business of any predecessor Member is to be carried on by an organization deemed to be a successor organization by the Exchange, the membership of such predecessor Member shall be extended to the successor organization subject to the notice and application requirements of the Rules and the right of the Exchange to place restrictions on the successor organization pursuant to the Rules; otherwise, any surviving organization shall be required to satisfy all of the membership application requirements of the Exchange's Rules.

Nasdaq Rule 1018(c) establishes that any membership or registration suspended or canceled under the Rules may be reinstated by the Exchange upon such terms and conditions as are permitted under the Act and the Exchange rules; provided, however, that any applicant for reinstatement of membership or registration shall possess the qualifications required for membership or registration in the Exchange.

Rule 1019

Nasdaq Rule 1019 (''Application to Commission for Review'') has no analogue rule in the Exchange's current General 3 title. Nasdaq Rule 1019 allows Applicants to request the Commission to review an Exchange final action, as provided under the Nasdaq Rule 1010 Series. Incorporating Nasdaq Rule 1019 by reference standardizes the process by which an Applicant may dispute any final action of the Exchange.

Nasdaq Rule 1019 provides that a person aggrieved by a Nasdaq's final action under Nasdaq Membership Rules may apply for review by the Commission pursuant to Section 19(d)(2) of the Act. The filing of an application for review shall not stay the effectiveness of a decision constituting final action of the Exchange, unless the Commission otherwise orders.

Revised Membership Application

As part of the harmonization of its membership rules and procedures with those of Nasdaq and BX, the Exchange is adopting a standardized Broker-Dealer Membership Application (''Membership Application''). The Membership Application is submitted as Exhibit 3A of this proposed rule change with underlined changes concerning the ISE market. Each Exchange Membership Application will be accompanied by a ''Membership Agreement'' (submitted as Exhibit 3B of the attached), which should be signed by all applicants to membership with the Exchange.

Conclusion

The changes proposed herein will allow the Exchange to harmonize its membership rules and processes with those of Nasdaq and BX, and ultimately, with the other Affiliated Exchanges, which will eventually provide a uniform criteria across the Affiliated Exchanges for membership qualifications and a consistent process across the Affiliated Exchanges for processing membership applications. The proposal will also provide for full membership reciprocity between Nasdaq, BX, and the Exchange—and hopefully, in time, across all of the Affiliated Exchanges—so that a member of one Affiliated Exchange would receive expedited treatment in applying for membership on any other Affiliated Exchange. Similarly, harmonized membership rules and processes will benefit Exchange Applicants and Members by establishing consistent membership requirements and processes that must be followed to apply for membership on the Exchange.

Moreover, as to the Exchange itself, the proposed changes described herein will render the Exchange's membership rules and processes clearer, better organized, simpler, and easier to comply with. Again, such changes will provide benefits both to the Exchange's Membership Department and to Exchange Applicants.

The proposed membership rules and processes are substantially similar to the existing rules and process, and where there are differences between the new and old processes, the Exchange believes that the new process does not disadvantage its Members or Associated Persons. To the contrary, the Exchange believes that the new rules and processes will benefit all parties as it again provides greater clarity, simplicity, and efficiency than the retired rules and processes.

Implementation

To facilitate an orderly transition from the existing rules under the General 3 title and the Nasdaq Membership Rules to be incorporated by reference, the Exchange is proposing to apply the existing Rules to all applications which have been submitted to the Exchange (including applications that are not yet complete) and are pending approval prior to the operative date. The Exchange also will apply the existing Rules to any appeal of an Exchange membership decision or any request for the Board to direct action on an application pending before the Exchange Review Council, the Board, or the Commission, as applicable. As a consequence of this transition process, the Exchange will retain the existing processes during the transition period until such time that there are no longer any applications or matters proceeding under the existing rules. To facilitate this transition process, the Exchange will retain a transitional rulebook that will contain the Exchange's membership

rules as they are at the time that this proposal is filed with the Commission. This transitional rulebook will apply only to matters initiated prior to the operational date of the changes proposed herein and it will be posted to the Exchange's public rules website. When the transition is complete, the Exchange will remove the transitional rulebook from its public rules website.

The Exchange will announce and explain this transition process in a regulatory alert.

The Exchange notes that Nasdaq applied the same process described above to govern its transition to its amended membership rules.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5) and of the Act,[20] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. It is also consistent with Section 6(b)(7) of the Act in that it provides for a fair procedure for denying Exchange membership to any person who seeks it, barring any person from becoming associated with an Exchange Member, and prohibiting or limiting any person with respect to access to services offered by the Exchange or a Member thereof.[21]

As a general matter, the Exchange believes that its proposal to delete its existing membership rules, incorporate by reference the Nasdaq Membership Rules, and other related changes will promote a free and open market, and will benefit investors, the public, and the markets, because the new rules will be clearer, better organized, and simpler.

The proposal is just and equitable because it will render the Exchange's membership rules easier for Applicants and Members to read and understand, including by doing the following:

- Establishing a ''roadmap'' paragraph as shown in Nasdaq Rule 1014(a) that sets forth the basic authority of the Membership Department to approve, approve with conditions, or deny applications for membership before the Rule goes on to enumerate criteria for the Membership Department to apply when taking each of those actions;
- Making the titles of the rules more accurate and descriptive (*e.g.,* Nasdaq Rule 1014(b));
- Grouping logically-related provisions together in the rules (*e.g.,* provisions governing resignation, termination, transfer, and reinstatement of membership) and recusals and disqualifications;
- Clarifying when the Membership Department will deem an application to be filed (when the application is ''substantially complete,'' as set forth in Nasdaq Rule 1013(a)(2)) and by requiring the Membership Department to notify an Applicant in writing of the filing date;
- Clarifying what the Exchange means when it states that an Applicant may ''waive-in'' to Exchange membership (as set forth in Nasdaq Rule 1013(b)); and

The proposal will also make compliance with the membership rules simpler and less burdensome for Applicants and Members by, for example, doing the following:

- Eliminating obsolete requirements to submit paper copies of Forms U–4 and BD or explain information listed on the forms where the Membership Department already has electronic access to the Forms and the information contained therein;
- Permitting electronic filing of applications (Nasdaq Rule 1012(a)(1);
- Allowing payment of application fees by means other than paper check (Nasdaq Rule 1013(a)(1)(C));
- Harmonizing disparate procedures under Nasdaq Rules 1013 and 1017 for filing, evaluating, and responding to initial membership applications and applications for approval of business changes;
- Detailing the circumstances in which an Applicant may waive-into Exchange membership to include the Applicant's membership in any of the affiliated exchanges and defining procedures for processing and responding to waive-in applications (Nasdaq Rule 1013(b));

In sum, the foregoing changes will update, rationalize, and streamline the Exchange's membership rules and processes, all to the benefit of Applicants and Members. Moreover, these changes will not adversely impact the rights of Applicants or Members to appeal adverse Membership Department decisions under these Rules or to request Board action to compel the Membership Department to render decisions on applications.

Last, the Exchange believes that its proposal to phase-in the implementation of the new membership rules and processes is consistent with Section 6(b)(7) of the Act[22] because both the current and proposed processes provide fair procedures for granting and denying applications for becoming an Exchange Member, becoming an Associated Person, and making material changes to the business operations of a Member. The Exchange is proposing to provide advanced notice of the implementation date of the new processes, and will apply the new processes to new applications, appeals, and requests for Board action that are initiated on or after that implementation date. Any application, appeal, or request for Board action initiated prior to the implementation date will be completed using the current processes. As a consequence, the Exchange will maintain a transitional rulebook on the Exchange's public rules website which will contain the Exchange Rules as they are at the time of filing this rule change. These transitional rules will apply exclusively to applications, appeals, and requests for Board action initiated prior to the implementation date. Upon conclusion of the last decision on a matter to which the transitional rules apply, the Exchange will remove the defunct transitional rules from its public rules website. Thus, the transition will be conducted in a fair, orderly, and transparent manner. Lastly, the proposed transition process is the same process that Nasdaq and BX implemented during its transition to new membership rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not expect that its proposed changes to the membership rules will have any competitive impact on its existing or prospective membership. The proposed changes will apply equally to all similarly situated Applicants and Members and they will confer no relative advantage or disadvantage upon any category of Exchange Applicant or Member. Moreover, the Exchange does not expect that its proposal will have an adverse impact on competition among exchanges for members; to the contrary, the Exchange hopes that by clarifying, reorganizing, and streamlining its membership rules, the Exchange's membership process will be less burdensome for Applicants and Members and the Exchange will

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(b)(7).

[22] 15 U.S.C. 78f(b)(7).

improve its competitive standing relative to other exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and subparagraph (f)(6) of Rule 19b–4 thereunder.[24]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2020–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number *SR–ISE–2020–43.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR–ISE–2020–43* and should be submitted on or before February 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–00948 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90906; File No. SR–PEARL–2020–38]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the MIAX PEARL Fee Schedule

January 12, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b-4 thereunder,[2] notice is hereby given that on December 31, 2020, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX PEARL Fee Schedule (the ''Fee Schedule'') for the Exchange's options market.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Add/Remove Tiered Rebates/Fees set forth in Section (1)(a) of the Fee Schedule that apply to the MIAX PEARL Market Maker [3] Origin, to: (i) Modify the volume threshold for the alternative Volume Criteria in Tier 2; and (ii) add a new, alternative Volume Criteria to Tier 3.

Background

The Exchange currently assesses transaction rebates and fees to all market participants which are based upon the total monthly volume

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* the Definitions Section of the Fee Schedule.

executed by the Member[4] on MIAX PEARL in the relevant, respective origin type (not including Excluded Contracts)[5] (as the numerator) expressed as a percentage of (divided by) TCV[6] (as the denominator). In addition, the per contract transaction rebates and fees are applied retroactively to all eligible volume for that origin type once the respective threshold tier (''Tier'') has been reached by the Member. The Exchange aggregates the volume of Members and their Affiliates.[7] Members that place resting liquidity, *i.e.,* orders resting on the book of the MIAX PEARL System,[8] are paid the specified ''maker'' rebate (each a ''Maker''), and Members that execute against resting liquidity are assessed the specified ''taker'' fee (each a ''Taker''). For opening transactions and ABBO[9] uncrossing transactions, per contract transaction rebates and fees are waived for all market participants. Finally, Members are assessed lower transaction fees and receive lower rebates for order executions in standard option classes in the Penny Interval Program[10] (''Penny Classes'') than for order executions in standard option classes which are not in the Penny Interval Program (''Non-Penny Classes''), where Members are assessed higher transaction fees and receive higher rebates.

Alternative Volume Criteria Threshold Change in Tier 2

The Exchange proposes to amend the Add/Remove Tiered Rebates/Fees set forth in Section (1)(a) of the Fee Schedule that apply to the MIAX PEARL Market Maker Origin, to modify the volume threshold for the alternative Volume Criteria in Tier 2. The MIAX PEARL Market Maker Origin set forth in Section 1)a) of the Fee Schedule currently provides an alternative Volume Criteria in Tier 2, which is based upon the total monthly volume executed by a MIAX PEARL Market Maker collectively in SPY/QQQ/IWM options on MIAX PEARL, expressed as a percentage of total consolidated national volume in SPY/QQQ/IWM options.[11] Pursuant to this alternative Volume Criteria, a Market Maker is able to reach the Tier 2 threshold if the Market Maker's total executed monthly volume, not including Excluded Contracts, in SPY/QQQ/IWM options on MIAX PEARL is above 0.45% of total consolidated national monthly volume in SPY/QQQ/IWM options. For this calculation, volume that is from resting liquidity (Maker) and taking liquidity (Taker) in SPY/QQQ/IWM options is counted towards the alternative Volume Criteria, and the 0.45% threshold does not have to be reached individually in each of the three symbols. A Market Maker is able to qualify for Tier 2 rebates and fees which will then be applicable to all volume executed by the MIAX PEARL Market Maker on MIAX PEARL. The two Volume Criteria available for Tier 2 is based upon either: (a) The total monthly volume executed by the Market Maker in all options classes on MIAX PEARL, not including Excluded Contracts, (as the numerator), expressed as a percentage of (divided by) TCV (as the denominator); or (b) the total monthly volume executed by the MIAX PEARL Market Maker collectively in SPY/QQQ/IWM options on MIAX PEARL, not including Excluded Contracts, (as the numerator), expressed as a percentage of (divided by) SPY/QQQ/IWM TCV[12] (as the denominator). Once either Volume Criteria threshold in Tier 2 is reached by the Market Maker, the Tier 2 per contract rebates and fees apply to all volume in all options classes executed by that MIAX PEARL Market Maker on MIAX PEARL.

The Exchange proposes to modify the threshold for the alternative Volume Criteria in Tier 2 from 0.45% to 0.75% of total consolidated national monthly volume in SPY/QQQ/IWM options. With the proposed change, a Market Maker will be able to reach the alternative Volume Criteria in Tier 2 if the Market Maker's total executed monthly volume, not including Excluded Contracts, in SPY/QQQ/IWM options on MIAX PEARL is above 0.75% of total consolidated national monthly volume in SPY/QQQ/IWM options. The Exchange is not modifying the calculation method for a Market Maker to reach the alternative Volume Criteria in Tier 2, only the threshold percentage. The Exchange proposes to make the corresponding change to the volume threshold percentage described in the explanatory paragraph for the alternative Volume Criteria for Tier 2 that is below the tables in Section 1)a) of the Fee Schedule.

The purpose of this proposed change is for business and competitive reasons. In order to attract order flow, the Exchange initially set its volume threshold for the alternative Volume Criteria in Tier 2 at a meaningful low level. The Exchange now believes that it is appropriate to adjust this volume threshold so that it is more in line with

[4] ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of the Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[5] ''Excluded Contracts'' means any contracts routed to an away market for execution. *See* the Definitions Section of the Fee Schedule.

[6] ''TCV'' means total consolidated volume calculated as the total national volume in those classes listed on MIAX PEARL for the month for which the fees apply, excluding consolidated volume executed during the period time in which the Exchange experiences an ''Exchange System Disruption'' (solely in the option classes of the affected Matching Engine (as defined below)). The term Exchange System Disruption, which is defined in the Definitions section of the Fee Schedule, means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hours or more, during trading hours. The term Matching Engine, which is also defined in the Definitions section of the Fee Schedule, is a part of the MIAX PEARL electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. The Exchange believes that it is reasonable and appropriate to select two consecutive hours as the amount of time necessary to constitute an Exchange System Disruption, as two hours equates to approximately 1.4% of available trading time per month. The Exchange notes that the term ''Exchange System Disruption'' and its meaning have no applicability outside of the Fee Schedule, as it is used solely for purposes of calculating volume for the threshold tiers in the Fee Schedule. *See* the Definitions Section of the Fee Schedule.

[7] ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX PEARL Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX PEARL Market Maker) that has been appointed by a MIAX PEARL Market Maker, pursuant to the process described in the Fee Schedule. *See* the Definitions Section of the Fee Schedule.

[8] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[9] ''ABBO'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Exchange Rule 1400(g) and calculated by the Exchange based on market information received by the Exchange from OPRA. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[10] *See* Securities Exchange Act Release No. 88992 (June 2, 2020), 85 FR 35142 (June 8, 2020) (SR–PEARL–2020–06).

[11] *See* Securities Exchange Act Release No. 84592 (November 14, 2018), 83 FR 58646 (November 20, 2018) (SR–PEARL–2018–23).

[12] ''SPY/QQQ/IWM TCV'' means total consolidated volume in SPY, QQQ, and IWM calculated as the total national volume in SPY, QQQ, and IWM for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in SPY, QQQ, or IWM options). *See* the Definitions Section of the Fee Schedule.

the volume threshold that Market Makers currently achieve in SPY/QQQ/IWM options on MIAX PEARL. The Exchange believes that the proposed volume threshold will still remain highly competitive such that the threshold should enable the Exchange to continue to attract order flow in SPY/QQQ/IWM options and maintain market share. The Exchange cannot predict with certainty how many Market Makers would achieve the alternative Volume Criteria in Tier 2 with the increased threshold percentage, but the Exchange anticipates that each Market Maker that is currently in Tier 2 with that alternative method will likely continue to reach that Tier.

Alternative Volume Criteria for Tier 3

The Exchange proposes to amend the Add/Remove Tiered Rebates/Fees set forth in Section (1)(a) of the Fee Schedule that apply to the MIAX PEARL Market Maker Origin, to add a new, alternative Volume Criteria to Tier 3, based upon the total monthly volume executed in SPY options on MIAX PEARL by a MIAX PEARL Market Maker when adding liquidity. Pursuant to this alternative Volume Criteria, Market Makers will qualify for: (i) Maker rebates of ($0.44) in SPY, QQQ and IWM options for their Market Maker Origin when trading against Origins not Priority Customer, and (ii) Maker rebates of ($0.42) in SPY, QQQ and IWM options for their Market Maker Origin when trading against Priority Customer Origins, if the Market Maker executes at least 1.10% in SPY options when adding liquidity. The Exchange proposes that, in Tier 3 for MIAX PEARL Market Makers, the alternative Volume Criteria (above 1.10% in SPY when Adding Liquidity) will be calculated based on the total monthly volume that added liquidity executed by the Market Maker solely in SPY options on MIAX PEARL, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY TCV [13] (as the denominator). The Exchange notes that Market Makers that achieve the standard Tier 3 volume percentage but do not qualify for the proposed alternative Volume Criteria in that Tier, will receive the Tier 3 rates in the Market Maker Origin table in Penny Classes and Non-Penny Classes. Members will receive the highest tier based on the thresholds achieved. Other Penny classes and Non-Penny classes will receive the Tier 3 rates in the Market Maker Origin table. The Exchange proposes to designate the Tier 3 alternative Volume Criteria with the new symbol "✦" in Tier 3 of the Market Maker Origin table in Section (1)(a) of the Fee Schedule, with an explanatory paragraph listed below the tables in Section (1)(a) of the Fee Schedule.

The purpose of this proposed change is for business and competitive reasons. The Exchange cannot predict with certainty how many Market Makers would achieve the proposed Tier 3 alternative Volume Criteria, but anticipates that approximately three Market Makers are within reasonable proximity to potentially achieve the higher rebates in SPY/QQQ/IWM options based upon the total monthly volume executed in SPY options on MIAX PEARL by the current MIAX PEARL Market Makers.

The proposed changes are scheduled to become operative January 4, 2021.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [14] in general, and furthers the objectives of Section 6(b)(4) of the Act,[15] in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange members and issuers and other persons using its facilities, and 6(b)(5) of the Act,[16] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes its proposal to modify the volume threshold for the alternative Volume Criteria in Tier 2 and add a new, alternative Volume Criteria to Tier 3 provides for the equitable allocation of reasonable dues and fees and is not unfairly discriminatory for the following reasons. The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies." [17] There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 15% of the market share of executed volume of multiply-listed equity and ETF options trades as of December 24, 2020, for the month of December 2020.[18] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, as of December 30, 2020, the Exchange had an approximately 3.10% market share of executed volume of multiply-listed equity and ETF options for the month of December 2020.[19]

The Exchange believes that the ever-shifting market shares among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to transaction and/or non-transaction fee changes. For example, on February 28, 2019, the Exchange filed with the Commission a proposal to increase Taker fees in certain Tiers for options transactions in certain Penny classes for Priority Customers and decrease Maker rebates in certain Tiers for options transactions in Penny classes for Priority Customers (which fee was to be effective March 1, 2019).[20] The Exchange experienced a decrease in total market share between the months of February and March of 2019, after the fees were in effect. Accordingly, the Exchange believes that the March 1, 2019 fee change may have contributed to the decrease in the Exchange's market share and, as such, the Exchange believes competitive forces constrain options exchange transaction fees and market participants can shift order flow based on fee changes instituted by the exchanges.

The Exchange believes its proposal to modify the volume threshold for the alternative Volume Criteria in Tier 2

[13] "SPY TCV" means total consolidated volume in SPY calculated as the total national volume in SPY for the month for which the fees apply, excluding consolidated volume executed during the period of time in which the Exchange experiences an Exchange System Disruption (solely in SPY options). *See* the Definitions Section of the Fee Schedule.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4).

[16] 15 U.S.C. 78f(b)(1) and (b)(5).

[17] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[18] *See https://www.cboe.com/us/options/market_share/.*

[19] *See id.*

[20] *See* Securities Exchange Act Release No. 85304 (March 13, 2019), 84 FR 10144 (March 19, 2019) (SR–PEARL–2019–07).

and add a new, alternative Volume Criteria to Tier 3 is reasonable, equitably allocated and not unfairly discriminatory because these changes are for business and competitive reasons. In order to attract order flow, the Exchange initially set its volume threshold for the alternative Volume Criteria in Tier 2 at a meaningful low level. The Exchange now believes that it is appropriate to adjust this volume threshold so that it is more in line with the volume threshold that Market Makers currently achieve in SPY/QQQ/IWM options on MIAX PEARL. The Exchange believes that the proposed volume threshold will still remain highly competitive such that the threshold should enable the Exchange to continue to attract order flow in SPY/QQQ/IWM options and maintain market share.

The Exchange believes its proposal to establish the alternative Volume Criteria for Tier 3 is reasonable, equitable, and not unfairly discriminatory, as it is a form of pricing already adopted by the Exchange [21] and a form of pricing based upon trading activity in a select group of symbols, which is a common practice on many U.S. options exchanges as a means to incentivize order flow to be sent to an exchange for execution in actively traded options classes. The Exchange's affiliate, Miami International Securities Exchange, LLC (''MIAX Options''), offers differentiated pricing for transactions in options underlying certain select symbols.[22] Other options exchanges' fee schedules distinguish by symbol and specifically assess different fees and rebates for transactions in select symbols for the same market participants.[23]

The Exchange believes its proposal to offer an alternative Tier 3 Volume Criteria based upon the total monthly volume executed in SPY options on MIAX PEARL by a MIAX PEARL Market Maker when adding liquidity, will incentivize Market Makers to improve their posted liquidity to the benefit of the entire market, which will increase order flow sent to the Exchange, benefiting all market participants through increased liquidity, tighter markets and order interaction.

The Exchange also believes that its proposal is not unfairly discriminatory as all Market Makers can qualify for the alternative Volume Criteria in Tiers 2 and 3 by meeting the requirements that are designed to incentivize Market Makers to maintain quality markets. In addition, the Exchange continues to believe that it is not unfairly discriminatory to offer rebates pursuant to this proposal to only Market Makers because Market Makers add value through continuous quoting and are subject to additional requirements and obligations (such as quoting obligations) that other market participants are not.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes its proposal will not impose any burden on intra-market competition because the Exchange believes that its proposal will not place any category of Exchange market participant at a competitive disadvantage. The proposal to modify the volume threshold for the alternative Volume Criteria in Tier 2 and add a new, alternative Volume Criteria to Tier 3, is intended to improve market quality. The Exchange believes that its proposal will encourage Market Makers to improve market quality by providing an additional incentive to Market Makers in SPY and QQQ/IWM options to send additional SPY and QQQ/IWM orders, which results in narrower bid-ask spreads and increased depth of liquidity. This in turn will attract additional order flow to the Exchange. Accordingly, the Exchange believes that the proposed changes will continue to attract order flow to the Exchange, thereby encouraging additional volume and liquidity to the benefit of all market participants.

The Exchange believes its proposal will not impose any burden on inter-market competition because the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other options exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's fees in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[24] and Rule 19b–4(f)(2) [25] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form *(http://www.sec.gov/rules/sro.shtml)*; or
- Send an email *to rule-comments@sec.gov.* Please include File Number SR–PEARL–2020–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

[21] *See supra* note 11. *See generally,* Section (1)(a) of the Fee Schedule for Market Maker Origin.

[22] *See* MIAX Options Fee Schedule, Section (1)(a)(iii).

[23] *See* Nasdaq ISE, LLC (''ISE'') Fee Schedule, Section 3, Regular Order Fees and Rebates. The ISE Fee Schedule provides for a ''Market Maker Plus'' program for Select and Non-Select Symbols, with tiered incentives for Market Makers. Further, the ISE Fee Schedule provides for a linked maker rebate for SPY, QQQ and IWM, in which the linked maker rebate applies to executions in SPY, QQQ, and IWM if the ISE Market Maker does not achieve the applicable tier in that symbol but achieves the tier (*i.e.,* any of the Market Maker Plus Tiers 2–4) for any badge/suffix combination in the other linked symbol, in which case the higher tier achieved applies to both symbols.

[24] 15 U.S.C. 78s(b)(3)(A)(ii).

[25] 17 CFR 240.19b–4(f)(2).

All submissions should refer to File Number SR–PEARL–2020–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2020–38 and should be submitted on or before February 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–00949 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34171; 812–15157]

Natixis ETF Trust II, et al.

January 12, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application to amend a prior order for exemptive relief.

SUMMARY OF APPLICATION: Applicants request an order (''Amended Order'') that would amend a prior order to permit the Funds, as defined below, to use Creation Baskets (as defined below) that include instruments that are not included, or are included with different weightings, in the Fund's proxy portfolio.

APPLICANTS: Natixis Advisors, L.P. (''Natixis''), Natixis ETF Trust II (the ''Trust'') and NYSE Group, Inc. (''NYSE'').

FILING DATES: The application was filed on August 31, 2020, and amended on November 16, 2020 and on December 8, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on February 8, 2021 and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Investment Company Act of 1940 (''Act''), hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: *peter.shea@klgates.com.*

FOR FURTHER INFORMATION CONTACT: Marc Mehrespand, Senior Counsel; Trace Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

I. Introduction

1. On December 10, 2019, the Commission issued an order (''Prior Order'')[1] under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.[2] The Prior Order permitted Applicants to introduce a novel type of actively-managed exchange-traded fund (''ETF'') that is not required to disclose its portfolio holdings on a daily basis (each, a ''Fund''). Rather, pursuant to the Prior Order, each Business Day[3] a Fund publishes a basket of securities and cash that, while different from the Fund's portfolio, is designed to closely track its daily performance (the ''Proxy Portfolio'').

2. Pursuant to the Prior Order, a Fund sells and redeems its shares (''Shares'') only in Creation Units and generally on an in-kind basis. Purchasers are required to purchase Creation Units by making a deposit of Deposit Instruments and shareholders redeeming their Shares receive a transfer of Redemption Instruments.[4] Under the Prior Order, the names and quantities of the instruments that constitute the Deposit Instruments and the Redemption Instruments for a Fund (collectively, the ''Creation Basket'') are the same as the Fund's Proxy Portfolio, except to the extent purchases and redemptions are made entirely or in part on a cash basis.

3. Applicants now seek to amend the Prior Order to, in effect, give the Funds the same flexibility with respect to Creation Basket composition as afforded to ETFs relying on rule 6c–11.[5] More

[1] *See* Natixis ETF Trust II, *et al.,* Investment Company Act Release No. 33684 (Nov. 14, 2019) (notice) and Investment Company Act Release No. 33711 (Dec. 10, 2019) (order). Except as specifically noted in the application, all representations and conditions contained in the application previously submitted with the Commission (File No. 812–14870), as amended and restated, and filed with the Commission on October 21, 2019 (the ''Prior Application'') remain applicable to the operation of the Funds and will apply to any Funds relying on the Amended Order.

[2] The relief granted in the Prior Order under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the 1940 Act (the ''Section 12(d)(1) Relief''), and relief under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act relating to the Section 12(d)(1) Relief, will expire one year from the effective date of rule 12d1–4. *See* Fund of Funds Arrangements, Investment Company Act Rel. No. 10871 (Oct. 7, 2020), at III.

[3] All capitalized terms not otherwise defined in this notice have the meanings ascribed to them in the Prior Application.

[4] Deposit Instruments and Redemption Instruments may include cash and/or securities.

[5] The Funds are not be able to operate in reliance on rule 6c–11 because they do not disclose their portfolio holdings on a daily basis as required by the rule. *See* rule 6c–11(c)(1)(i) (requiring an ETF to disclose prominently on its website, publicly available and free of charge, the portfolio holdings that will form the basis for each calculation of NAV per share).

specifically, Applicants have requested that the Funds be allowed to use Creation Baskets that include instruments that are not included, or are included with different weightings, in the Fund's Proxy Portfolio.

II. The Application

A. Applicants' Proposal

4. Upon amending the Prior Order, the names and quantities of the instruments that may constitute a Creation Basket will generally be the same as the Fund's Proxy Portfolio, but a Fund may accept Creation Baskets that differ from the Proxy Portfolio. Each Business Day, before the open of trading on the Exchange where a Fund is listed, the Fund will publish on its website the composition of any Creation Basket exchanged with an authorized participant on the previous Business Day that differed from such Business Day's Proxy Portfolio other than with respect to cash.

5. Applicants represent that, for portfolio management or other reasons, the Funds may determine that it is desirable to use Creation Baskets that differ from the Proxy Portfolio (beyond cash substitutions). For example, a Fund may want to use a Creation Basket that contains instruments that are not included in a Fund's Proxy Portfolio if the Adviser or Sub-Adviser seeks to add an instrument to the Fund's Actual Portfolio) without incurring transaction costs associated with the purchase of the instrument for cash. Similarly, if the Adviser or Sub-Adviser decides to sell an instrument from a Fund's Actual Portfolio, the instrument may be included in a Creation Basket with the expectation that the Fund will deliver it in-kind during a redemption transaction.

6. The Funds will use the requested basket flexibility only in circumstances under which Applicants believe there will be no harm to the Funds or their shareholders, and in order to benefit the Funds and their shareholders by reducing costs, increasing efficiency and improving trading.

7. Pursuant to condition 10 herein, each Fund will adopt and implement written policies and procedures regarding the construction of its Creation Baskets in accordance with rule 6c–11 under the Act. For purposes of the requirement to comply with the policies and procedures provision in rule 6c–11, only Creation Baskets that differ from a Fund's Proxy Portfolio will be treated as a ''custom basket'' under rule 6c–11(c)(3).

8. Furthermore, pursuant to condition 9 herein, each Fund will comply with the recordkeeping requirements of rule 6c–11.[6] For purposes of the requirement to comply with the recordkeeping provision in rule 6c–11, only Creation Baskets different from a Fund's Proxy Portfolio will be treated as a ''custom basket'' under rule 6c–11(d)(2)(ii).

B. Considerations Relating to the Requested Relief

9. Applicants represent that the ability to utilize a Creation Basket that includes instruments that are not included, or are included with different weightings, in a Fund's Proxy Portfolio, or are included in different weightings, does not raise any new policy concerns about reverse engineering of a Fund's portfolio, self-dealing or overreaching, or selective disclosure beyond those concerns addressed in connection with the Prior Order.

10. *Reverse Engineering.* Applicants acknowledge that, by using a Creation Basket that includes instruments that are not included in a Fund's Proxy Portfolio, or are included in different percentages, and by publishing such Creation Basket on its website, the Fund would provide market participants with additional information about which instruments it adds or removes from the Fund's Actual Portfolio. However, Applicants represent that they will operate the Funds in a manner designed to minimize the risk of reverse engineering and, for the reasons set forth in the application, believe successful front-running or free-riding is highly unlikely.

11. *Self-Dealing or Overreaching.* Applicants state that authorized participants and other market participants will not have the ability to disadvantage the Funds by manipulating or influencing the composition of Creation Baskets, including those that differ from the Proxy Portfolio. Like the basket and custom basket policies and procedures required of ETFs by rule 6c–11, the Funds will adopt and implement written policies and procedures that govern the construction of Creation Baskets and the process that will be used for the acceptance of Creation Baskets to safeguard the best interests of the Funds and their shareholders.[7]

12. *Selective Disclosure.* The Funds and each person acting on behalf of the Funds will continue to be required to comply with Regulation Fair Disclosure as if it applied to them (except that the exemptions provided in rule 100(b)(2)(iii) therein shall not apply). Applicants believe that the new Creation Basket flexibility being sought by the Applicants does not raise any new concerns about selective disclosure of non-public material information. First, a Fund's use of, or conversations with authorized participants about, Creation Baskets that would result in such disclosure would effectively be limited by the Funds' obligation to comply with Regulation Fair Disclosure. Second, as noted above, each Business Day, before the open of trading on the Exchange where a Fund is listed, the Fund will publish on its website the composition of any basket accepted by the Fund on the previous Business Day that differed from such Business Day's Proxy Portfolio other than with respect to cash.

III. Requested Exemptive Relief

For the reasons stated above, Applicants believe that the Prior Order, as amended, continues to meet the relevant standards for relief pursuant to section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.[8]

IV. Applicants' Conditions

Applicants agree that the Amended Order granting the requested relief will be subject to all of the conditions in the Prior Order, except that condition 9 of the Prior Order is deleted in its entirety and replaced with the conditions 9–10 as follows:

9. Each Fund will comply with the recordkeeping requirements of rule 6c–11 under the Act, as amended, except that for purposes of this condition, only Creation Baskets different from the Fund's Proxy Portfolio will be treated as a ''custom basket'' under rule 6c–11(d)(2)(ii). In addition, each Fund will maintain and preserve, for a period of not less than five years, in an easily accessible place, (i) a copy of the Proxy Portfolio published on the Fund's website for each Business Day; and (ii) a copy of each Creation Basket made available.

[6] Pursuant to condition 9, each Fund will also maintain and preserve a copy of the Proxy Portfolio published on the Fund's website for each Business Day and a copy of each Creation Basket made available.

[7] *See* Exchange-Traded Funds, Investment Company Act Release No. 33646 (Sept. 25, 2019) (''ETF Adopting Release''), at 80–94 (discussion of rule 6c–11 requirement for ETF policies and procedures concerning basket construction and acceptance and heightened policies and procedures for custom baskets).

[8] *See supra* note 2.

10. Each Fund will adopt and implement written policies and procedures that govern the construction of Creation Baskets, as required under rule 6c–11(c)(3) under the Act, as amended, except that for purposes of this condition, only Creation Baskets different from the Fund's Proxy Portfolio will be treated as a ''Custom Basket''. The Fund's basket policies and procedures will be covered by the Fund's compliance program and other requirements under rule 38a–1 under the Act, as amended.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–00961 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34170; 812–15182]

Invesco Capital Management LLC, et al.

January 12, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application to amend a prior order for exemptive relief.

SUMMARY OF APPLICATION: Applicants request an order (''Amended Order'') that would amend a prior order to permit the Funds, as defined below, to use Creation Baskets (as defined below) that include instruments that are not included, or are included with different weightings, in the Fund's Substitute Basket (as defined below).

APPLICANTS: Invesco Capital Management LLC, Invesco Actively Managed Exchange-Traded Fund Trust and Invesco Distributors, Inc.

FILING DATES: The application was filed on December 1, 2020, and amended on December 7, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on February 8, 2021 and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Investment Company Act of 1940 (''Act''), hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES:

The Commission: Secretarys-Office@sec.gov.

Applicants: anna.paglia@invesco.com, paulita.pike@ropesgray.com and *edward.baer@ropesgray.com.*

FOR FURTHER INFORMATION CONTACT: Marc Mehrespand, Senior Counsel; Trace Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

I. Introduction

1. On December 2, 2020, the Commission issued an order (''Prior Order'') [1] under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act. The Prior Order permitted Applicants to introduce a novel type of actively-managed exchange-traded fund (''ETF'') that is not required to disclose its portfolio holdings on a daily basis (each, a ''Fund''). Rather, pursuant to the Prior Order, each Business Day [2] a Fund publishes a basket of securities and cash that, while different from the Fund's portfolio, is designed to closely track its daily performance (the ''Substitute Basket'').

2. Pursuant to the Prior Order, a Fund sells and redeems its shares (''Shares'') only in Creation Units and generally on an in-kind basis. Purchasers are required to purchase Creation Units by making a deposit of Deposit Instruments and shareholders redeeming their Shares receive a transfer of Redemption Instruments.[3] Under the Prior Order, the names and quantities of the instruments that constitute the Deposit Instruments and the Redemption Instruments for a Fund (collectively, the ''Creation Basket'') are the same as the Fund's Substitute Basket, except to the extent purchases and redemptions are made entirely or in part on a cash basis.

3. Applicants now seek to amend the Prior Order to, in effect, give the Funds the same flexibility with respect to Creation Basket composition as afforded to ETFs relying on rule 6c–11.[4] More specifically, Applicants have requested that the Funds be allowed to use Creation Baskets that include instruments that are not included, or are included with different weightings, in the Fund's Substitute Basket.

II. The Application

A. Applicants' Proposal

4. Upon amending the Prior Order, the names and quantities of the instruments that may constitute a Creation Basket will generally be the same as the Fund's Substitute Basket, but a Fund may accept Creation Baskets that differ from the Substitute Basket. Each Business Day, before the open of trading on the Exchange where a Fund is listed, the Fund will publish on its website the composition of any Creation Basket exchanged with an authorized participant on the previous Business Day that differed from such Business Day's Substitute Basket other than with respect to cash.

5. Applicants represent that, for portfolio management or other reasons, the Funds may determine that it is desirable to use Creation Baskets that differ from the Substitute Basket (beyond cash substitutions). For example, a Fund may want to use a Creation Basket that contains instruments that are not included in a Fund's Substitute Basket if the Adviser

[1] *See* Invesco Capital Management LLC, *et al.,* Investment Company Act Release No. 34087 (Nov. 6, 2020) (notice) and Investment Company Act Release No. 34127 (Dec. 2, 2020) (order). Except as specifically noted in the application, all representations and conditions contained in the application previously submitted with the Commission (File No. 812–15070), as amended and restated, and filed with the Commission on November 6, 2020 (the ''Prior Application'') remain applicable to the operation of the Funds and will apply to any Funds relying on the Amended Order.

[2] All capitalized terms not otherwise defined in this notice have the meanings ascribed to them in the Prior Application.

[3] Deposit Instruments and Redemption Instruments may include cash and/or securities.

[4] The Funds are not be able to operate in reliance on rule 6c–11 because they do not disclose their portfolio holdings on a daily basis as required by the rule. *See* rule 6c–11(c)(1)(i) (requiring an ETF to disclose prominently on its website, publicly available and free of charge, the portfolio holdings that will form the basis for each calculation of NAV per share).

or Sub-Adviser seeks to add an instrument to the Fund's then-current portfolio (''Actual Portfolio'') without incurring transaction costs associated with the purchase of the instrument for cash. Similarly, if the Adviser or Sub-Adviser decides to sell an instrument from a Fund's Actual Portfolio, the instrument may be included in a Creation Basket with the expectation that the Fund will deliver it in-kind during a redemption transaction.

6. The Funds will use the requested basket flexibility only in circumstances under which Applicants believe there will be no harm to the Funds or their shareholders, and in order to benefit the Funds and their shareholders by reducing costs, increasing efficiency and improving trading.

7. Pursuant to condition 10 herein, each Fund will adopt and implement written policies and procedures regarding the construction of its Creation Baskets in accordance with rule 6c–11 under the Act. For purposes of the requirement to comply with the policies and procedures provision in rule 6c–11, only Creation Baskets that differ from a Fund's Substitute Basket will be treated as a ''custom basket'' under rule 6c–11(c)(3).

8. Furthermore, pursuant to condition 9 herein, each Fund will comply with the recordkeeping requirements of rule 6c–11.[5] For purposes of the requirement to comply with the recordkeeping provision in rule 6c–11, only Creation Baskets different from a Fund's Substitute Basket will be treated as a ''custom basket'' under rule 6c–11(d)(2)(ii).

B. Considerations Relating to the Requested Relief

9. Applicants represent that the ability to utilize a Creation Basket that includes instruments that are not included, or are included with different weightings, in a Fund's Substitute Basket, or are included in different weightings, does not raise any new policy concerns about reverse engineering of a Fund's portfolio, self-dealing or overreaching, or selective disclosure beyond those concerns addressed in connection with the Prior Order.

10. *Reverse Engineering.* Applicants acknowledge that, by using a Creation Basket that includes instruments that are not included in a Fund's Substitute Basket, or are included in different percentages, and by publishing such Creation Basket on its website, the Fund would provide market participants with additional information about which instruments it adds or removes from the Fund's Actual Portfolio. However, Applicants represent that they will operate the Funds in a manner designed to minimize the risk of reverse engineering and, for the reasons set forth in the application, believe successful front-running or free-riding is highly unlikely.

11. *Self-Dealing or Overreaching.* Applicants state that authorized participants and other market participants will not have the ability to disadvantage the Funds by manipulating or influencing the composition of Creation Baskets, including those that differ from the Substitute Basket. Like the basket and custom basket policies and procedures required of ETFs by rule 6c–11, the Funds will adopt and implement written policies and procedures that govern the construction of Creation Baskets and the process that will be used for the acceptance of Creation Baskets to safeguard the best interests of the Funds and their shareholders.[6]

12. *Selective Disclosure.* The Funds and each person acting on behalf of the Funds will continue to be required to comply with Regulation Fair Disclosure as if it applied to them (except that the exemptions provided in rule 100(b)(2)(iii) therein shall not apply). Applicants believe that the new Creation Basket flexibility being sought by the Applicants does not raise any new concerns about selective disclosure of non-public material information. First, a Fund's use of, or conversations with authorized participants about, Creation Baskets that would result in such disclosure would effectively be limited by the Funds' obligation to comply with Regulation Fair Disclosure. Second, as noted above, each Business Day, before the open of trading on the Exchange where a Fund is listed, the Fund will publish on its website the composition of any basket accepted by the Fund on the previous Business Day that differed from such Business Day's Substitute Basket other than with respect to cash.

III. Requested Exemptive Relief

For the reasons stated above, Applicants believe that the Prior Order, as amended, continues to meet the relevant standards for relief pursuant to section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

IV. Applicants' Conditions

Applicants agree that the Amended Order granting the requested relief will be subject to all of the conditions in the Prior Order, except that condition 9 of the Prior Order is deleted in its entirety and replaced with the conditions 9–10 as follows:

9. Each Fund will comply with the recordkeeping requirements of rule 6c–11 under the Act, as amended, except that for purposes of this condition, only Creation Baskets different from the Fund's Substitute Basket will be treated as a ''custom basket'' under rule 6c–11(d)(2)(ii). In addition, each Fund will maintain and preserve, for a period of not less than five years, in an easily accessible place, (i) a copy of the Substitute Basket published on the Fund's website for each Business Day; and (ii) a copy of each Creation Basket made available.

10. Each Fund will adopt and implement written policies and procedures that govern the construction of Creation Baskets, as required under rule 6c–11(c)(3) under the Act, as amended, except that for purposes of this condition, only Creation Baskets different from the Fund's Substitute Basket will be treated as a ''Custom Basket''. The Fund's basket policies and procedures will be covered by the Fund's compliance program and other requirements under rule 38a–1 under the Act, as amended.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–00957 Filed 1–15–21; 8:45 am]

BILLING CODE 8011–01–P

[5] Pursuant to condition 9, each Fund will also maintain and preserve a copy of the Substitute Basket published on the Fund's website for each Business Day and a copy of each Creation Basket made available.

[6] *See* Exchange-Traded Funds, Investment Company Act Release No. 33646 (Sept. 25, 2019) (''ETF Adopting Release''), at 80–94 (discussion of rule 6c–11 requirement for ETF policies and procedures concerning basket construction and acceptance and heightened policies and procedures for custom baskets).

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2016–0039]

Use of Electronic Payroll Data to Improve Program Administration

AGENCY: Social Security Administration.

ACTION: Notice and request for comments.

SUMMARY: This is advance notification to the public regarding the implementation of an information exchange between the Social Security Administration (SSA)

and Equifax, a payroll data provider. We expect that the information exchange will enable us to administer Social Security Disability Insurance (SSDI) benefits and Supplemental Security Income (SSI) payments more efficiently, while helping to prevent improper payments.

DATES: Comments must be received by February 18, 2021.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. No matter which method you choose, please state that your comments refer to Docket No. SSA–2016–0039 so that we may associate your comments with the correct document.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *https://www.regulations.gov/.* Use the ''Search'' function to find docket number SSA–2016–0039. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Reports Clearance Director, 3100 West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235.

Comments are available for public viewing on the Federal eRulemaking portal at *https://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Betsy Blair, Office of Income Security Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–0041. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Description of Information Exchange

Congress enacted the Bipartisan Budget Act (BBA) of 2015 [1] on November 2, 2015. Section 824 of the BBA added section 1184 to the Social Security Act (Act) [2] and authorized us to enter into information exchanges with payroll data providers for the purposes of efficient program administration and prevention of improper SSDI and SSI payments. Section 824 defines information exchanges as the automated comparison of our system(s) of records with records of payroll data providers.[3] Section 824 further defines payroll data providers to include payroll providers, wage verification companies, and other commercial or non-commercial entities that collect and maintain data regarding employment and wages.[4] Although the Act and our rules require individuals to report any changes that could affect SSDI entitlement, SSI eligibility, or benefit amounts, we do not always receive these reports timely. By entering into an information exchange with the payroll data provider Equifax, we will be able to obtain the wage and employment records of Equifax and will therefore be able to receive wage information timely without the need for additional verification from other sources.

We will request authorization [5] from SSDI and SSI claimants, recipients, or deemors, to obtain their wage and employment information from payroll data providers, like Equifax. However, failure to sign the authorization does not lead to ineligibility for benefits. Once the authorization is signed, it will remain in effect until the earliest of the following occurrences: (1) It has been revoked in writing by the individual or their legal guardian; (2) all entitlement to or eligibility for benefits or payments has terminated, there are no other claims or appeals pending, and all periods for appealing any adverse determinations or decisions have lapsed; (3) there has been an adverse determination or decision on the claim, the individual is not otherwise currently entitled to or eligible for payments, there are no other claims or appeals pending and all periods for appealing any adverse determinations or decisions have lapsed; or (4) for SSI deemors, the deeming relationship ends. Authorizing us to obtain information directly from a payroll data provider like Equifax protects the beneficiary or recipient from a penalty of non-payment or ineligibility under section 1129A of the Act,[6] for any omission or error from wages reported by Equifax. Additionally, we will find good cause and not subject recipients who receive SSI payments to a monetary deduction penalty of their payments under section 1631(e)(2) of the Act [7] if they fail or delay to report a change in employer and gave us the authorization to obtain information from Equifax.

We will request the wage and employment information listed below from Equifax via a secure means of electronic transmission, every month, for each beneficiary and recipient with a valid authorization and who is actively requesting or receiving benefits. In response to our request, Equifax will provide the wage and employment information or respond that it has no records. We will conduct this information exchange in accordance with all applicable laws, to include the Privacy Act of 1974, 5 U.S.C. 552a and the Social Security Act, 42 U.S.C. 1306(a).

Equifax will use reasonable procedures [8] to ensure maximum accuracy, relevance, and timeliness of its wage and employment information and must notify us within 24 hours if it discovers that it submitted incorrect information to us.

We have determined that the general quality of the wage and employment information that will be received via the information exchange meets our standards and is:

- Sufficiently accurate, up-to-date, and complete.
  - Equifax tests the data of employers to ensure it contains all of the data elements identified below and conforms to its system requirements; regularly conducts quality assurance assessments to ensure accuracy; and makes wage and employment data available within 24 hours of receipt from employers.
- Vital to accurately determine (a) entitlement to SSDI, (b) eligibility for SSI, and (c) SSI payment amounts.
  - We require this information because wage and employment data are factors that can affect entitlement, eligibility, and payment amounts.

[1] Public Law 114–74, 129 Stat. 584, 607.

[2] 42 U.S.C. 1320e–3.

[3] 42 U.S.C. 1320e–3(c)(2).

[4] 42 U.S.C. 1320e–3(c)(1).

[5] We request such authorization by using form SSA–8240, OMB 0960–0807, ''Authorization for the Social Security Administration to Obtain Wage and Employment Information from Payroll Data Providers.''

[6] 42 U.S.C. 1320a–8a.

[7] 42 U.S.C. 1383(e)(2).

[8] Equifax shall follow all technical specifications provided by us. We provided technical specifications, characteristics, and needs. The technical specifications include detailed requirements and pertinent information regarding the request, response, security requirements, Web Service, data retention, and processing guidelines related to the information exchange.

Because the information is coming directly from the employer through Equifax, we will receive timely and accurate wage and employment reporting and will be able to administer SSDI benefits and SSI payments more efficiently.

• Needed to prevent improper payments of SSDI and SSI benefits.

○ As indicated above, we do not always receive timely reports of changes that could affect SSDI entitlement, SSI eligibility, or SSI benefit amounts, and this may cause improper payments. Requirements to verify wages may also cause delays that lead to improper payments. Changes in a person's work and wages are a leading cause of improper payments in the SSDI and SSI programs. While we use a number of sources to verify wage amounts, verifying wages is currently a manual process, and we continue to rely on beneficiaries to self-report wages.[9] With automated information exchanges, we will be able to obtain the wage and employment records timely and without the need for additional verification from other sources.

Data Elements

The information exchange will require SSA and Equifax to exchange specific data elements. We will send the data elements below to Equifax to ensure we are requesting employment and wage information for the correct individual and timeframe. Equifax and SSA will use a federally compliant, secure means to exchange data and conduct the automated comparison of SSA to Equifax records under this information exchange.

In order to request wage and employment information, we will provide the following information from the Supplemental Security Income Record and Special Veterans Benefits for SSI[10] and the eWork for SSDI[11] to Equifax:

(1) Social Security number (SSN) of the beneficiary, recipient, or deemor;

(2) Start date and end date (month and year) of wage and employment information being requested;

(3) Tracking identification number.

(In response to our request, Equifax will provide the following wage and employment information to us, if available:

(1) Wage earner's SSN

(2) Wage earner's first name

(3) Wage earner's last name

(4) Employer name

(5) Employer identification number

(6) Employer address

(7) Transmission date of wage and employment response from Equifax to us

(8) Date of payment

(9) Amount of gross pay

(10) Frequency of pay

(11) Pay period begin and end date

(12) Year-to-date gross wage amount

(13) Applicable deductions, including but not limited to the following:

a. Federal, state and local taxes

b. Federal Insurance Contributions Act taxes

c. Medicare taxes

d. Garnishment

e. Cafeteria plans

(14) Employer telephone number

(15) Wage earner's job title

(16) Employment begin date

(17) Employment end date

(18) Amount of net pay

(19) Pay rate

(20) Hours worked per pay period

Request for Comments

We are requesting comments concerning the specifics of our proposal to implement an information exchange under section 824 of the BBA. We ask that, in preparing comments, you address questions such as:

1. Have we identified the appropriate design for an information exchange?

2. Are there any additional operational elements of an information exchange that we should include?

We will not respond to your comments, but we will consider them as we review our plan to implement the information exchange under section 824 of the BBA.

The Commissioner of the Social Security Administration, Andrew Saul, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

[FR Doc. 2021–01026 Filed 1–15–21; 8:45 am]

BILLING CODE 4191–02–P

[9] See page 22 of the Congressional Justification for SSA's Fiscal Year 2020 budget available here: *https://www.ssa.gov/budget/FY20Files/FY20-JEAC_2.pdf.*

[10] See 71 FR 1830 (Jan. 11, 2006) to view the System of Records Notice 60–0103.

[11] See 68 FR 54037 (Sep. 15, 2003) to view the System of Records Notice 60–0330.

DEPARTMENT OF STATE

[Public Notice: 11325]

In the Matter of the Designation of Ansarallah (and other Aliases) as a Foreign Terrorist Organization

Based upon a review of the Administrative Record assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that there is a sufficient factual basis to find that the relevant circumstances described in section 219 of the Immigration and Nationality Act, as amended (hereinafter ''INA'') (8 U.S.C. 1189), exist with respect to Ansarallah, also known as Ansar Allah; also known as Ansarullah; also known as Partisans of God; and also known as Supporters of God. Therefore, I hereby designate the aforementioned organization and its aliases as a foreign terrorist organization pursuant to section 219 of the INA.

This determination shall be published in the **Federal Register**.

Dated: January 12, 2021.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2021–01001 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11320]

30-Day Notice of Proposed Information Collection: Special Immigrant Visa Biodata Form

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to February 18, 2021.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

• *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection

title, and the OMB control number in the subject line of your message.

• *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Irving Jones, PRM/Admissions, 2025 E Street NW, SA–9, 8th Floor, Washington, DC 20522–0908, who may be reached on 202.453.9248 or at *JonesJI2@state.gov.*

SUPPLEMENTARY INFORMATION:

• *Title of Information Collection:* Special Immigrant Visa Biodata Form.

• *OMB Control Number:* 1405–0203.

• *Type of Request:* Revision of a Currently Approved Collection.

• *Originating Office:* Office of Admissions, Bureau of Population, Refugees, and Migration (PRM/A).

• *Form Number:* DS–0234.

• *Respondents:* Iraqi and Afghan Special Immigrant Visa Applicants.

• *Estimated Number of Respondents:* 14,000.

• *Estimated Number of Responses:* 14,000.

• *Average Time per Response:* 30 minutes.

• *Total Estimated Burden Time:* 7,000 annual hours.

• *Frequency:* On Occasion.

• *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Form DS–234 elicits information used to determine the eligibility of certain Iraqis and Afghan SIV recipients for refugee resettlement benefits.

Methodology

The SIV Biodata information form (DS–234) is submitted electronically by the applicant to the National Visa Center, which will forward the forms to the Refugee Processing Center of the Bureau of Population, Refugees, and Migration.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2021–01059 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–33–P

DEPARTMENT OF STATE

[Public Notice: 11327]

Designation of Abd al-Aziz Malluh Mirjirash al-Muhammadawi as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with sections 1(a)(ii)(A) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the person known as Abd al-Aziz Malluh Mirjirash al-Muhammadawi, also known as Abdul Aziz Al-Mohammedawi, also known as Abdulazeez Mlawwah Mjeresh Mjeresh, also known as Abu Fadak Al-Mohammedawi, also known as Abu Fadak, also known as Al Khal, is a foreign person who poses a significant risk of committing an act of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: September 3, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2021–01003 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11295]

60-Day Notice of Proposed Information Collection: Grant Request Automated Submissions Program (GRASP)

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to March 22, 2021.

ADDRESSES:

You may submit comments by any of the following methods:

• *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2020–0056'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.

• *Email: Shearertp@state.gov.*

• *Regular Mail:* Send written comments to: Thomas P. Shearer, Office of Overseas Schools, U.S. Department of State, Room H328, 2301 C Street NW, Washington, DC 20522–0132.

• *Fax:* 202–261–8224.

• *Hand Delivery or Courier:* Thomas P. Shearer, Office of Overseas Schools, U.S. Department of State, Room H328, 2401 E Street NW, Washington, DC 20037.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Thomas P. Shearer, Office of Overseas Schools, U.S. Department of State, Room H328, 2301 C Street NW, Washington, DC 20522–0132, who may be reached on 202–261–8201 or at *Shearertp@state.gov.*

SUPPLEMENTARY INFORMATION:

• *Title of Information Collection:* Grant Request Automated Submissions Program (GRASP)

- *OMB Control Number:* 1405–0036
- *Type of Request:* Extension of a Currently Approved Collection
- *Originating Office:* Bureau of Administration, A/OPR/OS
- *Form Number:* DS–0573, DS–0574, DS–0575, DS–0576
- *Respondents:* Recipients of grants
- *Estimated Number of Respondents:* 193
- *Estimated Number of Responses:* 193
- *Average Time per Response:* 90 minutes
- *Total Estimated Burden Time:* 289.5 hours
- *Frequency:* Annually
- *Obligation to Respond:* Required to Obtain or Retain a Benefit

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

In accordance with the Consolidated Overseas Schools Program as outlined in 2 FAM 610, the Office of Overseas Schools of the Department of State (A/OPR/OS) is responsible for determining that adequate educational opportunities exist at Foreign Service posts for dependents of U.S. Government personnel stationed abroad and for assisting American-sponsored overseas schools in demonstrating U.S. educational philosophy and practice. The information gathered enables A/OPR/OS to advise the Department and other foreign affairs agencies regarding current and constantly changing conditions, and enables A/OPR/OS to make judgments regarding assistance to schools for the improvement of educational opportunities.

The legal requirements that authorize the function of A/OPR/OS and thereby authorize the collection of information are the Foreign Assistance Act of 1961 (as amended), and the Mutual Educational and Cultural Affairs Act of 1961 (as amended), and the Department of State Basic Authorities Act of 1956, as amended by the Foreign Service Act of 1980, Public Law 96–465.

Methodology

Information is collected via electronic media.

Thomas P. Shearer,

Director, A/OPR/OS, Department of State.

[FR Doc. 2021–01046 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF STATE

[Public Notice: 11320]

30-Day Notice of Proposed Information Collection: Special Immigrant Visa Biodata Form

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to February 18, 2021.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Irving Jones, PRM/Admissions, 2025 E Street NW, SA–9, 8th Floor, Washington, DC 20522–0908, who may be reached on 202.453.9248 or at *JonesJI2@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Special Immigrant Visa Biodata Form.
- *OMB Control Number:* 1405–0203.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Office of Admissions, Bureau of Population, Refugees, and Migration (PRM/A).
- *Form Number:* DS–0234.
- *Respondents:* Iraqi and Afghan Special Immigrant Visa Applicants.
- *Estimated Number of Respondents:* 14,000.
- *Estimated Number of Responses:* 14,000.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 7,000 annual hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Form DS–234 elicits information used to determine the eligibility of certain Iraqis and Afghan SIV recipients for refugee resettlement benefits.

Methodology

The SIV Biodata information form (DS–234) is submitted electronically by the applicant to the National Visa Center, which will forward the forms to the Refugee Processing Center of the Bureau of Population, Refugees, and Migration.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2021–01040 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–33–P

DEPARTMENT OF STATE

[Public Notice: 11323]

U.S. Advisory Commission on Public Diplomacy Notice of Meeting

The U.S. Advisory Commission on Public Diplomacy (ACPD) will hold a virtual public meeting from 12:00 p.m. until 1:30 p.m., Thursday, February 11, 2021. The meeting will showcase the Commission's *2020 Comprehensive Annual Report on Public Diplomacy and International Broadcasting,* and a panel of independent experts will examine the challenges and opportunities facing U.S. government public diplomacy in 2021 and beyond. The ongoing COVID–19 pandemic and the continuously evolving information and political environments at home and abroad are profoundly affecting public diplomacy policies and practices in the new decade.

This meeting is open to the public, including the media and members and staff of governmental and non-governmental organizations. To obtain the web conference link and password and to request reasonable accommodation, please email ACPD Program Assistant Kristy Zamary at *ZamaryKK@state.gov.* Please send any request for reasonable accommodation no later than February 4, 2021. Requests received after that date will be considered, but might not be possible to fulfill. Attendees should plan to enter the web conference waiting room by 11:50 a.m. to allow for a prompt start. Since 1948, the ACPD has been charged with appraising activities intended to understand, inform, and influence foreign publics and to increase the understanding of, and support for, these same activities. The ACPD conducts research that provides honest assessments of public diplomacy efforts, and disseminates findings through reports, white papers, and other publications. It also holds public symposiums that generate informed discussions on public diplomacy issues and events. The Commission reports to the President, Secretary of State, and Congress. The Office of the Under Secretary of State for Public Diplomacy and Public Affairs supports it.

For more information on the U.S. Advisory Commission on Public Diplomacy, please contact Executive Director Vivian S. Walker at *WalkerVS@state.gov* or Senior Advisor Shawn Baxter at *BaxterGS@state.gov,* or please visit *https://www.state.gov/bureaus-offices/under-secretary-for-public-diplomacy-and-public-affairs/united-states-advisory-commission-on-public-diplomacy/.*

Kristina K. Zamary,

Department of State.

[FR Doc. 2021–01073 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–45–P

DEPARTMENT OF STATE

[Public Notice: 11324]

Designation of Ansarallah as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(a)(ii)(A) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the person known as Ansarallah, also known as Ansar Allah; also known as Ansarullah; also known as Partisans of God; and also known as Supporters of God, is a foreign person who has committed or has attempted to commit, or poses a significant risk of committing, or has participated in training to commit, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 12, 2021.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2021–01000 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice:11326]

Designation of Abdul Malik al-Houthi, Abd al-Khaliq Badr al-Din al-Houthi, and Abdullah Yahya al Hakim as Specially Designated Global Terrorists

Acting under the authority of and in accordance with section 1(a)(ii)(B) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the persons known as Abdul Malik al-Houthi, also known as Abdul-Malik al-Houthi, also known as Abdel-Malek al-Houthi, also known as Abdel-Malik al-Houthi, also known as Abdulmalik Bin Bader Al-Deen al-Houth, also known as Abdul Malik Badruddin Ameerudin Hussain al-Houthi; Abd al-Khaliq Badr al-Din al-Houthi, also known as Abdul Khaliq Badreddin al-Houthi, also known as Abd al-Khaliq al-Houthi, also known as Abd-al-Khaliq al-Huthi, also known as Abd-al-Khaliq Badr-al-Din al-Huthi, also known as 'Abd al-Khaliq Badr al-Din al-Huthi, also known as Abu-Yunus; and Abdullah Yahya al Hakim, also known as Abu Ali al Hakim, also known as Abu-Ali al-Hakim, also known as Abdallah al-Hakim, also known as Abu Ali Alhakim, also known as Abdallah al-Mu'ayyad, are leaders of Ansarallah, a group whose property and interests in property are concurrently blocked pursuant to a determination by the Secretary of State pursuant to Executive Order 13224.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 12, 2021.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2021–01002 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11322]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Asia Society Triennial: We Do Not Dream Alone (Part 2)'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Asia Society Triennial: We Do Not Dream Alone (Part 2)'' at the Asia Society Museum, New York, New York, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned are in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: See also the **Federal Register** notice for the ''Asia Society Triennial: We Do Not Dream Alone (Part 1)'' exhibition that was published August 20, 2020, on page 51544 (volume 85, number 162).

The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–00950 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice:11290]

Notice of Department of State Sanctions Actions; Reimposing Certain Sanctions With Respect to Iran

SUMMARY: The Secretary of State has imposed sanctions on 1 entity and 1 individual.

DATES: The Secretary of State's determination and selection of certain sanctions to be imposed upon the 1 entity and 1 individual identified in the **SUPPLEMENTARY INFORMATION** section are effective on December 16, 2020.

FOR FURTHER INFORMATION CONTACT: Taylor Ruggles, Director, Office of Economic Sanctions Policy and Implementation, Bureau of Economic and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647 7677, email: *RugglesTV@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 3(a) of E.O. 13846, the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Homeland Security, and the United States Trade Representative, and with the President of the Export-Import Bank, the Chairman of the Board of Governors of the Federal Reserve System, and other agencies and officials as appropriate, is authorized to impose on a person any of the sanctions described in section 4 or 5 of E.O. 13846 upon determining that the person met any criteria set forth in sections 3(a)(i)—3(a)(vi) of E.O. 13846.

The Secretary of State has determined, pursuant to Section 3(a)(ii) of E.O. 13846, that Vietnam Gas and Chemicals Transportation Corporation has knowingly, on or after November 5, 2018, engaged in a significant transaction for the purchase, acquisition, sale, transport, or marketing of petroleum products from Iran.

Pursuant to Section 5(a) of E.O. 13846, the Secretary of State has selected the following sanctions to be imposed upon Vietnam Gas and Chemicals Transportation Corporation:

- Prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which the entities have any interest;
- Prohibit any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of the entities;
- Block all property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the entities, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in;
- Prohibit any United States person from investing in or purchasing significant amounts of equity or debt instruments of the entities;
- Restrict or prohibit imports of goods, technology, or services, directly or indirectly, into the United States from the entities; and
- Impose on the principal executive officer or officers, or persons performing similar functions and with similar authorities, of the entities the sanctions described in sections 5(a)(i)–5(a)(iv) and 5(a)(vi) of E.O. 13846, as selected by the Secretary of State.

Pursuant to Sections 4(e) and 5(a) of E.O. 13846, the Secretary of State has selected the following sanctions to be imposed upon, Vo Ngoc Phung, who has been determined to be (i) a corporate officer or principal of the aforementioned entities and (ii) a principal executive officer of the aforementioned entities, or perform similar functions with similar authorities as a principal executive officer:

- Prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which, Vo Ngoc Phung, has any interest;
- Prohibit any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of, Vo Ngoc Phung;
- Block all property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of, Vo Ngoc Phung; and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in; and
- Restrict or prohibit imports of goods, technology, or services, directly or indirectly, into the United States from Vo Ngoc Phung.

Additionally, pursuant to Section 4(e) of E.O. 13846, the Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien that the Secretary of State determines is a corporate officer or principal of, or a shareholder with a controlling interest

in, a sanctioned person subject to this action.

Peter D. Haas,

Principal Deputy Assistant Secretary, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2020–29237 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 11308]

Designation of Yahya al-Sayyid Ibrahim Musa and Alaa Ali Ali Mohammed Al-Samahi as Specially Designated Global Terrorists

Acting under the authority of and in accordance with section 1(a)(ii)(B) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, Executive Order 13284 of January 23, 2003, and Executive Order 13886 of September 9, 2019, I hereby determine that the persons known as Yahya al-Sayyid Ibrahim Musa, also known as Yahya Alsayed Ibrahim Mohamed Moussa, also known as Yahia ElSayed Ibrahim Mohammad, also known as Basim Ibrahim and Alaa Ali Ali Mohammed Al-Samahi, also known as Allaa al-Samahy, are leaders of Harakat Sawa'd Misr, a group whose property and interests in property are blocked pursuant to a prior determination by the Secretary of State pursuant to Executive Order 13224.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 22, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2021–00620 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 11286]

60-Day Notice of Proposed Information Collection: Overseas Schools Grant Status Report

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to March 22, 2021.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2020–0054'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: shearertp@state.gov.*
- *Regular Mail:* Send written comments to: Office of Overseas Schools, U.S. Department of State, 2201 C Street NW, Washington, DC 20520.
- *Fax:* 202–261–8224.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Thomas Shearer, Department of State, Office of Overseas Schools, A/OPR/OS, Room H328, SA–1, Washington, DC 20522–0132, who may be reached on 202–261–8200 or at *shearertp@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Overseas Schools Grant Status Report.
- *OMB Control Number:* 1405–0033.
- *Type of Request:* Extension of a currently approved collection.
- *Originating Office:* Bureau of Administration, A/OPR/OS.
- *Form Number:* DS–2028.
- *Respondents:* Overseas schools grantees.
- *Estimated Number of Respondents:* 193.
- *Estimated Number of Responses:* 193.
- *Average Time per Response:* 15 minutes.
- *Total Estimated Burden Time:* 48.25 hours.
- *Frequency:* Annually.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Office of Overseas Schools of the Department of State (A/OPR/OS) is responsible for determining that adequate educational opportunities exist at Foreign Service Posts for dependents of U.S. Government personnel stationed abroad, and for assisting American-sponsored overseas schools to demonstrate U.S. educational philosophy and practice. The information gathered provides the technical and professional staff of A/OPR/OS the means by which obligations, expenditures and reimbursements of the grant funds are monitored to ensure the grantee is in compliance with the terms of the grant.

Methodology

Information is collected via electronic and paper submission. The Department has placed the form DS–2028 in a Microsoft Excel spreadsheet, and is sent as a link to the school along with the grant documents. School officials can complete the form electronically and forward the form to post for forwarding to A/OPR/OS.

Thomas P. Shearer,

Director, A/OPR/OS, Department of State.

[FR Doc. 2021–01042 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF STATE

[Public Notice: 11319]

Notice of Department of State Sanctions Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Syria

SUMMARY: The Secretary of State has imposed sanctions on three individuals.

DATES: The Secretary of State's determination and selection of certain sanctions to be imposed upon the six individuals identified in the **SUPPLEMENTARY INFORMATION** section were effective on December 22, 2020.

FOR FURTHER INFORMATION CONTACT: Taylor Ruggles, Director, Office of Economic Sanctions Policy and Implementation, Bureau of Economic and Business Affairs, Department of State, Washington, DC 20520, tel.: (202) 647 7677, email: *RugglesTV@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2(a) of E.O. 13894 of October 14, 2019, the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Homeland Security, and the United States Trade Representative, and with the President of the Export-Import Bank, the Chairman of the Board of Governors of the Federal Reserve System, and other agencies and officials as appropriate, is authorized to impose on a person any of the sanctions described in section 2(c) of E.O. 13894 upon determining that the person met any criteria set forth in section 2(a)(i) or section 2(a)(ii) of E.O. 13894.

The Secretary of State has determined, pursuant to Section 2(a)(i)(A) of E.O. 13894, that Kifah Moulhem is complicit in, has directly or indirectly engaged in, or attempted to engage in, or financed, the obstruction, disruption, or prevention of a ceasefire in northern Syria.

The Secretary of State has determined, pursuant to Section 2(a)(i)(D) of E.O. 13894, that Asma al-Assad is responsible the obstruction, disruption, or prevention of efforts to promote a political solution to the conflict in Syria, including: The development of a new Syrian government that is representative and reflects the will of the Syrian people, per Section 2(a)(i)(D)(3) of the E.O.

The Secretary of State has determined, pursuant to Section 2(a)(ii) of E.O. 13894, that Fawaz Akhras, Sahar Otri Akhras, Firas al-Akhras, and Eyad Akhras shall be designated as adult family members of a person (Asma al-Assad) designated under Section 2(a)(i) of E.O. 13894.

Pursuant to Sections 2(b) and 2(c) of E.O. 13894, the Secretary of State has selected the following sanctions to be imposed upon Kifah Moulhem, Asma al-Assad, Fawaz Akhras, Sahar Otri Akhras, Firas al-Akhras, and Eyad Akhras:

- Block all property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of Kifah Moulhem, Asma al-Assad, Fawaz Akhras, Sahar Otri Akhras, Firas al-Akhras, and Eyad Akhras, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in (Section 2(c)(iv) of E.O. 13894).

Peter D. Haas,

Principal Deputy Assistant Secretary, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2021–00955 Filed 1–15–21; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0099; Notice 1]

Tesla, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Tesla, Inc. (Tesla) has determined that certain Model Year (MY) 2012–2020 Tesla motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays.* Tesla filed a noncompliance report dated September 24, 2020. Tesla subsequently petitioned NHTSA on September 25, 2020, and later provided supplemental information on October 23, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of Tesla's petition.

DATES: Send comments on or before February 18, 2021.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview

Tesla has determined that certain MY 2012–2020 Tesla Model S, Tesla Model X, Tesla Model 3, and Tesla Model Y motor vehicles do not fully comply with the requirements of paragraph S5.2.1 (Table 1) of FMVSS No. 101, *Controls and Displays* (49 CFR 571.101). Tesla filed a noncompliance report dated September 24, 2020, pursuant to 49 CFR 573, *Defect and Noncompliance Responsibility and Reports.* Tesla subsequently petitioned NHTSA on September 25, 2020 for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR 556, *Exemption for Inconsequential Defect or Noncompliance.* Tesla also provided supplemental information related to the petition on October 23, 2020.

This notice of receipt of Tesla's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Motor Vehicles Involved

Approximately 612,065 MY 2012–2020 Tesla Model S, Tesla Model X, Tesla Model 3, and Tesla Model Y motor vehicles, manufactured between December 1, 2011, and August 31, 2020, are potentially involved.

III. Noncompliance

Tesla explains that the noncompliance is that the subject motor vehicles are equipped with speedometers that can be switched by the operator to display the vehicle's speed in units of either miles per hour (MPH) or kilometers-per-hour (km/h) and therefore, do not meet the requirements set forth in paragraph S5.2.1 and Table 1, Column 3 of FMVSS No. 101.

IV. Rule Requirements

Paragraph S5.2.1 and Table 1, Column 3 of FMVSS No. 101 includes the requirements relevant to this petition. Each passenger car, multipurpose passenger vehicle, truck, and bus that is fitted with a control, a telltale, or an indicator listed in Table 1 or Table 2 of FMVSS No. 101 must meet the requirements for the location, identification, color, and illumination of that control, telltale, or indicator. Each control, telltale, and indicator that is listed in column 1 of Table 1 or Table 2 must be identified by the symbol specified for it in column 2 or the word or abbreviation specified for it in column 3 of Table 1 or Table 2. Specifically, the speedometer must only allow the speed to be displayed in ''MPH, or MPH and km/h.''

V. Summary of Tesla's Petition

The following views and arguments presented in this section, ''V. Summary of Tesla's Petition,'' are the views and arguments provided by Tesla. They have not been evaluated by the Agency and do not reflect the views of the Agency. Tesla describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Tesla offers the following reasoning:

1. All affected vehicles are originally configured to display speed in mph and are delivered for first sale in the United States market in a compliant state. Because distance is most commonly measured in the United States in Imperial units (including mph), the majority of owners will continue to operate their vehicle using the factory-configured unit displayed (*i.e.,* with the speed displayed in mph) and are unlikely to ever attempt to change to metric units.

2. Only through driver interaction within the display settings menu can the unit of measurement be changed from miles to kilometers. This change must be done intentionally and cannot be accomplished inadvertently.

3. When the display is set to kilometers, the indicated vehicle speed in km/h is 1.6 times greater than the speed in mph. As a result, if a vehicle operator changes the display to indicate km/h and later forgets or neglects to change the display back to mph, they (or a subsequent operator) would be more likely to travel at a slower speed rather than a faster speed. Moreover, because the operator will be able to easily recognize that the vehicle is moving at a lower speed than intended, they will likely adjust their vehicle speed to match road and traffic conditions.

4. If the vehicle operator has set the display to kilometers, all functions relying on, or otherwise tied to, the speed limit (*e.g.,* Traffic Aware Cruise Control and Speed Assist) will convert mapped data from mph to km/h, resulting in the vehicle speed automatically matching the appropriate speed limit even though the display is km/h.

5. If the vehicle operator needs to change the display back from km/h to mph, the method for doing so can be easily located in the display menu and is not buried in sub-menus.

6. If the operator nevertheless has difficulty finding the menu to change the unit setting within the center display, instructions are available in the Owner's Manual. For example, in the chapter on Controls in the Model 3 Owner's Manual, there are instructions on how to navigate the menu and an explanation that within the ''Display'' menu, there is a ''Distance'' toggle that allows operators to ''Choose to display miles or kilometers for range, speed, energy, trip meters, map searches, and navigation routes.''

7. On September 1, 2020, factory firmware release 2020.28.102.2 was introduced in production, updating the speedometer units to display km/h and mph when the display distance is set to kilometers. The change was also included in firmware release 2020.36.11, which began rolling out to field vehicles on or about September 16, 2020, so all vehicles accepting the update (and future updates) will receive compliant speedometer units. Tesla expects a majority of vehicles will have the update completed within a few weeks and expects nearly all vehicles to have completed the update within 6 months.

8. To date, Tesla has not received any reports of loss of control, collision, injury or fatality, property damage, or fire related to this issue.

9. Finally, Tesla notes that NHTSA has recently granted two petitions for inconsequential treatment involving speedometer unit display noncompliances, both of which involved a km/h display that did not also display mph. *See, e.g.,* Volkswagen Group of America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance, 85 FR 39675 (July 1, 2020); BMW of North America, LLC, Grant of Petition for Decision of Inconsequential Noncompliance, 80 FR 61884 (Oct. 14, 2015). Because this issue is identical to the noncompliances in those cases, NHTSA should grant this petition for the same reasons.

10. In Tesla's supplemental materials they stated that the display setting has been corrected in production, as of September 1, 2020. Tesla states that more than 75 percent of the affected U.S. vehicles have accepted the firmware update released on September 16, 2020.

Tesla concludes by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and

30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles that Tesla no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Tesla notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2021–01088 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2020–0006]

Pipeline Safety: Request for Special Permit; Tennessee Gas Pipeline, L.L.C.

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from the Tennessee Gas Pipeline, L.L.C. (TGP). The special permit request is seeking relief from compliance with certain requirements in the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by February 18, 2021.

ADDRESSES: Comments should reference the docket number for this specific special permit request and may be submitted in the following ways:

- *E-Gov Website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov.*

Note: There is a privacy statement published on *http://www.Regulations.gov.* Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) § 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request from TGP seeking a waiver from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and § 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines. This special permit is being requested in lieu of pipe replacement or pressure reduction for six (6) special permit segments of 16,116 feet (3.052 miles) on the TGP pipeline system. The proposed special permit segments are located in Harris County, Texas, Ouachita Parish, Louisiana, and Robertson County, Tennessee. The TGP pipeline class location in the special permit segments has changed from a Class 1 or Class 2 to a Class 3 location. The TGP pipeline special permit segments are 24-inch, 26-inch, and 30-inch diameter pipelines with an existing maximum allowable operating pressure of 750 pounds per square inch gauge. The installation of the special permit segments occurred in 1966 and 1989.

The special permit request, proposed special permit with conditions, and Draft Environmental Assessment (DEA) for the TGP pipeline are available for review and public comment in Docket No. PHMSA–2020–0006. We invite interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comment closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2021–01025 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

[Docket Number: DOT–OST–2020–0254]

Extension of the Comment Deadline Date; Request for Information for the Inclusive Design Reference Hub

AGENCY: Office of the Secretary of Transportation (OST), Department of Transportation.

ACTION: Notice; request for information (RFI).

SUMMARY: On December 21, 2020, DOT published in the **Federal Register** a request for information (RFI) regarding an Inclusive Design Reference Hub. This notice extends the deadline date for receiving comments until February 19, 2021 at 5:00 p.m. (ET).

DATES: Responses to the RFI must be received by February 19, 2021, no later than 5:00 p.m. (ET) to ensure consideration of your views.

ADDRESSES: Written comments may be submitted using any one of the following methods:

- *Electronic mail:* Email comments to *inclusivedesign@dot.gov* with a courtesy copy to *Robin.Gates@dot.gov.* Responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and be no more than 5 pages in length, with 12-point font and 1-inch margins.
- *Internet:* To submit comments electronically, go to the Federal regulations website at *http://www.regulations.gov.* Search by using the docket number (DOT–OST–2020–0254). Follow the online instructions for submitting comments.

Respondents may answer as many or as few questions (see the questions below) as they wish.

DOT will not respond to individual submissions or publish publicly a compendium of responses. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed.

Respondents are requested to provide the following information at the beginning of their response to this RFI:

- Company/institution name
- Company/institution contact
- Contact's address, phone number, and email address

Proprietary Information

Because information received in response to this RFI may be used to structure future programs and/or otherwise be made available to the public, respondents are strongly advised to NOT include any information in their responses that might be considered business sensitive, proprietary, or otherwise confidential. However, respondents may choose to include such information in their submissions if they believe it will significantly assist DOT in the design of the program.

Responses containing confidential, proprietary, or privileged information must be conspicuously marked as described below. Failure to comply with these marking requirements may result in the disclosure of the unmarked information under the Freedom of Information Act, 5 U.S.C. 552.

If a response contains trade secrets or confidential commercial or financial information, the respondent must include a cover sheet identifying the specific pages containing that information. The cover sheet must also provide evidence that the respondent actually or customarily treats the information as private.

In addition, the respondent must (1) mark the header and footer of every page that contains trade secrets or confidential commercial or financial information with ''Contains Confidential Information Exempt from Public Disclosure'' and (2) identify every line and paragraph containing such information with double brackets or highlighting.

FOR FURTHER INFORMATION CONTACT: The monitored inbox at *inclusivedesign@dot.gov.* You may also contact the Contracting Officer, Robin Gates, at *Robin.Gates@dot.gov* or (202) 366–1408.

Please reference ''RFI for Inclusive Design Reference Hub'' in the subject line when submitting your response.

DOT looks forward to your submission in response to this notice.

SUPPLEMENTARY INFORMATION:

Summary

On December 21, 2020, DOT published in the **Federal Register** (85 FR 83152) a request for information (RFI) regarding an Inclusive Design Reference Hub. This notice extends the deadline date for receiving comments until February 19, 2021 at 5:00 p.m. (ET). *Note:* All other information in the December 21, 2020 **Federal Register** Notice (85 FR 83152) remain the same, and is included below for easy reference.

In July 2020, as part of an event celebrating the 30th anniversary of the Americans with Disabilities Act, DOT committed to undertake a new initiative to establish a library of resources for accessibility in automation, and work with outside experts to study voluntary best practices for ensuring accessibility in automated vehicles. DOT invites stakeholders to provide input on critical first steps in this process, the qualifications of entities that are best suited to perform this work, and considerations to ensure long-term sustainability of this initiative. This notice is not a Solicitation, and it does not seek the submission of formal, binding quotations/proposals. In the event OST–P determines that services will be procured, a formal Request for Quote/Proposal will be issued. OST–P cannot and will not reimburse any organization for its time, effort, or costs expended in responding to this RFI.

The purpose of this RFI is to collect input on a proposed initiative to establish and curate a *library* of existing technical specifications, voluntary consensus or consortia standards, and best practices and a *roadmap* of such resources that may be needed to enable accessibility of automated vehicles for persons with physical, sensory, and cognitive disabilities. This initiative, tentatively entitled the *Inclusive Design Reference Hub,* will involve consultation with a range of stakeholders. This RFI will serve to refine DOT's vision, next steps, and long-term ownership and maintenance plan for this initiative. Respondents are encouraged to visit *https://www.transportation.gov/accessibility* for more information on DOT's accessibility initiatives.

Background

As transportation evolves, DOT is committed to a more accessible future and exploring accessibility opportunities that may materialize as vehicles and mobility services evolve. DOT encourages research into technologies that have the potential to remove barriers to accessibility in the transportation system and will seek to complement research done by leading academic institutions, the private sector and other entities to fill gaps that industry is not already covering. To this end, DOT recently announced its intent to establish a library of resources for accessibility in automation, and to work with outside experts to study voluntary best practices for ensuring accessibility in automated vehicles.

Needs Statement

DOT has made early investments intended to begin unlocking this potential through its Accessible Transportation Technologies Research Initiative (ATTRI), the Inclusive Design Challenge, the Complete Trip—ITS4US Deployment Program, and numerous research projects.

Industry stakeholders and others have reported difficulty in finding existing technical specifications and best practices for designing accessible vehicle features, or in prioritizing development of new resources where there are knowledge gaps. In addition, the expertise for developing such resources is fragmented across traditional organizational and sectoral bounds, making it difficult to begin new technical resource development. Early and widespread action by a coalition of industry, disability advocacy, academia, and government partners can help ensure shared understanding of the needs of individuals with a range of disabilities and corresponding technical specifications and best practices. An open and inclusive partnership to develop voluntary, consensus-based technical specifications, best practices, and standards can provide a foundation for consistently and comprehensively meeting the needs of people with disabilities and inform the design of future automated vehicles (AVs).

A robust research pipeline can accelerate the accumulation of knowledge and encourage private sector experimentation. Tracking and sharing less mature, early stage research through technical specifications and best practices—in addition to developing and maintaining published technical standards—can help clarify where technical consensus is emerging and where investment and attention is most needed to fill long-term gaps.

Numerous voluntary consensus standards, technical specifications, recommended practices, and other technical resources currently exist that relate either directly to vehicle accessibility or could indirectly inform future automated vehicle accessibility. For example, the former category includes numerous voluntary consensus standards focused on the safety, functionality, and interoperability of wheelchair-accessible vehicles, while the latter includes voluntary consensus and consortia standards from the consumer electronics sector that provide insights into how to design interfaces that are useable by people with sensory or cognitive disabilities. A list of such resources is included at the end of this RFI for reference. While these existing resources form a starting point for considering the accessibility of passenger vehicles, DOT also recognizes that gaps likely exist between current technical standards and specifications and best practices and a set of resources that would comprehensively address the physical, sensory, and cognitive accessibility needs of future vehicle users, including users of automated vehicles.

Proposed Approach

This initiative will serve as a ''one-stop shop'' for engineers, designers, and individuals with disabilities to find and to collaborate on technical resources for an inclusive future. The *Hub* could either be a stand-alone resource or built within an existing platform. All content will need to be compliant with requirements stated in Section 508 of the Rehabilitation Act of 1973 and accompanying standards developed by the U.S. Access Board.

An initial investment to launch this initiative will seek to establish a process to maintain this resource in regular consultation with stakeholders, including relevant standards development organizations, primarily through existing forums. DOT will assess potential approaches in terms of how likely they are to result in a self-sustaining long-term effort that includes active participation from all stakeholders with relevant expertise and perspective.

Request for Information

In launching the proposed initiative outlined above, DOT is seeking input from its stakeholders and potential partners on defining its scope, the most critical first steps, the necessary qualifications and expertise to support it, and how to ensure long-term ownership and maintenance of the resulting resources. To clarify input provided in response to this notice, DOT may seek additional follow-up information. Through this notice specifically, DOT seeks input on the following questions:

Background and Current Condition Information

1. What existing initiatives, industry activities, best practices, or other resources/actions could help to inform this initiative?

2. What existing technical standards and specifications and best practices are relevant or potentially relevant to the accessibility of vehicles for people with physical, sensory, and cognitive disabilities? What dependencies exist between existing resources and needed resources?

3. What information could help stakeholders understand the user population, potential market, and business case for inclusive design solutions? What information does not exist but could potentially help fill gaps in knowledge regarding the user population, potential market, and business case for inclusive design solutions?

4. What existing and needed resources are applicable to all vehicles? What existing and needed resources are specific to automated vehicles and when will they be needed?

5. How can this initiative support improved accessibility of conventional vehicles in the short-term while also enabling the accessibility of automated vehicles in the long-term?

Initiative Scope, Focus, and Proposed Initial Steps

1. Are there any technical references in this area that do not currently exist and should be prioritized for development?

(a) Please describe the need and ways to expedite the development of needed references with relevant stakeholders, including consumers.

(b) Please also discuss the extent to which the topic(s) identified are at an appropriate stage for voluntary standards development in terms of industry consensus and technological maturity.

2. Are there any existing resources or programs on which DOT could build or model this effort? Should the Inclusive Design Reference Hub be developed as a stand-alone resource, or integrated into an existing platform?

3. Are there any aspects of DOT's vision for this effort that could be clarified or improved ahead of a potential procurement?

4. Should the DOT directly host the resource, or should it be hosted by a third-party organization or coalition of organizations serving as the convener(s) and technical curator(s) on behalf of DOT?

5. How can this initiative be maintained in the long term with more limited federal involvement? What conditions need to be met in order for partner organizations to continue support for this initiative following an initial phase?

6. How could DOT assess the success of this activity over a two-year period? How can processes to support long-term sustainability be established in this timeframe?

Performing Organization Qualifications—General Input

1. What entities, organizations, groups, or Government agencies are most qualified and appropriate to perform this work?
2. What perspectives need to be represented in the execution of this initiative? Which groups should represent these perspectives?
3. What partnerships are critical?
4. What organizations currently play a role with respect to the development of standards around automated vehicles, transportation accessibility, and the intersection of the two? For responding organizations that currently have a role, please discuss your organizational and technical capabilities and experience in this area. Please also discuss how you might augment your qualifications with those of potential partner organizations.

Additional Information

Below are existing resources that might be featured in the *Inclusive Design Reference Hub.*

- Automated Driving Systems:
  - *SAE J3171:* Identifying Automated Driving Systems-Dedicated Vehicles (ADS–DVs) Passenger Issues for Persons with Disabilities (SAE)
- Vehicles:
  - *49 CFR 571.141:* Minimum Sound Requirements for Hybrid and Electric Vehicles (NHTSA)
  - *49 CFR 571.206:* Door locks and door retention components (NHTSA)
  - *49 CFR 571.222:* School bus passenger seating and crash protection (NHTSA)
  - *49 CFR 571.403:* Platform Lift Systems for Motor Vehicles (NHTSA)
  - *49 CFR 571.404:* Platform Lift Installations in Motor Vehicles (NHTSA)
  - *49 CFR part 38:* Americans With Disabilities Act (ADA)—Accessibility Specifications For Transportation Vehicles (U.S. Access Board/U.S. DOT)
  - *QAP–103:* National Mobility Equipment Dealers Association Quality Assurance Program Guidelines (NMEDA)
  - *SAE J1725:* Structural Modification for Personally Licensed Vehicles to Meet the Transportation Needs of Persons with Disabilities (SAE)
  - *SAE J1903:* Automotive Adaptive Driver Controls, Manual (SAE)
  - *SAE J2092:* Testing of Wheelchair Lifts for Entry to or Exit from a Personally Licensed Vehicle (SAE)
  - *SAE J2093:* Design Considerations for Wheelchair Lifts for Entry to or Exit from a Personally Licensed Vehicle (SAE)
  - *SAE J2094:* Vehicle and Control Modifications for Drivers with Physical Disabilities Terminology (SAE)
  - *SAE J2603:* Recommended Practice for Powered Gas Brake Control Systems (SAE)
- Mobility Equipment:
  - *ANSI/RESNA WC–4:2017:* Wheelchairs and Transportation (RESNA)
  - *ISO 10542–1:* Technical systems and aids for disabled or handicapped persons—Wheelchair tiedown and occupant-restraint systems (ISO)
  - *ISO 10865:* Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers (ISO)
    - *ISO 10865: Part 1:* Systems for rearward-facing wheelchair-seated passengers (ISO)
    - *ISO 10865: Part 2:* Systems for forward-facing wheelchair-seated passengers (ISO)
  - *ISO 16840–4:* Wheelchair seating—Part 4: Seating systems for use in motor vehicles (ISO)
  - *ISO 7176–19:* Wheeled mobility devices for use as seats in motor vehicles (ISO)
  - *RESNA SP–3 (under development):* Universal Docking Interface Guidelines (UDIG) (RESNA)
  - *SAE J2249:* Wheelchair Tiedown and Occupant Restraint Systems for Use in Motor Vehicles (SAE)
- Electronic Interfaces/Devices:
  - *36 CFR 1194.1:* Standards for Section 508 of the Rehabilitation Act (U.S. Access Board)
  - *ANSI/RESNA CA–1:* Universal Criteria for Reporting the Cognitive Accessibility of Products and Technologies (RESNA)
  - *CTA–CEB27:* Recommended Practice for Audio Accessibility of Audiovisual Devices (CTA)
  - *ISO 21801–1:* Cognitive accessibility—Part 1: General guidelines (ISO)
  - *ISO 9241–171:* Ergonomics of human-system interaction—Part 171: Guidance on software accessibility (ISO)
  - *ISO/IEC 24786:* Information Technology—User interfaces—Accessible user interface for accessibility settings (ISO/IEC)
  - *ISO/IEC 29138–1:* Information technology—User interface accessibility—Part 1: User accessibility needs (ISO/IEC)
  - *ISO/IEC TS 20071–21:2015:* Information technology—User interface component accessibility—Part 21: Guidance on audio descriptions (ISO/IEC)
  - *WCAG 2.1:* Web Content Accessibility Guidelines Overview (W3C)
- General Product Usability and Accessibility:
  - *ISO/IEC 20282:* Ease of operation of everyday products (ISO)
    - *ISO/IEC 20282–1:* Part 1: Design requirements for context and use and user characteristics (ISO)
    - *ISO/IEC 20282–2:* Part 2: Summative test method (ISO)
    - *ISO/IEC 20282–3:* Part 3: Test method for consumer products (ISO)
    - *ISO/IEC 20282–3:* Part 4: Test method for the installation of consumer products (ISO)
  - *ISO/IEC 24756:* Framework for specifying a common access profile (CAP) of needs and capabilities of users, systems, and their environments (ISO)

Issued on: January 12, 2021.

Thomas Finch Fulton,

Deputy Assistant Secretary for Transportation Policy.

[FR Doc. 2021–00994 Filed 1–15–21; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Electronic Deposit of Tax Refund of $1 Million or More

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning electronic deposit of tax refund of $1 million or more.

DATES: Written comments should be received on or before March 22, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW,

Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Electronic Deposit of Tax Refund of $1 Million or More.

OMB Number: 1545–1763.

Form Number: 8302.

Abstract: This form is used to request an electronic deposit of a tax refund of $1 million or more directly into an account at any U.S. bank or other financial institution that accepts electronic deposits.

Current Actions: There is no change to the form, or the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households.

Estimated Number of Respondents: 584.

Estimated Time per Response: 2.96 hours.

Estimated Total Annual Burden Hours: 1,729.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 12, 2021.

Chakinna B. Clemons,

Supervisory Tax Analyst.

[FR Doc. 2021–00953 Filed 1–15–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Certain Returned Magazines, Paperbacks, or Records

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning certain returned magazines, paperbacks, or records.

DATES: Written comments should be received on or before March 22, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certain Returned Magazines, Paperbacks, or Records.

OMB Number: 1545–0879.

Regulation Project Number: TD 8426 (IA–195–78).

Abstract: The regulations provide rules relating to an exclusion from gross income for certain returned merchandise. The regulations provide that in addition to physical return of the merchandise, a written statement listing certain information may constitute evidence of the return. Taxpayers who receive physical evidence of the return may, in lieu of retaining physical evidence, retain documentary evidence of the return. Taxpayers in the trade or business of selling magazines, paperbacks, or records, who elect a certain method of accounting, are affected.

Current Actions: There is no change in the paperwork burden previously approved by OMB. The regulation is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 19,500.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 8,125.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 12, 2021.

Chakinna B. Clemons,

Supervisory Tax Analyst.

[FR Doc. 2021–01018 Filed 1–15–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for General Revision of Regulations Relating To Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning general revision of regulations relating to withholding of tax on certain U.S. source income paid to foreign persons.

DATES: Written comments should be received on or before March 22, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: General Revision of Regulations Relating to Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons.

OMB Number: 1545–1484.

Regulation Project Number: REG–242282–97 (TD 8881-final).

Abstract: This regulation prescribes collections of information for foreign persons that received payments subject to withholding under sections 1441, 1442, 1443, or 6114 of the Internal Revenue Code. This information is used to claim foreign person status and, in appropriate cases, to claim residence in a country with which the United States has an income tax treaty in effect, so that withholding at a reduced rate of tax may be obtained at source. The regulation also prescribes collections of information for withholding agents. This information is used by withholding agents to report to the IRS income paid to a foreign person that is subject to withholding under Code sections 1441, 1442, and 1443. The regulation also requires that a foreign taxpayer claiming a reduced amount of withholding tax under the provisions of an income tax treaty must disclose its reliance upon a treaty provision by filing Form 8833 with its U.S. income tax return. The burden for Form 8833 is reported under 1545–1354.

Current Actions: There is no change in the paperwork burden previously approved by OMB. The regulation is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, farms, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 1.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 1 hour.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 12, 2021.

Chakinna B. Clemons,

Supervisory Tax Analyst.

[FR Doc. 2021–00954 Filed 1–15–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0856]

Agency Information Collection Activity Under OMB Review: Authorization To Disclose Information to a Third Party

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0856''.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov.* Please refer to ''OMB Control No. 2900–0856'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Authorization to Disclose Information to a Third Party, VA Form 29–0975.

OMB Control Number: 2900–0856.

Type of Review: Extension of a currently approved collection.

Abstract: The Department of Veterans Affairs (VA), through its Veterans Benefits Administration (VBA), administers an integrated program of benefits and services, established by law, for veterans, service personnel, and their dependents and/or beneficiaries. Title 38 U.S.C. 5101(a) provides that a

specific claim in the form provided by the Secretary must be filed in order for benefits to be paid to any individual under the laws administered by the Secretary. This form will be used by Department of Veterans Affairs Insurance Center (VAIC) to enable a third party to act on behalf of the insured Veteran/beneficiary. Many of our customers are of advanced age or suffer from limiting disabilities and need assistance from a third party to conduct their affairs. The information collected provides an optional service and is not required to receive insurance benefits.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 85 FR 213 on November 3, 2020, pages 69696 and 69697.

Affected Public: Individuals or Households.

Estimated Annual Burden: 100 hours

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1,200.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2021–00941 Filed 1–15–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0788]

Agency Information Collection Activity: Description of Materials

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 22, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0788'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, (202) 421–1354 or email *Danny.Green2@va.gov.* Please refer to ''OMB Control No. 2900–0788'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Description of Materials, VA Form 26–1852.

OMB Control Number: 2900–0788.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 26–1852 is completed by builders in Specially Adapted Housing (SAH) projects involving construction as authorized under Title 38, U.S.C., section 2101 (a), section 2101 (b), and the Temporary Residence Adaptations (TRA) grant under Title 38, U.S.C., section 2102A. This form is also completed by builders who propose to construct homes to be purchased by veterans using their VA home loan benefit as granted in Title 38 U.S.C., section 3710(a)(1). SAH field staff review the data furnished on the form for completeness and it is essential to determine the acceptability of the construction materials to be used. In cases of new home construction, a technically qualified individual, not VA staff, is required to review the list of materials and certify they meet or exceed general residential construction material requirements, as specified by the International Residential Code and residential building codes adopted by local building authorities, and are in substantial conformity with VA Minimum Property requirements.

Affected Public: Private Sector.

Estimated Annual Burden: 9,518 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 16,950 per year and for SAH cases it is 2,086 per year.

By direction of the Secretary:

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2021–00942 Filed 1–15–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 217

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 201204–0326]

RIN 0648–BB38

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS, upon request from the Bureau of Ocean Energy Management (BOEM), hereby issues regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of five years. These regulations, which allow for the issuance of Letters of Authorization (LOA) to industry operators for the incidental take of marine mammals during the described activities and specified timeframe, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from April 19, 2021 through April 19, 2026.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

These incidental take regulations (ITR) establish a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the conduct of geophysical survey activities in the GOM. We received a petition from BOEM requesting the regulations. Subsequent LOAs may be requested by industry operators. Take is expected to occur by Level A and/or Level B harassment incidental to use of active acoustic sound sources. Please see the Background section below for definitions of harassment.

Legal Authority for the Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the ''least practicable adverse impact'' on the affected species or stocks and their habitat (see the discussion below in the Mitigation section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this rule containing the regulations, and for any subsequent LOAs. As directed by this legal authority, the regulations contain mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Regulations

Following is a summary of the major provisions of these regulations regarding geophysical survey activities. These measures include:

- Standard detection-based mitigation measures, including use of visual and acoustic observation to detect marine mammals and shut down acoustic sources in certain circumstances;
- A time-area restriction designed to avoid effects to bottlenose dolphins in times and places believed to be of particular importance;
- Vessel strike avoidance measures; and
- Monitoring and reporting requirements.

These incidental take regulations govern and allow for the subsequent issuance of letters of authorization for the take of marine mammals incidental to the specified activity described in this Notice, within the upper bounds of take that was evaluated for this rule, and prescribe measures for mitigation, monitoring, and reporting. They do not preclude a U.S. citizen from applying for an incidental take authorization for a specified activity with different parameters or required measures through a separate request and process.

Background

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq.*) directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made, regulations are issued, and notice is provided to the public.

An authorization for incidental taking shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring, and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill, any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On October 17, 2016, BOEM submitted a revised petition [1] to NMFS for rulemaking under section 101(a)(5)(A) of the MMPA to authorize take of marine mammals incidental to conducting geophysical surveys during

[1] In the notice of proposed rulemaking (83 FR 29212; June 22, 2018), NMFS provided a brief history of prior petitions received from BOEM's predecessor agencies.

oil and gas industry exploration and development activities in the GOM. This revised petition was deemed adequate and complete based on NMFS' implementing regulations at 50 CFR 216.104.

On December 8, 2016 (81 FR 88664), we published a notice of receipt of the petition in the **Federal Register**, requesting comments and information related to the request. This 30-day comment period was extended to January 23, 2017 (81 FR 92788), for a total review period of 45 days. The comments and information received during this public review period informed development of the proposed ITR, and all comments received are available online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.*

In August 2017, BOEM produced a final Programmatic Environmental Impact Statement (PEIS) to evaluate potential significant environmental effects of geological and geophysical (G&G) activities on the Outer Continental Shelf (OCS) of the GOM, pursuant to the National Environmental Policy Act (NEPA). The PEIS is available online at: *www.boem.gov/Gulf-of-Mexico-Geological-and-Geophysical-Activities-Programmatic-EIS/.* NOAA participated as a cooperating agency in the development of the PEIS.

NMFS published a notice of proposed rulemaking in the **Federal Register** for a 60-day public review on June 22, 2018 (83 FR 29212). The comments and information received during this public review period informed development of the final ITR, and NMFS has responded to all comments received (see Comments and Responses).

On February 24, 2020, BOEM submitted a notice to NMFS of its ''updated proposed action and action area for the ongoing [ITR] process[.]'' This update consisted of removal of the area currently under a Congressional leasing moratorium under the Gulf of Mexico Energy Security Act (GOMESA) (Pub. L. 109–432, § 104) from consideration in the ITR. BOEM stated in its notice to NMFS that G&G activities are not likely to be proposed within the area subject to the leasing moratorium during the 5-year period of effectiveness for the ITR and, therefore, that the ''number, type, and effects of any such proposed G&G activities are simply too speculative and uncertain for BOEM to predict or meaningfully analyze.'' These Congressional leasing restrictions are in place until June 30, 2022. Based on this updated scope, BOEM on March 26, 2020, submitted revised projections of expected activity levels and corresponding changes to modeled acoustic exposure numbers. BOEM's notice and updated information are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* These changes are addressed as appropriate throughout this final ITR. On September 8, 2020, the President effectively extended this moratorium through withdrawal under the Outer Continental Shelf Lands Act (OCSLA) of the same area covered by the GOMESA moratorium from disposition by leasing for 10 years, beginning on July 1, 2022, and ending on June 30, 2032.

Geophysical surveys are conducted in support of hydrocarbon exploration and development in the GOM, typically by companies that provide such services to the oil and gas industry. Broadly, these surveys include (1) deep penetration surveys using large airgun arrays as the acoustic source; (2) shallow penetration surveys using a small airgun array, single airgun, or similar systems as the acoustic source; and (3) high-resolution surveys, which may use a variety of acoustic sources. Generally speaking, these surveys may occur within Federal territorial waters and waters of the U.S. Exclusive Economic Zone (EEZ) (*i.e.,* to 200 nautical miles (nmi)) within the GOM, and corresponding with BOEM's GOM OCS planning areas (*i.e.,* Western Planning Area (WPA), Central Planning Area (CPA), Eastern Planning Area (EPA)). The use of these acoustic sources is expected to produce underwater sound at levels that have the potential to result in harassment of marine mammals. Cetacean species with the potential to be present in the GOM are described below (see Table 4).

These regulations establish a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) and NMFS' implementing regulations (50 CFR 216.101 *et seq.*) to allow for the authorization, through LOAs, of take of marine mammals incidental to the conduct of geophysical surveys for oil and gas activities in the GOM. The regulations are effective for five years.

Description of the Specified Activity

Overview

The specified activity consists of geophysical surveys conducted by industry operators for a variety of reasons related to hydrocarbon exploration, development, and production. These operators are typically companies that provide geophysical services, such as data acquisition and processing, to the oil and gas industry, including exploration and production companies. The petition describes a five-year period of geophysical survey activity and provides estimates of the amount of effort by survey type and location. BOEM's PEIS (BOEM, 2017) describes a range of potential survey effort. The levels of effort in the petition (which form the basis for the modeling effort described later in the Estimated Take section) were the high-end estimates. Following BOEM's update of the petition's geographic scope, these estimates were revised accordingly. Actual total amounts of effort (including by survey type and location) would not be known in advance of receiving LOA requests from industry operators, but take in excess of what is analyzed for this rulemaking would not be authorized. As noted above, BOEM has updated the scope of the specified activity/specified geographical region by removing the area currently under leasing moratorium through GOMESA from consideration. The removed area largely covers the EPA, including areas in which NMFS had proposed time-area restrictions as mitigation, but also includes a portion of the CPA. Applicants seeking authorization for take of marine mammals incidental to survey activities within the GOMESA area during the 5-year period of effectiveness for this rule will need to pursue a separate MMPA incidental take authorization. See Figures 1 and 2.

Geophysical surveys are conducted to obtain information on marine seabed and subsurface geology for a variety of reasons, including to: (1) Obtain data for hydrocarbon and mineral exploration and production; (2) aid in siting of oil and gas structures, facilities, and pipelines; (3) identify possible seafloor or shallow depth geologic hazards; and (4) locate potential archaeological resources and benthic habitats that should be avoided. In addition, geophysical survey data inform Federal government decisions. For example, BOEM uses such data for resource estimation and bid evaluation to ensure that the government receives a fair market value for OCS leases, as well as to help to evaluate worst-case discharge for potential oil-spill analysis and to evaluate sites for potential hazards prior to drilling.

Deep penetration seismic surveys using airgun arrays as an acoustic source (sound sources are described in the ''Detailed Description of Activities'' section) are a primary method of obtaining geophysical data used to characterize subsurface structure. These surveys are designed to illuminate

deeper subsurface structures and formations that may be of economic interest as a reservoir for oil and gas exploitation. A deep penetration survey uses an acoustic source suited to provide data on geological formations that may be thousands of meters (m) beneath the seafloor, as compared with a shallow penetration or high resolution geophysical (HRG) survey that may be intended to evaluate shallow subsurface formations or the seafloor itself (*e.g.,* for hazards).

Deep penetration surveys may be two-dimensional (2D) or three-dimensional (3D) (see Figure 1–2 of the petition), and there are a variety of survey methodologies designed to provide the specific data of interest. 2D surveys are designed to acquire data over large areas (thousands of square miles) in order to screen for potential hydrocarbon prospectivity, and provide a cross-sectional image of the structure. In contrast, 3D surveys may use similar acoustic sources but are designed to cover smaller areas with greater resolution (*e.g.,* with closer survey line spacing), providing a volumetric image of underlying geological structures. Repeated 3D surveys are referred to as four-dimensional (4D), or time-lapse, surveys that assess the depletion of a reservoir.

Shallow penetration and high-resolution surveys are designed to highlight seabed and near-surface potential obstructions, archaeology, and geohazards that may have safety implications during rig installation or well and development facility siting. Shallow penetration surveys may use a small airgun array, single airgun, or similar sources, while high-resolution surveys (which are limited to imaging the seafloor itself) may use a variety of sources, such as sub-bottom profilers, single or multibeam echosounders, or side-scan sonars.

Dates and Duration

The specified activities may occur at any time during the five-year period of validity of these regulations. Actual dates and duration of individual surveys are not known. Survey activities are generally 24-hour operations. However, BOEM estimates that a typical seismic survey involves approximately 20 to 30 percent of non-operational downtime due to a variety of factors, including technical or mechanical problems, standby for weather or other interferences, and implementation of mitigation measures.

Specified Geographical Region

The OCS planning areas are depicted in Figure 1, and the overlap of the GOMESA moratorium area with the planning areas (as well as with the modeling zones, see discussion of modeling zones below) is depicted in Figure 2, showing the updated specified geographical region.

Only the northern portion of the GOM contains Federal waters. BOEM manages development of U.S. Federal OCS energy and mineral resources within OCS regions, which are divided into planning areas. Within planning areas are lease blocks, on which specific production activities may occur. Geophysical survey activities may occur on scales ranging from entire planning areas to multiple or specific lease blocks, or could occur at specific potential or existing facilities within a lease block. NMFS provided a detailed discussion of the specified geographical region in the notice of proposed rulemaking (83 FR 29212; June 22, 2018).

The prospective survey activities may occur in the U.S. waters of the GOM, within BOEM's Western, Central, and Eastern GOM OCS planning areas (approximately within the U.S. EEZ; Figure 1), but excluding the GOMESA moratorium area (Figure 2). Although survey activity in the GOMESA moratorium area is no longer being considered, the region has not changed compared with what was described, nor has substantive new information regarding the region become available. Therefore, we do not reprint that discussion here and refer the reader to that notice of proposed rulemaking for additional detail.

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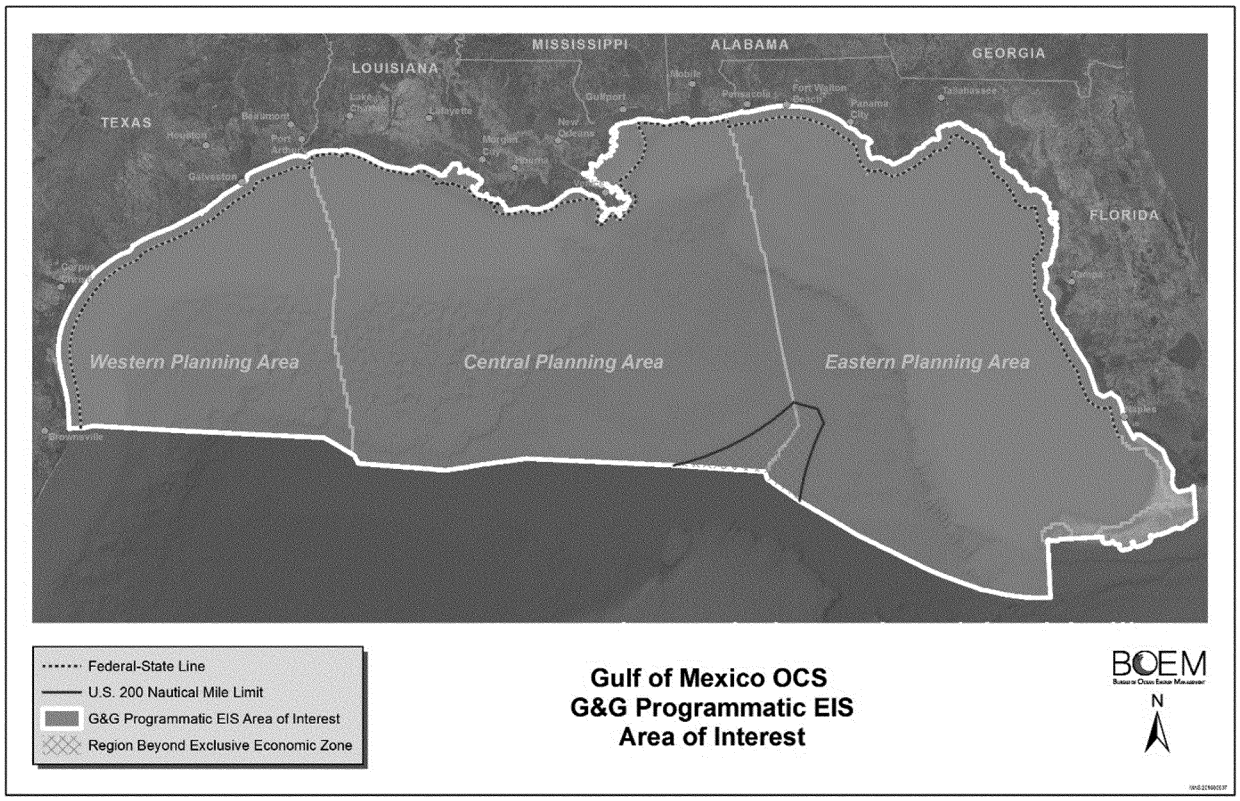

Figure 1. BOEM Planning Areas.

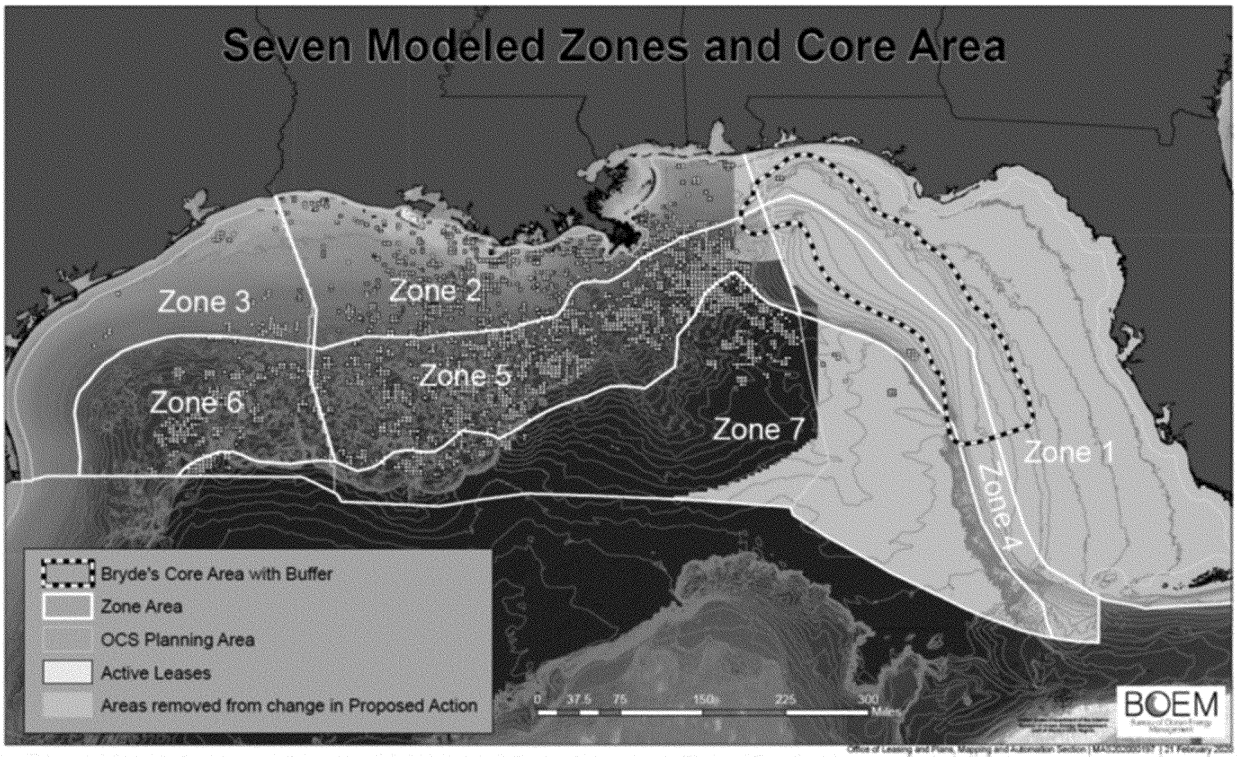

Figure 2. Specified Geographical Region.

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Detailed Description of Activities

An airgun is a device used to emit acoustic energy pulses into the seafloor, and generally consists of a steel cylinder that is charged with high-pressure air. There are different types of airguns; differences between types of airguns are generally in the mechanical parts that release the pressurized air, and the bubble and acoustic energy released are effectively the same. Airguns are typically operated at a firing pressure of 2,000 pounds per square inch (psi). Release of the compressed air into the water column generates a signal that reflects (or refracts) off the seafloor and/or subsurface layers having acoustic impedance contrast. Individual airguns are available in different volumetric sizes and, for deep penetration seismic surveys, are towed in arrays (*i.e.,* a certain number of airguns of varying sizes in a certain arrangement) designed according to a given company's method of data acquisition, seismic target, and data processing capabilities.

Airgun arrays are typically configured in subarrays of 6–12 airguns each. Towed hydrophone streamers (described below) may follow the array by 100–200 m and can be 5–12 kilometer (km) long. The airgun array and streamers are typically towed at a speed of approximately 4.5 to 5 knots (kn). BOEM notes that arrays used for deep penetration surveys typically have between 20–80 individual elements, with a total volume of 1,500–8,460 in^3. The output of an airgun array is directly proportional to airgun firing pressure or to the number of airguns, and is expressed as the cube root of the total volume of the array.

Airguns are considered to be low-frequency acoustic sources, producing sound with energy in a frequency range from less than 10 Hz to 2 kHz (though there may be energy at higher frequencies), with most energy radiated at frequencies below 500 Hz. Frequencies of interest to industry are below approximately 100 Hz. The amplitude of the acoustic wave emitted from the source is equal in all directions (*i.e.,* omnidirectional) for a single airgun, but airgun arrays do possess some directionality due to phase delays between guns in different directions. Airgun arrays are typically tuned to maximize functionality for data acquisition purposes, meaning that sound transmitted in horizontal directions and at higher frequencies is minimized to the extent possible.

When fired, a brief (~0.1 second) pulse of sound is emitted by all airguns in an array nearly simultaneously, in order to increase the amplitude of the overall source pressure signal. The combined signal amplitude and directivity is dependent on the number and sizes of individual airguns and their geometric positions within the array. The airguns are silent during the intervening periods, with the array typically fired on a fixed distance (or shot point) interval. The intervals are optimized for water depth and the distance of important geological features below seafloor, but a typical interval in relatively deep water might be approximately every 10–20 seconds (or 25–50 m, depending on vessel speed). The return signal is recorded by a listening device, and later analyzed with computer interpretation and mapping systems used to depict the subsurface. There must be enough time between shots for the sound signals to propagate down to and reflect from the feature of interest, and then to propagate upward to be received on hydrophones or geophones. Reverberation of sound from previous shots must also be given time to dissipate. The receiving hydrophones can be towed behind or in front of the airgun array (may be towed from the source vessel or from a separate receiver vessel), or geophone receivers can be deployed on the seabed. Receivers may be displaced several kilometers horizontally away from the source, so horizontal propagation time is also

considered in setting the interval between shots.

Sound levels for airgun arrays are typically modeled or measured at some distance from the source and a nominal source level then back-calculated. Because these arrays constitute a distributed acoustic source rather than a single point source (*i.e.,* the ''source'' is actually comprised of multiple sources with some predetermined spatial arrangement), the highest sound levels measurable at any location in the water will be less than the nominal source level. A common analogy is to an array of light bulbs; at sufficient distance—in the far field—the array will appear to be a single point source of light but individual sources, each with less intensity than that of the whole, may be discerned at closer distances (Caldwell and Dragoset (2000) define the far field as greater than 250 m). Therefore, back-calculated source levels are not typically considered to be accurate indicators of the true maximum amplitude of the output in the far field, which is what is typically of concern in assessing potential impacts to marine mammals. In addition, the effective source level for sound propagating in near-horizontal directions (*i.e.,* directions likely to impact most marine mammals in the vicinity of an array) is likely to be substantially lower (*e.g.,* 15–24 decibels (dB); Caldwell and Dragoset, 2000) than the nominal source level applicable to downward propagation because of the directional nature of the sound from the airgun array. The horizontal propagation of sound is reduced by noise cancellation effects created when sound from neighboring airguns on the same horizontal plane partially cancel each other out.

Survey protocols generally involve a predetermined set of survey, or track, lines. The seismic acquisition vessel(s) (source vessel) will travel down a linear track for some distance until a line of data is acquired, then turn and acquire data on a different track. In some cases, data is acquired as the source vessel(s) turns continuously rather than moving on a linear track (*i.e.,* coil surveys). The spacing between track lines and the length of track lines can vary greatly, depending on the objectives of a survey. In addition to the line over which data acquisition is desired, full-power operation may include run-in and run-out. Run-in is approximately 1 km of full-power source operation before starting a new line to ensure equipment is functioning properly, and run-out is additional full-power operation beyond the conclusion of a trackline (*e.g.,* half the distance of the acquisition streamer behind the source vessel, when used) to ensure that all data along the trackline are collected by the streamer. Line turns can require two to six hours when towed hydrophones are used, due to the long trailing streamers, but may be much faster when streamers are not used. Spacing and length of tracks varies by survey. Survey operations often involve the source vessel(s), supported by a chase vessel. Chase vessels typically support the source vessel(s) by protecting the long hydrophone streamer (when used) from damage (*e.g.,* from other vessels) and otherwise lending logistical support (*e.g.,* returning to port for fuel, supplies, or any necessary personnel transfers). Chase vessels do not deploy acoustic sources for data acquisition purposes; the only potential effects of the chase vessels are those associated with normal vessel operations.

The general activities described here could occur pre- or post-leasing and/or on- or off-lease. Pre-lease surveys are more likely to involve larger-scale activity designed to explore or evaluate geologic formations. Post-lease activities may also include deep penetration surveys, but would be expected to be smaller in spatial and temporal scale as they are associated with specific leased blocks. Shallow penetration and HRG surveys are more likely to be associated with specific leased blocks and/or facilities, with HRG surveys used along pipeline routes and to search for archaeological resources and/or benthic communities. Specific types of surveys, including 2D and 3D surveys and various survey geometries typically associated with 3D surveys (*e.g.,* narrow- and wide-azimuth (NAZ and WAZ) and coil surveys), were described in summary in the notice of proposed rulemaking (83 FR 29212; June 22, 2018). We also described surveys involving the placement of seismic sensors in a drilled well or borehole, including various types of vertical seismic profiling and other types of borehole seismic surveys. For full detail, please refer to that notice or sections 1.2 and 1.3 of BOEM's petition.

Surveys may be designed as either multi-source (*i.e.,* multiple arrays towed by one or more source vessel(s)) or single source. Surveys may also be differentiated by the way in which they record the return signals using hydrophones and/or geophones. Hydrophones may be towed in streamers behind a vessel (either the source vessel(s) or a separate vessel) or in some cases may be placed in boreholes (called vertical seismic profiling) or spaced at various depths on vertical cables in the water column. Sensors may also be incorporated into ocean-bottom cables (OBC) or autonomous ocean-bottom nodes (OBN) and placed on the seafloor—these surveys are referred to generally as ocean-bottom seismic (OBS). Autonomous nodes can be tethered to coated lines and deployed from ships or remotely-operated vehicles, with current technology allowing use in water depths to approximately 3,000 m. OBS surveys are most useful to acquire data in shallow water and obstructed areas, as well as for acquisition of four-component survey data (*i.e.,* including pressure and 3D linear acceleration collected via geophone). For OBS surveys, one or two vessels usually are needed to lay out and pick up cables, one ship is needed to record data, one ship tows an airgun array, and two smaller utility boats support survey operations.

In summary, 3D survey design involves a vessel with one or more acoustic sources covering an area of interest with relatively tight spatial configuration (compared with 2D surveys). In order to provide richer, more useful data, particularly in areas with more difficult geology, survey designs become more complicated with additional source and/or receiver vessels operating in potentially increasingly complicated choreographies.

As compared with 2D and 3D deep penetration surveys, shallow penetration and HRG surveys are conducted to provide data informing initial site evaluation, drilling rig emplacement, and platform or pipeline design and emplacement. Identification of geohazards (*e.g.,* gas hydrates, buried channels) is necessary to avoid drilling and facilities emplacement problems, and operators are required to identify and avoid archaeological resources and certain benthic communities. These surveys may use single airguns or small airgun arrays, but generally use various types of electromechanical acoustic sources. Please see our notice of proposed rulemaking or BOEM's petition for additional detail regarding these survey types and electromechanical acoustic sources.

Summary of Representative Sound Sources

Because the specifics of acoustic sources to be used cannot be known in advance of receiving LOA requests from industry operators, it was necessary to define representative acoustic source parameters, as well as representative survey patterns. BOEM determined realistic representative proxy sound sources and survey patterns, which were used in acoustic exposure

modeling and more broadly to support the analysis, after discussions with individual geophysical companies. Acoustic exposure modeling is described in detail in ''*Acoustic Propagation and Marine Mammal Exposure Modeling of Geological and Geophysical Sources in the Gulf of Mexico*'' and ''*Addendum to Acoustic Propagation and Marine Mammal Exposure Modeling of Geological and Geophysical Sources in the Gulf of Mexico*'' (Zeddies *et al.,* 2015, 2017a), hereafter referred to collectively as ''the modeling report,'' as well as in ''*Gulf of Mexico Acoustic Exposure Model Variable Analysis*'' (Zeddies *et al.,* 2017b), which evaluated a smaller, alternative airgun array. The reports are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.*

Representative sources for the modeling include a single airgun, an airgun array, and multiple electromechanical sources. Two major survey types were considered: Large-area seismic (including 2D, 3D NAZ, 3D WAZ, and coil surveys) and small-area, high-resolution geotechnical (including single airgun surveys and surveys using a CHIRP sub-bottom profiler in combination with multibeam echosounder and side-scan sonar; the single airgun was used as a reasonable proxy for surveys using a boomer). The nominal airgun sources used for analysis of the proposed action include a small single airgun (90 in^3 airgun) and a large airgun array (8,000 in^3). In addition, the supplemental Model Variable Analysis (Zeddies *et al.,* 2017b) provides analysis of an alternative 4,130 in^3 array (see Letters of Authorization section). We note that while high-resolution geophysical sources were conservatively included for consideration in this rule to allow for take authorization if necessary, some of these types of sources would not necessarily be expected to cause the incidental take of marine mammals, depending on the source type and/or the manner in which it is operated (*e.g.,* operational settings, mitigation measures), and Letters of Authorization would not be necessary in those cases.

Additional characteristics of the representative acoustic sources and representative operational parameters of the different survey types that were used in the modeling simulations to predict the exposure of marine mammals to different received levels of sound are described in the modeling report and in our notice of proposed rulemaking. Please see those documents for additional detail.

We note that while it was necessary to identify representative sources for the purposes of modeling the number of takes to be included in the analysis under the rule, the analysis is intended to be, and is appropriately, applicable to takes resulting from the use of other sizes or configurations of airguns (*e.g.,* the alternative, smaller airgun array modeled in the ''*Gulf of Mexico Acoustic Exposure Model Variable Analysis*'' report (Zeddies *et al.,* 2017b) referenced in the proposed rule and available for public review as supplementary material to the proposed rule).

While these descriptions reflect existing technologies and current practice, new technologies and/or uses of existing technologies may come into practice during the period of validity of these regulations. NMFS will evaluate any such developments on a case-specific basis to determine whether expected impacts on marine mammals are consistent with those described or referenced in this document and, therefore, whether any anticipated take incidental to use of those new technologies or practices may appropriately be authorized under the existing regulatory framework. We also note here that activities that may result in incidental take of marine mammals, and which would therefore appropriately require authorization under the MMPA, are not limited to those activities requiring permits from BOEM. There may be some activities that do not require permits from BOEM, such as certain ancillary activities, for which an LOA under this rule may be appropriate. Operators should consult NMFS regarding the appropriateness of applying for an LOA under this rule prior to conducting such activities.

Estimated Levels of Effort

As noted previously, actual total amounts of effort by survey type and location cannot be known in advance of receiving LOA requests from industry operators. Therefore, BOEM's PEIS provided projections of survey level of effort for the different survey types for a 10-year period (and BOEM's updated scope refined those projections to a five-year period). In order to construct a realistic scenario for future geophysical survey effort, BOEM evaluated trends in permit applications as well as industry estimates of future survey activity. In addition, GOMESA precludes leasing, pre-leasing, or any related activity (though not geophysical surveys) in the GOM east of 86°41′ W, in BOEM's Eastern Planning Area (EPA) and within 125 mi (201 km) of Florida, or in BOEM's Central Planning Area (CPA) and within 100 mi of Florida (and according to certain other detailed stipulations). These leasing restrictions are in place until June 30, 2022. On September 8, 2020, the President effectively extended this moratorium through withdrawal under OCSLA of the same area covered by the GOMESA moratorium from disposition by leasing for 10 years, beginning on July 1, 2022, and ending on June 30, 2032. This withdrawal prevents consideration of these areas for any leasing for purposes of exploration, development, or production during the 10-year period beginning on July 1, 2022, and ending on June 30, 2032. Although the withdrawal does not preclude geophysical survey activity, similar to the moratorium under GOMESA, the lack of leasing opportunities may be expected to curtail interest in exploratory surveys to some degree.

In order to provide some spatial resolution to the projections of survey effort and to provide reasonably similar areas within which acoustic modeling might be conducted, the geographic region was divided into seven zones, largely on the basis of water depth, seabed slope, and defined BOEM planning area boundaries. Shelf regions typically extend from shore to approximately 100–200 m water depths where bathymetric relief is gradual (off Florida's west coast, the shelf extends approximately 150 km). The slope starts where the seabed relief is steeper and extends into deeper water. In the GOM water deepens from 100–200 m to 1,500–2,500 m over as little as a 50 km horizontal distance. As the slope ends, water depths become more consistent, though depths can vary from 2,000–3,300 m. Three primary bathymetric areas were defined as shelf (0–200 m water depth), slope (200–2,000 m), and deep (>2,000 m).

Available information regarding cetacean density in the GOM (*e.g.,* Roberts *et al.,* 2016) shows that, in addition to water depth, animal distribution tends to vary from east to west in the GOM and appears correlated with the width of shelf and slope areas from east to west. The western region is characterized by a relatively narrow shelf and moderate-width slope. The central region has a moderate-width shelf and moderate-width slope, and the eastern region has a wide shelf and a very narrow slope. Therefore, BOEM's western, central, and eastern planning area divisions provide appropriate longitudinal separations for the shelf and slope areas. Due to relative consistency in both physical properties

and predicted animal distribution, the deep area was not subdivided. As shown in Figure 3, Zones 1–3 represent the shelf area (from east to west), Zones 4–6 represent the slope area (from east to west), and Zone 7 is the deep area.

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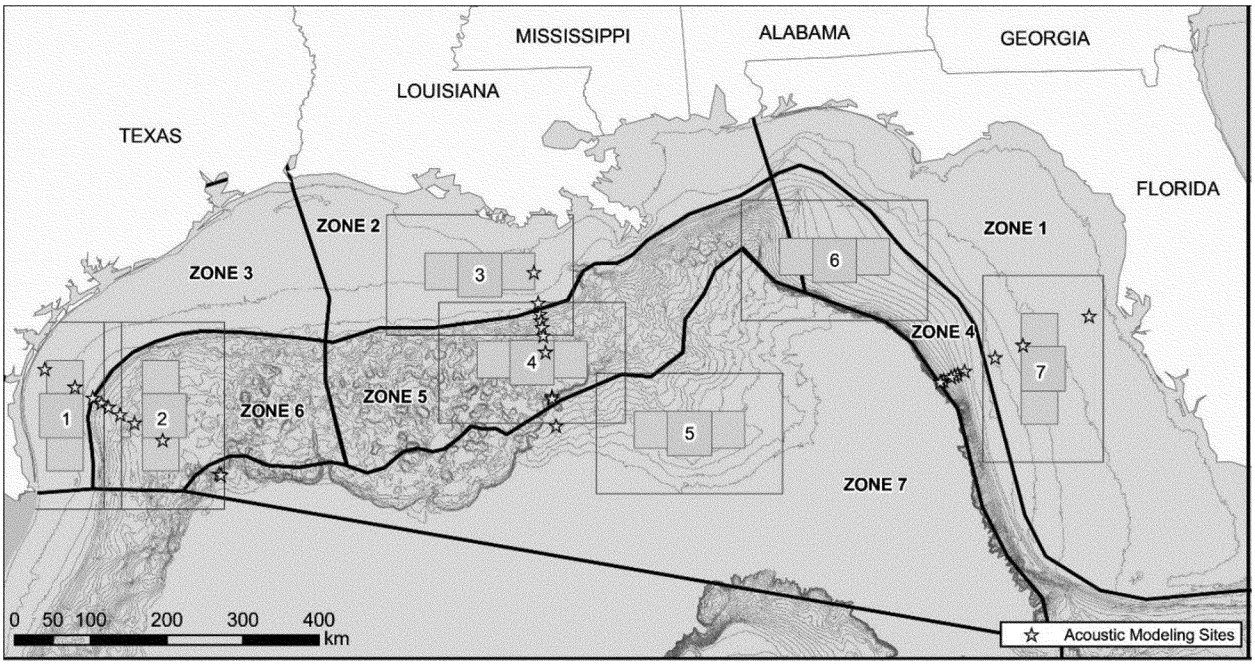

Figure 110 in Zeddies *et al.* (2015). Zones 1-3 represent the shelf region; Zones 4-6 the slope region, and Zone 7 the deep region. Within each of the seven zones, a set of representative survey-simulation rectangles (smaller numbered boxes) for each of the survey types was defined. For additional detail regarding Figure 3, please see discussion under "Modeling Overview," later in this document.

Figure 3. Gulf of Mexico Modeling Zones.

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Table 1 in the notice of proposed rulemaking provided the 10-year estimated levels of effort from BOEM's PEIS, estimated as 24-hr survey days, including annual totals by survey type and by zone for deep penetration and shallow penetration surveys, respectively. As the basis for the analysis supporting the proposed rulemaking, NMFS selected one high survey effort scenario and two each of moderate and low survey effort scenarios from the ten survey effort scenarios provided by BOEM. Of the ten ''years'' or effort scenarios, Year 1 (high), Years 4 and 5 (moderate), and Years 8 and 9 (low) were selected as representative effort scenarios and carried forward for further evaluation.

However, as noted previously, BOEM subsequently revised its proposed action by removing the area subject to leasing moratorium under GOMESA from consideration in the rule. In support of this revision, BOEM provided revised 5-year level of effort predictions and associated acoustic exposure estimates. BOEM's process for developing this information, described in detail in ''Revised Modeled Exposure Estimates,'' available online, was straightforward. Rather than using the PEIS's 10-year period, BOEM provided revised levels of effort for a 5-year period, using Years 1–5 of the original level of effort projections. BOEM stated that the first five years were selected to be carried forward ''because they were contiguous, they included the three years with the most activity, and they were the best understood in relation to the historical data upon which they are based.'' NMFS concurs with this choice. Levels of effort were revised based on the basic assumption that if portions of areas are removed from consideration, then the corresponding effort previously presumed to occur in those areas also is removed from consideration. Revised estimates of future effort and associated acoustic exposures draw upon the prior projections and modeling approach, which were subject to notice and comment. Table 1 shows the percentage reduction in survey area for each modeling zone that results from BOEM's scope revisions, and Table 2 provides the subsequent revised level of effort projections for the 5-year period.

TABLE 1—PERCENTAGE REDUCTION IN SURVEY AREA FOR EACH MODELED ZONE

Modeling zone	Percentage reduction in area
1	100.0
2	2.7
3	0.0
4	98.2
5	4.0
6	0.0
7	33.0

TABLE 2—PROJECTED LEVELS OF EFFORT IN 24-HR SURVEY DAYS FOR FIVE YEARS, BY ZONE AND SURVEY TYPE [1]

Year	Zone [2]	2D [3]	3D NAZ [3]	3D WAZ [3]	Coil [3]	VSP [3]	Total (deep) [3]	Shallow hazards [4]	Boomer [4]	HRG [4]	Total (shallow) [4]
1	1	0	0	0	0	0	0	0	0	1	1
	2	0	7	0	0	0	7	0	0	1	1
	3	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0
	5	2	16	8	3	0	29	0	0	1	1
	6	0	0	0	0	0	0	0	0	0	0
	7	23	170	82	35	1	311	0	0	11	11
Total		25	193	90	38	1	347	0	0	14	14
2	1	0	0	0	0	0	0	0	0	1	1
	2	0	10	1	0	0	11	0	0	1	1
	3	0	0	0	0	0	0	0	0	0	0
	4	27	0	0	0	0	27	0	0	0	0
	5	0	16	8	3	0	27	0	0	1	1
	6	0	0	0	0	0	0	0	0	0	0
	7	10	166	79	34	1	290	0	0	11	11
Total		37	192	88	37	1	355	0	0	14	14
3	1	0	0	0	0	0	0	0	0	1	1
	2	0	10	1	0	0	11	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0
	4	54	50	21	9	0	134	0	0	1	1
	5	1	10	4	2	0	17	0	0	1	1
	6	0	0	0	0	0	0	0	0	0	0
	7	31	125	46	20	1	223	0	0	12	12
Total		86	195	72	31	1	385	0	0	12	12
4	1	0	0	0	0	0	0	0	0	0	0
	2	0	10	1	0	0	11	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0
	4	54	50	21	9	0	134	0	0	1	1
	5	1	10	4	2	0	17	0	0	1	1
	6	0	0	0	0	0	0	0	0	0	0
	7	31	125	46	20	1	223	0	0	12	12
Total		86	195	72	31	1	385	0	0	14	14
5	1	0	0	0	0	0	0	0	0	0	0
	2	0	7	0	0	0	7	0	0	1	1
	3	0	0	0	0	0	0	0	0	0	0
	4	0	75	0	0	0	75	0	0	0	0
	5	0	12	8	3	0	23	0	0	1	1
	6	0	0	0	0	0	0	0	0	0	0
	7	0	154	79	34	1	268	1	1	11	13
Total		0	248	87	37	1	373	1	1	13	15

[1] Projected levels of effort in 24-hr survey days.
[2] Zones follow the zones depicted in Figure 3.
[3] Deep penetration survey types include 2D, which uses one source vessel with one large array (8,000 in^3); 3D NAZ, which uses two source vessels using one large array each; 3D WAZ and coil, each of which uses four source vessels using one large array each (but with differing survey design); and VSP, which uses one source vessel with a large array. ''Deep'' refers to survey type, not to water depth.
[4] Shallow penetration/HRG survey types include shallow hazards surveys, assumed to use a single 90 in^3 airgun or boomer, and high-resolution surveys using the multibeam echosounder, side-scan sonar, and chirp sub-bottom profiler systems concurrently. ''Shallow'' refers to survey type, not to water depth.

This description of the specified activity is a summary of critical information. The interested reader should refer to the notice of proposed rulemaking (83 FR 29212; June 22, 2018), as well as BOEM's petition (with recent addenda) and PEIS, for additional detail regarding these prospective activities and the region. Required mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting).

Changes From the Proposed Rule

This section provides a summary of changes from the proposed rule. Each section in which changes were made (*e.g.,* Mitigation) includes a more detailed list of changes made and a fuller description of the rationale. The following Comments and Responses section also provides additional detail relating to changes, in cases where the change resulted from a public comment.

Most notably, as described in greater detail above, BOEM updated the scope of the specified activity/specified geographical region that is the subject of this rule by removing from consideration the area that is subject to the GOMESA leasing moratorium. In accordance with this updated spatial scope, BOEM provided revised activity level projections and revised estimated acoustic exposure numbers based on the same modeling that informed the numbers evaluated in the proposed rule. BOEM's revised activity level projections correspond with Years 1–5 of the original 10-year projections (see Table 1 of the notice of proposed rulemaking), which is a conservative choice as these years contained higher levels of effort than Years 6–10. In the proposed rule, NMFS selected years that were representative of different levels of effort as the basis for the total taking over five years, including one year of relatively high effort (Year 1), two years of relatively moderate effort (Years 4 and 5), and two years of relatively low effort (Years 8 and 9). This selection is now in part supplanted (with the two

representative ''low effort'' years replaced by one relatively high effort year and one relatively moderate effort year) by BOEM's selection of Years 1–5 and the associated updated levels of effort.

The revised acoustic exposure numbers form the basis for our analyses in this final rule. Of note, the maximum total taking, as well as the annual maximum, that would be allowable under the regulations has decreased for most species and stocks, with the exception of the annual maximums for Atlantic spotted dolphin and bottlenose dolphins, and the total taking over five years for the Atlantic spotted dolphin, which have increased slightly (please see Estimated Take for additional information). These changes (largely decreases) in the take numbers do not have a meaningful effect on the analysis (except where impacts are significantly reduced, *e.g.,* for Bryde's whales) and do not change any of the findings.

In the proposed rule, NMFS included several time-area restrictions, including a seasonal restriction on airgun survey activity in the ''Bryde's whale core habitat'' area (as well as alternatives to this proposal that were offered for public comment, including a year-round restriction in the same area). Following BOEM's update to the scope of the rule, two of these areas (the Bryde's whale area and the ''Dry Tortugas'' area that was, in part, designed to provide protection for sperm whales and beaked whales) were removed from consideration, as the specified activity/specified geographical region no longer includes surveys in the areas where these proposed restrictions are located.

A third time-area restriction—the ''Coastal Restriction,'' designed to protect bottlenose dolphins in coastal waters most heavily impacted by the Deepwater Horizon oil spill—has been modified in consideration of public comments. The restriction was proposed to be GOM-wide within coastal waters inside the 20-m isobath, and to be in effect from February through May. The area encompassed by the restriction has been reduced to match the assumed range of the northern coastal stock of bottlenose dolphins (*i.e.,* between 90–84° W, but in effect only to the eastern extent of the coastal waters portion of BOEM's updated specified geographic region) while the temporal window has been expanded to include January. In addition, a proposed 13-km buffer to this area has been removed.

In the proposed rule, NMFS defined ''deep penetration'' surveys as those using arrays greater than 400 in^3 total volume. That delineation has been revised to include surveys using arrays greater than 1,500 in^3 total volume, with arrays of 1,500 in^3 total volume and less considered ''shallow penetration'' surveys.

In the notice of proposed rulemaking, NMFS proposed an exception to the general shutdown requirements for certain species of dolphins in relation to airgun surveys, in which the acoustic source would be powered down to the smallest single element of the array. Power-down conditions would be maintained until the animal(s) is observed exiting the exclusion zone or for 15 minutes beyond the last observation of the animal, following which full-power operations may be resumed without ramp-up. NMFS also provided an alternative proposal for consideration by the public, in which no shutdown or power-down would be required upon observation of the same species of dolphins. Following review of public comments, NMFS removes the power-down measure for small delphinids, in favor of the no-shutdown and no power-down alternative. No shutdown or power-down is required for these species.

NMFS proposed a number of extended distance shutdown requirements on the basis of detections of certain species deemed particularly sensitive (*e.g.,* beaked whales) or of particular circumstances deemed to warrant the extended distance shutdown requirement (*e.g.,* whales with calves). These extended distance shutdowns were all conditioned upon observation or detection of these species or circumstances ''at any distance'' from the vessel. However, NMFS also included as an alternative proposal for public consideration a distance limit of 1,000 m for these shutdown requirements. Following review of public comments, NMFS determined that a distance limit on extended shutdown zones for relevant species or circumstances was appropriate, but determined 1,500 m was the appropriate distance (rather than 1,000 m).

The proposed rule included an extended distance shutdown for sperm whales that was applicable upon acoustic detection, but was not applicable to visual detection. Following review of public comments, the shutdown requirement has been expanded to include any detection of sperm whales within the extended distance shutdown zone, including visual detection.

For shallow penetration surveys, NMFS reduces the standard exclusion zone from 200 m to 100 m, while including an extended distance shutdown requirement mirroring the requirements for deep penetration surveys, but within a distance of 500 m. NMFS eliminates shutdown requirements for HRG surveys (defined here as surveys using electromechanical sources such as multi-beam echosounders, side-scan sonars, and chirp sub-bottom profilers). The proposed regulations required shutdown for marine mammals within the proposed exclusion zone for surveys operating in water depths greater than 200 m.

NMFS eliminates proposed requirements for visual observation during nighttime ramp-up and pre-clearance, and for the use of third-party PSOs aboard node retrieval vessels.

In the proposed rule, NMFS discussed the use of an extrapolation method recommended by the Marine Mammal Commission for use in estimating potential unobserved takes. NMFS agrees with public commenters that the appropriateness of the method for application to observations conducted from working source vessels (versus research vessels) is unknown and, as suggested through public comment, NMFS will not require use of this method but will continue to evaluate approaches for assessment of effects to marine mammal stocks, including those based on extrapolation of marine mammal detections, through the adaptive management process and subsequently apply them through LOAs as appropriate.

NMFS has revised requirements relating to reporting of injured or dead marine mammals and has added newly crafted requirements relating to actions that should be taken in response to notification of live stranding events in certain circumstances, in order to reflect current best practice.

The proposed rule indicated that LOA applications with take estimates based on modeling other than that specifically included in the modeling report used to support the EIS and the proposed rule (the modeling report; Zeddies *et al.,* 2015, 2017a) would necessarily be published for public comment prior to the issuance of an LOA. Upon consideration of public comment and related supplemental materials, the final rule more flexibly allows that if applicants do not use the modeling provided by the rule, NMFS will publish a notice in the **Federal Register** soliciting public comment, when the model or inputs differ substantively from those that have been reviewed by NMFS and the public previously. Please see the Letters of Authorization section for more detail.

Comments and Responses

NMFS published a notice of proposed rulemaking in the **Federal Register** on June 22, 2018 (83 FR 29212), beginning a 60-day comment period. In that notice, we requested public input on the proposed rule and regulations, including the variations of the proposed rule, two economic baselines, and other information provided in the Regulatory Impact Analysis and associated appendices, and requested that interested persons submit relevant information, suggestions, and comments. In response to BOEM's change in scope and in consideration of public comments, we modified our action, as discussed in the following responses to comments. Please also see the Changes from the Proposed Rule section, above. We note that one area of significant concern for some members of the public was potential impacts to Bryde's whales and related mitigation measures. The reduced geographic scope eliminates the need to consider activity in the Bryde's whale ''core habitat area'' and eliminates the majority of the incidental take of Bryde's whale that was evaluated in the proposed rule.

During the 60-day comment period, we received 17 comment letters. A letter was submitted jointly by the International Association of Geophysical Contractors, the American Petroleum Institute, the National Ocean Industries Association, and the Offshore Operators Committee (hereafter, the ''Associations''). A separate letter was submitted jointly by the Natural Resources Defense Council (NRDC), Center for Biological Diversity, Earthjustice, Gulf Restoration Network, Humane Society Legislative Fund, The Humane Society of the United States, and Sierra Club (hereafter, ''NRDC''). Additional letters were submitted by the following: BP Exploration & Production Inc. (BP), Consumer Energy Alliance, CGG, Chevron USA Inc. (Chevron), the Center for Regulatory Effectiveness (CRE), the Florida Department of Environmental Protection, the Marine Mammal Commission (MMC), and eight private citizens. NMFS has reviewed all public comments received on the proposed rulemaking. All relevant comments and our responses are described below, with comment responses outlined by major categories. All comments received are available online at: *www.regulations.gov.* A direct link to these comments is provided at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.*

General Comments

As an initial matter, we note that under the MMPA, NMFS generally does not have discretion regarding issuance of requested incidental take authorizations for small numbers of marine mammals, provided that (1) the total taking associated with a specified activity will have a negligible impact on the affected species or stock(s); (2) the total taking associated with a specified activity will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (not relevant here); and (3) mitigation, monitoring, and reporting of such takings are set forth, including mitigation measures sufficient to meet the standard of least practicable adverse impact on the affected species or stocks and their habitat.

In addition, NMFS' proposed action—the issuance of the ITR and any subsequent LOAs authorizing incidental take of marine mammals—addresses only marine mammals (and their habitat). As such, effects of the surveys on other aspects of the marine environment are not relevant to NMFS' analyses under the MMPA.

The MMPA does require that we evaluate potential effects to marine mammal habitat, which includes prey species (*e.g.,* zooplankton, fish, squid). However, consideration of potential effects to taxa other than marine mammals and their prey, or consideration of effects to potential prey species in a context other than the import of such effects on marine mammals, is not relevant to our action under the MMPA. We have appropriately considered effects to marine mammal habitat. Separately, BOEM evaluated effects to all relevant aspects of the human environment (including marine mammals and other taxa) through the analysis presented in BOEM's PEIS (available online at: *www.boem.gov/Gulf-of-Mexico-Geological-and-Geophysical-Activities-Programmatic-EIS/*), and effects to all potentially affected species that are listed under the Endangered Species Act (ESA) and any critical habitat designated for those species were addressed through consultation between BOEM and NMFS pursuant to section 7 of the ESA. That Biological Opinion, which evaluated NMFS' proposed action (issuance of the ITR and any subsequent LOAs) as well as all BOEM and Bureau of Safety and Environmental Enforcement (BSEE) approvals of activities associated with the OCS oil and gas program in the GOM, is available online at: *www.fisheries.noaa.gov/national/endangered-species-conservation/biological-opinions-issued-noaa-fisheries-office-protected.* We do not further address taxa other than marine mammals and marine mammal prey.

Comment: The Associations comment that the proposed ITR is a well-structured and thorough document that appropriately concludes that geophysical activities in the GOM would have no more than a negligible impact on marine mammal populations, and that they appreciate NMFS' effort in preparing the proposed ITR and consideration of some of the Associations' previous comments.

Response: NMFS appreciates the comment.

Comment: The Associations comment that geophysical surveys play a critical role in the safe and orderly development of the oil and gas resources of the GOM.

Response: We acknowledge the background operational information provided by the Associations.

Comment: BP comments that the ITR is a much-needed process to govern the authorization of incidental takes of marine mammals associated with geophysical survey activity in the GOM. Chevron also indicates support for promulgation of the ITRs.

Response: NMFS appreciates the comments.

Comment: BP comments that projected survey efforts are underestimated but did not provide specific justification or recommendations.

Response: Projected levels of survey effort were formulated by BOEM and included in their PEIS. BOEM's PEIS stated, ''the scenarios contain projections based on the analysis of recent historic activity levels and trends made by BOEM's subject-matter experts who also considered industry-projected activity levels in their estimates.'' These projected levels of survey effort were made available for public review on multiple occasions during the development of the PEIS, as well as during the notice of receipt comment period, in which the public was given the opportunity to review and comment on the petition itself (81 FR 88664; December 8, 2016). Neither BP nor other industry stakeholders submitted comments on the BOEM-developed effort levels, and no evidence was provided that projected survey efforts are underestimated. The projected levels of effort were subsequently updated by BOEM based on the removal of the GOMESA area from consideration.

Comment: The Florida Department of Environmental Protection (FLDEP) expressed its concern regarding the potential impacts of OCS oil and gas

activities on marine and coastal environments and the biological resources and critical habitats associated with them. The FLDEP also indicated that former Secretary of the Interior Zinke had made a commitment to former Governor Scott to remove the State of Florida from future consideration for offshore drilling.

Response: NMFS acknowledges the comments. Assuming that the requirements of the MMPA are met, *e.g.,* findings of negligible impact and small numbers are made, NMFS does not have discretion as to whether it may issue ITRs and LOAs under those ITRs, and NMFS has no authority to limit oil and gas activities outside of prescribing appropriate mitigation requirements.

Marine Mammal Impacts

Comment: The Associations (as well as other industry commenters and the CRE) stated, in summary, that there is no scientific evidence that geophysical survey activities have caused adverse consequences to marine mammal stocks or populations, and that there are no known instances of injury to individual marine mammals as a result of such surveys, stating that similar surveys have been occurring for years without significant impacts. The Associations stated that surveys have been ongoing in the GOM for years and have not resulted in any negative impacts to marine mammals, including reducing fitness in individuals or populations. Referring to other regions, the commenters stated that bowhead whale numbers have increased in the Arctic despite survey activity. The Associations go further in claiming that ''NMFS misconstrues its legal obligations'' and ''NMFS violates the MMPA's best available science requirement.''

Response: Disruption of behavioral patterns (*i.e.,* Level B harassment) has been documented numerous times for marine mammals in the presence of airguns, in the form of avoidance of areas, notable changes in vocalization or movement patterns, or other shifts in important behaviors. See Potential Effects of the Specified Activity on Marine Mammals and Their Habitat in the notice of proposed rulemaking. In addition, there is growing scientific evidence demonstrating the connections between sub-lethal effects, such as behavioral disturbance, and population-level effects on marine mammals (*e.g.,* Lusseau and Bedjer, 2007; New *et al.,* 2014; Pirotta *et al.,* 2018). Disruptions of important behaviors, in certain contexts and scales, have been shown to have energetic effects that can translate to reduced survivorship or reproductive rates of individuals (*e.g.,* feeding is interrupted, so growth, survivorship, or ability to bring young to term may be compromised), which in turn can adversely affect populations depending on their health, abundance, and growth trends.

With specific regard to sound, as a 2017 report from the National Academy of Sciences noted, while it is true that ''[n]o scientific studies have conclusively demonstrated a link between exposure to sound and adverse effects on a marine mammal population,'' this is largely because such impacts are very difficult to demonstrate (NRC, 2005; NAS, 2017), not because they do not exist. Population-level effects are inherently difficult to assess because of high variability, migrations, and multiple factors affecting the populations. Appropriate studies are exceedingly difficult to carry out, and no appropriate study and reference populations have yet been established. Nonetheless there is a growing body of literature and science illustrating the connections between prolonged behavioral disturbance and impacts to reproductive success and survivorship. Accordingly, it is not defensible to conclude that sub-lethal acoustic stressors cannot have population level consequences. Based on the available evidence, a sufficient analysis of the potential impacts of airgun noise requires consideration of impacts on individuals *and* the potential for population level effects. NMFS has carefully considered the available evidence in making the necessary determinations (see Negligible Impact Analysis and Determinations) and determining the most appropriate suite of mitigation measures.

Because some commenters repeatedly cite (and misunderstand) public statements by BOEM in support of a contention that there is ''no harm from seismic,'' we clarify the record by citing BOEM's own responses to similar comments on their PEIS (BOEM, 2017). BOEM stated: ''It is critically important to understand that BOEM's . . . Science Note . . . refers to impacts on marine mammal . . . population sustainability rather than effects on individual animals. Studies have shown that marine mammals may and do react to sound through physical displacement from or avoidance of the area of ensonification and/or by altering their vocalizations. This [PEIS] acknowledges that significant acute physical injury to or death of marine mammals is not likely to be a direct result of seismic noise. It does, however, acknowledge that sublethal injurious effects are possible and may, over time, result in the eventual death of the individual(s) from these physical injuries and/or loss of hearing with (as in the case of marine mammals) the resultant inability to forage and communicate with conspecifics. Another prominent concern is whether anthropogenic sounds such as those generated during seismic survey activities may ''mask'' communications between some marine mammals. Depressed survival rates related to energetic effects or other impacts of noise are difficult to determine. BOEM, however, does not assume that lack of demonstrated adverse population-level effects from seismic surveys means that those effects may not occur.''

In support of assertions that there are ''no effects'' to marine mammals from seismic surveys and that there is a ''lack of any harm'' to marine mammals, CRE cites statements made by NMFS, in which we conclude that there is no evidence that serious injury, death, or stranding is reasonably likely to occur as a result of such surveys, and that Level A harassment is not reasonably likely to occur for mid-frequency cetaceans. CRE's assertion that there are ''no effects'' and ''no harm'' to marine mammals as a result of seismic surveys is based on the fact that marine mammals still exist in the GOM despite survey activity. CRE overlooks the evidence put forward for Level B harassment, and the potential effects of behavioral disruption, as well as the additional effects of noise that do not rise to the level of a take, but which nevertheless must be considered when evaluating the effects of a specified activity on a species or stock.

The Associations assert that we premise our decisions on the idea that we must act conservatively because effects that have not been conclusively proven—which the Associations claim, without evidence, do not and cannot occur—could occur in the future. The Associations state that we misconstrue our legal obligations via the application of ''an additional layer of precautionary bias'' beyond that established in the MMPA standards themselves, though they do not demonstrate that the bias exists. The Associations acknowledge that the MMPA requires mitigation sufficient to meet the standard of least practicable adverse impact. Therefore, some portion of the mitigation requirements contained in the proposed ITR would be necessary to meet that standard. However, they provide no analysis to support the contention that specific mitigation requirements exceed that standard. In fact, we have declined to adopt the recommendations of other commenters that are based on vague and unexplained standards of

''conservatism'' that are not required in the MMPA. Here, we conducted the requisite analyses of mitigation and found that the requirements contained in this final ITR, as modified on the basis of new information and review of public comments, meet the least practicable adverse impact (LPAI) standard.

We base our conclusions, relating to the potential effects of the specified activity on the affected species and stocks, on reasonable interpretation of the available science, which we summarize in this preamble and described in detail in our notice of proposed rulemaking. While we acknowledge the lack of conclusive evidence for population-level consequences, this is an artifact of the extreme difficulty of empirically demonstrating such effects (as concluded by the National Academies of Science, stated above). The best available scientific information provides considerable evidence that the activities evaluated in this ITR have the potential to adversely affect the fitness of individual animals. The best available science clearly demonstrates that, given adverse impacts to an animal's fitness, population-level effects are plausible. The Associations' comments on this topic treat the lack of empirical evidence as evidence that such effects do not occur. However, NMFS does not agree that absence of evidence is evidence of absence of effects. The comments further incorrectly frame our decision-making as being premised on the idea that such effects could occur in the future, when they are actually based on a reasonable interpretation of the best available scientific information regarding what the effects of the specified activity are likely to be in the absence of prescribed mitigation. Despite the paucity of empirical research on population effects, the best available information demonstrates impacts at the individual level that, at a high enough level of take, have reasonably foreseeable population-level impacts.

Similarly, the Associations imply that our interpretation of the existing scientific information reflects speculation about what future research might demonstrate. The Associations' statements that NMFS dismissed current scientific findings and premised decisions on hypothesized future impacts are inaccurate, and their assertion that NMFS ''has effectively required conclusive scientific proof that seismic surveys do not impact marine mammal populations'' misunderstands NMFS' use of the scientific literature. The best available information demonstrates that the effects of seismic surveys on marine mammals may include adverse impacts on behavior in ways that can also have energetic consequences. To draw different conclusions regarding the need for the strong suite of mitigation requirements included in this final ITR, NMFS would require scientific evidence that demonstrates that seismic surveys do not have energetic consequences or, alternatively, do not reach a point where there are population-level consequences. NMFS is not aware of such evidence. NMFS' final rule is based on the best available scientific information and the requirements of the MMPA.

Chevron states that we do not account for ''real-world'' protected species observer (PSO) observations, calling this ''arbitrary and capricious,'' and seems to imply that these ''ignored'' PSO observations of marine mammals are evidence that seismic activities produce no more than ''negligible effects on species.'' Chevron does not provide evidence to support its comment or otherwise develop the suggestion to enable a specific response. However, we incorporated the best available scientific information for our analysis, as evidenced (for example) by our references in the notice of proposed rulemaking to BOEM's synthesis study of PSO data from 2002–08 (Barkaszi *et al.,* 2012) (as well as other similar syntheses from other locations). In this final rulemaking, we have incorporated analysis of a newly available study of PSO data from 2009–15 (Barkaszi and Kelly, 2018). These data are also key to the evaluation of direct costs found in our RIA. We disagree with Chevron's apparent contention that we ''ignore[d]'' BOEM's earlier ''admissions that no scientific evidence exists contradicting the real-world observations of negligible impact'' (citing to BOEM's ''Science Notes''). NMFS addressed BOEM's ''Science Notes'' in some detail in our notice of proposed rulemaking (83 FR 29264–65). Chevron misinterprets a statement from BOEM regarding the absence of evidence (''no documented evidence of noise from air guns . . . adversely affecting animal populations) as evidence itself of no adverse effects. According to Chevron, our ''failure to account for'' this is ''arbitrary and capricious.'' These issues have been addressed both above and in the notice of proposed rulemaking.

Comment: NRDC referenced studies showing that noise from airgun surveys can travel great distances underwater, suggesting that due to the scale of this propagation, marine mammals in the GOM are consistently compromised in their ability to perform important life functions.

Response: NMFS acknowledges that relatively loud, low-frequency noise (as is produced by airgun arrays) has the potential to propagate across large distances. However, propagation and received sound levels are highly variable based on many biological and environmental factors. For example, while one commonly cited study (Nieukirk *et al.,* 2012) described detection of airgun sounds almost 4,000 km from the acoustic source, the sensors were located within the deep sound channel (SOFAR), where low-frequency signals may travel great distances due to the advantageous propagation environment. While sounds within this channel are unlikely to be heard by most marine mammals due to the depth of the SOFAR channel—which is dependent primarily on temperature and water pressure and therefore variable with latitude—it is arguable whether sounds that travel such distances may be heard by whales as a result of refraction to shallower depths (Nieukirk *et al.,* 2012; McDonald *et al.,* 1995). Regardless, while the extreme propagation distances cited in some comments may not be realistic, we acknowledge that contraction of effective communication space for Bryde's whales, which vocalize and hear at frequencies overlapping those emitted by airgun arrays, can occur at distances on the order of tens to hundreds of kilometers (*e.g.,* Hatch *et al.,* 2012). However, attenuation to levels below which more acute effects are likely to occur is expected over much shorter distances (Zeddies *et al.,* 2015, 2017a) and, therefore, we do not agree with the contention that the GOM would be ensonified to a degree that marine mammals would find it an unsuitable habitat or would be consistently compromised in their ability to perform important life functions. Rather, it is likely that displacement would occur within a much smaller region in the vicinity of the acoustic source (*e.g.,* within 10–20 km of the source, depending on season and location). Overall, the specific geographic region and marine mammal use of the area is sufficiently large that, although some displacement may occur (*i.e.,* Level B harassment as a result of acoustic exposure beyond the exclusion zone), the GOM offers enough habitat for marine mammals to seek temporary viable habitat elsewhere, if necessary. Many of the affected species occupy a wide portion of the GOM, and it is expected that individuals of these species can reasonably find temporary

foraging grounds or other suitable habitat areas consistent with their natural use of the region. Further, although the surveys are expected to occur over large portions of the GOM, they will only be transitory in any given area. Therefore, NMFS does not expect displacement to occur frequently or for long durations. Please see Negligible Impact Analysis and Determinations for additional analysis.

Comment: NRDC states that airgun surveys have been linked to significant reductions in the probability of calf survival in western Pacific gray whales (an endangered baleen whale population), implying that these findings indicate that such surveys would similarly have significant negative effects on whales in the GOM.

Response: Commenters cite a preliminary report (Cooke *et al.,* 2015) that documented a reduction in calf survival that the authors suggested may be related to disruption of foraging from airgun survey activity and pile driving in Russia due to presumed avoidance of foraging areas. However, a more recent analysis (Cooke *et al.,* 2017) invalidated these findings, showing that this was a sampling effect, as those calves that were assumed dead in the 2015 study have since been observed alive elsewhere. The new study found no significant annual variation in calf survival. Johnson *et al.* (2007) had previously reported that foraging gray whales exposed to airgun sounds during surveys in Russia did not experience any biologically significant or population-level effects.

Comment: NRDC asserts that we have not adequately accounted for vessel collision risk, stating that the surveys will drive marine mammals into shipping lanes, thereby increasing their risk of ship strike. Relatedly, NRDC noted that NMFS' conclusion that ship strikes will not occur indicates an assumption that required ship-strike avoidance procedures will be effective. NRDC disagrees that the ship-strike avoidance measures will be effective.

Response: NMFS is not aware of any scientific information suggesting that the surveys would drive marine mammals into shipping lanes and disagrees that this would be a reasonably anticipated effect of the specified activities. While the primary stressor to marine mammals from the specified activities is acoustic exposure to the sound source, NMFS takes seriously the risk of vessel strike and has prescribed measures sufficient to avoid the potential for ship strike to the extent practicable (see Mitigation). NMFS has required these measures despite a very low likelihood of vessel strike; vessels associated with the surveys will add a discountable amount of vessel traffic to the specific geographic region and, furthermore, vessels towing survey gear travel at very slow speeds (*i.e.,* roughly 4–5 kn).

Comment: The MMC criticizes one aspect of the methodology for the analysis of chronic effects to Bryde's and sperm whales conducted by NMFS with the support of JASCO Applied Sciences (JASCO), *i.e.,* removing the top ten percent of the greatest pulse exposures. (JASCO is a consulting company contracted by NMFS and BOEM to model acoustic exposures of marine mammals to noise produced by industry survey activity.) The MMC recommends re-estimation of the various lost listening and communication space parameters without removing the greatest ten percent of pulse exposures.

Response: The goal of this modeling exercise was to create a tool that could help evaluate loss of ability to detect signals of biological importance over spatial scales relevant to the sources and hearing capabilities of a wide variety of regional animals. In order to do so, we attempt to examine the portion of low-frequency acoustic energy lost from seismic surveys that has been empirically measured in many contexts around the world to generate higher chronic, longer-term average noise levels. Masking experienced by individual calling and receiving animals due to noise at relatively close proximity to a single intermittent source is an important but limited aspect of the real-world contexts within which populations of marine mammals are exposed to noise from multiple seismic surveys in a region like the GOM. This modeling sought to account for the known attributes of airgun noise, by which low-frequency energy lost laterally attenuates over large spatial scales with loss of impulsive features, leading to elevated background noise conditions, particularly when multiple surveys are concurrent within an acoustic region. Close range pulse energy would entirely drown out such evaluation, and would not account for the different acoustic characteristics of the signal and potential masking at such scales. Thus, while masking of specific signals relative to the near-field of operating airgun arrays is an impact that may occur, for the purposes of the analysis conducted for this rule, near-field impacts have been addressed through the modeling of acoustic exposures. The chronic and cumulative impacts analysis that is the subject of this comment addresses far-field chronic impacts. Additionally, there are technical concerns with modifying the analysis specifically as recommended and, accordingly, we disagree with the recommendation for purposes of this analysis of potential chronic effects.

The purpose of this modeling exercise was not to evaluate exposure implications for animals close to the modeling locations (*i.e.,* ''acute'' effects). Evaluation of acute effects, such as injury and behavioral disruption, was achieved through the primary acoustic exposure modeling effort (Zeddies *et al.,* 2015, 2017a). These evaluated effects (evaluated through the primary acoustic modeling effort) are separate and separable from loss of hearing opportunities experienced by animals farther from source locations, which are evaluated through the chronic and cumulative effects modeling discussed here.

Marine Mammal Impacts—Habitat

Comment: NRDC expressed concern regarding potential impacts to marine mammal prey and/or food webs from the planned surveys. NRDC provided numerous citations in claiming that the surveys could impact marine mammal prey through the following: (1) Cause severe physical injury and mortality; (2) damage hearing and sensory abilities of fish and marine invertebrates; (3) impede development of early life history stages; (4) induce stress that physically damages marine invertebrates and compromises fish health; (5) cause startle and alarm responses that interrupt vital behaviors; (6) alter predator avoidance behavior that may reduce probability of survival; (7) affect catchability of prey species; (8) mask important biological sounds essential to survival; (9) reduce reproductive success, potentially jeopardizing long-term sustainability of fish populations; (10) interrupt feeding behaviors and induce other species-specific effects that may increase risk of starvation, reduce reproduction, and alter community structure; and (11) compromise orientation of fish larvae with potential ecosystem-level effects. Additionally, NRDC cited a publication by McCauley *et al.* (2017) as evidence that the surveys could potentially impact zooplankton and consequently marine mammal food webs.

Response: NMFS strongly disagrees with the suggestion that we ignored effects to prey species. In fact, we considered relevant literature (including that cited by NRDC) in finding that the most likely impact of survey activity to prey species such as fish and invertebrates would be temporary avoidance of an area, with a rapid return to pre-survey distribution and behavior,

and minimal impacts to recruitment or survival anticipated. While there is a lack of specific scientific information to allow an assessment of the duration, intensity, or distribution of effects to prey in specific locations at specific times and in response to specific surveys, NMFS' review of the available information does not indicate that such effects could be significant enough to impact marine mammal prey to the extent that marine mammal fitness would be affected. We agree that seismic surveys could affect certain marine mammal prey species, and addressed these potential effects, as well as the potential for those effects to impact marine mammal populations, in our notice of proposed rulemaking (83 FR 29241–29242). As stated in that notice, our review of the available information and the specific nature of the activities considered herein suggest that the activities evaluated in this ITR are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to prey species are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations. In support of this conclusion, we refer the commenter to discussion provided in our notice of proposed rulemaking. Additional information is summarized below.

In summary, fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. However, the reaction of fish to airguns depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. While we agree that some studies have demonstrated that airgun sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017), our review shows that the weight of evidence indicates either no or only a slight reaction to noise (*e.g.,* Miller and Cripps, 2013; Dalen and Knutsen, 1987; Pena *et al.,* 2013; Chapman and Hawkins, 1969; Wardle *et al.,* 2001; Sara *et al.,* 2007; Jorgenson and Gyselman, 2009; Blaxter *et al.,* 1981; Cott *et al.,* 2012; Boeger *et al.,* 2006), and that, most commonly, while there may be impacts to fish as a result of noise from nearby airguns, any effects will be temporary. For example, investigators reported significant, short-term declines in commercial fishing catch rate of gadid fishes during and for up to five days after seismic survey operations, but the catch rate subsequently returned to normal (Engas *et al.,* 1996; Engas and Lokkeborg, 2002). Other studies have reported similar findings (*e.g.,* Hassel *et al.,* 2004). Skalski *et al.* (1992) also found a reduction in catch rates—for rockfish (*Sebastes* spp.) in response to controlled airgun exposure—but suggested that the mechanism underlying the decline was not dispersal but rather decreased responsiveness to baited hooks associated with an alarm behavioral response. A companion study showed that alarm and startle responses were not sustained following the removal of the sound source (Pearson *et al.,* 1992). Therefore, Skalski *et al.* (1992) suggested that the effects on fish abundance may be transitory, primarily occurring during the sound exposure itself. In some cases, effects on catch rates are variable within a study, which may be more broadly representative of temporary displacement of fish in response to airgun noise (*i.e.,* catch rates may increase in some locations and decrease in others) than any long-term damage to the fish themselves (Streever *et al.,* 2016).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality and, in some studies, fish auditory systems have been damaged by airgun noise (McCauley *et al.,* 2003; Popper *et al.,* 2005; Song *et al.,* 2008). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a temporary threshold shift (TTS) of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long—both of which are conditions unlikely to occur for surveys that are necessarily transient in any given location and likely result in brief, infrequent noise exposure to prey species in any given area. For these surveys, the sound source is constantly moving, and most fish would likely avoid the sound source prior to receiving sound of sufficient intensity to cause physiological or anatomical damage. In addition, ramp-up may allow certain fish species the opportunity to move further away from the sound source.

NMFS considered the research provided by NRDC and disagrees with its interpretation of the literature. A recent comprehensive review (Carroll *et al.,* 2017) found that results are mixed as to the effects of airgun noise on the prey of marine mammals. While some studies suggest a change in prey distribution and/or a reduction in prey abundance following the use of seismic airguns, others suggest no effects or even positive effects in prey abundance. As one specific example—regarding Paxton *et al.* (2017), which describes findings related to the effects of a 2014 seismic survey on a reef off of North Carolina—NRDC asserts that the study supports a conclusion that seismic surveys ''cause significant shifts in distribution that may compromise life history behaviors.'' However, our own review of this work shows that a reasonable interpretation leads to a more moderate conclusion. While the study did show a 78 percent decrease in observed nighttime abundance for certain species—which NRDC interprets as a significant shift in distribution that could compromise life history behaviors—it is important to note that the evening hours during which the decline in fish habitat use was recorded (via video recording) occurred on the same day that the seismic survey passed, and no subsequent data is presented to support an inference that the response was long-lasting. Additionally, given that the finding is based on video images, the lack of recorded fish presence does not support a conclusion that the fish actually moved away from the site or suffered any serious impairment because fish may remain present yet not be recorded on video. In summary, this particular study corroborates prior studies demonstrating a startle response or short-term displacement.

Available data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Similar to fish, however, the transient nature of the surveys leads to an expectation that effects will be largely limited to

behavioral reactions and would occur as a result of brief, infrequent exposures.

We discussed impacts to benthic communities from impulsive sound generated by active acoustic sound sources in our notice of proposed rulemaking, including one study showing that exposure to airgun signals was found to significantly increase mortality in scallops, in addition to causing significant changes in behavioral patterns and disruption of hemolymph chemistry during exposure (although the authors state that the observed levels of mortality were not beyond naturally occurring rates) (Day *et al.,* 2017). In addition, Fitzgibbon *et al.* (2017) found significant changes to hemolymph cell counts in spiny lobsters subjected to repeated airgun signals, with the effects lasting up to a year post-exposure. However, despite the high levels of exposure, direct mortality was not observed. Further, in reference to the study, Day *et al.* (2016) stated that ''[s]eismic surveys appear to be unlikely to result in immediate large scale mortality [. . .] and, on their own, do not appear to result in any degree of mortality'' and that ''[e]arly stage lobster embryos showed no effect from air gun exposure, indicating that at this point in life history, they are resilient to exposure and subsequent recruitment should be unaffected.'' A majority of the studies reviewed by NMFS have observed no increased mortality in invertebrates exposed to airgun noise (*e.g.,* Wardle *et al.,* 2001; Parry *et al.,* 2002; Christian *et al.,* 2003; Andriguetto-Filho *et al.,* 2005; Parry and Gason, 2006; Payne *et al.,* 2007; Harrington *et al.,* 2010; Przeslawski *et al.,* 2018).

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km of the airguns. However, the authors also stated that in order to have significant impacts on *r*-selected species (*i.e.,* those with high growth rates and that produce many offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011). Most prior research on this topic, which has focused on relatively small spatial scales, has showed minimal effects (*e.g.,* Kostyuchenko, 1973; Booman *et al.,* 1996; Sætre and Ona, 1996; Pearson *et al.,* 1994; Bolle *et al.,* 2012).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.*), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that a full-scale airgun survey would impact copepod abundance within the survey area, but that effects at a regional scale were minimal (2 percent decline in abundance within 150 km of the survey area and effects not discernible over the full region). The authors also found that recovery within the survey area would be relatively quick (3 days following survey completion), and suggest that the quick recovery was due to the fast growth rates of zooplankton, and the dispersal and mixing of zooplankton from both inside and outside of the impacted region. The authors also suggest that surveys in areas with more dynamic ocean circulation in comparison with the study region and/or with deeper waters (*i.e.,* typical GOM survey locations) would have less net impact on zooplankton.

Notably, a recently described study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to airgun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 5 m or less from the airguns. Mortality one week after the airgun blast was significantly higher in the copepods placed 10 m from the airgun but was not significantly different from the controls at a distance of 20 m from the airgun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the airgun. Moreover, the authors caution that even this higher mortality in the immediate vicinity of the airguns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sublethal effects on the escape performance or the sensory threshold needed to initiate an escape response at any of the distances from the airgun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 509–658 m, with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 25 m, with no reported mortality at that distance.

Regardless, if we assume a worst-case likelihood of severe impacts to zooplankton within approximately 1 km of the acoustic source, the typically wide dispersal of survey vessels and brief time to regeneration of the potentially affected zooplankton populations does not lead us to expect any meaningful follow-on effects to the prey base for odontocete predators (the region considered in this rule is not an important feeding area for taxa that feed directly on zooplankton, *i.e.,* mysticetes).

Given the inconsistency of the McCauley *et al.* (2017) results with prior research on impacts to zooplankton as a result of exposure to airgun noise and with the research of Fields *et al.* (2019), further validation of those findings would be necessary for NMFS to reach a determination that these impacts are likely to occur. Moreover, a single study is not sufficient to evaluate the potential impacts, and further study in additional locations must be conducted. Therefore, BOEM proposed to fund such a study as part of their 2019–21 Studies Development Plan (*www.boem.gov/FY-2019-2021-SDP/*).

A recent review article concluded that, while laboratory results provide scientific evidence for high-intensity and low-frequency sound-induced physical trauma and other negative effects on some fish and invertebrates, the sound exposure scenarios in some cases are not realistic to those encountered by marine organisms during routine seismic operations (Carroll *et al.,* 2017). The review finds that there has been no evidence of reduced catch or abundance following seismic activities for invertebrates, and that there is conflicting evidence for fish with catch observed to increase, decrease, or remain the same. Further, where there is evidence for decreased catch rates in response to airgun noise, these findings provide no information about the underlying biological cause of catch rate reduction (Carroll *et al.,* 2017).

NRDC's assertions regarding the likely effects of airgun survey noise on marine mammal prey include, for example, the assertion that the specified activity would harm fish and invertebrate species over the long-term, cause reductions in recruitment and effects to behavior that may reduce reproductive potential and foraging success and

increase the risk of predation, and induce changes in community composition via such population-level impacts. We have addressed these claims both in this response and in our review of the available literature. We also reviewed available information regarding populations of representative prey stocks in the northern GOM, *i.e.,* the only U.S. location where marine seismic surveys are a routinely occurring activity. While we recognize the need for caution in assuming correlation between the ongoing survey activity in the GOM and the health of assessed stocks there, we also believe this information has some value in informing the likelihood of population-level effects to prey species and, therefore, the likelihood that the specified activity would negatively impact marine mammal populations via effects to prey. We note that the information reported below is in context of managed commercial and recreational fishery exploitation, in addition to any other impacts (*e.g.,* noise) on the stocks. The species listed below are known prey species for marine mammals and represent groups with different life histories and patterns of habitat use. Numerous other managed stocks are similarly healthy.

• Red snapper (*Lutjanus campechanus*): Red snapper are bottom-dwelling fish generally found at approximately 10–190 m deep that typically live near hard structures on the continental shelf that have moderate to high relief (for example, coral reefs, artificial reefs, rocks, ledges, and caves), sloping soft-bottom areas, and limestone deposits. Larval snapper swim freely within the water column. Increases in total and spawning stock biomass are predicted beginning in about 1990 (Cass-Calay *et al.,* 2015). Regional estimates suggest that recruitment in the west has generally increased since the 1980s, and has recently been above average, while recruitment in the east peaked in the mid-2000s, and has since declined. However, the most recent assessment suggests a less significant decline (to moderate levels) (Cass-Calay *et al.,* 2015).

• Yellowfin tuna (*Thunnus albacares*): Yellowfin tuna are highly migratory, living in deep pelagic waters, and spawn in the GOM from May to August. However, we note that a single stock is currently assumed for the entire Atlantic, with additional spawning grounds in the Gulf of Guinea, Caribbean Sea, and off Cabo Verde. The most recent assessment indicates that spawning stock biomass for yellowfin tuna is stable or increasing somewhat and that, overall, the stock is near levels that produce the maximum sustainable yield (ICCAT, 2016).

• King mackerel (*Scomberomorus cavalla*): King mackerel are a coastal pelagic species, found in open waters near the coast in waters from approximately 35–180 m deep. King mackerel migrate in response to changes in water temperature, and spawn in shelf waters from May through October. Estimates of recruitment demonstrate normal cyclical patterns over the past 50 years, with a period of higher recruitment most recently (1990–2007) (SEDAR, 2014). Long-term spawning stock biomass patterns indicate that the spawning stock has been either rebuilding or remained relatively consistent over the last 20 years, with nothing indicating that the stock has declined in these recent decades (SEDAR, 2014).

In summary, the scientific literature demonstrates that impacts of seismic surveys on marine mammal prey species will likely be limited to behavioral responses, the majority of prey species will be capable of moving out of the area during surveys, a rapid return to normal recruitment, distribution, and behavior for prey species is anticipated, and, overall, impacts to prey species, if any, will be minor and temporary. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to airgun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in a given survey area would be temporary avoidance of the area. Surveys using towed airgun arrays move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once a survey moves out of the area or ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of most surveys and the likelihood of temporary avoidance behavior suggest that impacts would be minor.

Finally, and relevant to NMFS' findings under the MMPA, NRDC does not demonstrate that even the asserted worst-case effects on prey species would have any meaningful impact on marine mammals or their respective populations. Referencing a single study on zooplankton effects (*i.e.,* McCauley *et al.,* 2017), NRDC implies that airgun surveys will definitively reduce ''the abundance and diversity of zooplankton over vast areas and induc[e] changes in community composition due to the aggregation of individual- and population-level impacts across multiple fish and invertebrate species,'' thereby leading to ecosystem-level effects that would harm marine mammal populations. NMFS disagrees with this interpretation of the scientific literature and notes the presence of healthy stocks of marine mammal prey species currently found in the GOM, despite decades of routine geophysical survey operations, but also a devastating oil spill (discussed in detail in the notice of proposed rulemaking). NMFS believes that no evidence is presented to contradict our conclusions regarding likely impacts to marine mammals due to effects on prey species, *i.e.,* that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species, and that any effects that do occur are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Comment: The Associations object to NMFS' use of an analysis of chronic and cumulative impacts of noise on marine mammals in the GOM (*i.e.,* the CCE report), which was described in detail in our notice of proposed rulemaking. The Associations state that ''[c]oncepts such as ''soundscape,'' ''communication space,'' or ''acoustic footprint'' have no basis in any existing statutory or regulatory authorities, and are therefore inapplicable to this rulemaking.''

Response: The purpose of the analysis was to evaluate the more cumulative nature of low-frequency, long-distance propagation of relatively low-intensity energy from multiple seismic surveys operating concurrently in a region, and to evaluate potential loss of ability to detect signals of biological importance over spatial scales relevant to the sources and hearing capabilities of representative species. NMFS is required to evaluate the effects of the specified activity on the potentially impacted marine mammal stocks and their habitat. Noise can disrupt marine mammals' behavioral patterns through the contraction of their communication

space, among other impacts. Moreover, NMFS is required to mitigate impacts on marine mammal species or stocks and their habitat. Concepts such as listening area and communication space are not novel, having been published in peer-reviewed literature and previously applied in impact assessment contexts. NMFS is required to consider these effects.

Comment: NRDC argues that NMFS fails to consider chronic harm, including masking effects and impacts on acoustic habitat. For example, NRDC asserts that the consideration of masking in NMFS' negligible impact analysis was cursory in that it only came through the vulnerability ratings and ''seems to misapprehend the spatial and temporal scope of the effects'' of masking. Similarly, in addition to citing general concerns about chronic effects to Bryde's whales and other species, NRDC asserts that acoustic habitat is discussed, but not factored into the negligible impact analysis.

Response: The potential impacts of masking were properly considered. NRDC significantly understates the consideration given to masking effects in the Expert Working Group (EWG) risk assessment framework (see Negligible Impact Analysis and Determinations). Broadly, the results of the EWG analysis for any given species are based on the integration of two components: The severity of the impacts (which reflects the extent of the activities overlaid with the presence and distribution of the given species) and the vulnerability of that species based on multiple biological and environmental risk factors, including explicit consideration of masking. The maximum possible vulnerability score any species can attain under the assessment across all of these factors is 30. The masking component of the vulnerability score considers communication masking, foraging masking, and navigation/orientation masking—for a total of seven points. The minimum score that any species assessed in the context of these survey activities could (and did) attain is 1, while the Bryde's whale was given the maximum scores across all types of masking for a score of 7. The differential across the highest and lowest possible masking scores is 6, out of a maximum possible total of 30 for the overall vulnerability score, which means that masking accounts for twenty percent of a species' vulnerability rating. Twenty percent is an appropriate and not insubstantial proportion of the vulnerability score, given that the total score (with its 30-point maximum) also accounts for behavioral impacts, whether there are biologically important areas or times overlaying the activities, whether there are additional chronic anthropogenic (*e.g.,* other anthropogenic noise) or chronic biological factors (*e.g.,* disease), and the status and trends of the population.

NMFS recognizes that masking is not necessarily co-extensive with harassment and explicitly recognizes this in our discussion of effects, although we also note that the distances at which behavioral harassment is quantified for this rule are farther than those contemplated in the past, due to the behavioral harassment thresholds used (see the Estimated Take section and comment responses later in this section for further discussion of acoustic thresholds). As discussed elsewhere, NMFS designed and supported the implementation of a chronic and cumulative effects analysis (the CCE report, discussed later in this preamble) for the specific purpose of addressing the effects of these activities on the listening space of all species and the communication space of Bryde's whales specifically. This modeling effort explicitly considered the effects of masking over realistic spatial scales. In their 2017 public comments on incidental harassment authorizations NMFS had proposed for seismic survey activities in the Atlantic Ocean, NRDC specifically recommended that NMFS conduct a modeling exercise like the effort conducted here for the GOM rule to better support those findings (see 83 FR 63268; December 7, 2018), yet they now suggest that this analysis is inadequate, even paired with the quantitative analysis included in the EWG analysis as it is here. See Potential Effects of the Specified Activities on Marine Mammals and Their Habitat in the notice of proposed rulemaking for additional discussion.

Comment: A private citizen offers commentary and clarifications regarding the discussions of acoustic masking and acoustic habitat provided in our notice of proposed rulemaking.

Response: We appreciate the discussion provided by the commenter, but note that no specific recommendations are provided towards an improved assessment of the effects of chronic aggregate noise from survey activity, as the commenter suggests is needed.

Cumulative Impacts and Related Issues

Comment: NRDC expressed concern regarding cumulative impacts, claiming that NMFS' negligible impact determination underestimates impacts to marine mammal species and populations because it fails to consider the effects of other anticipated activities on the same marine mammal populations. NRDC also stated that NMFS must include geophysical surveys occurring within state waters within the scope of the ITR.

Response: Neither the MMPA nor NMFS' codified implementing regulations address consideration of other unrelated activities and their impacts on populations. However, the preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989) states in response to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the baseline. Consistent with that direction, NMFS has factored into its negligible impact analysis the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline, *e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, the chronic and cumulative effects analysis (the ''CCE report'' discussed later in this preamble), and other relevant stressors. Some of these are addressed explicitly through the environmental risk factor scoring in the population vulnerability analysis of the Expert Working Group Assessment (including consideration of Deepwater Horizon (DWH) oil spill effects and risk from other anthropogenic activities). In addition, we consider these factors as relevant contextual elements of the analysis. See the Negligible Impact Analysis and Determinations section of this notice for full detail.

Our 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There we stated that such effects are not considered in making findings under section 101(a)(5) concerning negligible impact. We indicated (1) that NMFS would consider cumulative effects that are reasonably foreseeable when preparing a NEPA analysis, and (2) that reasonably foreseeable cumulative effects would also be considered under section 7 of the ESA for ESA-listed species.

Here, we recognize the potential for cumulative impacts, as analyzed through BOEM's PEIS, which addressed the impacts of an extended time period of survey activity that may be permitted by BOEM (ten years versus the five years that the ITR is limited to), and which NMFS adopted as the basis for its Record of Decision. In that analysis, the assessment was focused on whether the predicted level of take from the forecasted level of survey effort, when considered in context, would have a

meaningful biological consequence at a species or population level. NMFS, therefore, assessed and integrated other contextual factors (*e.g.,* species' life history and biology, distribution, abundance, and status of the stock; mitigation and monitoring; characteristics of the surveys and sound sources) in determining the overall impact of issuance of the ITR and subsequent LOAs on the human environment. Key considerations included the nature of the surveys and the required mitigation. In all cases, it is expected that sound levels will return to previous background levels once the acoustic source moves a certain distance from the area, or the surveys cease. The proposed rule also identified several time-area restrictions to minimize risk or severity of impacts to the extent practicable, consistent with the MMPA's least practicable adverse impact standard. In the final rule, two of those areas were removed from consideration based on the reduction in the scope of the rule per BOEM's request. The other proposed mitigation area remains (as modified; see Mitigation). Although those two areas have been removed from consideration as mitigation due to the reduction in scope of the rule, the practical effect on GOM stocks is similar, in that no survey activity within those areas may be considered for take authorization pursuant to the rule. The similar result is a reduction in the overall numbers of take but also, importantly, elimination or minimization of impacts to marine mammal species or stocks in the areas most important to them for feeding, breeding, and other important functions. Therefore, the severity of takes that may occur pursuant to the rule is expected to be meaningfully lower due to the reduction in impacts that could reduce reproductive success or survivorship.

In summary, NMFS does not expect aggregate impacts from the forecast level of survey effort to affect rates of recruitment or survival for marine mammals, either alone or in combination with other past, present, or ongoing activities. The cumulative impacts of these surveys (*i.e.,* the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions) were addressed as required through the NEPA documents cited above. These documents, as well as the relevant Stock Assessment Reports, are part of NMFS' Administrative Record for this action, and provided the decision-maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determinations made under the MMPA.

Separately, cumulative effects were analyzed as required through NMFS' required intra-agency consultation under section 7 of the ESA, which concluded that NMFS' action of issuing the ITR and subsequent LOAs was not likely to jeopardize the continued existence of listed marine mammals.

We disagree with NRDC's suggestion that we include geophysical surveys in state waters within the scope of this rulemaking. Section 101(a)(5)(A) of the MMPA requires NMFS to make a determination that the take incidental to a ''specified activity'' will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. NMFS' implementing regulations require applicants to include in their request a detailed description of the specified activity or class of activities that can be expected to result in incidental taking of marine mammals. 50 CFR 216.104(a)(1). Thus, the ''specified activity'' for which incidental take coverage is being sought under section 101(a)(5)(A) is generally defined and described by the applicant. Here, BOEM is the applicant for the ITR in support of industry operators, and we are responding to the specified activity as described in that petition (and making the necessary findings on that basis). As BOEM's PEIS makes clear, BOEM does not have a regulatory role regarding surveys occurring in state waters. (See, *e.g.,* BOEM's PEIS, Chapter 1.1.3)

NRDC's representation of our action—''The agency's decision to evaluate the impacts of state water surveys separately as if they would occur in isolation''—also ignores the fact that we have no information about the possible extent of potential future geophysical survey activity in state waters, including type, amount, duration, timing, location, etc., even if such activity were to occur. Although it may be reasonable to assume that such activity occurs, we have no specific knowledge of any past, present, or reasonably foreseeable future survey activity in state waters. No prospective applicant has contacted NMFS to request incidental take authorization for any such survey activity planned or expected within state waters, on either a programmatic or specific basis. NRDC did not provide any information about the expected future extent of survey activity in state waters.

Acoustic Thresholds

Comment: NRDC expressed concerns regarding NMFS' proposed use of the probabilistic response function described by Wood *et al.* (2012), in which 10 percent, 50 percent, and 90 percent of individuals exposed are assumed to produce a behavioral response (of a sufficient degree of severity to constitute Level B harassment) at exposures of 140, 160, and 180 dB root mean square (rms), respectively. (The function is shifted for the more behaviorally sensitive beaked whales such that 50 percent and 90 percent response probabilities are assumed to occur at 120 and 140 dB rms, respectively.) NRDC stated that the function is inconsistent with the best available science, asserting that behavioral disruptions occur at higher percentages at lower noise exposure levels than those suggested by Wood *et al.* (2012). NRDC's criticism of the function also focused on the use of horizontal displacement studies as the supposed basis of analysis for Wood *et al.* (2012), as well as on the function's nature as a series of step functions. In addition, NRDC expressed concerns that the use of frequency weighting in the Wood *et al.* (2012) approach is inappropriate. NRDC requested that NMFS revise the threshold as suggested in Nowacek *et al.* (2015), which recommended a similar function (but centered on 140 dB rms rather than 160 dB rms), while simultaneously stating that the use of such step-based risk functions is ''biologically irrational.'' Overall, NRDC claims that reliance on this function results in underestimation of impacts. A private citizen echoed some of NRDC's comments on this topic while CRE supports use of the Wood *et al.* approach.

Response: NMFS has been criticized in the past for the use of the single-step 160-dB rms approach. Those criticisms are based on the idea that an approach reflecting a more complex multi-step probabilistic function would more effectively represent the known variation in responses at different levels due to differences in the receivers, the context of the exposure, and other factors, as well as the science indicating that animals may react in ways constituting Level B harassment when exposed to lower received levels. In developing the acoustic exposure analysis for the proposed rulemaking, we reviewed relevant past public comments as well as the best available science, determining that a more complex probabilistic function is indeed better reflective of available scientific information, and that it was appropriate

to take the fundamental step of recognizing the potential for Level B harassment occurring at exposures to received levels below 160 dB rms (as well as the potential for *no* Level B harassment occurring at exposures above 160 dB rms). This approach necessarily also accounts for differential hearing sensitivity by incorporating frequency-weighting functions, as behavioral responses in cetaceans are best explained by the interaction between sound source type and functional hearing group (Gomez *et al.,* 2016). NMFS has determined that the general approach used for this rule—a probabilistic risk function that allows for the likelihood of differential response probability at given received levels on the basis of multiple factors, including behavioral context and distance from the source, and that addresses particularly sensitive species—is appropriate in light of the best available scientific information.

However, because behavioral responses to sound depend on the context in which an animal receives the sound, including the animal's behavioral mode when it hears sounds, prior experience, additional biological factors, and other contextual factors, defining sound levels that disrupt behavioral patterns is extremely difficult. Even experts have not previously been able to suggest specific new criteria due to these difficulties (*e.g.,* Southall *et al.* 2007; Gomez *et al.,* 2016). Agency expertise is appropriate in defining the particular steps at which specific response probabilities are assumed to occur, and while we acknowledge our approach reduces a complex suite of interactions to make reasonable inferences, it is consistent with the best available science.

NRDC expressed concerns regarding our approach by noting the size discrepancy between the area ensonified to 140 dB versus that ensonified to 160 dB, implying that we ignore potential responses at the lower received level. To clarify, the difference between our approach and NRDC's recommendation is solely in the proportion of a population assumed to be taken upon exposure to the specified received level which, as stated above, is determined on the basis of expert judgement based on the best available science. We believe that the Wood *et al.* (2012) function is consistent with the best available science, and is therefore an appropriate approach. Below, we address NRDC's concerns in greater detail.

NRDC referenced ''recent'' research they claim is not consistent with the recommendations of Wood *et al.* (2012). We note that, of the nine studies cited by NRDC, five were published prior to the Wood *et al.* (2012) study, and were therefore available for those authors' consideration (and some were specifically referenced by those authors in discussion of their recommendations). Further, we disagree that the referenced findings are inconsistent with Wood *et al.* (2012). First, a mere reaction to noise exposure does not mean that a take by Level B harassment, as defined by the MMPA, has occurred. For a take to occur requires that an act have ''the potential to disturb by causing disruption of behavioral patterns,'' not simply result in a detectable change in motion or vocalization. NRDC also suggests that some of these studies were not incorporated into Wood *et al.'*s recommendations, or our consideration of those and other potential approaches in context of the available science, and criticize what they view as an over-reliance on horizontal displacement studies as the supposed basis of analysis. While it is true that the majority of available behavioral data focus on avoidance responses, Wood *et al.* (2012) does not mention excluding behavioral studies involving vocal changes, and the precedent Southall *et al.* (2007) specifically incorporates numerous studies that do mention changes in vocalization associated with sound exposure. Thus, these datasets were not excluded and, as discussed in our notice of proposed rulemaking, we adequately considered all studies addressed by NRDC.

Regarding baleen whales, we acknowledge that changes in vocalization have been observed in association with exposure to airgun surveys within migratory and non-migratory contexts (*e.g.,* Castellote *et al.,* 2012; Blackwell *et al.,* 2013; Cerchio *et al.,* 2014). The potential for such effects to occur over relatively large spatial scales is not surprising for species with large communication spaces (*e.g.,* Clark *et al.,* 2009), but we reiterate our disagreement with NRDC's apparent contention that every detected change to vocalizations rises to the level of a take. NRDC cites reports of changes in vocalization, typically for baleen whales, as evidence in support of lower thresholds, claiming these reactions result in biological consequences indicating that the reaction was indeed a take. However, NMFS is not aware of research that provides a well-supported link between the reported reactions at lower received levels and the putative consequences. In conflict with NRDC's interpretation of the literature are documented instances of marine mammal exposure to greater received levels that did not elicit any response (*e.g.,* Malme *et al.,* 1983, 1984, 1985, 1988; McCauley *et al.,* 1998, 2000a, 2000b; Barkaszi *et al.,* 2012; Stone, 2015a; Gailey *et al.,* 2016; Barkaszi and Kelly, 2018).

The received level associated with stoppage of calling for bowhead whales (*Balaena mysticetus*) observed by Blackwell *et al.* (2013, 2015)—a response that may arguably rise to the level of harassment—is consistent with the Wood *et al.* (2012) scheme, in which the potential for take upon exposure to received levels as low as 140 dB is accounted for. Similarly, the findings of Pirotta *et al.* (2014) for harbor porpoise (*Phocoena phocoena*) are consistent with the treatment of behaviorally sensitive species by Wood *et al.,* in which the potential for take at even lower received levels is accounted for (though irrelevant here, as harbor porpoise are not found in the GOM). The response levels reported by McDonald *et al.* (1995) and Di Iorio and Clark (2009) for blue whales (*Balaenoptera musculus*) also comport with the Wood *et al.* function, if we assume that the observed responses equate to harassment (though it is not clear that they do). With regard to NRDC's citation of Clark and Gagnon (2006), a non-peer reviewed white paper, NRDC incorrectly overestimated the area over which the effect was observed by an order of magnitude (the paper discusses an area of 100 x 100 nmi, which equates to 10,000 nmi^2—not 100,000 nmi^2).

In regard to Cerchio *et al.* (2014), it is important to note that received levels provided in this study are those recorded at locations of their underwater recording devices. The authors indicated ''we did not have the ability to locate the singers or the seismic survey vessel, estimate the source level of the pulses, the distance between the source and potentially impacted singers, or the received level of the pulses at the singers.'' The same situation, *i.e.,* actual received levels at the location of the animals are unknown, is true for Castellote *et al.* (2012) and Clark and Gagnon (2006), which provide average background sound levels with and without the presence of airgun surveys. Thus, not having the location of the animals at the time of exposure makes it difficult to draw conclusions based strictly on received level. NMFS has evaluated the papers and determined they are not informative about appropriate Level B harassment thresholds.

Regarding sperm whales, NMFS disagrees that assuming a 100 percent

probability of take of sperm whales upon exposure to survey noise at 135 dB—as suggested by NRDC—is an accurate reflection of the results of the Miller *et al.* (2009) study. While we agree that the work of Miller *et al.* (2009) suggests that sperm whales in the GOM may be susceptible to disruption of foraging behavior upon exposure to relatively moderate sound levels, NRDC incorrectly interprets results of the study in claiming that sperm whale ''foraging success'' was found to ''decline significantly.'' Instead, the authors report that buzz rates (a proxy for attempts to capture prey) were approximately 20 percent lower, meaning that the appropriate interpretation would be that foraging activity (versus foraging success) was reduced by 20 percent (Jochens *et al.,* 2008). Of the eight whales tagged in that study, only one was observed to actually cease foraging.

Moreover, while we do believe that these results support a conclusion that exposure to survey noise can impact foraging activity, other commenters have interpreted them differently, *e.g.,* by focusing on the finding that exposed whales did not change behavioral state during exposure or show horizontal avoidance (a finding replicated in other studies, *e.g.,* Madsen *et al.,* 2002a; Winsor *et al.,* 2017). Importantly, the observed effect was not statistically significant and, as reported by the authors, constituted ''subtle effects on their foraging behavior.'' Furthermore, the authors of the Wood *et al.* (2012) study explicitly described their consideration of Miller *et al.* (2009) in the development of their recommended criteria. Therefore, the Wood *et al.* (2012) recommendation is indeed consistent with the Miller *et al.* (2009) study.

In referencing Bowles *et al.* (1994), NRDC fails to state that the observed cessation of vocalization was likely in response to a low-frequency tone (dissimilar to airgun signals), though a distant airgun survey was noted as producing signals that were detectable above existing background noise. NRDC recommends that NMFS base a sperm whale threshold on the findings of a separate study of exposure of sperm whales and other species to sonar signals (Miller *et al.,* 2012). NMFS disagrees that behavioral response data for sperm whales exposed to mid-frequency active sonar (Miller *et al.,* 2012) is more appropriate than using data from the airgun exposures described by Miller *et al.* (2009) and already considered within the Wood *et al.* function. Furthermore, the alternative recommendation of Nowacek *et al.* (2015), which is repeatedly mentioned by NRDC as a more appropriate alternative to Wood *et al.* (2012), does not make a distinction between sperm whales and other odontocetes and instead advocates for a criteria that treats all marine mammal species the same (we address this in greater detail below).

Regarding other odontocetes, NRDC's representation of the available scientific information is also inaccurate. Miller *et al.* (2005) specifically state that ''[s]lighting rates at distances of 10–20 km from the airgun array were significantly lower than those in areas 20–30 km from the airgun array, where sighting rates were unexpectedly high'' (*i.e.,* the study indicates sighting rates of beluga whales (*Delphinapterus leucas*) were lower, not ''100% avoidance'' as claimed by NRDC). Miller *et al.* (2005) reported seven aerial beluga whale sightings from 8 to 18 km from the survey vessel and two vessel-based beluga whale sightings at 1.5 and 2.5 km from the survey vessel. Furthermore, Southall *et al.* (2007) described the findings of the Miller *et al.* (2005) study as temporary avoidance behaviors at these lower received levels, while Gomez *et al.* (2016) (which NRDC agrees reflects the best available science) evaluated Miller *et al.* (2005) based on a received level of 150 dB. Thus, the Wood *et al.* (2012) approach does capture responses associated with this study.

Additionally, Wood *et al.* (2012) has the advantage of accounting for sensitive species such as beaked whales, meaning that a response of a beaked whale at 140 dB (as cited by NRDC) is covered within the Wood *et al.* (2012) recommended criteria (*e.g.,* Wood *et al.* assumes 90 percent of an exposed beaked whale population will respond at 140 dB). If Nowacek *et al.* (2015) was instead used, as advocated by NRDC, the probability of response would only be 50 percent at 140 dB.

It should be noted that the systematic review by Gomez *et al.* (2016), cited by NRDC in support of their position, found that received level was not appropriate as the sole indicator of behavioral response. For example, this review shows that ''low'' effects were actually found to reach peak probability at a higher received level than ''moderate'' effects for baleen whales. As we discussed in our notice of proposed rulemaking, the results of the Gomez *et al.* (2016) review are not inconsistent with Wood *et al.* (2012). With regard to NRDC's comment that the authors consider their results ''non-conservative,'' Gomez *et al.* (2016) only indicates that they may have scored the severity of vocal responses higher if they had more information on the ecological significance of these types of responses. There is no indication elsewhere in Gomez *et al.* (2016) that their overall results and analysis are ''non-conservative.''

NRDC repeatedly cites Nowacek *et al.* (2015) in public comments. We note first that while NRDC repeatedly refers to this paper as a ''study'' (implying that it presents new scientific data or the results of new analyses of existing scientific data), the paper (which is co-authored by the author of NRDC's comment letter) in fact makes policy recommendations rather than presenting any new science. The more substantive reviews presented by Southall *et al.* (2007) and Gomez *et al.* (2016) were unable to present any firm recommendations, as noted above. We addressed the Nowacek *et al.* (2015) approach relative to the Wood *et al.* (2012) approach, in context of the best available scientific information, in detail in our notice of proposed rulemaking. Then, as now, we found that those recommendations are not justified by the available scientific evidence.

Other than suggesting a 50 percent midpoint for a probabilistic function, Nowacek *et al.* (2015) offer minimal detail on how their recommended probabilistic function should be derived/implemented or exactly how this midpoint value (*i.e.,* 140 dB rms) was derived (*i.e.,* what studies support this point). In contrast with elements of a Level B harassment function that NRDC indicates as important, Nowacek *et al.* (2015) does not make distinctions between any species or species groups and provides no quantitative recommendations for acknowledging that behavioral responses can vary by species group and/or behavioral context. In summary, little substantive support is provided by Nowacek *et al.* (2015) for the proposal favored by NRDC. Few studies are offered in support of the recommended midpoint and the proposal is offered only in a one-page supplementary document. The Nowacek *et al.* (2015) approach is not well-supported scientific consensus, as NRDC's comment suggests.

Additionally, the application of the Nowacek *et al.* (2015) approach disregards the important role that distance from a source plays in the likelihood that an animal will respond to a given received level from that source type in a particular manner. By assuming, for example, a 50 percent midpoint at 140 dB rms, the approach implies an unrealistically high probability of marine mammal response

to signals received at very far distances from a source (*e.g.,* greater than 50 km). DeRuiter *et al.* (2013) found that beaked whales exposed to similar received levels responded when the sound was coming from a closer source and did not respond to the same level received from a distant source. Although the Wood *et al.* (2012) approach does not specifically include a distance cut-off, the distances at which marine mammals are predicted to respond better comport with the distances at which behavioral responses have been detected and reported in the literature.

NRDC also criticizes the use of weighting functions in evaluating potential Level B harassment, and specifically criticizes use of the M-weighting scheme of Southall *et al.* (2007). Gomez *et al.* (2016) suggest that incorporation of frequency-weighting is necessary to account for differential hearing sensitivity, as behavioral responses in cetaceans are best explained by the interaction between sound source type and functional hearing group. That is, implementing weighting functions allows for consideration that different marine mammal groups do not hear varying frequencies of sound equally well. Thus, it is appropriate to account for sounds below a group's best hearing range having a lower likelihood of resulting in a behavioral response (let alone that animals are likely unable to effectively detect sounds at frequencies completely outside their hearing range).

The M-weighting functions are described in Southall *et al.* (2007) as ''intentionally precautionary (wide)'' (as opposed to the weighting functions used in NMFS' 2018 Revised Technical Guidance [2] to account for noise-induced hearing loss) and are used to account for the functional hearing ranges of different marine mammal hearing groups. This frequency weighting scheme was intentionally selected because it is more conservative in accounting for hearing sensitivity (as is appropriate in evaluating potential Level B harassment) than are more recently developed filters designed to better assess potential noise-induced hearing loss.

NRDC asserts that because M-weighting assumes that mid- and high-frequency (MF and HF) cetaceans are relatively insensitive to noise below 1 kHz, it is likely that the incorporation of M-weighting has a significant downwards effect on take estimates. This is incorrect. The table below illustrates the impact of M-weighting functions on frequencies ranging from 100 Hz to 1 kHz.

TABLE 3—IMPACT OF M-WEIGHTING FUNCTIONS ON FREQUENCIES RANGING FROM 100 HZ TO 1 kHz

	Weighting (−dB)			
Hearing group	1 kHz	500 Hz	250 Hz	100 Hz
Mid-frequency Cetaceans	−0.186 dB	−0.76 dB	−2.77 dB	−10 dB.
High-frequency Cetaceans	−0.034 dB	−1.33 dB	−4.45 dB	−13.6 dB.

We see that, at 250 Hz and above, the M-weighting functions do not result in a significant reduction (less than 3 dB for MF cetaceans and less than 5 dB for HF cetaceans). Furthermore, the lower bound of the functional hearing range of these groups is 150 Hz for MF cetaceans and 275 Hz for HF cetaceans (*i.e.,* sounds below 100 Hz, where most energy in airgun noise is found and where M-weighting results in the greatest reductions, are outside functional hearing range). At 1 kHz, where these species are most likely to be able to detect and respond to airgun noise, there is very little assumed reduction in sensitivity.

Finally, NRDC advocates for the use of a linear risk function as opposed to the multiple step function of Wood *et al.* (2012), stating that linear risk functions are scientifically accepted methodology that better acknowledge individuals may vary in responsiveness. Although NRDC does not specifically define what they mean by ''linear risk function,'' NMFS assumes a linear risk function is a smooth, continuous function, as opposed to a function defined by multiple steps, as is the case of Wood *et al.* (2012) (and Nowacek *et al.* (2015), which NRDC recommends as an alternative to Wood *et al.*). NRDC states that Wood *et al.* (2012) ''has a significant negative bias on take estimates'' where ''all exposures from 140 dB to 159.9 dB are considered to produce the same risk.'' While it is true that relying upon Wood *et al.* (2012) results in all exposures within a particular step (*e.g.,* 140 dB and 159.9 dB) having the same risk, and future risk functions may be further refined by incorporating more steps, Wood *et al.* (2012) better represents known variation in behavioral responses at different received levels than Nowacek *et al.* (2015), which provides only a suggested midpoint for a risk function without any guidance on what should be done above or below this midpoint, much less the linear risk function NRDC states should be used. Wood *et al.* (2012) does acknowledge that responsiveness varies with received levels, while relying on broad steps, rather than a continuous function. These broad steps allow for easier implementation of a risk function and are more practical for most users, which is an important consideration, especially in the context of users that may not have the ability or access to more sophisticated modeling (*i.e.,* non-Navy users). Therefore, if new linear risk functions become available, NMFS may still provide a more simplistic function broken down in broad steps, so that it can be applied by all users.

In referencing NMFS' proposal to use the recommendations of Wood *et al.,* and prior to even attempting to characterize the scientific evidence, NRDC states, ''Incredibly [NMFS'] approach produces take estimates that are substantially lower than the much-criticized, non-conservative, 160 dB threshold [. . .].'' NRDC (1) mischaracterizes criticism of the historic 160-dB threshold as being about the results of its use, rather than being about whether it adequately represents the best available science; (2) introduces an MMPA standard that does not exist in the statute (implying that NMFS is being unlawfully or improperly ''non-conservative''); and (3) suggests that NRDC favors whichever method of evaluating potential Level B harassment returns the highest estimate. This is repeated later in their comment when they assert that use of the Wood *et al.* recommendations are ''arbitrary and capricious'' because use of the recommendations ''appears, in its results, even less conservative than the outdated 160 dB threshold.'' However,

[2] NMFS. 2018. 2018 revision to: Technical guidance for assessing the effects of anthropogenic sound on marine mammal hearing (Version 2.0). NOAA Technical Memorandum NMFS–OPR–59, National Marine Fisheries Service: 178.

selection of an evaluation scheme on the basis of the results it returns, rather than on how well the scheme reflects the available scientific literature, would be truly arbitrary and capricious and run counter to our mandates.

Overall, we reiterate the lack of scientific consensus regarding what criteria might be most appropriate for evaluating Level B harassment. Defining sound levels that disrupt behavioral patterns is difficult because responses depend on complex, difficult to predict contextual factors much more so than received level. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict. However, although better methods of assessing likely behavioral response to acoustic stimuli than the relatively simple multi-step function used here may be forthcoming from the scientific community, NMFS is compelled to move forward with the best available information. We believe the recommendations of Wood *et al.* (2012) reflect the best available science.

Comment: NRDC notes NMFS' reference to a ''preliminary analysis'' in the discussion of acoustic thresholds for Level B harassment and asserts that NMFS must make the analysis publicly available and allow opportunity for public comment before finalizing the rule.

Response: Our use of the phrase ''preliminary analysis'' in the notice of proposed rulemaking merits some clarification. The particular analysis we referred to is not in and of itself pre-decisional or preliminary. Rather, it is a discrete analytical product with a result that will not change—it is one way (non-parametric regression method) of looking at one subset (Malme *et al.,* 1984, 1988; Houser *et al.,* 2013; Antunes *et al.,* 2014; Moretti *et al.,* 2014) of the data related to marine mammal behavioral responses to intermittent sound. NMFS conducted an analysis of relevant data starting with the premise of deriving a generic exposure-response curve using previously published exposure-response curves. This exercise was conducted as part of an ongoing separate and broader agency effort to evaluate behavioral response data. We also clarify that the Level B harassment criteria for this rule did not substantively rely upon that analysis.

Comment: NRDC claims that NMFS misapplies the MMPA's statutory definition of harassment by adopting a probability standard other than ''potential'' in setting thresholds for auditory injury, stating that a take estimate based on ''potential'' should either count take from the lowest exposure level at which hearing loss can occur or establish a probability function that accounts for variability in the acoustic sensitivity of individual marine mammals. NRDC states that NMFS instead derived auditory injury thresholds from average exposure levels at which tested marine mammals experience hearing loss, which discounts instances of hearing loss at lower levels of exposure. The comment further states that for purposes of take estimation, thresholds based on mean or median values will lead to roughly half of an exposed cohort experiencing the impacts that the threshold is designed to avoid, at levels that are considered ''safe,'' therefore resulting in substantial underestimates of auditory injury. NRDC makes similar statements with regard to the criteria for Level B harassment.

Response: The 2018 Revised Technical Guidance's (NMFS, 2018) onset thresholds for TTS for non-impulsive sounds encompass more than 90 percent of available TTS data (*i.e.,* for mid-frequency cetaceans, only two data points are below the onset threshold, with maximum point only 2 dB below), and in some situations 100 percent of TTS data (*e.g.,* high-frequency cetaceans; although this group is data-limited). Thus, the 2018 Revised Technical Guidance thresholds provide realistic predictions, based on currently available data, of noise-induced hearing loss in marine mammals. For impulsive sounds, data are limited to two studies, and NMFS directly adopted the TTS onset levels from these two studies for the applicable hearing groups.

Our **Federal Register** notice announcing the availability of the original 2016 Technical Guidance (81 FR 51694; August 4, 2016; NMFS, 2016), indicated that onset of auditory injury (*i.e.,* permanent threshold shift (PTS)) equates to Level A harassment under the MMPA. We explained in that notice that because the acoustic thresholds for PTS conservatively predict the onset of PTS, they are inclusive of the ''potential'' language contained in the definition of Level A harassment. See 81 FR 51697, 51721.

Regarding Level B harassment, based on the language and structure of the definition of Level B harassment, we interpret the concept of ''potential to disturb'' as embedded in the assessment of the behavioral response that results from an act of pursuit, torment, or annoyance (collectively referred to hereafter as an ''annoyance''). The definition refers to a ''potential to disturb'' by causing disruption of behavioral patterns. Thus, an analysis that indicates a disruption in behavioral patterns establishes the ''potential to disturb.'' A separate analysis of ''potential to disturb'' is not needed. In the context of an ITR such as this, our analysis is forward-looking. The inquiry is whether we would reasonably expect a disruption of behavioral patterns; if so, we would conclude a potential to disturb and therefore expect Level B harassment. We addressed NRDC's concerns regarding the scientific support for the Level B harassment criteria in a previous comment response.

Comment: NRDC raised concerns regarding use of NMFS' 2018 Revised Technical Guidance (NMFS, 2018), claiming that the guidance is not based on the best available science and underestimates potential auditory injury. We also note that NRDC's comment references an attachment that was not provided.

Response: The 2018 Revised Technical Guidance (NMFS, 2018) is a compilation, interpretation, and synthesis of the scientific literature that provides the best available information regarding the effects of anthropogenic sound on marine mammals' hearing. The 2016 Technical Guidance was classified as a Highly Influential Scientific Assessment and, as such, underwent three independent peer reviews, at three different stages in its development, including a follow-up to one of the peer reviews, prior to its dissemination by NMFS. In addition, there were three separate public comment periods, during which time NMFS received and responded to similar comments on the guidance (81 FR 51694), and more recent public and interagency review under Executive Order 13795. While new information may help to improve the guidance in the future, and NMFS will review the available literature to determine when revisions are appropriate, the final guidance reflects the best available science and all information received through peer review and public comment. The concerns raised by NRDC have been addressed by NMFS in responses associated with the guidance (see *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*). In light of these considerations, NRDC's argument that use of the guidance is ''arbitrary and capricious'' is unpersuasive. As was stated in our notice of proposed rulemaking, NMFS considers the 2018 Revised Technical Guidance to represent the best scientific information currently available and, given the incorporation of multiple peer reviews and public comment opportunities during its development, we did not solicit and are not

responding in detail to comments concerning the contents of the Technical Guidance (NMFS, 2016, 2018), as such comments are outside the scope of this rulemaking.

NRDC also referenced information related to occupational noise standards established by the National Institute of Occupational Safety and Health (NIOSH). Human noise risk assessments (NIOSH, 1998) are not equivalent (or applicable) to thresholds provided in the guidance, because they are used to predict hearing loss based on a daily 8-h exposure over 40 years (*i.e.,* current marine mammal TTS data are only available to predict exposure periods of 24-h or less and cannot be used to assess or predict risk associated with a lifetime of exposure) and are based on larger sample sizes of human listeners (*e.g.,* NIOSH 1972 and 1997 risk assessments were based on a sample size of 1,172 people). As pointed out in Wright (2015), NIOSH criteria provide a 95 percent confidence interval for their human noise standards but also allow for an excess risk of material hearing impairment, defined as an average threshold elevation for both ears that exceeds 25 dB, of eight percent (*i.e.,* human noise standards limits do allow for some risk; risk is not zero percent and specifically that eight percent of the population is still capable of developing noise-induced hearing loss exceeding 25 dB when exposed to the 85 dB NIOSH level).

Finally, we note that a group of scientists recently published an update to their original, seminal publication concerning noise exposure criteria to predict the onset of auditory effects in marine mammals (Southall *et al.,* 2007, 2019a), the topic of this comment. The newer publication evaluates the recommendations of the original publication in light of subsequent scientific findings, including those findings that form the basis for the recommendations of NMFS (2018). While Southall *et al.* (2019a) provide recommendations for future research that could lead to revisions, the fundamental aspects of an evaluation of the onset of auditory effects for the marine mammals considered in this ITR (*i.e.,* auditory weighting functions and noise exposure criteria) are identical to those presented by NMFS (2018) and incorporated into the modeling process developed for this ITR.

Sound Field Modeling

Comment: NRDC asserts that NMFS has not appropriately accounted for hard-bottom habitat in our propagation analysis, stating that there are areas of hard bottom in the GOM and that we cannot assume that proposed surveys will take place entirely in areas with soft or sandy bottoms.

Response: Sound propagation modeling performed in support of BOEM's PEIS and this ITR was developed to adequately represent a wide range of conditions for a variety of parameters, including bottom composition. NMFS does not assume that hard bottom does not exist in the GOM, but rather that it is not sufficiently predominant to warrant specific representation in a propagation modeling exercise covering the whole GOM. As shown in Figure 50 of the modeling report—depicting a compilation of surficial sediment composition available through a hydrographic survey database from NOAA's National Ocean Service and its predecessor, the U.S. Coast and Geodetic Survey—muds and sands are the dominant substrate types throughout the GOM (as stated in our notice of proposed rulemaking), with only small, scattered areas of hard bottom. The Minerals Management Service (MMS) report cited by NRDC, which concerns conversion of seafloor maps existing at the time to MMS-approved GIS format for use in geohazards evaluations, does not contradict this.

Substrate types for propagation modeling are based on grain size, porosity, and shear velocity, etc., and do not include ''hard'' or ''coral'' bottom. It is also important to note that, while some hard bottom habitats would increase propagation due to increased reflectivity, NRDC's statement that coral bottom can ''significantly increase propagation of airgun noise'' is erroneous. In fact, the roughness of the coral habitat would cause severe bottom loss due to scattering. As noted above, bottom composition in the region is mostly mud and sand and, therefore, selection of parameter values associated with these bottom types for propagation modeling is appropriate. We also note that, for the shelf region of the eastern GOM, where sand is predominant, a larger grain size value was selected to account for this. The acoustic modeling provided by Zeddies *et al.* (2015, 2017a) appropriately and reasonably accounts for variability in bottom composition throughout the region.

The modeling process requires the use of simplifying assumptions about oceanographic and seabed parameters, and these assumptions carry some uncertainty, which may lead to uncertainty in the form of variance or error in individual model outputs and in the final estimates of marine mammal acoustic exposures. It is for this reason that parametric uncertainty analysis was performed to evaluate the effects of this uncertainty ''envelope.'' (This analysis was summarized in our notice of proposed rulemaking and described in detail in the modeling report. NRDC does not reference this assessment.) Uncertainties in the results of acoustic propagation modeling were estimated by examining the variation in model outputs when model inputs were offset by realistic errors. The environmental properties were selected so that the median, or expected, value could be compared to a worst-case outcome (*e.g.,* assuming an extreme case of a more reflective bottom), which was generated by selecting extreme values for several input parameters. These comparisons represent the maximum errors in the predicted sound fields that result from incorrect specification of the parameters tested. As described in the modeling report, the greatest uncertainty due to geoacoustic parameters of the sea bottom is 4 dB (in the deep zone). The effect of the geoacoustic uncertainty increased when the sound speed profile was downwardly refracting. In the case of a surface channel (slope zone, winter season), the average difference between the median and worst-case was only 0.5 dB, *i.e.,* in this case the geoacoustic parameters had virtually no effect on the sound levels at the top of the water column (where marine mammals are likely to be present).

Marine Mammal Densities

Comment: NRDC criticized NMFS' use of the Roberts *et al.* (2016) model outputs for purposes of deriving abundance estimates, as used for comparison to exposure estimates herein. NRDC states that we should use the NMFS Stock Assessment Report (SAR) abundance estimates for this purpose, while allowing that model-predicted abundance estimates may be used for ''data-deficient'' stocks. NRDC implies that use of model-predicted abundances would overestimate actual abundances, apparently based on the fact that the density models are informed by many years of data rather than only the most recent year of data. Where model-predicted abundance estimates are used, NRDC recommends that we adjust the averaged model outputs to the lower bound of the standard deviation estimated by the model for each grid cell.

Response: The approach recommended by NRDC is inappropriate. Comparing take estimates generated through use of the outputs of a density model to an unrelated abundance estimate provides a meaningless comparison. As explained in our notice of proposed rulemaking,

we compare the take estimates generated through use of the density outputs to the abundance predicted through use of the model precisely to provide a meaningful comparison of predicted takes to predicted population.

The two potential sources of abundance data—the output of cetacean density models (Roberts *et al.,* 2016) and the available SARs data—provide different results, with the SARs estimates typically much lower. Differences between the two separate sets of abundance estimates result from key methodological differences. In order to produce sufficiently reliable and detailed density surfaces (maps), Roberts *et al.* (2016) combined multiple NMFS cetacean surveys and modeled density using a habitat-based approach (Miller *et al.,* 2013), while the SARs estimates utilized only the most recent NMFS survey and estimated density using traditional distance sampling (Buckland *et al.,* 2001). The two approaches, while compatible and based on a common statistical framework (distance sampling), can yield different results, depending on complex factors such as whether population sizes have changed, or species habitat preferences have shifted over time. Neither approach will necessarily yield a higher abundance estimate than the other, but use of multiple years of data in developing an abundance estimate minimizes the influence of interannual variation in over- or underestimating actual abundance. By linking sightings with environmental conditions, habitat-based density layers represent smoothed surfaces that are not biased by anomalous conditions. This makes them particularly appropriate for the five-year timeframe of this ITR, which will span varying environmental conditions.

To illustrate why this smoothing of interannual variation helps to create a meaningful comparison to take estimates, we provide the extreme example of the GOM Clymene dolphin. NMFS' three most recent SAR abundance estimates for this stock have fluctuated between 129 and 17,355 animals, *i.e.,* varying by a maximum factor of more than 100. For most species, such fluctuations across these ''snapshot'' abundance estimates (*i.e.,* that are based on only the most recent year of survey data) reflect interannual variations in dynamic oceanographic characteristics that influence whether animals will be seen when surveying in predetermined locations, rather than any true increase or decline in population abundance. In fact, NMFS' SARs typically caution that trends should not be inferred from multiple such estimates, that differences in temporal abundance estimates are difficult to interpret without an understanding of range-wide stock abundance, and that temporal shifts in abundance or distribution cannot be effectively detected by surveys that only cover portions of a stock's range (*i.e.,* U.S. waters). The corresponding density model for Clymene dolphins predicts a mean abundance of 11,000 dolphins. Therefore, in this example, NRDC would have us compare takes predicted by a model in which 11,000 dolphins are assumed to exist against an abundance estimate of 129 dolphins. Our goal in assessing predicted takes is to generate a meaningful comparison, which is accomplished through use of the model-predicted abundance.

A second key methodological difference explains the tendency for the model-predicted abundance estimates to be higher than the SARs estimates. SAR abundance estimates are typically underestimates of actual abundance because they do not account for bias on the ability of observers to detect animals—in contrast, Roberts *et al.* (2016) do account for availability bias and perception bias on the probability of sighting an animal. Availability bias occurs when a model assumes that animals are always available to be observed by the survey team when, in fact, they are not. Cetaceans are diving animals; while submerged, they are unavailable. Assuming diving animals are always available results in an underestimation of abundance, because while they are diving they are present but not counted by the survey team. Perception bias occurs when a model assumes that animals will always be detected when they are on the survey trackline, when, in fact, detection is not certain.

With regard to bias correction, NRDC suggests that such corrections are incorporated into NMFS' GOM SARs. However, some correction has been performed only for the more-recently surveyed shelf and coastal stocks of bottlenose dolphin, *i.e.,* four out of the 25 stocks of GOM marine mammals considered herein. NRDC also strangely suggests that ''NMFS doesn't show that applying trackline correction factors consistent with Barlow (2015), who reported trackline detection probabilities for marine mammals in the Pacific, would result in population estimates consistent with the ones the agency has derived from Roberts *et al.* (2016).'' We can safely assume that these would be consistent, given that the models developed by Roberts *et al.* (2016) considered, and in some cases directly incorporated, the correction factors of Barlow (1999) and Barlow and Forney (2007) (the original work upon which Barlow (2015) builds).

These issues, which are typical for NMFS' SAR abundance estimates, are particularly exacerbated for GOM stocks. For the majority of stocks, the most recent abundance estimates are derived from the results of vessel-based surveys in 2009, *i.e.,* even if one believes that such ''snapshot'' estimates are most appropriate, the GOM estimates are out of date and NMFS' guidelines state that data greater than eight years old should not be used for abundance estimates. (We note that more recent survey effort has been conducted, but corresponding abundance estimates have only recently been made available via unpublished draft SARs for most stocks that have yet to be available for public comment or finalized at the time the analyses were completed for these regulations.) More important for cryptic species, *i.e.,* those species that spend little time at the surface and/or are difficult to detect when at the surface, is the lack of any bias correction. For example, the Cuvier's beaked whale—a cosmopolitan species and perhaps the most widespread and most commonly observed species of beaked whale—is officially estimated by NMFS to number 74 individuals in the GOM, a clear underestimate. For purposes of reference, current abundance estimates for the U.S. Pacific and Atlantic stocks—for which some bias corrections have been made—are 3,274 and 5,744 individuals, respectively. Marine mammal scientists working in the GOM have acknowledged that the likely abundance of beaked whales (and other cryptic species, such as *Kogia* spp.) should be expected to be closer to the values predicted by Roberts *et al.* (2016) than those given in the SARs. For example, Dias and Garrison (2016) state that current abundance estimates for *Kogia* spp. may be considerably underestimated due to the cryptic behavior of these species and difficulty of detection in Beaufort sea state greater than one, while density estimates for certain species derived from long-term passive acoustic monitoring are much higher than are estimates derived from visual observations (*e.g.,* Hildebrand *et al.,* 2015). Separately, NMFS' announcement of a negative 90-day finding on a petition to list the GOM Cuvier's beaked whale as endangered (84 FR 11058) included adoption of the abundance estimate of Roberts *et al.* (2016) as being most appropriate. Roberts *et al.* (2015b) summarize this situation: ''Because [NMFS' SAR] estimates are very low relative to the

abundance we estimated, it is likely that if our [density] results are used to estimate population-level impacts from potentially harmful human activities (*i.e.* ''takes'', as defined by the Marine Mammal Protection Act), the estimated impacts will be very high [. . .].''

NRDC suggests that the SARs are an appropriate representation of ''actual'' abundance, whereas the Roberts *et al.* (2016) predictions are not. NRDC also appears to claim, without substantiation, that an abundance estimate derived from multiple years of data would typically overestimate actual abundance. However, these estimates are not directly comparable—not because one represents a ''snapshot,'' while one represents multiple years of data—but because one does not correct for one or more known biases against the probability of observing animals during survey effort, while the other does. Because of this important caveat, NMFS' SAR abundance estimates should not be considered ''actual'' abundance more than any other accepted estimate. Therefore, when multiple estimates of a stock's abundance are available, they should be evaluated based on quality, *e.g.,* does the estimate account for relevant biases, does it minimize the effect of interannual variability, and, importantly, should provide a meaningful comparison. In this light, our use of the Roberts *et al.* (2016) abundance estimates are not a ''radical departure from past practice,'' as claimed by NRDC. Our practice, as mandated by our implementing regulations, is to use the best scientific evidence available. NRDC states that ''NMFS cannot simply discard this Congressionally mandated estimate in favor of the larger population estimates derived from its misapplication of the [. . .] model.'' The statute does not mandate use of the SARs for comparison with take estimates.

Aside from their failure to explain the claim of ''misapplication,'' and the unwarranted implication that we must make use of the model-generated abundance estimates simply because they are larger (and not because they are the best available scientific information), NRDC errs in asserting that the MMPA requires that we use SAR abundance estimates. Section 117 of the MMPA requires the development of SARs, and dictates certain information that SARs must provide. However, there is no part of the MMPA that requires the population abundance estimates given in a SAR to be used in any specific application and, importantly, the MMPA does not even require that the SAR include a best population estimate. The MMPA requires only that SARs provide a minimum population estimate, which is used in the formulation of a potential biological removal (PBR) level, which is then required by section 118 of the MMPA for certain uses in the management of marine mammal take incidental to commercial fisheries. In summary, NRDC's comment reflects an inaccurate interpretation of the available information, and NMFS disagrees with the approach recommended by the comment.

Take Estimates

Comment: The Associations state that ''NMFS substantially overestimates the number of incidental takes predicted to result'' from the specified activity. The comment goes on to discuss the modeling that is ''intentionally designed to overestimate takes,'' and discusses the findings of the *Acoustic Exposure Model Variable Analysis* (Zeddies *et al.,* 2017b) (which was provided for public review in association with the proposed rule). Other industry commenters and the CRE echo these points.

Response: The commenters' statements that NMFS has substantially overestimated takes are incorrect. We used current scientific information and state-of-the-art acoustic propagation and animal movement modeling to reasonably estimate potential exposures to noise. Chevron stated that the modeling used ''admittedly erroneous models'' but provides no supporting information or citation. Chevron further describes ''errors in methodology'' and ''admissions'' that the modeling methodology and the data used are not ''rigorous science,'' while asserting that NMFS ''repeatedly rejects and omits science that is available.'' Chevron's comments do not provide any illumination as to what specifically these errors may be, what data it believes is flawed, or what ''science'' NMFS has rejected or omitted. NMFS has considered all relevant available scientific information.

To summarize in a basic way, it is foreseeable that a large amount of noise-producing activity, such as BOEM's application and PEIS describe, results in a substantial number of predicted acoustic exposures. Despite recommending that ''a better approach would be to use the best and most likely values for all of the input variables to the model,'' the Associations' comments do not include substantive recommendations for improvement. They do not specify which of the many data inputs are ''conservative'' or to what degree, nor do they recommend alternatives to the choices that were painstakingly documented in developing the modeling.

As was noted in the notice of proposed rulemaking, NMFS disagrees with the Associations' characterization of the modeling and with certain statements in BOEM's draft PEIS regarding the modeling that are frequently cited by the Associations. As we stated in the notice, BOEM's draft PEIS included unsupported and erroneous statements that characterized the modeling results—which BOEM and NMFS developed collaboratively—as ''unrealistically high,'' ''overly conservative,'' and representative of a ''worst-case scenario,'' among other things. These statements were included in that document without NMFS' prior knowledge. Importantly, as a result of NOAA's public comments on that draft PEIS in its role as a cooperating agency, the statements referenced by the commenters were properly removed from the final PEIS, which more accurately characterizes the modeling process and results.

The Associations take out of context a number of statements from the discussion in NMFS' notice of proposed rulemaking of the modeling process, data inputs, and user selections. We address these in turn:

- The Associations quote NMFS as stating that our modeling likely ''leads to substantial overestimates of the numbers of individuals potentially disturbed [and] . . . to an overestimation of the population-level consequences of the estimated exposures'' and that, even with the application of a correction factor, the modeling still represents an ''overestimate.'' (83 FR 29261, 29291). But the full statement in our notice is as follows: ''While the modeling provides reasonable estimates of the total number of instances of exposure exceeding Level B harassment criteria, it is likely that it leads to substantial overestimates of the numbers of individuals potentially disturbed, given that all animals within the areas modeled are unlikely to be completely replaced on a daily basis. Therefore, in assuming an increased number of individuals impacted, these results would lead to an overestimation of the potential population-level consequences of the estimated exposures.'' Our point was that, although the modeling provides reasonable estimates of the total amount of acoustic exposures, it would be an overestimate to interpret this total as representative of the number of individuals impacted. We then discussed our development of a correction factor to address this issue

(see Table 12 of the notice of proposed rulemaking).

• The Associations highlight our ''admission'' that the modeling is purposely conservative. We address this below by explaining why, in some cases, it is appropriate to make reasonably conservative choices.

• The Associations mischaracterize the Wood *et al.* (2012) Level B harassment criteria as ''expressly rejecting the best available science.'' In discussing different versions of frequency weighting functions, we stated that ''Type III filters'' are better designed to predict the onset of auditory injury, while explaining why use of ''Type I filters'' (or M-weighting) was appropriate for use in evaluation of Level B harassment (83 FR 29248). The Type III filters, as adopted by NMFS (2018), were appropriately used for evaluation of Level A harassment (which includes auditory injury).

• Although characterized as ''conservative'' NMFS has made reasonable choices through the application of professional judgment by subject matter experts. For example, using single airgun modeling results in lieu of boomer results was a choice made for computational efficiency precisely because it was not significantly influential on the results. (83 FR 29251). And selecting an estimate for standard deviation in an investigation of model sensitivity to source level variance was in response to a concern of the commenters—overall sensitivity of the model to uncertainty in input parameters and the resulting uncertainty in model results—and had no bearing on the model results (83 FR 29257).

• The Associations also highlight our statement that ''the lack of aversion within the animal movement modeling process results in overestimates of potential injurious exposure,'' without noting that we corrected this issue through a post-hoc correction to reasonably account for aversion.

The modeling required that a number of assumptions and choices be made by subject matter experts and, in most cases, the most representative data or methods were used. As we acknowledged, in some cases, some assumptions or choices are purposely conservative (where the conservative choice is reasonable) to minimize the likelihood of underestimating the potential impacts on marine mammals represented by a specified level of survey effort. These are reasonable, scientifically acceptable choices that do not create, as the Associations state, ''multiplicatively accumulating bias as the conservative assumptions interact with each other to multiply uncertainty''). To the extent that the results of the modeling may be conservative, they are the most credible, science-based information available at this time (assuming the notional 8,000 in^3 array and activity level projections specified by BOEM in the petition).

These comments provide no reasonable justification as to why the modeling results in overestimates of take. The Associations instead seem to rely on the incorrect premise that real-time mitigation would somehow reduce actual levels of acoustic exposure (versus reducing the duration and/or intensity of exposure). NMFS disagrees that ''each of the inputs is purposely developed to be conservative''—again, the Associations do not provide any support for this assertion, and none is to be found in the administrative record for this action. Although it may be correct that some conservativeness accumulates throughout the analysis, the Associations do not adequately describe the nature of conservativeness associated with model inputs or the degree to which such conservativeness ''accumulates'' (either quantitatively or qualitatively), nor do they offer more appropriate alternatives.

The modeling effort incorporated representative sound sources and projected survey scenarios (both based on the best available information obtained by BOEM), physical and geological oceanographic parameters at multiple locations within the GOM and during different seasons, the best available information regarding marine mammal distribution and density, and available information regarding known behavioral patterns of the affected species. Current scientific information and state-of-the-art acoustic propagation and animal movement modeling were used to reasonably estimate potential exposures to noise. The notice of proposed rulemaking described all aspects of the modeling effort in significant detail, including numerous investigations (test scenarios) designed by the agencies to understand various model sensitivities and the effects of certain choices on model results. The modeling report itself was provided for public review, in association with both BOEM's PEIS and NMFS' notice of proposed rulemaking.

We quote the Marine Mammal Commission's public comment on this topic: ''Complex sound propagation and animat modeling was used to estimate the numbers of potential takes from various types of geophysical surveys in the Gulf. NMFS received comments from industry operators suggesting that the modeling results were overly conservative and that the take estimates were 'higher than BOEM expects would actually occur in a real world environment.' However, the Commission has reviewed the modeling approach and parameters used to estimate takes and believes they represent the best available information regarding survey scenarios, sound sources, physical and oceanographic conditions in the Gulf, and marine mammal densities and behavior. As such, the Commission agrees with NMFS and BOEM that the resulting take estimates were conservative but reasonable, thereby minimizing the likelihood that actual takes would be underestimated.''

The CRE says, absent citation or reference, that ''everyone agrees'' that takes are overestimated. Their assertion that we ''greatly overestimate both exposures and takes'' is based on their view that we relied on ''flawed models and on Risk Assessment Frameworks that are unfinished and have not been peer reviewed.'' While the Associations focus on supposed conservatism built into the modeling process, the CRE appears to believe that there is some unknown process by which modeled exposures are ''converted'' to takes. (''These take overestimates stem primarily from [NMFS'] use of various models to convert exposures to takes [. . .]. They have no credible framework for converting exposure to takes.'') We believe the CRE is likely referring to the EWG risk assessment framework, which is a systematic analysis used as an aid to understanding the significance of the modeled takes to the affected stocks. However, this framework plays no role in the estimation of takes (takes are an input to the EWG framework) and is not itself a ''model.'' CRE also makes the claim, addressed elsewhere in this response, that the take estimates ''do not include the impact of mitigation measures.''

Regarding the modeling variable analysis submitted by the Associations (Zeddies *et al.,* 2017b), we have fully considered the results in developing this final ITR,[3] but do not find that the

[3] The Associations misunderstand the timeline relating to the availability of the report for NMFS' consideration for developing the proposed rule. (''NMFS inexplicably dismisses [the report] as being provided too late despite the fact that it was provided to NMFS 11 months ago''). We must correct the record on this point. The analysis was submitted by IAGC for NMFS' consideration on September 6, 2017, well after the total 45-day comment period on the petition had closed (81 FR 88664 (December 8, 2016, notice of receipt of petition providing for 30-day comment period); 81 FR 92788 (extending comment period an additional 15 days to January 23, 2017)). The final PEIS was then issued in August 2017. Subsequent materials could no longer be considered as NMFS prepared

analysis supports any changes to the modeling. IAGC and API contracted with JASCO Applied Sciences, which performed the original modeling effort, to conduct additional analysis regarding the effect that various acoustic model parameters or inputs have on the outputs used to estimate numbers of animals exposed to threshold levels of sound from geophysical sources used in the GOM. The analysis investigated five factors:

- Airgun array size (including total volume, number of array elements, element air pressure, array geometry and spacing) used in source and propagation models;
- Acoustic threshold criteria and associated weighting used to calculate exposures;
- Animal densities used for adjusting simulated computer model exposures to potential real-world animal exposures;
- Natural aversive behaviors of marine mammals; and
- The addition of mitigative measures that lessen the potential for animals' exposure to threshold levels of seismic sound.

The primary finding of the Acoustic Exposure Model Variable Analysis is that use of appropriate acoustic injury criteria (*i.e.,* NMFS, 2016, 2018) decreased predictions of injurious exposure. At the time the Associations submitted this report, they were apparently unaware that, as described herein, *NMFS had already made the change that the Associations' analysis indicates is most significant:* The appropriate acoustic injury criteria (*i.e.,* NMFS, 2016, 2018), representing the best available science, were used in NMFS' analysis in the proposed rule. Other significant investigations in the Associations' modeling variable analysis included an alternative array size and quantitative consideration of animal aversion and mitigation effectiveness. We address these below.

The Associations state that the selected array (8,000 in^3) is unrealistically large, resulting in an overestimation of likely source levels and, therefore, size of the sound field with which marine mammals would interact. Zeddies *et al.* (2017b) evaluated the use of a substitute 4,130 in^3 array, finding that reduction in array volume reduces the number of predicted exposures. Use of a smaller airgun array volume with lower source level unsurprisingly creates a smaller ensonified area resulting in fewer numbers of animals expected to exceed exposure thresholds. However, selection of the representative array to be used in the modeling was directed by the ITR applicant (*i.e.,* BOEM). Given that the array used was selected by the applicant and included in the petition for the ITR (which was available for public comment in our **Federal Register** notice of receipt of BOEM's application), any complaint regarding this or other aspects of the specified activity, including activity level projections and representative source characteristics or survey geometry, should be addressed to BOEM. According to BOEM, the particular array was selected as a realistic representative proxy after BOEM's discussions with individual geophysical companies. An 8,000-in^3 array was considered reasonable, as it falls within the range of typical airgun arrays currently used in the GOM, which are roughly 4,000–8,475 in^3 (BOEM, 2017). According to BOEM's permitting records, approximately one-third of arrays used in a recent year were 8,000 in^3 or greater. Also, as noted previously, regardless of the representative airgun array size used to model the number of takes of marine mammals for the purposes of the analysis conducted in this rule, the analysis of the take and the associated findings are applicable to take incurred from the use of other sizes of airgun arrays, including smaller ones such as those modeled in the Acoustic Exposure Model Variable Analysis report.

The Associations' comments also focus significantly on the need to incorporate quantitative adjustments to account for aversion and mitigation. As discussed in the notice of proposed rulemaking, the effects of mitigation and aversion on exposure estimates were investigated via test scenarios, and NMFS acknowledges that both of these factors would lead to a reduction in likely injurious exposure to some degree. (As noted above, the issue of aversion was addressed via post-hoc quantitative adjustment). Ultimately these factors were not quantified in the modeling because, in summary, there is too much inherent uncertainty regarding the effectiveness of detection-based mitigation for these activities to support any reasonable quantification of its effect in reducing injurious exposure, and there is too little information regarding the likely level of onset and degree of aversion to justify its use in the modeling via precise quantitative control of animat movements (as compared to post-hoc adjustment of the modeling results, as is done here). Zeddies *et al.* (2017b) found that incorporation of aversion into the modeling process appears to reduce the number of predicted injurious exposures, though the magnitude of the effect was variable. The authors state that this variability is likely because there are few samples of injurious exposure exceedance, meaning that the statistical variability of re-running simulations is evident.

While aversion and mitigation implementation are expected to reduce somewhat the modeled levels of injurious exposure, it is important to note that they would not be expected to result in any meaningful reduction in assumed exposures resulting in Level B harassment, nor in total takes by harassment, as any averted injurious (Level A harassment) takes would not be alleviated, but rather would be appropriately changed to behavioral disturbance (Level B harassment) takes. The Associations, acknowledging the analysis we have done to produce more realistic estimates of potential Level A harassment, are focused on the supposed overestimation of Level B harassment. Yet their focal areas of complaint are limited to array size, which is a decision made by BOEM, and mitigation effectiveness, a factor that would have no effect on the amount of predicted Level B harassment. With regard to the large number of other data inputs and/or choices made in the modeling, the Associations conclude that ''NMFS has admittedly chosen conservative numerical values to assess allegedly uncertain variables to overestimate adverse effects,'' without specifically identifying a single issue where they feel a meaningful data or process error was made.

Comment: The CRE recommends a different method of estimating potential take of marine mammals, stating that NMFS ''should continue to use Line Transect to estimate exposures and takes.''

Response: Although CRE does not actually describe the method they recommend, we infer that they are referencing a relatively simplistic method historically used in estimating acoustic exposures, typically on a survey-specific basis. Essentially, this methodology consists of: (1) Determination of estimated isopleth ranges from the source for a specified acoustic threshold (nominally this threshold was historically the 160 dB

the draft proposed rule for interagency review. The rule was submitted to OMB on October 3, 2017. Upon submission, no further changes could be made to the rule other than those arising pursuant to the interagency review. The Office of Information and Regulatory Affairs cleared the proposed rule on June 11, 2018, whereupon it was submitted to the **Federal Register** on June 12 and published on June 22. Therefore, the analysis was not able to be considered by NMFS in the notice of proposed rulemaking despite the length of time between submission of the report to NMFS and publication of the proposed rule.

rms received level for Level B harassment); (2) assumption that a cylinder whose radius matched the range to these isopleths and encompassed the entire water column was ensonified to that threshold; (3) calculating the surface area ensonified by this water column as the source moved along its track; and (4) multiplying that resultant ensonified surface area by the density of each marine mammal species present to estimate potential harassment takes. (Note that this process is somewhat more complicated for evaluation of 3D surveys.) In this case, following a modeling workshop held in 2014 as a collaborative effort between the American Petroleum Institute (API) and the International Association of Geophysical Contractors (IAGC), NMFS, and BOEM, the agencies determined that it would be most appropriate to collaborate on a more sophisticated approach, in which more detailed modeling of the source and its properties, the acoustic propagation field in three dimensions, and three dimensional animal placement and movement is used to better calculate the potential impacts to marine mammals. To summarize aspects of the process:

- *Operational Scenario Development:* According to BOEM, the source and operations scenarios presented in the petition and which underlie the modeling effort were based on historical permit information. BOEM sought industry input and used historical data to develop the specification of the nominal airgun array. The array specifications and level of survey effort were intended to be representative of future activity, not a conservative over-estimate.
- *Acoustic Modeling:* The propagation model output has been compared with measured data and been shown to be reliable. The physical inputs to the model are the best available data. The full sound field was used to predict exposures, not a 'maximum over depth' simplification.
- *Animal Modeling:* The animal movement model used is one of the few models available that incorporates full four-dimensional movement. Properly applied, such models provide the most accurate predictions of acoustic exposure.
- *Animal Density:* The density and distribution data used were the best available and represent the latest synthesis and analysis.
- *Effects Criteria:* The historical Level B harassment threshold of 160 dB has been criticized for multiple reasons, and the use of the Wood *et al.* (2012) criteria in this analysis allows for the application of current scientific information to address some of the issues raised. The best available science relating to potential auditory injury, as synthesized in NMFS (2018) and more recently described by Southall *et al.* (2019a), was used in the modeling effort.

Taking advantage of these more sophisticated tools allows for a more accurate and detailed model of the exposures of a population of marine animals in the three dimensions and time, and also provides: (1) Statistical data on each individually modeled animal and the population as a whole; (2) rate of exposure (threshold exceedance per unit time) over the duration of a survey; and (3) the data necessary to determine effects based on more sophisticated thresholds, such as cumulative sound exposure level. A comparison of these methods—animat method involving three-dimensional animal movement modeling and static distribution, in which a static two-dimensional density is overlaid on a simplified representation of the sound field—found that differences consistently arise between the two methods. The static distribution method was found to consistently underestimate the number of takes by Level B harassment compared with the animat method. In addition, repeating many simulations with the animat method provides a more robust risk assessment and provides a better measure of variability (Schecklman *et al.,* 2011).

We agree with CRE (and our own statements, as cited by CRE) that sophisticated modeling is not a requirement of the MMPA process. However, all take estimation requires the use of modeling; the difference between various approaches to estimating take is the degree of sophistication of the modeling approach employed. We note that the National Science Foundation (NSF) typically utilizes the method espoused by CRE in take authorization requests for specific surveys. In order to derive the necessary estimated isopleth distance, NSF applications typically use Nucleus (a source model) in conjunction with ray trace modeling to approximate propagation of the acoustic signatures. The modeling developed by BOEM and NMFS supports both BOEM's 2017 PEIS and the analyses conducted for this rulemaking, and additionally is available for use in supporting LOA applications to maximize efficiency of the LOA process for disparate applicants. However, we have made clear that LOA applicants are free to pursue a different method of estimating takes than the modeling effort developed collaboratively by NMFS and BOEM. Use of a different analytical method in support of an LOA application will necessarily require additional review.

CRE compares ''Line Transect'' modeling performed in support of a 2004 Minerals Management Service Environmental Assessment to that developed in support of this effort, stating that the take estimates generated in that effort are ''orders of magnitude smaller than the take estimates'' evaluated here. CRE's erroneous implication is that the only difference between the two efforts is the modeling approach. (''The great difference between GOM takes as estimated by Line Transect, and as estimated by [NMFS]'s current models, demonstrates just how inaccurate and exaggerated the model take estimates are.'') However, the inputs to the two efforts are significantly different. Most notably, the assumptions relating to projected effort, animal occurrence, and sound source output are not comparable. Effort projections for the 2004 modeling were roughly 53 percent of those given by BOEM for the high effort scenario in the PEIS, and included only relatively archaic 3D survey geometries, versus the more complex azimuth designs and coil surveys considered herein. Advances in cetacean density modeling provide estimates for use here that are, in some cases, multiple orders of magnitude greater than the poor estimates used in the 2004 effort. The 15-year old modeling held up by CRE as a good example assumed a 4,550 in^3 acoustic source with a uniform 3 km isopleth distance to the 160-dB rms threshold. BOEM specified use of an 8,000 in^3 acoustic source for the modeling effort here, with a mean distance to the 160 dB isopleths of 12.7 km, but even more recent modeling of a more comparable source (4,130 in^3) shows that the isopleth distance may be as large as 8.4 km, depending on the season (Zeddies *et al.,* 2017b). Moreover, the 2004 modeling reduced even that ensonified area by an arbitrary 50 percent to account for an ''elliptical zone of ensonification.'' It is clear that the two modeling efforts are in no way comparable.

Comment: NRDC asserts that NMFS fails to account for forms of injury that are reasonably anticipated, stating that permanent hearing loss (*i.e.,* Level A harassment) may occur through mechanisms other than PTS, and that behaviorally-mediated injury may occur as a result of exposure to airgun noise. NRDC states that NMFS must account for these mechanisms in its assessment of potential injury.

Response: NMFS is aware of the work by Kujawa and Liberman (2009), which is cited by NRDC. The authors report that in mice, despite completely reversible threshold shifts that leave cochlear sensory cells intact, there were synaptic level changes and delayed cochlear nerve degeneration. However, the large threshold shifts measured (*i.e.,* maximum 40 dB) that led to the synaptic changes shown in this study are within the range of the large shifts used by Southall *et al.* (2007, 2019a) and in NMFS' 2018 Revised Technical Guidance to define PTS onset (*i.e.,* 40 dB). It is unknown whether smaller levels of TTS would lead to similar changes or what may be the long-term implications of irreversible neural degeneration. The effects of sound exposure on the nervous system are complex, and this will be re-examined as more data become available. It is important to note that NMFS' 2018 Revised Technical Guidance incorporated various conservative factors, such as a 6-dB threshold shift to represent TTS onset (*i.e.,* minimum amount of threshold shift that can be differentiated in most experimental conditions); the incorporation of exposures only with measured levels of TTS (*i.e.,* did not incorporate exposures where TTS did not occur); and assumed no potential of recovery between intermittent exposures. NMFS disagrees that consideration of likely PTS is not sufficient to account for reasonably expected incidents of auditory injury.

There is no conclusive evidence that exposure to airgun noise results in behaviorally-mediated forms of injury. Behaviorally-mediated injury (*i.e.,* mass stranding events) has been primarily associated with beaked whales exposed to mid-frequency active (MFA) navy sonar. Military tactical sonar and the alerting stimulus used in Nowacek *et al.* (2004) are very different from the noise produced by airguns. One should therefore not expect the same reaction to airgun noise as to these other sources. Yet NRDC infers that because strandings of beaked whales have been correlated with navy MFA sonar use, strandings are also likely to occur due to seismic surveys. As explained below, navy MFA sonar is very different from airguns, and it is not reasonable to assume that airguns will cause the same effects as navy MFA sonar (including strandings).

To understand why navy MFA sonar affects beaked whales differently than airguns do, it is important to note the distinction between behavioral sensitivity and susceptibility to auditory injury. To understand the potential for auditory injury in a particular marine mammal species in relation to a given acoustic signal, the frequency range the species is able to hear is critical, as well as the species' auditory sensitivity to frequencies within that range. Current data indicate that not all marine mammal species have equal hearing capabilities across all frequencies and, therefore, species are grouped into hearing groups with generalized hearing ranges assigned on the basis of available data (Southall *et al.,* 2007, 2019a). Hearing ranges as well as auditory sensitivity/susceptibility to frequencies within those ranges vary across the different groups. For example, in terms of hearing range, the high-frequency cetaceans (*e.g., Kogia* spp.) have a generalized hearing range of frequencies between 275 Hz and 160 kHz, while mid-frequency cetaceans—such as dolphins and beaked whales—have a generalized hearing range between 150 Hz to 160 kHz. Regarding auditory susceptibility within the hearing range, while mid-frequency cetaceans and high-frequency cetaceans have roughly similar hearing ranges, the high-frequency group is much more susceptible to noise-induced hearing loss during sound exposure, *i.e.,* these species have lower thresholds for these effects than other hearing groups (NMFS, 2018). Referring to a species as behaviorally sensitive to noise simply means that an animal of that species is more likely to respond to lower received levels of sound than an animal of another species that is considered less behaviorally sensitive. So, while dolphin species and beaked whale species—both in the mid-frequency cetacean hearing group—are assumed to (generally) hear the same sounds equally well and be equally susceptible to noise-induced hearing loss (auditory injury), the best available information indicates that a beaked whale is more likely to behaviorally respond to that sound at a lower received level compared to an animal from other mid-frequency cetacean species that is less behaviorally sensitive. This distinction is important because, while beaked whales are more likely to respond behaviorally to sounds than are many other species (even at lower levels), they cannot hear the predominant, lower frequency sounds from seismic airguns as well as sounds that have more energy at frequencies that beaked whales can hear better (such as navy MFA sonar).

Navy MFA sonar affects beaked whales differently than airguns do because it produces energy at different frequencies than airguns. Mid-frequency cetacean hearing is generically thought to be best between 8.8 to 110 kHz, *i.e.,* these cutoff values define the range above and below which a species in the group is assumed to have declining auditory sensitivity, until reaching frequencies that cannot be heard (NMFS, 2018). However, beaked whale hearing is likely best within a higher, narrower range (20–80 kHz, with best sensitivity around 40 kHz), based on a few measurements of hearing in stranded beaked whales (Cook *et al.,* 2006; Finneran *et al.,* 2009; Pacini *et al.,* 2011) and several studies of acoustic signals produced by beaked whales (*e.g.,* Frantzis *et al.,* 2002; Johnson *et al.,* 2004, 2006; Zimmer *et al.,* 2005). While precaution requires that the full range of audibility be considered when assessing risks associated with noise exposure (Southall *et al.,* 2007, 2019a), animals typically produce sound at frequencies where they hear best. More recently, Southall *et al.* (2019a) suggested that certain species amongst the historical mid-frequency hearing group (beaked whales, sperm whales, and killer whales) are likely more sensitive to lower frequencies within the group's generalized hearing range than are other species within the group and state that the data for beaked whales suggest sensitivity to approximately 5 kHz. However, this information is consistent with the general conclusion that beaked whales (and other mid-frequency cetaceans) are relatively insensitive to the frequencies where most energy of an airgun signal is found. Navy MFA sonar is typically considered to operate in the frequency range of approximately 3–14 kHz (D'Amico *et al.,* 2009), *i.e.,* outside the range of likely best hearing for beaked whales but within or close to the lower bounds, whereas most energy in an airgun signal is radiated at much lower frequencies, below 500 Hz (Dragoset, 1990).

It is important to distinguish between energy (loudness, measured in dB) and frequency (pitch, measured in Hz). In considering the potential impacts of mid-frequency components of airgun noise (1–10 kHz, where beaked whales can be expected to hear) on marine mammal hearing, one needs to account for the energy associated with these higher frequencies and determine what energy is truly ''significant.'' Although there is mid-frequency energy associated with airgun noise (as expected from a broadband source and as we acknowledged in the notice of proposed rulemaking), airgun sound is predominantly below 1 kHz (Breitzke *et al.,* 2008; Tashmukhambetov *et al.,* 2008; Tolstoy *et al.,* 2009). As stated by Richardson *et al.* (1995), ''[. . .] most emitted [seismic airgun] energy is at 10–120 Hz, but the pulses contain some

energy up to 500–1,000 Hz.'' Tolstoy *et al.* (2009) conducted empirical measurements, demonstrating that sound energy levels associated with airguns were at least 20 decibels (dB) lower at 1 kHz (considered ''mid-frequency'') compared to higher energy levels associated with lower frequencies (below 300 Hz) (''all but a small fraction of the total energy being concentrated in the 10–300 Hz range'' [Tolstoy *et al.,* 2009]), and at higher frequencies (*e.g.,* 2.6–4 kHz), power might be less than 10 percent of the peak power at 10 Hz (Yoder, 2002). Energy levels measured by Tolstoy *et al.* (2009) were even lower at frequencies above 1 kHz. In addition, as sound propagates away from the source, it tends to lose higher-frequency components faster than low-frequency components (*i.e.,* low-frequency sounds typically propagate longer distances than high-frequency sounds) (Diebold *et al.,* 2010). Although higher-frequency components of airgun signals have been recorded, it is typically in surface-ducting conditions (*e.g.,* DeRuiter *et al.,* 2006; Madsen *et al.,* 2006) or in shallow water, where there are advantageous propagation conditions for the higher frequency (but low-energy) components of the airgun signal (Hermannsen *et al.,* 2015). This should not be of concern because the likely behavioral reactions of beaked whales that can result in acute physical injury would result from noise exposure at depth (because of the potentially greater consequences of severe behavioral reactions) and because, even if near-surface exposure to such higher-frequency components were of concern, oceanographic conditions in the GOM do not consistently support such ducting conditions. In summary, the frequency content of airgun signals is such that beaked whales will not be able to hear the signals well (compared to MFA sonar), especially at depth where we expect the consequences of noise exposure could be more severe.

Aside from frequency content, there are other significant differences between MFA sonar signals and the sounds produced by airguns that minimize the risk of severe behavioral reactions that could lead to strandings or deaths at sea, *e.g.,* significantly longer signal duration, horizontal sound direction, typical fast and unpredictable source movement. All of these characteristics of MFA sonar tend towards greater potential to cause severe behavioral or physiological reactions in exposed beaked whales that may contribute to stranding. Although both sources are powerful, MFA sonar contains significantly greater energy in the mid-frequency range, where beaked whales hear better. Short-duration, high energy pulses—such as those produced by airguns—have greater potential to cause damage to auditory structures (though this is unlikely for mid-frequency cetaceans, as explained later in this document), but it is longer duration signals that have been implicated in the vast majority of beaked whale strandings. Faster, less predictable movements in combination with multiple source vessels are more likely to elicit a severe, potentially anti-predator response. Of additional interest in assessing the divergent characteristics of MFA sonar and airgun signals and their relative potential to cause stranding events or deaths at sea is the similarity between the MFA sonar signals and stereotyped calls of beaked whales' primary predator: The killer whale (Zimmer and Tyack, 2007). Although generic disturbance stimuli—as airgun noise may be considered in this case for beaked whales—may also trigger antipredator responses, stronger responses should generally be expected when perceived risk is greater, as when the stimulus is confused for a known predator (Frid and Dill, 2002). In addition, because the source of the perceived predator (*i.e.,* MFA sonar) will likely be closer to the whales (because attenuation limits the range of detection of mid-frequencies) and moving faster (because it will be on faster-moving vessels), any antipredator response would be more likely to be severe (with greater perceived predation risk, an animal is more likely to disregard the cost of the response; Frid and Dill, 2002). Indeed, when analyzing movements of a beaked whale exposed to playback of killer whale predation calls, Allen *et al.* (2014) found that the whale engaged in a prolonged, directed avoidance response, suggesting a behavioral reaction that could pose a risk factor for stranding. Overall, these significant differences between sound from MFA sonar and the mid-frequency sound component from airguns and the likelihood that MFA sonar signals will be interpreted in error as a predator are critical to understanding the likely risk of behaviorally-mediated injury due to seismic surveys.

The available scientific literature also provides a useful contrast between airgun noise and MFA sonar regarding the likely risk of behaviorally-mediated injury. There is strong evidence for the association of beaked whale stranding events with MFA sonar use, and particularly detailed accounting of several events is available (*e.g.,* a 2000 Bahamas stranding event for which investigators concluded that MFA sonar use was responsible; Evans and England, 2001). D'Amico *et al.* (2009) reviewed 126 beaked whale mass stranding events over the period from 1950 (*i.e.,* from the development of modern MFA sonar systems) through 2004. Of these, there were two events where detailed information was available on both the timing and location of the stranding and the concurrent nearby naval activity, including verification of active MFA sonar usage, with no evidence for an alternative cause of stranding. An additional ten events were at minimum spatially and temporally coincident with naval activity likely to have included MFA sonar use and, despite incomplete knowledge of timing and location of the stranding or the naval activity in some cases, there was no evidence for an alternative cause of stranding.[4] Separately, the International Council for the Exploration of the Sea reported in 2005 that, worldwide, there have been about 50 known strandings, consisting mostly of beaked whales, with a potential causal link to MFA sonar (ICES, 2005). In contrast, very few such associations have been made to seismic surveys, despite widespread use of airguns as a geophysical sound source in numerous locations around the world.

A more recent review of possible stranding associations with seismic surveys (Castellote and Llorens, 2016) states plainly that, ''[s]peculation concerning possible links between seismic survey noise and cetacean strandings is available for a dozen events but without convincing causal evidence.'' The authors' ''exhaustive'' search of available information found ten events worth further investigation via a ranking system representing a rough metric of the relative level of confidence offered by the data for inferences about the possible role of the seismic survey in a given stranding event. Only three of these events involved beaked whales. Whereas D'Amico *et al.* (2009) used a 1–5 ranking system, in which ''1'' represented the most robust evidence connecting the event to MFA sonar use, Castellote and Llorens (2016) used a 1–6 ranking system, in which ''6'' represented the most robust evidence

[4] The U.S. Navy has publicly stated its agreement that five such events since 1996 were associated in time and space with MFA sonar use, either by the U.S. Navy alone or in joint training exercises with the North Atlantic Treaty Organization. The U.S. Navy additionally noted that, as of 2017, a 2014 beaked whale stranding event in Crete coincident with naval exercises was under review and had not yet been determined to be linked to sonar activities (DoN, 2017).

connecting the event to the seismic survey. As described above, D'Amico *et al.* (2009) found that two events were ranked ''1'' and ten events were ranked ''2'' (*i.e.,* 12 beaked whale stranding events were found to be associated with MFA sonar use). In contrast, Castellote and Llorens (2016) found that none of the three beaked whale stranding events achieved their highest ranks of 5 or 6.[5] However, we acknowledged in the notice of proposed rulemaking that one of these stranding events, involving two Cuvier's beaked whales, was contemporaneous with and reasonably associated spatially with a 2002 seismic survey in the Gulf of California, and here acknowledge the same for the 2007 Gulf of Cadiz seismic survey discussed by Castellote and Llorens (also involving two Cuvier's beaked whales). However, neither event was considered a ''true atypical mass stranding'' (according to Frantzis [1998]) as used in the analysis of Castellote and Llorens (2016). While we agree with the authors that this lack of evidence should not be considered conclusive, it is clear that there is very little evidence that seismic surveys should be considered as posing a significant risk of acute harm to marine mammals.

Comment: NRDC asserts that NMFS has failed to account adequately for the effects of stress on marine mammals.

Response: As NRDC acknowledges, we addressed the available literature regarding potential impacts of stress resulting from noise exposure in marine mammals. As described in that discussion, stress responses are complicated and may or may not have meaningful impacts on marine mammals. NRDC implies that NMFS must (1) enumerate takes resulting from stress alone and (2) specifically address stress in its negligible impact analysis. The effects of stress are not straightforward, and there is no information available to inform an understanding of whether it is reasonably likely that an animal may experience a stress response upon noise exposure that would not be accounted for in NMFS' existing enumeration of takes via exposure to noise, which includes an accounting for exposures above received levels as low as 140 dB rms (and as low as 120 dB rms for beaked whales). NRDC provides nothing informative regarding how such an analysis might be carried out. With regard to NMFS' negligible impact analysis, we believe that the potential effects of stress are addressed and subsumed within NMFS' considerations of severity of effect and vulnerability of affected populations. Similarly, NRDC provides no justification as to why stress would appropriately be considered separately in this analysis, and no useful recommendation as to how to do so, if appropriate. We believe we have appropriately acknowledged the potential effects of stress, and that these potential effects are accounted for within our overall assessment of potential effects on marine mammals.

Comment: NRDC states that masking results in take of marine mammals and that NMFS must account for this in its take estimates.

Response: We addressed our consideration of masking in greater detail in a previous response. We acknowledge that masking may impact marine mammals, particularly baleen whales such as the Bryde's whale, and particularly when considered in the context of the full suite of regulated and unregulated anthropogenic sound contributions overlaying an animal's acoustic habitat. We acknowledge that masking can constitute a take, depending on the particular circumstances, but do not agree that masking effects from the incremental noise contributions of individual activities or sound sources always rise to the level of take. Further, not all takes are readily quantifiable. In this case, while masking is considered in the analysis, we do not believe it will result in take of marine mammals beyond those that have already been quantified as taken by behavioral harassment. Specifically, in the case of these proposed activities, in the event that some masking incidents rise to the level of a take, we would expect them to be accounted for in the quantified exposures above the harassment thresholds. Given the short duration of expected noise exposures, any take by masking in the case of these surveys would be most likely to be incurred by individuals either exposed briefly to notably higher levels or those that are generally in the wider vicinity of the source for comparatively longer times. Both of these situations would be captured in the enumeration of takes by Level B harassment, which accounts for takes that may occur upon exposure at relatively low levels of received sound (*e.g.,* 140 dB).

Comment: MMC commented that the aversion adjustment applied to estimates of Level A harassment proposed by NMFS for low- and high-frequency cetaceans is not supported. NRDC provided similar comments.

Response: NMFS disagrees with these comments, and clarifies our position given the misunderstanding evident in the comments. The MMC cites NMFS' statements that ''too little is known about the factors that lead to avoidance of sounds to quantify aversive behavior for survey activities when modeling marine mammal exposure to sound'' and that ''aversion is a context-dependent behavioral response affected by biological factors, including energetic and reproductive state, sociality, and health status of individual animals'' in characterizing our subsequent use of a post-hoc correction factor to account for aversion as an ''apparent contradiction.'' Similarly, NRDC cites NMFS' statement that aversion was not quantified in the modeling process due to lack of information regarding species-specific degree of aversion and level of onset in criticizing the adjustment that was later made.

Aversion is a known real-world phenomenon. It is well-known that animals will avoid unpleasant stimuli, such as very high received levels of sound. A large and growing literature has demonstrated behavioral aversion in a number of contexts for many marine mammal species in increasingly controlled and well-documented contexts. While considerable species, individual, and context-dependencies exist in terms of received noise levels associated with behavioral aversion, clear patterns of behavioral aversion have been demonstrated empirically within odontocetes and mysticetes (*e.g.,* Miller *et al.,* 2012, 2014; DeRuiter *et al.,* 2013; Southall *et al.,* 2019b). This is particularly true for exposure scenarios in which animals occur relatively close to sources and at the high levels that would be required for even TTS (much less PTS) to occur. In some instances, in these and other studies, behavioral avoidance has been measured at received levels many orders of magnitude below those required for predicted PTS onset and even below the nominal, 50 percent behavioral response probability at 160 dB rms that NMFS has applied historically.

However, accounting for aversion quantitatively in an acoustic exposure modeling process is a significantly data-

[5] Of the ten total events, none achieved the highest rank of 6. Two events were ranked as 5: One stranding in Peru involving dolphins and porpoises and a 2008 stranding in Madagascar. This latter ranking can only broadly be associated with the survey itself, as opposed to use of seismic airguns. An exhaustive investigation of this stranding event, which did not involve beaked whales, concluded that use of a high-frequency mapping system (12-kHz multibeam echosounder) was the most plausible and likely initial behavioral trigger of the event, which was likely exacerbated by several site- and situation-specific secondary factors. The review panel found that seismic airguns were used after the initial strandings and animals entering a lagoon system, that airgun use clearly had no role as an initial trigger, and that there was no evidence that airgun use dissuaded animals from leaving (Southall *et al.,* 2013).

heavy endeavor and, as we noted, despite the growing body of evidence there is at this time still not sufficient data regarding the specific degree of aversion and level of onset on a species-specific basis. That is, in order to account for aversion within the modeling process, one must program individual animats representing different species to respond at a specific received level by changing their direction of travel by a specific degree and assuming a specific rate of speed. Through a test scenario evaluation (discussed in the notice of proposed rulemaking), we determined that while this is possible to do, the specific values that must be used in programming the animat response could not be adequately derived. Instead, a nominal offset factor was applied to the modeled injurious exposures based on published model result evaluation to account for aversion.

Ellison *et al.* (2016) modeled scenarios using animal movement models to evaluate predicted PTS in which no aversion was assumed relative to scenarios where reasonable assumptions were made about aversion, in line with historical response probability assumptions and that existing scientific literature suggest are appropriate. Scenarios where no aversion probability was used overestimated the potential for high levels of exposure required for PTS by about five times. Accordingly, total modeled injurious exposures calculated without accounting for behavioral aversion (for low- and high-frequency species) were multiplied by 0.2 as part of the EWG risk analysis. NMFS consulted the EWG in selecting the specific offset factor, and discussed that selection again in context of the public comments received. The EWG—which is composed of some of the foremost scientists in the field of marine mammal behavioral response study, and includes the lead author of the Ellison *et al.* (2016) study—agreed that the approach and specific offset factor was a reasonable and likely conservative approach to addressing the issue of aversion.

The commenters do not dispute that aversion is a meaningful real-world phenomenon that is significantly influential on actual occurrence of Level A harassment. As NRDC acknowledges, ''it is certainly true that some marine mammals will flee the sound.'' Yet the commenters would have us ignore this phenomenon and assume unrealistically high amounts of auditory injury for marine mammals in the GOM. NMFS does not agree that this would be appropriate. As described above, there is extensive information supporting the aversion concept in marine mammals, but limited quantitative data with which to develop precise, species-specific offset factors. Accordingly, utilizing the available data and expert input, NMFS applied its professional judgement in order to account for this meaningful phenomenon.

Comment: NRDC disagrees with NMFS' conclusion that Level A harassment is not likely to occur for mid-frequency (MF) cetaceans and states that this ''problem [. . .] must be addressed.''

Response: As was explained in the notice of proposed rulemaking, the number of modeled incidents of Level A harassment for MF cetacean species is not realistic. The modeled isopleth distance to the relevant Level A harassment threshold, *i.e.,* the predominant MF peak pressure threshold, is only 18 m. As we explained in the notice of proposed rulemaking, it is understandable that even such a small assumed area could lead to the results given when a real-world density value is sufficiently high to lead to non-zero scaled 24-hr modeled exposure results, which are then multiplied by large numbers of notional survey days. We explain in greater detail below why relatively small zones, *i.e.,* zones contained within the near-field of an airgun array, should not be expected to result in actual injurious exposure. NRDC also appears to be under the impression that the conclusion was based on what they refer to as ''shorter injurious take distances assumed in the Gulf of Mexico modeling than in modeling for seismic in other regions, such as the Atlantic,'' an apparent misunderstanding on the part of the commenter that they refer to as a ''discrepancy'' that is ''never explained'' and ''appears arbitrary.'' Given the lack of detail provided, NMFS cannot be sure what NRDC is referring to. However, we do know that state-of-science propagation modeling performed for a notional array here provided the 18 m result described above. For five different, real-world arrays evaluated for use in the Atlantic Ocean (83 FR 63268; December 7, 2018), the calculated isopleth distance to the 230 dB peak sound pressure level (SPL) MF Level A harassment threshold was an average 27 m (range 14–63 m), in keeping with the value calculated here.

For MF cetaceans, the only potential injury zones will be based on the peak pressure metric, as such zones will be larger than those calculated on the basis of the cumulative sound exposure level (SEL) metric (which are essentially non-existent for MF and HF cetaceans). As noted, the estimated zone size for the 230 dB peak threshold for MF cetaceans is only 18 m. In a theoretical modeling scenario, it is possible for animats to engage with such a small assumed zone around a notional point source and, subsequently, for these interactions to scale to predictions of real-world exposures given a sufficient number of predicted 24-hr survey days in confluence with sufficiently high predicted real-world animal densities—*i.e.,* the modeling process that resulted in the predicted exposure estimates for MF cetaceans in the modeling report. However, this is not a realistic outcome. The source level of the array is a theoretical definition assuming a point source and measurement in the far-field of the source (MacGillivray, 2006). As described by Caldwell and Dragoset (2000), an array is not a point source, but one that spans a small area. In the far-field, individual elements in arrays will effectively work as one source because individual pressure peaks will have coalesced into one relatively broad pulse. The array can then be considered a ''point source.'' For distances within the near-field, *i.e.,* approximately 2–3 times the array dimensions, pressure peaks from individual elements do not arrive simultaneously because the observation point is not equidistant from each element. The effect is destructive interference of the outputs of each element, so that peak pressures in the near-field will be significantly lower than the output of the largest individual element. Here, the 230 dB peak isopleth distances would be expected to be within the near-field of the arrays where the definition of source level breaks down. Therefore, actual locations within this distance (*i.e.,* within 18 m) of the array center where the sound level exceeds 230 dB peak SPL would not necessarily exist. In general, Caldwell and Dragoset (2000) suggest that the near-field for airgun arrays is considered to extend out to approximately 250 m.

In order to provide quantitative support for this theoretical argument, we calculated expected maximum distances at which the near-field would transition to the far-field for five specific, real-world arrays proposed for use in the Atlantic Ocean (83 FR 63268). The average distance to the near-field calculated for the five arrays, following the process described below, was 203 m (range 80–417 m).

For a specific array one can estimate the distance at which the near-field transitions to the far-field by:

$$D = \frac{L^2}{4\lambda}$$

with the condition that $D >> \lambda$, and where D is the distance, L is the longest dimension of the array, and λ is the wavelength of the signal (Lurton, 2002). Given that λ can be defined by:

$$\lambda = \frac{v}{f}$$

where f is the frequency of the sound signal and v is the speed of the sound in the medium of interest, one can rewrite the equation for D as:

$$D = \frac{fL^2}{4v}$$

and calculate D directly given a particular frequency and known speed of sound (here assumed to be 1,500 meters per second in water, although this varies with environmental conditions).

To determine the closest distance to the array at which the modeled source level prediction is valid (*i.e.,* maximum extent of the near-field), we calculated D based on an assumed frequency of 1 kHz. A frequency of 1 kHz is commonly used in near-field/far-field calculations for airgun arrays (Zykov and Carr, 2014; MacGillivray, 2006; NSF and USGS, 2011), and based on representative airgun spectrum data and field measurements of an airgun array used on the R/V *Marcus G. Langseth,* nearly all (greater than 95 percent) of the energy from airgun arrays is below 1 kHz (Tolstoy *et al.,* 2009). Thus, using 1 kHz as the upper cut-off for calculating the maximum extent of the near-field should reasonably represent the near-field extent in field conditions.

If the largest distance to the peak sound pressure level threshold was equal to or less than the longest dimension of the array (*i.e.,* under the array), or within the near-field, then received levels that meet or exceed the threshold in most cases are not expected to occur. This is because within the near-field and within the dimensions of the array, the specified source level is overestimated and not applicable. In fact, until one reaches a distance of approximately three or four times the near-field distance, the average intensity of sound at any given distance from the array is still less than that based on calculations that assume a directional point source (Lurton, 2002). For example, an airgun array used on the R/V *Marcus G. Langseth* has an approximate diagonal of 29 m, resulting in a near-field distance of 140 m at 1 kHz (NSF and USGS, 2011). Field measurements of this array indicate that the source behaves like multiple discrete sources, rather than a directional point source, beginning at approximately 400 m (deep site) to 1 km (shallow site) from the center of the array (Tolstoy *et al.,* 2009), distances that are actually greater than four times the calculated 140-m near-field distance. Within these distances, the recorded received levels were always lower than would be predicted based on calculations that assume a directional point source, and increasingly so as one moves closer towards the array (Tolstoy *et al.,* 2009). Given this, relying on the calculated distances as the distances at which we expect to be in the near-field is a conservative approach because even beyond this distance the acoustic modeling still overestimates the actual received level.

Within the near-field, in order to explicitly evaluate the likelihood of exceeding any particular acoustic threshold, one would need to consider the exact position of the animal, its relationship to individual array elements, and how the individual acoustic sources propagate and their acoustic fields interact. Given that within the near-field and dimensions of the array source levels would be below the modeled notional source level, we believe exceedance of the peak pressure threshold would only be possible under highly unlikely circumstances.

Therefore, we expect the potential for Level A harassment of MF cetaceans to be *de minimis,* even before the likely moderating effects of aversion and/or other compensatory behaviors (*e.g.,* Nachtigall *et al.,* 2018) are considered. We do not believe that Level A harassment is a likely outcome for any MF cetacean.

Comment: The MMC comments that the estimated numbers of Level B harassment must be increased to account for the incidents of acoustic exposure that were modeled as injurious but subsequently discounted due to aversion. NRDC commented similarly.

Response: NMFS agrees that animals that avoid Level A harassment through aversive behavior should be considered as having been subject to Level B harassment and increased the Level B harassment estimates accordingly. However, these estimates have been superseded by the revised estimates submitted by BOEM in support of their revised scope of activity.

Marine Mammal Protection Act—General

Comment: The MMC recommended that any ''formal interpretation'' by NMFS of MMPA standards, such as the least practicable adverse impact standard and small numbers standard, be issued in stand-alone, generally applicable rulemakings (*e.g.,* in amendments to 50 CFR 216.103 or 216.105) or in a separate policy directive, rather than in the preambles to individual proposed rules.

Response: We appreciate the recommendation and may consider the recommended approaches in the future. However, providing directly relevant explanations of programmatic approaches or interpretations related to the incidental take provisions of the MMPA in a proposed incidental take authorization is an effective and efficient way to provide information to and solicit focused input from the public. Further, this approach ultimately affords the same

opportunities for public comment as a stand-alone rulemaking would.

Regarding the least practicable adverse impact standard, NMFS has provided similar explanations in other recent section 101(a)(5)(A) rules. See, *e.g.,* 83 FR 66846 (December 27, 2018) (U.S. Navy Training and Testing Activities for Hawaii-Southern California Study Area).

Least Practicable Adverse Impact

Comment: NRDC believes NMFS relies on a ''flawed interpretation'' of the least practicable adverse impact standard. They state that NMFS (1) wrongly imports a population-level focus into the standard, contrary to the ''clear'' holding of the Ninth Circuit in *NRDC* v. *Pritzker,* 828 F.3d 1125 (9th Cir. 2016); and (2) inappropriately ''balances'' or weighs effectiveness against practicability without sufficient analysis, counter to *Pritzker.*

Response: NMFS carefully evaluated the Ninth Circuit's opinion in *Pritzker* and believe we have fully addressed the court's concerns. NMFS' discussion of the least practicable adverse impact standard in the Mitigation section explains why we believe a population focus is a reasonable interpretation of the standard.

With regard to the second point, NMFS disagrees that the analysis is insufficient. NMFS' interpretation of the LPAI standard is a reasonable interpretation that gives effect to the language in the statute and the underlying legislative intent. Congress intended the agencies administering section 101(a)(5)(A) to consider practicability when determining appropriate mitigation, and we do not believe the analysis must be conducted in a rigid sequential fashion. There is a tension inherent in the phrase ''least practicable adverse impact'' in that ''least [. . .] adverse impact'' pulls in favor of one direction (*i.e.,* expanding mitigation) while ''practicable'' pulls in favor of the other direction (*i.e.,* limiting mitigation), and weighing the relative costs and benefits is, in NMFS' view, a meaningful way to address and resolve this tension. Further, as described in the proposed rule and augmented in this final rule in both the Mitigation section and the response to comments, NMFS considered all recommended mitigation in the context of both the reduction of impacts on marine mammal species and stocks and their habitat and the practicability of such mitigation in reaching the required set of measures that we believe satisfy the least practicable adverse impact standard.

Comment: The Associations assert that NMFS failed to provide sufficient practicability analyses for the proposed mitigation requirements.

Response: No guidance is provided by the MMPA or NMFS' implementing regulations as to what constitutes ''practicability'' for the non-military readiness activities considered here, or how to ascertain whether a proposed measure is practicable. Neither the term ''practicable'' nor the phrase ''least practicable adverse impact'' is defined by the MMPA or in NMFS' implementing regulations. (See Mitigation, later in this document, for extensive discussion on NMFS' interpretation of the meaning of ''least practicable adverse impact.'') Therefore, while the MMPA's requirement to prescribe mitigation achieving the ''least practicable adverse impact'' demands consideration of practicability, the need for additional ''analysis'' of unspecified scope, detail, or methodology, as demanded by the Associations, cannot be found in the statute, legislative history, regulations, or case law.

However, NMFS does not start from scratch. Our implementing regulations at 50 CFR 216.104(a)(11) require applications for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, their habitat, and on their availability for subsistence uses, paying particular attention to rookeries, mating grounds, and areas of similar significance. This often provides the foundation of NMFS' proposed mitigation, after consideration of the objectives of those and other possible measures and how they may achieve those objectives as well as, when possible, what we know about the practicability of the proposed measures.

As a general matter, where an applicant proposes measures that are likely to reduce impacts to marine mammals, the fact that they are included in the proposal and application indicates that the measures are practicable, and it is not necessary for NMFS to conduct a detailed analysis of the measures the applicant proposed (rather, they are simply included). However, it is incumbent on NMFS to consider whether there are other practicable measures that would contribute to the reduction of risk or severity of adverse effects on the species or stocks.

We then seek public comment on the proposal and, if contradictory information is presented by members of the public (including prospective applicants), the information is considered in making a decision regarding whether to retain, modify, or eliminate a proposed measure.

Our notice of proposed rulemaking presented specific discussion of practicability considerations, including both the monetized direct costs of proposed measures as well as what we understand about potential indirect costs, and provided detailed discussion relating to certain measures. While much of this analysis was conducted under a regulatory impact analysis (RIA) conducted pursuant to Executive Order 12866, as stated by the Associations, the utility of the analysis is not limited to use there. For example, while the Associations claim that NMFS fails to ''consider impacts beyond immediate operational impacts,'' the RIA provides a detailed analysis of the sort of speculative indirect costs of concern to industry, and the RIA's analysis is incorporated into NMFS' consideration of practicability. Overall, we note that the Associations' comments are peppered with reference to cost increases, both vague (''resulting in millions of dollars of added cost'') and specific (''increase costs an estimated 5% to 20%''), but without sufficient supporting data.

NMFS interprets ''practicable'' simply as capable of being put into practice or of being done or accomplished. Practicability of the standard operational protocols was reasonably assumed in consideration of the fact that they are included in many incidental take authorizations and that we did not receive any specific public comments to the contrary. Moreover, many of these measures were proposed by the applicant (BOEM) in their petition for regulations, including ramp-up and shutdown requirements and a requirement to observe a time-area restriction in coastal waters to protect bottlenose dolphins during the time of their reproductive activity peak. The Associations claim that our proposal applies these standard measures in such a way as to extend their ''geographic and temporal scope or to circumstances where they are unnecessary or impossible to implement,'' but provide no specific information as to what measures they specifically refer to, in what circumstances they believe specific measures are unnecessary, or in what circumstances specific measures are impossible to implement. The Associations assert that NMFS' considerations of practicability ''fail to adequately estimate levels of current and future geophysical work or consider costs and impacts beyond the immediate survey work,'' but their

comments provide no specific information to enable NMFS to assess its consideration of practicability. NMFS' consideration of practicability was sufficient and in accordance with law, and the Associations provided no specific contradictory information for NMFS' evaluation.

Comment: The MMC recommended that NMFS rework its evaluation criteria for applying the least practicable adverse impact standard to separate the factors used to determine whether a potential impact on marine mammal species or stocks or their habitat is adverse and whether possible mitigation measures would be effective. In this regard, the MMC asserted that it seems as though the proposed ''effectiveness'' criterion more appropriately fits as an element of practicability and should be addressed under that prong of the analysis. In other words, a measure not expected to be effective should not be considered a practicable means of reducing impacts.

Response: In the Mitigation section, NMFS has explained in detail its interpretation of the least practicable adverse impact standard, the rationale for the interpretation, and our approach for implementing the interpretation. The ability of a measure to reduce effects on marine mammals is entirely related to its ''effectiveness'' as a measure, whereas the effectiveness of a measure is not connected to its practicability. The MMC did not support its argument with scientific information, and NMFS has not implemented the suggestion.

Comment: The MMC recommended that NMFS address the habitat component of the least practicable adverse impact provision in greater detail. It asserted that NMFS' discussion of critical habitat, marine sanctuaries, and biologically important areas (BIA) in the proposed rule is not integrated with the discussion of the least practicable adverse impact standard. As stated by the MMC, it would seem that, under the least practicable adverse impact provision, adverse impacts on important habitat should be avoided whenever practicable. Therefore, to the extent that activities would be allowed to proceed in these areas, NMFS should explain why it is not practicable to constrain them further. The MMC also suggests that NMFS intends to defer consideration of measures to protect habitat to individual LOAs, rather than addressing such measures in the regulations, as the MMC contends is required.

Response: Marine mammal habitat value is informed by marine mammal presence and use and, in some cases, there may be overlap in mitigation measures for the species or stock directly and for use of habitat. In this rule, NMFS has identified one time-area restriction (carried forward from the proposed rule) based on a combination of factors that include higher densities and observations of specific important behaviors of marine mammals themselves, but also that clearly reflect preferred habitat. In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features, among others for some BIAs), the high densities and concentration of certain important behaviors (*e.g.,* feeding) in these particular areas indicate the presence of preferred habitat. The MMC seems to suggest that NMFS must always consider separate measures aimed at marine mammal habitat. However, the MMPA does not specify that effects to habitat must be mitigated in separate measures, and NMFS has identified measures that provide significant reduction of impacts to both ''marine mammal species and stocks and their habitat,'' as required by the statute. Finally, we clarify here that all measures to reduce impacts to both marine mammal species and stocks and their habitat are included in the regulations and then implemented through activity-specific LOAs.

Negligible Impact

Comment: The Associations and Chevron concur with NMFS' finding that the incidental taking that may be authorized under the ITR will have a negligible impact on the affected marine mammal stocks. The Associations additionally specify their agreement with NMFS' conclusions that Level A harassment will not play a meaningful role in the overall degree of impact experienced by marine mammal populations as a result of the projected survey activity and that mid-frequency cetaceans are unlikely to incur Level A harassment, as well as with NMFS' use of the Wood *et al.* (2012) probabilistic risk function.

Response: NMFS appreciates the comments.

Comment: NRDC claims that NMFS did not define the total amount of take it evaluated in making the negligible impact determination and asserts that the proposed rule is unclear about the data and calculations that informed the basis of the negligible impact finding.

Response: NMFS disagrees with these comments. NMFS explicitly defined the basis, as well as the process, for the negligible impact analysis. Although the negligible impact analysis was built upon relatively sophisticated acoustic exposure modeling, and incorporated advances in the science of risk assessment, the informational inputs to the analysis and the analytical framework were clearly elucidated and the supporting documentation identified and provided as companion documents to the public for review in association with our negligible impact analysis. The notice of proposed rulemaking identified a point of contact available to provide further information or answer questions if necessary.

NMFS stated that the ''specified activity'' for the proposed regulations is a broad program of geophysical survey activity that could occur at any time of year in U.S. waters of the GOM. This conceptual program, as defined by BOEM through projected levels of survey effort, was described and shown in Table 1 of the notice of proposed rulemaking. These annual survey projections aligned generally with ''low,'' ''moderate,'' and ''high'' effort years (83 FR 29224). These projected levels of survey effort informed the acoustic modeling report (Zeddies *et al.* 2015, 2017a), which was extensively and clearly summarized in the notice of proposed rulemaking, while the report itself was made available for public review concurrently with the notice of proposed rulemaking. In order to reasonably estimate the actual effort that might occur over the five-year timeframe of the proposed ITR, NMFS determined for the proposed rule analysis that it would be appropriate to assume that one high-effort year, two moderate-effort years, and two low-effort years (and, therefore, associated acoustic exposure estimates) would occur. NMFS then selected and identified the specific effort scenarios that formed the basis for the analysis in association with Table 9 of the notice of proposed rulemaking, titled ''Scenario-Specific Expected Take Numbers and Mean Annual Take Level.'' Table 9 of the notice identified the annual and total amounts of take that NMFS expected to occur under the ITR. The preliminary negligible impact analysis then referred back to Table 9 as the basis for the analytical process and discussion provided therein (See 83 FR 29290–29291).

NRDC complains that ''NMFS never defines the total amount of take it proposes to authorize.'' However, as is typical for a programmatic analysis, the ITR and its associated analysis (including negligible impact) do not propose to authorize take per se, but rather to provide a description of the upper bound within which take may be authorized via LOAs. The upper bounds of the instances of take that may be authorized under this rule are indicated

in Table 9 in this final rule. The actual amount of take authorized through LOAs under the ITR will be determined by applicant interest (subject to the upper bound).

NMFS also identified the Expert Working Group (EWG) report (Southall *et al.,* 2017) as an essential companion to the notice of proposed rulemaking and, similar to the acoustic modeling report, provided the document for concurrent public review. The EWG report describes the systematic risk assessment framework that, in part, forms the basis for the negligible impact analysis. We concisely described the analytical framework in the notice and provided the results of that analysis. Ultimately, the EWG report provides overall evaluated relative risk for each of the three effort scenarios (low, moderate, high) for each species in each of seven different zones. As stated in the notice, the severity and vulnerability ratings (facets of the analytical framework that are also clearly explained both in the EWG report and the notice) are integrated to provide relative impact ratings of overall risk. These zone-specific relative impact ratings for each species were then integrated using basic calculations to produce species-specific, GOM-wide overall evaluated relative risk ratings for each of the three effort scenarios. Overall vulnerability scores for each species were produced by summing the zone-specific vulnerability scores, as scaled to the zone-specific population. For example, the Zone 1 vulnerability score is multiplied by the ratio of the Zone 1 population to the total population. These zone-specific products are then summed. Overall severity scoring is calculated as the proportion of the sum of scenario-specific takes to the total population. These two factors are then integrated as described in the EWG report.

NRDC also states that the ''actual percentages of populations affected by takes'' are not provided. NMFS disagrees, as this information can be replicated using information that was provided to the public via the acoustic modeling report. Additional underlying data are necessary to replicate zone-specific findings. Excel workbooks containing these data were made publicly available by BOEM during review of their PEIS. NMFS did not view these additional data as essential to understanding the modeling report or the proposed ITR and did not publish these data on its website. Members of the public interested in further exploration of the information provided in the modeling report, or in need of assistance regarding their independent analysis of the modeling report, could have contacted the NMFS point of contact identified in the notice of proposed rulemaking.

In sum, NMFS provided sufficient information in support of its negligible impact analysis affording the public meaningful opportunity to comment. Further, consistent with a potential alternative scope identified in the proposed rule that would remove the Eastern Planning Area (EPA), the scope of this final rule has been modified to remove the GOMESA area, which includes most of the EPA (and a small portion of the Central Planning Area), based on BOEM's update to its action. This has resulted in a reduction in the upper bounds of the instances of take that may be authorized for all species pursuant to this final rule (see Tables 8 and 9).

Comment: The MMC commented similarly to NRDC, expressing some concern regarding the risk assessment framework and asserting ''apparent inconsistencies,'' while recommending that NMFS (1) provide the final risk assessment framework, underlying results, and its interpretation of those results to the public and (2) allow for an additional 30-day comment period to review the findings sufficiently in advance of issuing the final rule.

Response: NMFS disagrees with the MMC comments. They state that the EWG report and analysis ''has some apparent inconsistencies'' as compared against the preamble to the proposed rule because the scenario-specific high, moderate, and low values presented in Table 3 of the EWG report do not align with the summary minimum, maximum, and mean values given in Table 2 of the notice of proposed rulemaking. We note that the MMC provided clarifying questions to NMFS during the public comment period in advance of submitting a formal comment letter and expressed some confusion regarding Table 2 of that notice at that time. As was explained to the MMC then, Table 2 of the preamble was provided for illustrative purposes only, as a way of providing a more concise look at the information given in Table 1 of the preamble. As was explained, the values given in Table 2 were not consequential with regard to anything that followed in the preamble. NMFS regrets any confusion caused by inclusion of Table 2 in the notice of proposed rulemaking but explained clearly to the MMC that the table was not related to the analysis. It has been removed from this final rule.

Separately, the MMC states that ''neither NMFS nor BOEM stipulated why only certain years were selected for analysis,'' claiming that NMFS indicated that years 1, 4, and 9 were used in the analysis ''upon further inquiry.'' This is incorrect. In the notice of proposed rulemaking, we stated that ''Year 1 provides an example of what might be a high-effort year in the GOM, while Year 9 is representative of a low-effort year. A moderate level of effort in the GOM, according to these projections, would be similar to the level of effort projected for Year 4.'' (83 FR 29224.) NMFS provided explanation of its choices in the notice of proposed rulemaking (see, *e.g.,* 83 FR 29261–29262, 29290).

This portion of the MMC's recommendation regarding representative years is no longer relevant to this final rule. As discussed previously, BOEM revised the scope of the activity and provided revised effort projections and resulting take estimates accordingly. The revised take estimates provided by BOEM reflect years 1–5 of their original level of effort projections and, therefore, the question of rationale behind the selection of years 1, 4, and 9 is no longer relevant.

Regarding the notice of proposed rulemaking, the MMC also states that supposed discrepancies between zone-specific risk ratings and risk derived per year across the GOM are ''inconsistencies.'' Zone-specific risk ratings for any given effort scenario are driven by the actual effort within that zone for that scenario, while the overall level of effort GOM-wide underlies the labeling of scenarios as ''high,'' ''moderate,'' and ''low.'' For example, although year 1 was designated as the ''high'' effort scenario and year 4 the ''moderate'' effort scenario on the basis of the total projected GOM-wide survey days (2,286 and 1,902, respectively), the ''high'' effort scenario actually includes significantly less projected effort in zones 2 and 4 than does the ''moderate'' effort scenario. Therefore, risk ratings for certain species were higher in those specific zones for the ''moderate'' effort scenario than they were for the ''high'' effort scenario. This was explained in our notice of proposed rulemaking: ''[P]er-zone ranges can provide a different outlook than does an assessment of total year projected effort across zones. For example, in the ''high'' effort annual scenario (Year 1; considering total projected survey days across zones), there are 263 projected survey days in Zone 2, while the ''moderate'' effort annual scenario (Year 4) projects 446 survey days in Zone 2.'' This was explained directly to the MMC upon its informal inquiry during the public comment period. The MMC also stated to NMFS at that time that ''the

relative risk scores for certain species [. . .] do not make sense, presumably because they are based on the incorrect number of estimated survey days,'' giving as an example that ''rough-toothed dolphins in Zone 5 have an overall Moderate risk in the High and Low scenario years, but a Low risk in the Moderate scenario year.'' We reiterated to the MMC at that time that what the MMC viewed as illogical and erroneous did not in fact reflect errors, but rather the confluence of zone-specific activity levels and species presence for a given year. The effort scenarios used as the basis for the analysis were clearly identified, and there were no inconsistencies in terms of risk ratings in consideration of the zone-specific information underlying those ratings (which was explained in the notice of proposed rulemaking).

Separately, the MMC stated its view that ''the basis for determining the relative risk thresholds, relative rating thresholds, species-specific biological risk factors, and environmental risk factors was not provided'' and that ''many of the quantitative aspects have not been substantiated.'' While NMFS disagrees with this statement and refers the reader to the EWG report (Southall *et al.,* 2017), we also point out that, in the absence of precise quantitative information on these aspects of the risk assessment framework (on a species- and zone-specific basis), the application of the framework necessarily requires the application of professional judgment. As NMFS acknowledged, ''[e]lements of this approach are subjective and relative within the context of this program of projected actions and, overall, the analysis necessarily requires the application of professional judgment.'' (83 FR 29290.) The MMC comments do not find fault with any specific element or attribute of the framework or with any specific value chosen to represent a particular risk threshold or a particular species' vulnerability. NMFS does not agree that the MMC's recommendation to allow for an additional 30-day comment period for the public to review the risk assessment framework findings in advance of issuing the final rule is warranted and has not implemented the suggestion.

Comment: NRDC asserts that NMFS has erroneously used the relativistic assessment presented in the EWG report as the basis for the negligible impact determination, incorrectly applying it as though it evaluated absolute risk. A private citizen offers similar comments.

Response: NMFS disagrees with the comment. The EWG analysis is an important component of the negligible impact analysis, but is not the sole basis for our determination. While the EWG analysis comprehensively considered the spatial and temporal overlay of the activities and the marine mammals in the GOM, as well as the number of takes predicted by the described modeling, there are details about the nature of any ''take'' anticipated to result from these activities that were not considered directly in the EWG analysis and which warrant explicit consideration in the negligible impact analysis. Accordingly, NMFS' analysis considers the results of the EWG analysis, the effects of the required mitigation, and the nature and context of the takes that are predicted to occur. NMFS' analysis also explicitly considers the effects of predicted Level A harassment and impacts to marine mammal habitat, which were, respectively, not integrated into or included in the EWG risk ratings. These components of the full analysis, along with any germane species or stock-specific information, are integrated and summarized for each species or stock in the Species and Stock-specific Negligible Impact Analysis Summaries section of the negligible impact analysis.

In addition, while the EWG framework comprehensively considers the aggregate impacts to marine mammal populations from the activities addressed in this rule in the context of both the severity of the impacts and the vulnerability of the affected species, it does not fully consider the absence of survey activity in the eastern GOM (within the GOMESA moratorium area), following BOEM's update to the scope of activity. While this is to some degree reflected in the updated take estimates, and thereby incorporated into the EWG framework's risk ratings, the absence of survey activities within areas of increased biological importance for certain species benefits those species GOM-wide beyond what is simply reflected in the updated take numbers. The negligible impact analysis considers the reduction of both acute and chronic effects afforded through the revised scope of the rule.

Also, we note that while the EWG framework produces relativistic risk ratings, its components consist of absolute concepts, some of which are also absolutely quantified (*e.g.,* whether the specified activity area contains greater than 30 percent of total region-wide estimated population, between 30 and 15 percent, between 15 and 5 percent, or less than 5 percent). Further, NMFS provided substantive input into the scoring used in implementing the EWG framework for the GOM, to ensure that the categories associated with different scores, the scores themselves, and the weight of the scores within the overall risk rating all reflected meaningful biological, activity, or environmental distinctions that would appropriately inform the negligible impact analysis. Accordingly, and as intended, we used our understanding of the framework and best professional judgment to interpret the relativistic results of the EWG analysis appropriately into the larger negligible impact analysis, with the other factors discussed above, to make the necessary findings specific to the effects of the total taking on the affected species and stocks.

Comment: NRDC asserts that the vulnerability ratings used in the EWG framework fail to account for several factors appropriately, which undermine the framework's ability to contribute accurately to the overall evaluation of relative risk. NRDC cites the following as problematic factors: Application of vulnerability ratings on a zone-by-zone basis, which they state negatively biases the habitat use and temporal overlap factors; unaccountably low ratings for non-seismic stressors (specifically citing the DWH oil spill); relatedly, failure to account appropriately for all other stressors; and failure to fully account for stock structure and status.

Response: NMFS first notes that the application of the EWG framework, and specifically the development of appropriate vulnerability ratings, necessarily involves the use of professional judgment, here on the part of a group of experts in the fields of marine mammal biology, ocean acoustics, and the effects of noise on marine mammals, among other things (and in consultation with NMFS and BOEM). Reasonable people may disagree about the specific numerical values assigned to any one of the 11 different factors contributing to the overall species-specific vulnerability score generated for each of the seven zones (with seven factors that are static GOM-wide and four that vary spatially, scoring for 18 taxa and seven zones means that 630 individual numerical value selections underlie the vulnerability scores); but this does not imply that any of the specific values selected are unreasonable. All relevant factors were considered in generating the species- and zone-specific vulnerability scores.

NRDC misapprehends one of the fundamental values of the analytical framework, in that it is structured in a spatially explicit way that can be applied at multiple scales, based on the scope of the action and the information available to inform an assessment of the risk associated with the activity (or suite

of activities). This allows one to generate overall risk ratings while also evaluating risk on finer scales. In this case, severity ratings were generated on the basis of seven different GOM zones, allowing an understanding not only of the relative scenario-specific risk across the entire GOM, as is demanded for this analysis, but also to better understand the particular zones where risk may be high (depending on actual future survey effort) and what part of the stock's range may be subject to relatively high risk. The framework recognizes, fundamentally, that the spatial, temporal, and spectral overlaps between noise-generating activities and animal distribution are the primary factors that drive the type, magnitude, and overall evaluated risk of potential noise effects on marine mammals. These considerations are inherent and fundamental in both the severity and vulnerability ratings and are deliberately integrated into both the vulnerability and severity assessments; in fact, key features of the analytical framework include explicit recognition of the importance of species distribution relative to activity spatial distribution and temporal and contextual differences in exposure scenarios. If the spatially explicit nature of the framework were removed, as it seems NRDC is suggesting, there would be no value in generating a ''habitat use'' factor (*i.e.,* the spatial scale would be the GOM, and it would necessarily contain 100 percent of the estimated population). Spatial overlap is a central consideration for the extent of physical overlap between species and other environmental stressors, with consideration of species distribution across all zones, as well as the extent of population concentration and habitat specialization (as expressed through zone-specific vulnerability assessment). Regarding the temporal overlap factor referenced by NRDC, overall activity duration is a limited consideration within the vulnerability assessment rating but is expressed as a central consideration within magnitude-duration functions used to evaluate severity.

Despite the explanations provided in the EWG report, NRDC characterizes certain aspects of the vulnerability scoring as ''unaccountably low.'' However, NRDC does not provide specific recommendations for revisions to the assigned numerical values, or justification for their contention that scoring is too low. All relevant stressors were accounted for in the vulnerability scoring and specific scores were reasonably made on the basis of expert professional judgment. Contrary to NRDC's assertion, the effects of the DWH oil spill were considered in the vulnerability scoring (as well as in our development of mitigation in consideration of the MMPA's least practicable adverse impact standard). Overall, NRDC seems to provide a blanket suggestion, without adequate justification or evidence, that for all species, impacts should be considered to be higher than we have determined. We believe that we have satisfied the statutory standards after careful consideration of the available science.

Regarding stock structure, NRDC criticizes the treatment of bottlenose dolphins in the vulnerability scoring. Overall, species-level take and abundance estimates are used to support findings for bottlenose dolphins out of necessity. The best available information (Roberts *et al.,* 2016) was used to inform combined species values and did not support further quantitative apportionment of estimated take or abundances to stocks. However, NRDC's specific criticism of the ''population'' vulnerability scoring for bottlenose dolphins is unwarranted. The population score comprises three components: Status, *i.e.,* is the stock listed under the ESA and/or designated as depleted under the MMPA; trend, *i.e.,* does information over the available time series of abundance estimates indicate a trend; and size, *i.e.,* is the population defined as small (less than 2,500). None of the five designated stocks of bottlenose dolphin in Federal waters of the GOM are listed under the ESA or designated as depleted under the MMPA, and none would be classed as small. Regarding trend, multiple SAR abundance estimates are available for three of the five stocks (oceanic stock and northern and western coastal stocks); and available information does show an increasing trend for these stocks. We recognize that the effects of the DWH oil spill included likely population reductions for all GOM marine mammal stocks (other than the eastern coastal stock of bottlenose dolphins, which was not impacted by the spill); however, the best available information indicates that these reductions were likely modest for all bottlenose dolphin stocks other than the northern coastal stock (Table 5), and no more recent population abundance estimates that might reflect any potential reduction are yet available. While the likely decline in population abundance for northern coastal bottlenose dolphins is subsumed within the population score assigned for bottlenose dolphins at the species level, vulnerability scoring is necessarily performed at the species level such that it may appropriately be integrated with the take-based severity scoring and used to generate an overall risk rating. As mentioned above, the best available scientific information does not allow for stock-specific parsing of take for bottlenose dolphins. Moreover, the trend component of the population score is a relatively small contribution to the overall vulnerability scoring, accounting for a maximum of two out of 30 potential points. The likely decline in population abundance for northern coastal bottlenose dolphins, although not reflected in the existing vulnerability scoring, is insignificant as a contribution to the overall vulnerability score for bottlenose dolphins as a species. As noted above, the effects of the DWH oil spill are separately accounted for in the vulnerability scoring. Importantly, and also not accounted for in the EWG framework, we include significant mitigation (time-area restriction) intended to alleviate impacts to northern coastal bottlenose dolphins during periods of greatest importance for their reproductive behavior.

Comment: NRDC states that NMFS' use of daily exposure durations ''to justify its negligible impact determination'' is arbitrary and capricious. They state that we incorrectly used exposure times above the 160-dB threshold (rather than the lower threshold associated with the multi-step probabilistic risk function); assumed low severity for certain exposure durations; and disregarded repeated exposures. A private citizen offers similar comments.

Response: As an initial matter, while it is true that NMFS evaluated exposure durations for the negligible impact analysis, it is not the only factor that we considered ''to justify'' the determination, as described fully in the Negligible Impact Analysis and Determinations section. Moreover, the consideration of exposure duration is entirely appropriate in assessing the severity of a likely exposure, which is critical to understanding how the authorized takes are likely to impact individual marine mammals. This was not addressed in the EWG assessment but was incorporated into the negligible impact analysis.

NMFS appreciates NRDC's comments regarding use of exposure times above the 160-dB threshold, and we have re-evaluated the exposure duration information and better integrated discussion of this information into the negligible impact analysis (see Negligible Impact Analysis and Determinations and Table 16 for more

information). However, it is incorrect that ''NMFS' time-exposure analysis is predicated on its use of 160 dB as the operative threshold of harm'' and that our use of exposure information above the 160-dB threshold is a ''back-door return'' of the ''outdated 160 dB threshold.'' Inherent in the concept of a multi-step probabilistic risk function is the assumption that varying proportions of an exposed population will be harassed upon exposure at the different steps of the function. We presented the 160-dB exposure durations in the notice of proposed rulemaking because exposure above this step represents the 50 percent midpoint of the function (for all species other than beaked whales) and, therefore, was deemed an appropriate representation of durations where a significant proportion of exposed animals would be expected to experience harassment (versus 10 percent of the population exposed to received sound levels between 140 and 160 dB). In Table 16 of this final rule, we present these durations for both the 160-dB and 140-dB steps of the function. It is important to keep in mind that, of the animals exposed above the 160-dB threshold for the indicated species-specific durations, not all are considered harassed. The risk function assumes 50 percent of animals exposed between 160-dB and 180-dB will be harassed. For the longer exposure durations associated with the 140-dB threshold, only 10 percent are expected to be harassed.

As we indicate in the Negligible Impact Analysis and Determinations discussion of this final rule, to put the predicted amount of take into meaningful context, it is useful to understand the duration of exposure at or above a given level of received sound (as well as the likely number of repeated exposures across days). While a momentary exposure above the criteria for Level B harassment counts as an instance of take, that accounting does not make any distinction between fleeting exposures and more severe encounters in which an animal may be exposed to that received level of sound for a longer period of time. This information is meaningful to an understanding of the likely severity of the exposure, which is relevant to the negligible impact evaluation. For example, for bottlenose dolphin exposed to noise from 3D WAZ surveys in Zone 6, the modeling report shows that approximately 72 takes (Level B harassment) would be expected to occur in a 24-hr period. However, each animat modeled has a record or time history of received levels of sound over the course of the modeled 24-hr period. The 50th percentile of the cumulative distribution function indicates that the time spent exposed to levels of sound above 160 dB rms SPL (*i.e.,* the 50 percent midpoint for Level B harassment) would be only 1.8 minutes—a minimal amount of exposure carrying little potential for significant disruption of behavioral activity.

The Species and Stock-specific Negligible Impact Analysis Summaries discussion considers the relative impact ratings in conjunction with required mitigation and other relevant contextual information—including exposure durations at the various thresholds—to produce an assessment of impact to the stock or species, *i.e.,* the negligible impact determinations. For beaked whales, take is estimated on the basis of a risk function shifted down such that 90 percent of the animals exposed to received levels above 140 dB and 50 percent exposed to received levels above 120 dB are expected to be harassed. We used this approach based on the documented behavioral sensitivity of beaked whales. However, as NRDC acknowledges, context is important when assessing behavioral responses to sound. The exposures above 120 dB here occur at significant distance from the source (*i.e.,* greater than 50 km). It is generally accepted that an animal's distance from the sound source plays an important role in the animal's behavioral response to a received sound level (*e.g.,* Gomez *et al.,* 2016). NMFS believes that exposures to the relevant harassment thresholds at significant modeled distances from the actual sound source, although included in the take estimates based on the risk function, will not carry significant consequences for the potentially exposed animals. Rather, these exposures are likely to result in significantly less severe responses (if any). Examples provided by NRDC purporting to demonstrate greater severity of response than we have assumed include irrelevant examples—beaked whales are known to respond with greater severity to mid-frequency active military sonar than to other sources, as discussed in greater detail in a previous comment response—and examples of ''responses'' entailing changes to vocalization patterns over longer durations, but these responses do not necessarily rise to the level of a take, much less a take event of significant severity.

Regarding repeated exposures, despite the figures cited by NRDC concerning potential days of activity, it is unlikely that any given individual animal would in fact experience repeated take events of the magnitude suggested. Each of the seven GOM zones is an extremely large area (average zone size approximately 100,000 km^2), and the likely harassment ''footprint'' of any given survey would be relatively small. Modeled isopleth distances to the 160-dB threshold are approximately 12 km for low-frequency cetaceans (*i.e.,* the Bryde's whale), 7 km for mid-frequency cetaceans (*i.e.,* sperm whales, beaked whales, dolphins), and 6 km for high-frequency cetaceans (*i.e., Kogia* spp.). Distances to the 140-dB isopleths are substantially larger, but we again emphasize that only ten percent of the animals exposed at that level would be expected to incur harassment, while 50 percent of the animals exposed at the 160-dB level would be expected to incur harassment. It is clear that, in reality, there is a relatively low chance of any given individual marine mammal being repeatedly taken within relatively short timeframes, much less that such events would result in fitness consequences for those individuals. Additionally, NRDC suggests that NMFS fails to consider repeated takes at all, when in fact this likelihood is inherently addressed through the severity rating of the EWG assessment.

NRDC concludes their comment by claiming that NMFS failed to undertake sufficient analysis in support of the negligible impact determinations. We disagree with this assertion, and refer to the Negligible Impact Analysis and Determinations section in support of this final rule. NRDC focuses in particular on sperm whales, implying that they are likely to incur impacts to reproductive fitness and stating that NMFS cannot make a negligible impact finding for sperm whales without additional mitigation requirements. NMFS agrees that the bioenergetics simulations of Farmer *et al.* (2018a)—cited by NRDC in support of their argument—show that frequent disruptions in foraging can have potentially severe fitness consequences for individual sperm whales. However, a follow-up study (Farmer *et al.,* 2018b), which additionally accounted for the population-level effects of the DWH oil spill on GOM sperm whales, modeled the potential population level consequences of the specific disturbance events underlying this analysis (*i.e.,* the acoustic exposure modeling of Zeddies *et al.,* 2015, 2017a). This follow-up study found that, under realistic modeled scenarios, no sperm whales were projected to reach terminal starvation and no fetal abortions were predicted as a result of long-term disturbance effects (*i.e.,* over ten years of projected survey activity). Similarly,

predicted declines in relative body condition (expressed as the percentage of available reserves for a disturbed individual whale relative to an undisturbed whale with identical characteristics) as a result of long-term disturbance effects were not significant under realistic modeled scenarios. When evaluating the additional effects of modeled disturbance on the DWH oil spill-impacted trajectory, the modeling did not predict any significant additional stock declines (Farmer *et al.,* 2018b). We believe the administrative record for this final rule amply demonstrates that NMFS used the best available science during our administrative process to inform our analyses and satisfy the standards under section 101(a)(5)(A). Of note, and as indicated in Changes from the Proposed Rule, as a result of BOEM's updated scope of the activities and the associated revisions to the levels of effort, both the maximum allowable amount of take and the maximum annual take under the rule have decreased (significantly in some cases, including for Bryde's whales and sperm whales) for all except two species/stocks. For the two exceptions these figures increased only slightly, and the severity of many of the impacts has been lessened via the removal and/or reduction of take in areas of greater biological importance previously considered as mitigation areas.

Comment: Chevron comments that NMFS should make the final version of the EWG report available to the public for review and suggests expanding the description of the inputs of the analysis. Chevron states that the ''vulnerability'' assessment, in particular, would benefit from additional discussion to explain how professional judgments led to specific rankings for each species. Chevron also comments that NMFS should provide an additional plain language discussion of the risk analysis process, including background on the development of the risk analysis framework, including any relevant analogues in other ecosystems or regulatory contexts, the ways in which species may be considered ''vulnerable,'' and the meaning of the ''risk'' discussed.

Response: NMFS appreciates the comment. The final report is available to the public online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* The content of the final report was determined by NMFS and BOEM in conjunction with the EWG. We believe that we have provided sufficient plain language discussion of the EWG framework.

Comment: NRDC claims that NMFS' negligible impact analysis is inappropriately reliant upon the prescribed mitigation and, further, that the mitigation will be ineffective.

Response: First, NMFS did not rely solely on the mitigation in order to reach its findings under the negligible impact standard. As is stated in the analysis, consideration of the implementation of prescribed mitigation is one factor in the analysis but is not determinative in any case. In certain circumstances, mitigation is more important in reaching the negligible impact determination, *e.g.,* when mitigation helps to alleviate the likely significance of taking by avoiding or reducing impacts in important areas. Second, while NRDC dismisses the importance of the prescribed mitigation by stating (mistakenly) that it is ''unsupported by evidence,'' NRDC offers no support for their conclusions.

NRDC misunderstands the degree to which NMFS relies on shutdowns for sensitive or vulnerable species, including beaked whales, at extended distances. We agree that these measures in and of themselves will have limited benefit for cryptic species such as beaked whales that are unlikely to be observed. However, we believe that it makes sense to minimize the duration and intensity of disturbance for these species when they are observed, and because they are practicable we include them in the suite of prescribed measures and discuss them where appropriate. For more readily detected species, such as the sperm whale, which is easily detected when at the surface and which vocalizes frequently while underwater, the extended distance shutdowns (for both visual and acoustic detections) should appropriately be considered influential in our assessment of impacts to affected individuals and, therefore, ultimately on the stock. Despite NRDC's dismissal of these requirements, we presume they would agree that the duration and intensity of disturbance of sensitive species should be minimized where practicable.

In summary, we consider these measures appropriately as mitigating factors when considering context as part of our negligible impact analysis.

Comment: The Associations state that the Expert Working Group framework was applied without following all of the recommended steps, such as conducting expert elicitation to derive risk functions for species that do not have parameterized Population Consequences of Disturbance (PCOD) models. The Associations recommend that NMFS seek input and advice on the framework and its conclusions from independent experts.

Response: There is extensive scientific interest in forecasting how short-term behavioral responses by individual animals may aggregate and result in population-level consequences. The concept was introduced by the National Research Council (2005) as Population Consequences of Acoustic Disturbance. However, given the lack of data on acoustic responses, research studies have generalized the issue to look at environmental and anthropogenic stressors in general and renamed the concept Population Consequences of Disturbance. New *et al.* (2014) presented a modified conceptual framework to help forecast long-term impacts. Conceptually, a series of transfer functions connect increasingly broader impacts from the initial disturbance to effects on individual health, individual vital rates, and finally population dynamics. The concept has been demonstrated with a few species for which there are extensive data from tagged or photo-identified animals so that effects on individuals can be quantified. Northern elephant seals were the first study species for which the data from time-depth recorders were able to be linked to an individual animal's body fat condition (Aoki *et al.,* 2011; Adachi *et al.,* 2014), which provided insight into foraging success and ultimately individual health and vital rates (Robinson *et al.,* 2010). Rolland *et al.* (2016) used photographic data of North Atlantic right whales to evaluate individual health and link it to demographic groups and population status. Additional studies exploring population consequences are ongoing, but a common theme is that extensive data documenting individual health and population vital rates are necessary for such analyses. These are considered the gold standards for future studies, but, at present, studies within the GOM have not occurred in sufficient detail for such analyses.

For purposes of the analysis contained herein, the disturbance severity rating facet of the EWG framework involves a relativistic framework relating Level B harassment to the zone-specific population size and then evaluating this proportion to specified severity criteria common across species. In the idealized framework discussed by the EWG (Southall *et al.,* 2017), the severity rating involves consideration of the magnitude of population affected and the duration of disturbance, *i.e.,* by deriving magnitude-duration risk functions that describe the potential effects of

exposure to noise on affected populations. The EWG considered that a better approach would apply values obtained using software developed to implement the Interim PCOD approach (Harwood *et al.,* 2014; King *et al.,* 2015).

While various models have been developed implementing the PCOD approach (*e.g.,* New *et al.,* 2013), the approach is problematic for general application because it is very data-heavy, and sufficient data specific to a taxon and/or disturbance context is not typically available. Few marine mammal populations have been as intensively studied as the PCOD case study populations, and the lack of appropriate datasets that link exposure to disturbance with behavioral change, and behavioral change with health, currently limits the general applicability of the full PCOD model. This difficulty led to development of the Interim PCOD approach, which uses results from an expert elicitation process, rather than empirical data, to predict the effects that a specific amount of disturbance will have on the vital rates of an individual marine mammal. In evaluating potential use of the Interim PCOD approach for developing magnitude-duration curves suitable for use in assessing risk associated with the projected survey activity considered here, the EWG used the results of an expert elicitation process that considered potential effects of pile driving noise associated with the construction of offshore wind farms on bottlenose dolphins, harbor porpoises, and minke whales in the North Sea. While this evaluation provided proof-of-concept and highlighted areas for future improvement of the process, such evaluations are not appropriately extrapolated to a risk assessment involving dissimilar species, stressors, and locations. For example, demographic rates and population growth rates specific to those species in U.K. waters of the North Sea were used and, further, even in that expert elicitation the authors warned that the results for the minke whale were likely not reliable due to a lack of available data. The EWG recommended that the available elicitation results not be used towards the current analysis, and NMFS and BOEM concurred. Currently, results of these expert elicitation processes are additionally viewed as potentially unreliable because experts may misinterpret the questions they are asked (Booth *et al.,* 2016).

Overall, while we agree with the Associations that it would be ideal to evaluate the effects of the specified activity on the affected populations by incorporating a PCOD or Interim PCOD approach to the EWG framework, sufficient data are not available to conduct a PCOD approach, and sufficient resources were not available to NMFS to develop and implement an expert elicitation process specific to seismic and the affected GOM populations on a timeline amenable to this ITR. With regard to the Associations' suggestion that outside experts review the EWG framework, we note that the EWG comprises experts outside NMFS and BOEM who were contracted for the express purpose of developing the framework. We do not believe it necessary to engage outside experts to review the work of other experts outside NMFS and BOEM, which is itself subject to review by experts within both NMFS and BOEM.

Comment: The Associations object to the terminology used for the relative severity ratings in the EWG framework approach, stating their disagreement with the implications of rating descriptors such as ''severe,'' and reiterating their belief that the modeled exposure levels are incompatible with the available data. Relatedly, the Associations assert that there is ''little scientific support'' for the relative risk ratings for sperm and beaked whales.

Response: Respectfully, NMFS believes this comment involves a semantic issue. The Associations do not suggest alternative terminology for the relative risk ratings. Regarding the risk ratings for sperm whales and beaked whales, these ratings are a product of a relatively straightforward analysis of severity (*i.e.,* amount of predicted disturbance relative to population size) and vulnerability (*i.e.,* consideration of factors inherent to the population that make it more or less vulnerable to the disturbance considered via the severity rating). The Associations provide no specific critique of any of these aspects of the analysis. We have addressed the Associations' criticism of the acoustic exposure modeling elsewhere in these comment responses.

Comment: The Associations object to use of the potential biological removal (PBR) metric as the basis for evaluating severity of Level A harassment within the EWG framework, stating that its use in evaluating non-serious injury is inappropriate because the metric was developed for evaluation of the significance of serious injury and mortality.

Response: We acknowledge that the PBR metric defines a level of removals from a population (*i.e.,* mortality) that would allow that population to remain at its optimum sustainable population level or, if depleted, would not increase the population's time to recovery by more than 10 percent, and therefore that it is inappropriate to make comparisons between Level B harassment takes and the PBR value for any stock. However, as discussed in the EWG report and in the notice of proposed rulemaking, while NMFS does not expect PTS (Level A harassment) that might be accrued through noise exposure to result in mortality of marine mammals, PBR can serve as a good surrogate for population vulnerability/health. Accordingly, PBR or a related metric can be used appropriately as a value against which to evaluate the potential severity to the population of a permanent impact such as PTS on a given number of individuals, and it is only in this sense that we use the PBR value. The Associations do not provide an alternative recommendation.

Small Numbers

Comment: The Associations and other industry commenters express agreement with NMFS' interpretation of the small numbers requirement as allowing that the finding may be made at the individual LOA level.

Response: We thank the Associations for their comment in support of the small numbers approach. NMFS' analysis generally comports with many of the points they raise, as discussed in this preamble.

Comment: NRDC states that the interpretation of ''small numbers'' presented by NMFS in the notice of proposed rulemaking is contrary to the plain meaning and purpose of the MMPA, in part because NMFS allegedly did not provide a reasoned basis for the take limit proposed (*i.e.,* one-third of the best available species or stock abundance estimate). NRDC makes four specific claims. First, NRDC states that one-third cannot be considered a ''small number.'' Second, NRDC states that Congress intended that takes be limited to ''infrequent, unavoidable'' occurrences, and that NMFS has not explained why the taking would be infrequent or unavoidable. Third, NRDC contends that NMFS should define different small numbers thresholds on the basis of the conservation status of individual species. Finally, NRDC believes that NMFS must account for ''additive and adverse synergistic effects'' that may occur due to multiple concurrent surveys in conducting a small numbers analysis. Industry commenters suggest that additional detail is necessary regarding the basis for NMFS' small numbers threshold.

Response: NMFS disagrees with NRDC's arguments on this topic. Although there is limited legislative history available to guide NMFS and an apparent lack of biological

underpinning to the concept, we have worked to develop a reasoned approach to small numbers. As discussed in the section of the notice of proposed rulemaking entitled Small Numbers, NMFS explains the concept of ''small numbers'' in recognition that there could also be quantities of individuals taken that would correspond with ''medium'' and ''large'' numbers. As such, NMFS has established that one-third of the most appropriate population abundance number—as compared with the assumed number of individuals taken—is an appropriate limit with regard to ''small numbers.'' This relative approach is consistent with the statement from the legislative history that ''[small numbers] is not capable of being expressed in absolute numerical limits'' (H.R. Rep. No. 97–228, at 19 (September 16, 1981)), and relevant case law (*Center for Biological Diversity* v. *Salazar,* 695 F.3d 893, 907 (9th Cir. 2012) (holding that the U.S. Fish and Wildlife Service reasonably interpreted ''small numbers'' by analyzing take in relative or proportional terms)).

NRDC claims that a number may be considered small only if it is ''little or close to zero'' or ''limited in degree.'' We note that the comment selectively picks a definition in support of NRDC's favored position. For example, the definition of ''small'' in Webster's New Collegiate Dictionary (1981) included ''having little size, esp. as compared with other similar things.'' See also *www.merriam-webster.com/dictionary/small* (defining ''small'' as ''having comparatively little size''). These definitions comport with the small numbers interpretation developed by NMFS, which utilizes a proportionality approach. The comment also selectively quotes the relevant legislative history language, stating that Congress ''intended that the agency limit takes to 'infrequent, unavoidable' occurrences.'' The actual statement from the legislative history is that taking of marine mammals should be ''infrequent, unavoidable, *or* accidental.'' H.R. Rep. No. 97–228, at 19 (September 16, 1981) (emphasis added). This language suggests that taking that is unavoidable (or accidental) may qualify as small numbers, even if not infrequent.

The argument to establish a small numbers threshold on the basis of stock-specific context is unnecessarily duplicative of the required negligible impact finding, in which relevant biological and contextual factors are considered in conjunction with the amount of take. Similarly, NRDC's assertion that NMFS' proposed approach fails to account for ''additive and adverse synergistic effects'' from multiple surveys is not required by section 101(a)(5)(A) of the MMPA, and it is unclear how NRDC defines this concept or how it may be related to the ''small numbers'' concept. These suggestions are not founded in any relevant requirement of statute or regulation, discussed in relevant legislative history, or supported by relevant case law.

A private citizen echoed certain of NRDC's comments on this topic, adding that NMFS' approach is ''embarrassing and scientifically indefensible.'' However, the commenter does not provide a more scientifically defensible interpretation of small numbers, suggesting only that ''[o]ne could approach this in many ways.''

Regarding the comment that additional explanation is needed for NMFS' interpretation of the small numbers standard, we believe the proposed and final rule provide sufficient explanation for setting one-third as the upper limit for small numbers where reasonably reliable quantified take estimates are available. See the Small Numbers section later in this preamble.

Comment: Several commenters suggest that the small numbers finding need not be based on a quantitative threshold.

Response: NMFS agrees that a more qualitative small numbers finding may be permissible. See, *e.g., Center for Biological Diversity* v. *Salazar,* 695 F.3d at 906–908. However, in this case, where take estimates can be predicted with relative confidence, we have elected to set a quantitative threshold. Moreover, the commenters do not provide any specific recommendations for an appropriate qualitative approach in this case.

Comment: The MMC recommended that any ''formal interpretation'' of the small numbers standard by NMFS be issued in a stand-alone, generally applicable rulemaking (*e.g.,* in amendments to 50 CFR 216.103 or 216.105) or in a separate policy directive, rather than in the preambles to individual proposed rules.

Response: We appreciate the MMC's recommendation and may consider the recommended approaches in the future. We note, however, that providing relevant explanations in a proposed ITR is an effective and efficient way to provide information to the reader and solicit focused input from the public, and ultimately affords the same opportunities for public comment as a stand-alone rulemaking would.

Comment: NRDC asserts that NMFS' interpretation of the MMPA's small numbers requirement is contrary to law, stating their belief that NMFS must make a small numbers determination in the rule, rather than for issuance of individual LOAs; that NMFS must evaluate the same amount of take in order to separately determine that the total take will both meet the small numbers standard and have a negligible impact; and that NMFS' approach impermissibly cuts the public out of the agency's findings.

Response: Based on NMFS' analysis of the language and structure of section 101(a)(5)(A) and the implementing regulations for that provision, NMFS disagrees that the small numbers finding must be based on the total of all take over the five-year (or less) period from all potential survey activity. The MMPA does not define small numbers or explain how to apply the term in either section 101(a)(5)(A) or the similar provision for incidental harassment authorizations (IHAs) in section 101(a)(5)(D),[6] including how to apply the term in a way that allows for consistency across those two provisions that are similar but allow for potentially different time and activity scales. (See Small Numbers below.) Especially when taken together with NMFS' implementing regulations, our approach is consistent with the structure of section 101(a)(5)(A), which provides:

(i) Upon request therefor by citizens of the United States who engage in a specified activity (other than commercial fishing) within a specified geographical region, *the Secretary shall allow,* during periods of not more than five consecutive years each, *the incidental, but not intentional, taking* by citizens while engaging in that activity within that region *of small numbers of marine mammals of a species or population stock* if the Secretary, after notice (in the **Federal Register** and in newspapers of general circulation, and through appropriate electronic media, in the coastal areas that may be affected by such activity) and opportunity for public comment—

(I) *finds that the total of such taking during each five-year (or less) period*

[6] Section 101(a)(5)(D) states in relevant part:

(i) Upon request therefor by citizens of the United States who engage in a specified activity (other than commercial fishing) within a specific geographic region, the Secretary shall authorize, for periods of not more than 1 year, subject to such conditions as the Secretary may specify, the incidental, but not intentional, taking by harassment of small numbers of marine mammals of a species or population stock by such citizens while engaging in that activity within that region if the Secretary finds that such harassment during each period concerned—

(I) will have a negligible impact on such species or stock, and

(II) will not have an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses[.]

concerned will have a negligible impact on such species or stock and will not have an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses [. . .]. (emphasis added).

Section 101(a)(5)(A)(i)(I) is explicit that the ''negligible impact'' determination for a specified activity must take into account the ''total of such taking'' (*i.e.,* all of the taking that the Secretary may conceivably allow (or authorize) under individual LOAs during the five year (or less) period considered for the rule). In contrast, the ''small numbers'' language in 101(a)(5)(A) is not subject to the same time period requirement of five years (or less in cases where the period being considered for a rule is less than five years).

In our view, the statutory language for small numbers and the negligible impact finding indicates that the negligible impact finding is made based on consideration of an aggregation of potential authorizations (LOAs) for taking small numbers of marine mammals, and allows for different temporal periods in applying the two different standards. The statute contemplates that the Secretary shall allow taking during the five year (or less) period, which in our view also implies that there could be multiple allowances or authorizations (*i.e.,* LOAs), so long as the maximum allowable total taking from all of those authorizations combined is considered in the upfront assessment of whether the negligible impact standard is met.

As we have noted, the regulatory vehicle for authorizing (*i.e.,* allowing) the take of marine mammals is the LOA, a creature of NMFS' long-standing implementing regulations that is not in the statute. See 50 CFR 216.106. Those 1989 implementing regulations requiring an LOA to effectuate an authorization were in effect when Congress amended the MMPA in 1994 to add section 101(a)(5)(D) for issuance of one-year IHAs, and over the years when Congress amended section 101(a)(5)(A) for various reasons (including most recently in 2018, to extend the maximum authorization period to seven years for military readiness activities, Pub. L. 115–232 (John S. McCain National Defense Authorization Act for Fiscal Year 2019) (Aug. 13, 2018)). Presumably Congress was aware of these implementing regulations and the framework they created for authorizing take under section 101(a)(5)(A) and could have invalidated those regulations had it so desired.

Under NMFS' approach, the negligible impact analysis for the rulemaking is conducted for the time period covered by the rule (five years in this case, the maximum under the statute for a non-military readiness activity), but the small numbers analysis attaches to the instrument that actually ''allows'' or authorizes taking, *i.e.,* the LOA. The statute does not preclude NMFS from issuing an LOA that comports with the small numbers level set forth in the relevant rule for the specified activity. Consistent with the MMPA requirement, here the Secretary (through NMFS) has prescribed the necessary specified activity regulations after notice and comment. At that point, once the regulations are effective, NMFS thereafter may authorize incidental take through the issuance of LOAs, provided that they satisfy the requirements set forth in the rule and regulations, including the small numbers standard articulated in the rule.

NRDC cites *Conservation Council for Hawaii* v. *NMFS,* 97 F. Supp. 3d 1210 (D. Hawaii 2015), in stating that the MMPA ''plainly requires that the agency evaluate both whether there will be small numbers of take and whether there will be a negligible impact'' before issuing regulations, and that these determinations ''must be based on the same amount of take.'' We disagree. In NMFS' view, *Conservation Council for Hawaii* stands for the proposition that NMFS cannot authorize more take than it has analyzed under the negligible impact standard. 97 F. Supp. 3d at 1221. There the court found that there were substantial differences between the anticipated take numbers, which were the basis for the negligible impact finding, and the amount of take that NMFS was prepared to authorize incidental to U.S. Navy military readiness activities. That case did not even involve the small numbers provision, which does not apply in the case of military readiness activities. 16 U.S.C. 1371(a)(5)(F)(i). The court in *Conservation Council for Hawaii* did not consider or make any pronouncements about whether the small numbers provision must be applied to the total annual taking under the rule or whether it could be applied at the LOA stage.

NRDC repeatedly states that the negligible impact and small numbers provisions must have separate meaning. NMFS agrees that the two provisions do have separate meanings, and this rule satisfies that requirement. Each LOA must meet the small numbers requirement as NMFS has interpreted it in this rule. In other words, it is not sufficient for the survey activity described in an LOA application to fall within the scope of the activity analyzed for the rule and NMFS' negligible impact determination. The small numbers limitation also must be satisfied. For example, NMFS may receive an application for an LOA where the take estimates exceed the small numbers standard identified in the rule. In that case, the request would be denied, *even if* the amount of taking was considered in the negligible impact evaluation. Thus the negligible impact and small numbers inquiries are separate and have different meanings.

To summarize, the MMPA is silent on how to apply ''small numbers'' in either section 101(a)(5)(A) or (D), including in a way that allows for consistency across those two very similar provisions. Moreover, NMFS' implementing regulations for section 101(a)(5)(A) make it clear that LOAs are the instrument for authorizing take. Thus, the mere existence of regulations under 101(a)(5)(A) for a specified activity is not sufficient to authorize take under that provision. An LOA is required.

As we have previously stated, the small numbers standard has limited biological relevance (*i.e.,* there is a lack of a biological underpinning for the concept), but NMFS' application of the small numbers standard at the LOA stage does not rely on that view for the approach taken here (and moreover, NMFS did not receive any public comments offering an alternative definition that is rooted in biological concepts or is not conflated with negligible impact considerations). As the notice of proposed rulemaking explained, NMFS' interpretation and approach are based on analysis of the governing section 101(a)(5)(A) and limited legislative history, as well as consideration of section 101(a)(5)(D), and our long-standing approach to implementing section 101(a)(5)(A) through separate LOAs. NMFS has determined that the statute is ambiguous in terms of what small numbers means and how ''small numbers'' must be applied, which affords the agency reasonable discretion in how to do so. After weighing various policy considerations, NMFS exercised its discretion to define small numbers and apply small numbers determinations at the LOA level.

Importantly, the final rule, which was subject to notice and comment, sets the small numbers standard for future LOAs issued under the rule. Moreover, contrary to NRDC's assertions, NMFS has set the total taking allowable for all LOAs issued under the rule for this specified activity—*i.e.,* the taking that was analyzed for the negligible impact determination. If an LOA application for

a survey provides take estimates that are within the small numbers threshold set in this rule, then the LOA for that survey will be deemed to satisfy the small numbers requirement.

As NRDC correctly points out, NMFS' implementing regulations require issuance of LOAs to be consistent with the ''total taking allowable'' under the activity-specific regulations. The regulations for the specified activity also reflect this. The rulemaking for these regulations evaluated the level of activity projected in BOEM's update for its petition, and NMFS' negligible impact determination is based on consideration of that level (as are the corresponding take estimates). Any LOA must be within the amount analyzed for the scope of the rule, and the total amount of take under all issued LOAs combined cannot exceed the amount analyzed and ''allowable'' under the rule for this activity.

Regarding the differences between the processes under sections 101(a)(5)(A) and (D), we did not mean to suggest that section 101(a)(5)(A) is necessarily or always more protective than and preferable to 101(a)(5)(D). Rather, section 101(a)(5)(A), which can span a longer period of time and cover multiple applicants through issuance of LOAs, allows for a more comprehensive/holistic analysis by the agency (one negligible impact analysis for all activities over the five-year (or less) period and consideration of mitigation appropriate for the full suite of activities). Such an approach has the potential to be more protective because it allows for a more comprehensive understanding of impacts, as well as a mechanism to include holistic mitigation that can more effectively address both acute and chronic effects resulting from multiple activities covered under a rule. Section 101(a)(5)(A) also focuses public attention on one rulemaking (rather than—as would be the case for these survey activities—potentially dozens of IHA actions per year, each with separate notice and comment), and allows for other administrative efficiencies. We note that BOEM applied for the regulations in support of the oil and gas industry, and prepared an EIS in support of its own program related to the permitting of the survey activities that are the subject of this MMPA application and rulemaking.

NRDC claims that the approach ''is a novel interpretation of the MMPA.'' However, the rule cited in support of their argument (81 FR 47240; July 20, 2016) is consistent with one aspect of our approach here, in that the small numbers determinations in both contexts are based on annual take estimates, not total take over the five-year period of the regulations.[7] We acknowledge that we have not previously determined that small numbers could be applied at the individual LOA stage where more than one LOA applicant may apply under the activity-specific regulations. However, that is simply because the issue had not previously presented itself. In nearly all cases to date,[8] there has been a single operator who is the sole applicant for both the LOA (or LOAs if they cover less than the five-year period) and the governing specified activity regulations. As a result, in such a scenario, the small numbers determination by default corresponds to the maximum annual taking covered by the regulation (and the LOA). But even when there is only one applicant for LOAs under a regulation, NMFS does not tally take across the five-year period for purposes of assessing small numbers. Rather, NMFS assesses annual levels of take. (This also promotes consistency between 101(a)(5)(A) and 101(a)(5)(D) to avoid incentivizing IHAs at the expense of LOAs issued under more comprehensive rules.)

Finally, NRDC's statement that the public is impermissibly cut out of the agency's findings is incorrect. The proposed rule set forth the maximum total taking and annual taking that would be allowable (via the issuance of LOAs) for the five-year period that the regulations will be effective, which was based on information contained in BOEM's publicly available application and PEIS. Those figures decreased for all but two species. For the two species where the figures increased, we evaluated those changes and determined they do not represent a meaningful change for our analyses. See Changes From the Proposed Rule.

The proposed rule included a 60-day public comment period. We also believe that our rulemaking afforded a full and focused opportunity for public review of and comment on the full scope of survey activities and proposed mitigation, rather than through dozens of individual IHAs, each with 30-day public comment periods and shorter timeframes for NMFS to consider the public comments. Thus the public had a meaningful opportunity to comment.

Comment: Citing their interpretation of the statute and multiple judicial decisions, the MMC suggests that NMFS' interpretation and implementation of the small numbers standard is contrary to law and further recommends that NMFS adopt a policy interpreting the small numbers requirement of section 101(a)(5)(A) such that it:

- Requires determinations be made when issuing incidental take regulations (as opposed to when LOAs are issued);
- makes such determinations based on the total take authorized incidental to the specified activity and for the full duration covered by those regulations (as opposed to for each LOA and on an annual basis); and
- provides an opportunity for public notice and comment on all small numbers determinations.

Response: As explained in the responses above and discussion under the Small Numbers section of this preamble, NMFS disagrees, based on our analysis of the statute, the legislative history, the implementing regulations, and relevant case law.

NMFS issues incidental take authorizations under section 101(a)(5)(A) through LOAs, provided that we satisfy the relevant statutory standards. Analysis of that statutory provision and relevant legislative history, including when read in conjunction with section 101(a)(5)(D), leads NMFS to conclude that the small numbers limitation may be applied at the LOA stage, provided that we make the negligible impact finding for the total taking allowable under the regulations for the specified activity and

[7] We further note that population biology often focuses on annual cycles. See, *e.g.,* 50 CFR 216.103 (negligible impact defined in terms of impacts on annual rates of recruitment or survival); 16 U.S.C. 1386(a), (c) (requiring stock assessment reports to estimate the annual human-caused mortality and serious injury of the stock, and annual review of stock assessments when significant new information is available that may indicate the stock assessment should be revised); 16 U.S.C. 1362(26) (defining ''net productivity rate'' as the annual per capita rate of increase in a stock resulting from additions due to reproduction, less losses due to mortality); 16 U.S.C. 1383a(l)(ii) (requiring MMC's recommended guidelines to govern the incidental taking of marine mammals in the course of commercial fishing operations, to the maximum extent practicable, to include as a factor to be considered and utilized in determining permissible levels of taking ''the abundance and annual net recruitment of such stocks'').

[8] The one exception to date is NMFS' regulation governing the incidental take from explosive removal of offshore structures in the GOM (EROS), promulgated at the request of the Minerals Management Service on behalf of multiple private removal companies that individually submitted LOA requests. NMFS' rulemaking for the EROS regulations evaluated the estimated annual take based on MMS' projections for the specified activity as a whole, *i.e.,* for all operators combined. Our rule here is consistent with the EROS rulemaking as it relates to the approach for the negligible impact evaluation. However, the EROS rule also concluded the total annual taking (by species) for all operators combined met the small numbers requirement. Thus NMFS did not have occasion before now to consider whether it could apply the small numbers provision at an individual LOA level where there are multiple concurrent LOA holders. Having now considered the question, NMFS believes the MMPA affords the discretion to do so.

set the small numbers standard for future LOAs in the notice and comment rulemaking.

As noted above, the term ''small numbers'' is not defined in the statute. Over the years NMFS has grappled with how to define the term, particularly given the limited legislative history (*i.e.,* ''accidental, infrequent, or unavoidable''; ''not capable of being expressed in absolute numerical terms''). Recent court decisions lend support for NMFS' proportional approach to the concept. See *Center for Biological Diversity* v. *Salazar,* 695 F.3d 893 (9th Cir. 2012). In terms of what proportion may constitute ''small numbers'' for purposes of what the Secretary may authorize, NMFS has determined that small numbers means up to one-third of a species or stock. NMFS has further determined that this limit can be applied at the LOA level, subject to a finding that the total taking allowable (through any and all LOAs issued under the activity-specific rule and corresponding regulations) satisfies the negligible impact standard.

The MMC inaccurately states that the ''interpretation of the small numbers requirement proposed by NMFS in many ways seeks to maximize the numbers of takes of marine mammals that may be authorized under a single rulemaking.'' With one exception, the points raised by the MMC reflect NMFS' existing practice. The decision to make small numbers findings on an LOA-specific basis is the only new development and, as explained in the response to the previous comment, came about only when the issue arose for the first time in the context of this rulemaking. NMFS considered the specific issue, determined that section 101(a)(5)(A) does not unambiguously speak to it, and reasonably exercised its discretion in determining that small numbers findings could apply at the LOA stage, provided that the standard is set forth in the rule itself, which it is.

We acknowledge that section 101(a)(5)(A) does not expressly contemplate the issuance of LOAs, which are a creature of NMFS and U.S. Fish and Wildlife Service (FWS) joint implementing regulations for section 101(a)(5)(A). (See 50 CFR 216 subpart I (NMFS regulations); 50 CFR 18.27 (FWS regulations)). Those implementing regulations, in effect since 1989, established LOAs as the regulatory instrument to authorize lawful incidental take under section 101(a)(5)(A), after the promulgation of activity-specific regulations that undergo notice and comment rulemaking.

Although not the typical scenario, NMFS' implementing regulations allow for the issuance of LOAs to more than one ''U.S. citizen'' taking marine mammals under a specified activity regulation, see, *e.g.,* 50 CFR 216.105(a); 216.106(e); (54 FR 40338 (September 29, 1989)), provided that the negligible impact finding is made for the total taking for the specified activity as a whole, by all entities conducting that activity.

NMFS also administers section 101(a)(5)(D), a very similar provision enacted in 1994 that established an expedited process for the issuance of one-year incidental take authorizations for the taking of small numbers of marine mammals by harassment only when the taking from the specified activity is found to have a negligible impact on the affected species or stocks of marine mammals (referred to as incidental harassment authorizations, or ''IHAs''). See the Small Numbers section later in this Notice. The small numbers standard in section 101(a)(5)(D) applies to each individual one-year IHA, yet the same small numbers language also appears in section 101(a)(5)(A). In NMFS' view, the statute is silent on how to apply the same small numbers limitation in these two provisions across potentially different scales and timeframes. In the case such as here, where serious injury or mortality is not expected from the activity (and would not be authorized in any LOA), each prospective LOA applicant could instead opt to apply for an IHA under section 101(a)(5)(D). It would be an absurd result to deny an LOA for a single geophysical survey on the sole basis that small numbers is not satisfied because the take numbers from that survey must be aggregated with the takes from other surveys occurring under the same regulations, only to turn around and issue an IHA for the same survey, simply because the applicant has decided to avail itself of section 101(a)(5)(D) instead. But that would be the result under the MMC's approach. Given NMFS' implementing regulations for section 101(a)(5)(A), which are authorized under 16 U.S.C. 1382(a), and when viewed in light of section 101(a)(5)(D) and applying our administrative experience, NMFS has determined our approach is a reasonable interpretation of how to carry out section 101(a)(5)(A) and the implementing regulations in the context of these two statutory provisions. This is a reasoned approach that draws on NMFS' expertise.

Further, authorization of take incidental to geophysical survey activity within the covered regions of the GOM under this ITR allows for the more comprehensive evaluation and management of take of marine mammals than if NMFS were to authorize take for those same activities under IHAs. NMFS worked with BOEM and its predecessor agency over many years to ensure a process that holistically analyzed the impacts from expected geophysical surveys in the GOM. This is preferable first and foremost for its greater likelihood of achieving the best substantive impact analysis and comprehensive management (including mitigation and monitoring) scheme, but the process is also efficient for stakeholders (regulated industry and interested members of the public) and results in more efficient use of administrative agency resources.

The MMC argues that NMFS' implementing regulations support the MMC's view of the application of small numbers, because ''whereas the regulatory section governing the issuance of incidental take regulations (50 CFR 216.105) includes a reference to the small numbers requirement, the section governing LOAs (50 CFR 216.106) omits any reference to that requirement.'' However, the implementing regulations originally defined small numbers as synonymous with negligible impact. NMFS no longer interprets small numbers in that way, but as a result of that original approach, the MMC's particular citations do not shed light on the permissible approach for making a small numbers determination as that term is now interpreted.

NMFS agrees with the MMC that workload alone would not be a sufficient basis for our interpretation, and it is not what we rely on. Rather, the analysis we presented leads us to conclude that NMFS has discretion to apply small numbers at the LOA level and, in this case, policy considerations supported that approach.

Comment: NRDC states that NMFS' interpretation of small numbers ''leads to absurd results and permits excessive take.''

Response: NMFS' negligible impact assessment evaluated the risk to the affected species and stocks of marine mammals, taking into account the amount and severity of anticipated take (and take the agency is prepared to authorize) as well as the status of the species and mitigation/monitoring. Of note, and as indicated in Changes from the Proposed Rule, as a result of BOEM's updated scope of the activities and the associated revisions to the levels of effort, both the maximum allowable amount of take under the rule, as well as the maximum annual take,

has decreased (significantly in some cases) for all species and stocks except two, for which maximum allowable take and/or maximum annual take increased slightly, and the severity of many of the impacts has been lessened via the elimination and/or reduction of take in areas of greater biological importance previously considered as mitigation areas.

The numbers of potential incidents of take or animals taken are only part of an assessment and are not, alone, decisively indicative of the degree of impact. In order to adequately evaluate the effects of noise exposure at the population level, the total number of take incidents must be further interpreted in context of relevant biological and population parameters and other biological, environmental, and anthropogenic factors and in a spatially and temporally explicit manner. The effects to individuals of a ''take'' are not necessarily equal. Some take events represent exposures that only just exceed a Level B harassment threshold, which would be expected to result in lower-level impacts, while other exposures (fewer, as the exposure modeling effort illustrates) occur at higher received levels and would typically be expected to have comparatively greater potential impacts on an individual. Further, responses to similar received levels may result in significantly different impacts on an individual dependent upon the context of the exposure or the status of the individuals (*e.g.,* if it occurred in an area and time where concentrated feeding was occurring, or to individuals weakened by other effects). Last, impacts of a similar degree on a proportion of the individuals in a stock may have differing impacts to the stock based on its status, *i.e.,* smaller stocks may be less able to absorb deaths or reproductive suppression and maintain similar growth rates as larger stocks.

Comment: The MMC recommended that if such determinations are made based on a proportion of a species' or stock's abundance, NMFS adopt a policy interpreting the small numbers requirement of section 101(a)(5)(A) such that it: (1) Include a sliding scale, such that a lower proportion is allowed as stock size increases, and (2) include an evaluation of the relative risk that the established threshold would be exceeded if the best available population estimate or some other metric, such as a minimum or intermediate population, is used.

Response: NMFS disagrees with these recommendations. Under the ''one-third'' interpretation offered here, and on which we will base our small numbers analyses when evaluating LOA applications under this rule, take equating to greater than one-third of the predicted individuals in the population would generally not be considered small numbers. The MMC presents an example from a very large population, asserting that an amount of take that would meet NMFS' proportional small numbers standard would not appropriately be considered ''small'' because it is large in terms of absolute magnitude. The MMC does not present a rationale for why its proposed sliding scale approach is more appropriate, nor does it provide an explanation of what the drawbacks are (biological or otherwise) of authorizing takes of large numbers of marine mammals (in the absolute sense) from a significantly large (and arguably healthier and more robust) population (even where still less than one-third of the population under NMFS' proportional approach). We have determined that a proportional approach is the appropriate way to interpret small numbers, not an absolute ''on its face'' numeric standard. Accordingly, absolute numbers would not be relevant to our small numbers determinations. There is no meaningful way to define what should be considered as a ''small'' number on the basis of absolute magnitude, and the MMC offers no such recommendation.

Mitigation, Monitoring, and Reporting

Comment: NRDC states that NMFS should include a year-round area closure for Bryde's whales. Specifically, NRDC states that this should include the following: (1) Excluding airgun surveys year-round from the whales' occupied habitat; (2) excluding airgun surveys from areas identified, through modeling, as most likely to propagate low-frequency sound into the Bryde's whales' habitat; and (3) establishing mitigation to reduce noise in the whales' unoccupied habitat, *i.e.,* areas they are likely to have inhabited according to the whaling records and have habitat characteristics similar to those of the De Soto canyon. The MMC also recommends that NMFS include a year-round area closure for Bryde's whales, while agreeing that the area defined by NMFS in the proposed rule is appropriate. In addition, a private citizen commented that a year-round closure is more appropriate than a seasonal closure, because Bryde's whales use the area year-round. The Associations and other industry commenters argue to the contrary, stating that there should be no restriction within the Bryde's whale area and that, if a restriction is required, it should be seasonal rather than year-round. The Associations also state that if implemented, the restriction area should be smaller. With regard to the other alternative offered by NMFS for comment—no restriction but a requirement to conduct real-time whale detection through use of a moored listening array—the Associations state, ''the final ITR should not impose a moored array requirement because the limits inherent in such data are outweighed by the impracticability of such arrays.'' The CRE also comments, with no supporting information, that there should be no restriction on survey effort in the Bryde's whale core habitat area.

Response: As described in the proposed rule, NMFS agrees with NRDC and the MMC that the status (*e.g.,* small population size, restricted distribution, anthropogenic effects, small population effects) of the recently ESA-listed GOM Bryde's whale warranted the consideration of a year-round closure to airgun surveys within the area described as core habitat for the whale (Area #3). We disagree with the Associations' arguments that no requirement is warranted. However, the comments specifically relating to the need (or lack thereof) to impose a restriction on survey effort in Bryde's whale core habitat, the duration of any such restriction, or any additional requirements in the core habitat area, are no longer relevant following BOEM's updated scope of activity. This update means that no survey effort within Bryde's whale core habitat is considered through this rulemaking and the vast majority of any anticipated or authorized impacts to this species have been eliminated. Please see Table 1 and Figure 2, earlier in this notice.

Regarding NRDC's recommendations for establishing Bryde's whale mitigation measures beyond the core habitat area identified in the notice of proposed rulemaking, NMFS does not believe these are warranted. We initially note that the comment uses the terms ''occupied and ''unoccupied'' to describe habitat. These are terms of art in the Endangered Species Act and implementing regulations for designation of ''critical habitat.'' For this MMPA rulemaking, the correct standard is measures to effect the ''least practicable adverse impact'' on the affected species or stocks and their habitat. NMFS has now determined that additional geographic-based mitigation for Bryde's whales is not warranted. Following BOEM's update to the scope of their specified activity, expected takes of Bryde's whales are significantly reduced in the remaining area where the specified activity will occur under this

rule (*i.e.,* there are now no more than 10 anticipated instances of take annually; see Table 9).

Regarding NRDC's comments that additional protections are needed in areas that are ''unoccupied'' by the Bryde's whale, we disagree. NMFS' objective in requiring a closure would be to minimize the effects of airgun surveys on Bryde's whales while in important habitat. In areas where modeling and/or observational data show a species or stock is unlikely to occur during the period of the rule, it is generally unlikely that a geographic or other mitigative restriction would reduce impacts from the specified activities on the species or stock and its habitat, and therefore is not justifiable absent some other compelling basis. Finally, we are unsure of what NRDC might mean in recommending exclusion of surveys from areas identified as most likely to propagate low-frequency sound into Bryde's whale habitat, or whether such areas are still covered by the rule given BOEM's updated scope, and NRDC provides no meaningful justification for the recommendation, nor any useful recommendations for how such areas could be identified.

Comment: In reference to NMFS' statement that the agency does not consider towed passive acoustic monitoring (PAM) to be a useful tool with regard to detection of Bryde's whales, the Associations state that they do believe more typical real-time detection-based mitigation, such as use of towed PAM, should provide sufficient protection for Bryde's whales, and assert that we did not provide sufficient information to meaningfully comment on the conclusion.

Response: It is generally well-accepted fact that, even in the absence of a firing airgun, using a towed passive acoustic sensor to detect baleen whales (including Bryde's whales) is not typically effective because the noise from the vessel, the flow noise, and the cable noise are in the same frequency band and will mask the vast majority of baleen whale calls. Further, Bryde's whales have relatively short calls, further exacerbating the problem. As background, airguns produce loud, broadband, impulsive signals at low frequencies (*e.g.,* Hildebrand, 2004). Source characteristics are variable but typically peak pressures are in the 5–300 Hz frequency range, with source levels as high as 260 dB peak re 1 μPa at 1 m output pressure (Hildebrand, 2009). Pulse rates are typically one per 10–20 s (Hildebrand, 2009). Seismic survey noise can raise background noise levels by 20 dB or more over large areas while present. Because the seismic pulse and the whale's call are within the same frequency range, and the seismic pulse is much louder than the whale's call (see below), it is extremely unlikely that a baleen whale can be detected during the pulse. In addition to the actual seismic pulse (approximately every 10–20 s), the background noise level is expected to be significantly increased as a result of the reverberant field generated from seismic pulses (Guerra *et al.,* 2011; Guan *et al.,* 2015), *i.e.,* during the inter-pulse interval. The level of elevated inter-pulse noise levels can be as high as 30–45 dB within 1 km of an active 3,147 in^3 airgun array (Guerra *et al.,* 2011). Given that towing hydrophones for PAM used for marine mammal monitoring would be within 1 km from the airgun source, the received noise spectral density during the inter-pulse interval is expected to be very high.

Vessels also produce low-frequency noise, primarily through propeller cavitation, with main energy also in the 5–300 Hz frequency range. Source levels range from about 140 to 195 dB re 1 μPa at 1 m (NRC, 2003; Hildebrand, 2009), depending on factors such as ship type, load, and speed, and ship hull and propeller design. Studies of vessel noise show that it appears to increase background noise levels in the 71–224 Hz range by 10–13 dB (Hatch *et al.,* 2012; McKenna *et al.,* 2012; Rolland *et al.,* 2012). PAM systems employ hydrophones towed in streamer cables approximately 500 m behind a vessel. Noise from water flow around the cables and from strumming of the cables themselves is also low-frequency and typically masks signals in the same range.

GOM Bryde's whale calls have relatively low source levels (155 dB re 1μPa) and frequency ranges (78–110 Hz; Širović *et al.,* 2014) that overlap the sounds described above. In addition, GOM Bryde's whales call only infrequently (*i.e.,* a 3.5 hour research encounter with 4 whales resulted in detections of 14 calls). The chances of acoustically detecting these whales is low under ideal research circumstances, is much lower with elevated background noise from the ship and towing cable, and essentially impossible with an airgun array shooting. Whales are routinely detected acoustically using moored systems and sonobuoys, or using autonomous gliders. However, these platforms are all quiet. A leading provider of observer services for the seismic industry, including PAM, reports that they have never detected a baleen whale (other than rare detections of humpback whales, which have significantly higher frequency content in their call) using PAM aboard a working seismic vessel (S. Milne, RPS Group, pers. comm.). Experienced PAM operators participating in a recent workshop (Thode *et al.,* 2017) emphasized that a PAM operation could easily report no acoustic encounters, depending on species present, simply because background noise levels rendered any acoustic detection impossible. The same workshop report stated that a typical eight-element array towed 500 m behind a seismic vessel could be expected to detect delphinids, sperm whales, and beaked whales at the required range, but not baleen whales, due to expected background noise levels (including seismic noise, vessel noise, and flow noise).

Comment: The Associations provided comments regarding NMFS' proposed power-down exception to the general shutdown requirements for certain species of dolphin, as well as the related alternative of no shutdown or power-down requirement. The Associations stated that no shutdowns for dolphins are warranted, and added that an exception should not be limited to small dolphins but rather should be expanded to all delphinid species. The MMC recommended that NMFS not require a shutdown or power-down when small delphinids enter the exclusion zone, and relatedly suggested that NMFS should provide clarification as to the basis for exempting only small delphinids from shutdowns. The MMC stated their agreement with NMFS that shutting down when small delphinids enter the exclusion zone is not warranted and may result in additional survey activity. Furthermore, as indicated in the MMC comments, power-down may not be effective. The MMC stated that, given the variation in array characteristics and configuration, a requirement to ''power-down'' does not provide sufficient assurance that the resulting received levels would be below the Level B harassment threshold. CGG provided a detailed analysis of the potential operational costs associated with dolphin shutdowns or power-downs, supporting their comment that these costs would be substantial and that shutdown or power-down should not be required. NRDC provided multiple objections to NMFS' proposals, stating that of the two proposals they favor power-down.

Response: Following review of the available information and public comments, NMFS agrees that a general exception to the standard shutdown requirement is warranted for small delphinids, and that the alternative power-down requirement may not be effective and yet could impose costs on

operators. (Here we refer to ''large delphinids'' and ''small delphinids'' as shorthand for generally deep-diving versus surface-dwelling/bow-riding groups, respectively, as the important distinction is their dive behavior rather than their size.) As NMFS discussed in the notice of proposed rulemaking, mid- and high-frequency cetaceans are relatively insensitive to the frequencies where the most energy in an airgun signal is found. In order to demonstrate this quantitatively, a ''spectral ratio'' may be calculated for each hearing group. This ratio essentially compares the energy in a group-specific weighted airgun source spectrum with the energy in an unweighted airgun source spectrum, providing a representation of the proportion of total energy from the unweighted airgun spectrum that is available for animals to hear based on their group-specific general auditory filter shapes, which presumably influences the probability of behavioral response. Using M-weighting (*i.e.,* Type I filters), spectral ratios for the three hearing groups are as follows: LF, 0.71; MF, 0.03; HF, 0.02.

However, NMFS does not agree that the available evidence supports certain commenters' assertions that seismic surveys do not have any adverse effects on dolphin species. As discussed in Mitigation, auditory injury is not expected for dolphins, but the reason for dolphin behavior around vessels (when they are attracted) is not understood and cannot be assumed to be harmless. In fact, the analyses of Barkaszi *et al.* (2012), Stone (2015a), Stone *et al.* (2017), and Barkaszi and Kelly (2018) show that dolphins do avoid working vessels. That said, the available information does not suggest that such reactions are likely to have meaningful energetic effects to individuals such that the effectiveness of such measures outweighs the practicability concerns raised by commenters, in terms of the operational costs as well as the difficulty of implementation.

As noted above, the proposed rule included an alternative in which a power-down requirement would be required. However, following review of public comments, NMFS believes that a power-down requirement would potentially lead to the need for termination of survey lines and infill of the line where data were not acquired if a power-down was performed according to accepted practice, in which the power-down condition would last until the dolphin(s) are no longer observed within the exclusion zone. The need to revisit missed track line to reacquire data is likely to result in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area.

NMFS disagrees with comments that no shutdown requirements should apply to any delphinid species regardless of behavior. As noted above, industry commenters have asserted that no shutdown requirements are warranted for any delphinid species, stating that the best available science does not support imposing such requirements. The industry comments acknowledge that small delphinids are more likely to approach survey vessels than large delphinids, but claim without supporting data that there is no evidence that large delphinids will benefit from a shutdown requirement. In contrast to the typical behaviors of (and observed effects on) the small delphinid species group, the typical deep diving behavior of the relatively rarely occurring large delphinid group of species makes these animals potentially susceptible to interrupted/delayed feeding dives, which can cause energetic losses that can accrue to affect fitness. As described in greater detail in the notice of proposed rulemaking, there are ample data illustrating the responses of deeper diving odontocetes (including large delphinids) to loud sound sources (including seismic) to include interrupted foraging dives, as well as avoidance with increased speed and stroke rate, both of which may contribute to energetic costs through lost feeding opportunities and/or increased energy demands. Significant advances in study of the population consequences of disturbance are informing our understanding of how disturbances accrue to effects on individual fitness (reproduction and survival) and ultimately to populations via the use of energetic models, where data are available for a species, and expert elicitation when data are still limited. The link between behavioral disturbance, reduced energy budgets, and impacts on reproduction and survival is clear, as is the value in reducing the probability or severity of these behavioral disturbances where possible. Therefore, NMFS finds that there is support for the effectiveness of the standard shutdown requirement as applied to the large delphinid species group.

Further, the claim that shutdowns for these deep-diving species would be impracticable was not accompanied by supporting data. The data available to NMFS demonstrates that this requirement is practicable. For example, recent synthesis of observer data in the GOM shows that large delphinids were sighted only rarely, and that of these sightings, almost half were not within the 500-meter exclusion zone. We note that the Associations provided a quantitative analysis of ''historical PSO and PAM data from over 32,000 survey activity hours conducted in the GOM between 2007 and 2017,'' but provide no citation for these data (nor the data itself). Therefore, we cannot verify or meaningfully evaluate the industry-supplied analysis. Nevertheless, as detailed herein, NMFS agrees in substantial part with the comments received and accordingly do not require shutdown or power-down for small delphinids detected within the exclusion zone.

Comment: Several commenters criticized our proposal to require shutdowns upon detection of certain species or circumstances (*e.g.,* beaked whales, Bryde's whales) at any distance. The Associations suggest that such requirements are ''arbitrary and unlawful'' because they require shutdowns in ''circumstances in which no disturbance or harassment will occur.'' The Associations contend that PSOs are likely to make frequent ''precautionary'' shutdown calls for uncertain observations ''at any distance,'' and that these measures will have negative impacts on the effectiveness of visual PSOs. CGG makes similar claims, stating that ''there is no proven or likely efficacy to initiate a shutdown for cetaceans that are well outside of incidental take range'' and concluding that the standard 500-m exclusion zone should be applied in these circumstances. The MMC commented that, in reference to the two proposals of ''at any distance'' or ''within 1 km,'' they support the implementation of shutdowns for detections at any distance (rather than within 1 km of the airgun array), based on the status of the applicable species, their small population sizes, and their sensitivity to seismic sound.

Response: As discussed below and in Mitigation, an extended shutdown distance of 1.5 km is included in the final rule, in lieu of the ''at any distance'' shutdown included in the proposed rule. We first note that the industry comments against proposed shutdowns for certain species, in their view beyond the range at which harassment may occur, appears to reflect an assumption that the single-step 160-dB threshold is the relevant metric for harassment. Even if this were the case, the minimum distance to the 160-dB isopleth, based on 60 different propagation modeling scenarios, would be beyond the likely detection distance for visual observers. The smallest

threshold radius to the 160-dB isopleth is more than 7 km. However, the multi-step probabilistic risk function used here assumes that 10 percent of the population exposed above 140 dB would experience harassment; isopleth distances to 140 dB, based on the same modeling exercise, are typically greater than 50 km (minimum of approximately 29 km). Even the 90 percent harassment isopleth (*i.e.,* 180 dB) has a mean distance of 1.6 km. Therefore, the claims that shutdowns upon detection ''at any distance'' would occur in circumstances where there is no harassment are incorrect. The Associations' comments are also inconsistent in that they imply both that marine mammals are likely to be detected at ranges significantly distant from the vessel, where shutdowns would be effected on detection of animals not subject to harassment, and that marine mammals cannot be adequately identified beyond close distances, resulting in unnecessary ''precautionary'' shutdowns. NMFS agrees that visual monitoring under typical circumstances is unlikely to be effective at ranges much beyond the extended distance shutdown of 1.5 km, while under ideal circumstances acoustic detectability will also be limited to within the exclusion zone distance. (NMFS presented a detailed analysis in the notice of proposed rulemaking demonstrating that acoustic detections of sperm whales during active firing of an airgun array are not likely beyond approximately 500 m). Moreover, we specify in these regulations that shutdowns are required on positive identification of relevant species (as determined through professional judgment), meaning that there is no real likelihood that there would be numerous shutdowns based on false positive detections. Overall, it is unlikely that there will be ''unnecessary'' shutdowns to any significant degree.

The MMC provided the following supporting rationale to their comment: ''Bryde's whales are LF cetaceans with particular sensitivity to the predominantly low-frequency energy output of airguns. Beaked whales are well-documented to react behaviorally to sound levels well below those thought to cause injury, and larger exclusion zones have been recommended for beaked whales and other deep-diving whales (such as *Kogia* spp. and sperm whales) as they are more likely to exhibit a stress response when disturbed (Wright *et al.,* 2011).'' NMFS agrees with these comments. In these cases, we have identified species or circumstances with particular sensitivities for which we determined it appropriate to minimize the duration and intensity of the behavioral disruption, as well as to minimize the potential for auditory injury (for low- and high-frequency cetaceans).

NMFS disagrees with industry comments regarding the likelihood that trained, experienced professional PSOs would misunderstand the intent of a requirement to shut down upon detection ''at any distance'' and would therefore spend undue time focusing observational effort at distances beyond approximately 1,000 m from the acoustic source (*i.e.,* the zone within which we assume that monitoring is typically focused, though not necessarily exclusively). Nevertheless, in order to ensure that this potential is minimized, and to address commenters' concerns regarding the potential costs associated with shutdowns at any distance, especially in light of the diminished benefits of the measure beyond 1.5 km, we limit these shutdowns to within 1.5 km (versus at any distance). The rationale for this distance is explained later in this document in Mitigation.

Comment: NRDC states that NMFS should require that ramp-up occur over several stages in order to minimize exposure.

Response: NMFS agrees with NRDC on this point, which appears to restate the ramp-up procedures described by NMFS in the notice of proposed rulemaking. NMFS believes this approach is consistent with the Australian study referenced by NRDC.

Comment: NRDC states that the standard 500-m exclusion zone is ''not conservative,'' asserting that NMFS did not explain why the proposed zone achieves the least practicable adverse impact and stating that NMFS must consider other exclusion zone distances.

Response: NMFS has acknowledged that some limited occurrence of auditory injury is likely, for low- and high-frequency cetaceans. However, we disagree that a larger standard exclusion zone is warranted. As explained in the notice of proposed rulemaking, NMFS' intent in prescribing a standard exclusion zone distance is to (1) encompass zones for most species within which auditory injury could occur on the basis of instantaneous exposure; (2) provide additional protection from the potential for more severe behavioral reactions (*e.g.,* panic, antipredator response) for marine mammals at relatively close range to the acoustic source; (3) provide consistency and ease of implementation for PSOs, who need to monitor and implement the exclusion zone; and (4) to define a distance within which detection probabilities are reasonably high for most species under typical conditions. The use of 500 m as the zone is not based directly on any quantitative understanding of the range at which auditory injury would be entirely precluded or any range specifically related to disruption of behavioral patterns. Rather, NMFS believes it is based on a reasonable combination of factors. In summary, a practicable criterion such as this has the advantage of familiarity and simplicity while still providing in most cases a zone larger than relevant auditory injury zones, given realistic movement of source and receiver. Increased shutdowns, without a firm idea of the outcome the measure seeks to avoid, simply displace survey activity in time and increase the total duration of acoustic influence as well as total sound energy in the water, which NMFS seeks to avoid.

NMFS agrees that, when practicable, the exclusion zone should encompass distances within which auditory injury is expected to occur on the basis of instantaneous exposure. For high-frequency cetaceans, this distance was modeled as 457 m (though we acknowledged that the actual distance would be dependent on the specific airgun array and could be larger). However, we require an extended exclusion zone of 1.5 km for certain sensitive species, including *Kogia* spp. Potential auditory injury for low-frequency cetaceans is based on the accumulation of energy, and is therefore not a straightforward consideration. However, the extended exclusion zone is required for the only low-frequency cetacean in the GOM (Bryde's whale). In keeping with the four broad goals outlined above, and in context of the information given here, the standard 500-m exclusion zone is appropriate. NRDC does not provide any substantive reasoning for a larger zone.

Comment: Several industry commenters criticized the requirement for use of buffer zones in addition to the standard exclusion zones, claiming in part that there is no scientific basis for monitoring a zone larger than the exclusion zones.

Response: NMFS disagrees with the suggestion that there is no scientific basis for this requirement. It is important to implement a larger zone during pre-clearance, when naïve animals may be present and potentially subject to severe behavioral reactions if airguns begin firing at close range. While the delineation of zones is typically associated with shutdown, the period during which use of the acoustic source is being initiated is critical, and

in order to avoid more severe behavioral reactions it is important to be cautionary regarding marine mammal presence in the vicinity when the source is turned on. This requirement has broad acceptance in other required protocols: The Brazilian Institute of the Environment and Natural Resources previously required a 1,000-m pre-clearance zone before recently extending the exclusion zone to encompass the entire 1,000-m zone (IBAMA, 2005, 2018), the New Zealand Department of Conservation requires that a 1,000-m zone be monitored as both a pre-clearance and a shutdown zone for most species (DOC, 2013), and the Australian Department of the Environment, Water, Heritage and the Arts requires an even more protective scheme, in which a 2,000-m ''power down'' zone is maintained for higher-power surveys (DEWHA, 2008). Broker *et al.* (2015) describe the use of a precautionary 2-km exclusion zone in the absence of sound source verification (SSV), with a minimum zone radius of 1 km (regardless of SSV results). We believe that the simple doubling of the exclusion zone required here is appropriate for use as a pre-clearance zone.

Comment: CGG comments that shutdowns based on acoustic detections should be required only when the acoustic PSO is confident that the vocalization is from a non-delphinid species within the exclusion zone, as opposed to when the PSO is confident that the animal is outside of the exclusion zone.

Response: We are unclear as to the practical impact of what appears to be a fairly nuanced difference, but clarify that shutdown upon acoustic detection of non-delphinids within the exclusion zone is required when the animal is detected acoustically and localized within the exclusion zone. However, we also note that PSO decision-making regarding shutdown implementation shall be informed to a reasonable extent by professional judgment.

Comment: NRDC suggests that NMFS is remiss in not limiting the amount of activity that can occur overall (to a lesser amount than analyzed in the rule). Relatedly, NRDC suggests that NMFS must consider ''placing a cap on the amount of allowable seismic activity.''

Response: Such a requirement is not within NMFS' authority under the MMPA, assuming that the requisite findings are made. NMFS' responsibility is to evaluate the potential effects of the specified activity as presented by the applicant (BOEM in this case, acting on behalf of future industry applicants) and to determine whether the total taking will have a negligible impact on the affected species or stocks (among other things). If NMFS is unable to make the necessary finding, the applicant may then consider a revision to the specified activity that could lead to NMFS being able to make the necessary finding of negligible impact (or in some cases additional mitigation may enable a negligible impact finding). However, in this case, NMFS has made a finding of negligible impact, and it is not within NMFS' authority to unilaterally impose a reduction in activity levels to some degree (NRDC does not specify the degree or distribution of reduction in time or space that they would find acceptable).

Comment: NRDC expressed concern regarding the efficacy of the prescribed visual and acoustic monitoring methods, stating that species could go undetected.

Response: While NMFS disagrees with some specific comments regarding efficacy, we generally agree with the overall point that there are limitations on what may reasonably be expected of either visual or acoustic monitoring. While visual and acoustic monitoring effectively complement each other, and acoustic monitoring is the more effective monitoring method (for certain species) during periods of impaired visibility, there is no expectation that these methods will detect all marine mammals present. In general, NRDC appears to misunderstand what NMFS claims with regard to what such monitoring may reasonably be expected to accomplish and/or the extent to which we rely on assumptions regarding the efficacy of monitoring in reaching the necessary findings. We acknowledge these limitations in prescribing these monitoring requirements, while stating why NMFS believes that visual and acoustic monitoring, and the related protocols we have prescribed, are an appropriate part of the suite of mitigation measures here that satisfy the MMPA's least practicable adverse impact standard. However, the negligible impact finding is not conditioned on the presumption of a specific degree of monitoring efficacy.

Comment: The MMC recommends that NMFS expand its shutdown requirement for sperm whales to include both visual and acoustic detections at extended distance, stating that vital functions of sperm whales, including both foraging and resting, should be afforded the additional protection of the extended shutdown zone. NRDC asserts that acoustic shutdowns for sperm whales, which they believe are not required under the ITR, would not be effective. The CRE comments that they ''agree with [NMFS] that sperm whale shutdowns are not warranted.''

Response: NMFS agrees with the MMC's recommendation and has made the recommended change (albeit within a revised extended distance shutdown zone of 1.5 km; see Mitigation). However, we note the MMC's statement that ''[t]he requirement for implementing shut-down procedures upon acoustic detection of a sperm whale was inadvertently omitted from the proposed regulatory text.'' NMFS disagrees with this statement. The proper interpretation of the proposed regulatory text was that such shutdowns would be required. Nevertheless, the revised, final regulatory text makes this requirement clearer, in addition to making the change to be inclusive of visual detections at the greater distance. Regarding the CRE's comment, NMFS did not determine that ''sperm whale shutdowns are not warranted.'' Shutdowns for sperm whales have been required in the GOM for over a decade, and NMFS does not make any findings that this should change.

With regard to NRDC, we reference this comment only to provide necessary clarification. Because NRDC mistakenly claims that ''NMFS hasn't included an acoustic shutdown requirement for sperm whales in its proposed regulation,'' we refer the reader to the notice of proposed rulemaking, in which we state that shutdown of the acoustic source is required upon acoustic detection of a sperm whale (29274–29275). (''We are proposing that shutdown of the acoustic source should also be required in the event of certain other observations [. . .]. Circumstances [. . .] include [. . .] acoustic detection of a sperm whale.'') This requirement is carried forward in this final ITR, as modified (see Mitigation).

With regard to the efficacy of the measure, we are confused as to NRDC's comments. NRDC first asserts that sperm whales are the only species for which acoustic detection may reasonably be assumed, but then seemingly states that implementation of the measure is not sufficiently effective as to be considered in context of reducing impacts to sperm whales. As discussed in greater detail elsewhere, NMFS believes that shutdowns for sperm whales at an extended distance, on the basis of both acoustic and visual detections (the latter added in this final ITR), will meaningfully reduce impacts to the species.

Comment: NRDC asserts that NMFS does not fulfill the MMPA's requirement to prescribe mitigation achieving the

''least practicable adverse impact'' to marine mammal habitat, and specifically notes that NMFS does not separately consider mitigation aimed at reducing impacts to marine mammal habitat, as the MMPA requires.

Response: NMFS disagrees with this comment. Our discussion of least practicable adverse impact points out that because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat. In the notice of proposed rulemaking, NMFS identified time-area restrictions based on a combination of factors that include higher densities and observations of specific important behaviors of the animals themselves, but also clearly reflect preferred habitat. In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features, among others), the high densities and concentration of certain important behaviors (*e.g.,* feeding) in these particular areas clearly indicates the presence of preferred habitat. Also, NRDC asserts that NMFS must ''separately'' consider measures aimed at marine mammal habitat. The MMPA does not specify that effects to habitat must be mitigated in separate measures, and the notice of proposed rulemaking clearly identified measures that provide significant reduction of impacts to both ''marine mammal species and stocks and their habitat,'' as required by the statute. Last, we note that NRDC acknowledges that the measures identified in the notice of proposed rulemaking measures would reduce impacts on ''acoustic habitat.'' Following BOEM's update to the scope of activity, two of the three time-area restrictions identified and proposed by NMFS now fall outside the area in which survey activity may be considered under this rule.

Comment: NRDC recommends that NMFS should consider a year-round restriction on geophysical survey activity within coastal waters in the footprint of the DWH oil spill, and that NMFS must expand its proposed GOM-wide coastal restriction temporally to include the month of January. Conversely, the Associations state that no coastal restriction should be required. The MMC recommends that the proposed coastal closure be expanded temporally such that the timeframe is from January through August.

Response: NMFS finds aspects of both NRDC's and the Associations' statements with which we agree and disagree and, as discussed in Mitigation, have revised the time-area restriction. This restriction on airgun survey activity (''Area 1'') was proposed as including all GOM waters inside the 20-m isobath, from February through May. The revised restriction is limited to those waters inside the 20-m isobath from 90° to 84° W. Temporally, the restriction is expanded to be in effect from January through May.

The Associations provide extensive comments relating to the impacts on practicability presented by the proposed restriction. The potential economic consequences of the measure are addressed in greater detail in the regulatory impact analysis (RIA), which analysis we adopt as a portion of our practicability assessment for the revised measure. NMFS agrees that there will likely be negative economic and operational consequences of the restriction, though these consequences are difficult to assess (and cannot reasonably be assessed quantitatively) (see the RIA for full analysis). While the Associations express concerns regarding the practicability analysis as being too vague, they fail to provide additional specific information that would help to improve the analysis. For example, the Associations state that data from the area contained within the restriction are outdated and that the restriction will impede industry's ability to identify prospects in coastal areas, but provide no specific information to support these claims, such as information about the data that do exist or the areas where industry anticipates having interest in identifying prospects. Despite the lack of information provided in support of the practicability concerns, NMFS takes seriously the Associations' concerns, and therefore did consider eliminating the restriction.

The Associations also assert that the restriction would not result in any meaningful benefit to coastal bottlenose dolphin populations. NMFS disagrees that this is the case. Although dolphins are less sensitive to the frequencies at which the greatest energy in an airgun signal is found, we have described the large body of evidence of adverse or aversive behavior by various dolphin species during airgun firing (*e.g.,* Goold and Fish, 1998; Stone and Tasker, 2006; Barkaszi *et al.,* 2012; Stone, 2015a; Barkaszi and Kelly, 2018). Considered in context of a generic dolphin population with no notable issues affecting the population as part of the environmental baseline, it may be reasonable to assume that such effects are not indicative of any response of a severity such that the need to avoid it outweighs the impact on practicability for the industry and operators. However, as was described in the notice of proposed rulemaking, and as discussed in NRDC's comment, coastal bottlenose dolphins in the GOM—particularly the northern coastal stock of bottlenose dolphins—were severely impacted by the DWH oil spill.

As explained in the notice of proposed rulemaking, while none of the dolphin strandings or deaths have been attributed to airgun survey activities, stocks in the area are stressed and the northern coastal stock in particular is in extremely poor health. The Associations' discussion of NMFS' analysis—claiming that our justification for the restriction was premised merely on ''the broad understanding that 'marine mammals react to underwater noise' ''—is factually mistaken. As we stated, behavioral disturbance or stress may reduce fitness for individual animals and/or may exacerbate existing declines in reproductive health and survivorship. For example, stressors such as noise and pollutants may be expected to induce responses involving the neuroendocrine system, which controls reactions to stress and regulates many body processes (NAS, 2017), and there is strong evidence that petroleum-associated chemicals can adversely affect the endocrine system, providing a potential pathway for interactions with other stressors (Mohr *et al.,* 2008, 2010). Romano *et al.* (2004) found that upon exposure to noise from a seismic watergun, bottlenose dolphins had significantly elevated levels of a stress-related hormone and, correspondingly, a decrease in immune cells. As we stated, the restriction is intended specifically to avoid additional stressors to these coastal bottlenose dolphin populations during the time period believed to be of greatest importance as a reproductive period. The Associations do not contradict this information, instead weakly relating the concern to the potential for dolphins to experience damage to auditory structures (which NMFS agrees is unlikely) or to the idea that ''reactions'' to noise are innocuous.[9]

Population-level impacts related to energetic effects or other impacts of noise are difficult to determine, but the addition of other stressors can add

[9] The Associations also apparently misunderstand some discussion of stranding events (which have occurred primarily as a result of military use of mid-frequency active sonar) provided in the notice of proposed rulemaking, interpreting this discussion as NMFS' ''suggestion that seismic surveys are similar to mid-frequency sonar (which has been implicated in strandings) simply because seismic signatures include a mid-frequency component.'' We suggested no such thing and agree with the Associations that airguns and sonar are very different sound sources with very different potential to cause strandings.

considerable complexity due to the potential for interaction between the stressors or their effects (NAS, 2017). When a population is at risk, NAS (2017) recommends identifying those stressors that may feasibly be mitigated. We cannot undo the effects of the DWH oil spill, but the potentially synergistic effects of noise due to the activities that are the subject of this rule may be mitigated. However, NMFS does acknowledge that the two populations of greatest concern—the western and northern coastal stocks of bottlenose dolphin—do not have the same status. As identified in the notice of proposed rulemaking, while both stocks were impacted by the DWH oil spill, the northern coastal stock in particular was perhaps the single most heavily impacted stock, with 82 percent of animals belonging to the stock expected to have been exposed to oil, resulting in a possible population reduction of 50 percent (this latter figure was only five percent for the western stock). The northern coastal stock was also subject to a recent Unusual Mortality Event (UME), described later in this notice (see Description of Marine Mammals in the Area of the Specified Activity). NMFS acknowledges the uncertainty associated with predicting the ways in which different stressors may interact, or how the effects of a stressor might be exacerbated in an unhealthy population. However, as an example, Schwacke *et al.* (2014a) described findings indicating that a significant proportion of the population is expected to exhibit adrenal insufficiency as a result of oil exposure. Adrenal insufficiency can lead to adrenal crisis and death in animals that are challenged with other stressors (Venn-Watson *et al.,* 2015b). NMFS agrees that the potential practicability concerns warrant consideration and, in light of the differential baselines for the potentially affected coastal stocks, has determined it appropriate to contract the restriction. However, the post-DWH oil spill baseline condition of the northern coastal stock, as exacerbated by the recent UME, requires caution. This restriction may reasonably be anticipated to provide additional protection to these populations during their peak reproductive activity. We note that NRDC's proposed focus area for heightened restriction aligns generally with this area of concern, but that in aligning with the footprint of the spill rather than with the stock boundaries, this recommendation would not necessarily encompass the animals of greatest concern and which we assume are the population targeted by the proposal.

With regard to the timing of the closure, there is no definitive definition of the ''peak reproductive activity'' associated with the stock and, additionally, there is some uncertainty as to whether the more important focus is on effects to pregnant mothers or on the post-partum period when energetic or stress effects would lead to greater risk for lactating mothers and/or disruption of mother-calf bonding and ultimate effects on rates of neonate and/or calf survivorship. We acknowledged this uncertainty in discussing the recommendations of NMFS' subject matter experts and describing the proposed temporal extent of February through May in the notice of proposed rulemaking. Upon review of the information presented in the comments of NRDC (*e.g.,* reference to the data presented by, *e.g.,* Carmichael *et al.,* 2012; Mattson *et al.,* 2006; Urian *et al.,* 1996), which supported NRDC's assertion that, in summary, inclusion of January would cover the remainder of the dolphins' peak calving and late gestation periods as well as the beginning of the period of highest reproductive failure, NMFS agrees that this temporal expansion is appropriate (within the contracted region of our revised restriction area). In contrast, the MMC does not provide compelling information in support of the recommendation to expand the restriction by an additional three months (through August), stating only that ''calves can be born at any time of the year'' and referencing a bimodal peak in neonate strandings from the Sarasota Bay area. Given the exacerbation of practicability concerns that this expansion would entail and the lack of information to support it, NMFS does not believe it appropriate to expand the restriction through August.

We do note that one concern of the Associations, which is that the restriction may result in an inability to complete surveys within one year, may be alleviated to some degree by the ability under this ITR to issue LOAs for any term up to five years. The Associations recommend that, if the restriction is included in the ITR, NMFS allow for multi-year LOAs, which we have done.

Comment: The Associations state that the proposed time-area restriction in the Dry Tortugas region of the eastern GOM should not be required. However, the MMC concurs with NMFS' proposal, stating that the imposition of this restriction is appropriate.

Response: NMFS appreciates the comments. The proposed time-area restriction referenced here is no longer relevant following BOEM's update to the geographic scope of activity, as no survey activity within this area can be considered through this rule.

Comment: NRDC comments that NMFS must consider restrictions and limitations on survey activity in the Central Planning Area (CPA) restriction area analyzed in the proposed rule. NRDC states that NMFS' practicability analysis must focus on (1) how much oil and gas development is projected to occur within the proposed areas over the next five years; (2) what effect the proposed mitigation area would have on that projected development; and (3) whether that projected development would be offset by exploration in other parts of the GOM.

Response: NRDC accurately characterizes the area as being important for sperm whales [10] and beaked whales, as was described by NMFS in the notice of proposed rulemaking, and accurately describes that this area is projected to be subject to significant survey effort. NMFS acknowledges these issues. However, NRDC provides no serious rebuttal of NMFS' practicability analysis, which includes incorporation by reference of the findings of the RIA for this rule, instead providing only a cursory rejection of the analysis as inadequate. We also note that the third prong of NRDC's suggested analysis is not reasonable: Development foregone due to a lack of survey data in the closure areas cannot be ''offset by exploration'' elsewhere.

As discussed in detail in the RIA, there are significant uncertainties associated with assessing the indirect costs of restricting survey effort within the described area. Notable areas of uncertainty include the demand for and timing of oil and gas production in the GOM over the next five years, the suitability of existing data to direct oil and gas production in the closure areas, and the most likely substitute sites for oil and gas production. These uncertainties foreclose the possibility of the analysis demanded by NRDC. However, what information is available strongly suggests that the economic impacts of the evaluated CPA restrictions would be significant. A mitigation requirement that could lead

[10] However, we note that NRDC mischaracterizes sperm whale buzz rates as ''a measure of foraging success,'' as opposed to a measure of foraging effort. The study referenced by NRDC did not find that sperm whale foraging success ''declined substantially'' on exposure to airgun noise. Moreover, the measured decline in foraging effort was not a statistically significant result and, therefore, cannot appropriately be referred to as a substantial decline. See Miller *et al.* (2009).

to regional- to national-scale economic impacts is not practicable.

The impacts of year-round area closures are highly dependent on volatile oil and gas market conditions over the next five years, which dictate the demand for activities in the GOM. The greater the demand for oil and gas, the greater the expected impacts of the restrictions. The extent to which oil and gas production is delayed because of the need for newer, better data is a key source of uncertainty. Some sites may be able to employ existing data from recent surveys. However, even for relatively recent data, the inability to collect new seismic data could affect oil and gas development given that oil companies typically use targeted seismic data to refine their geologic analysis before drilling a well.

It is possible that some fraction of reductions in production from the closure areas may be made up for with production in other areas in the GOM, mitigating potential regional economic impacts. However, uncertainty with regard to the location of ''substitute'' production has potentially critical impacts on the ultimate economic impacts of the closure. If a closure requirement reduces exploration and development activity in the GOM, the displaced capital expenditures would likely shift to the next-lowest-cost opportunities promising the greatest development potential. Given that oil is produced and sold in a global market, the next-lowest-cost areas may be elsewhere within the GOM, but also may be international locations. To the extent that substitute areas are outside of the GOM but within the United States, national-level impacts of the closure areas would likely be limited. However, to the extent that industry moves displaced activities outside of the United States, national-level impacts associated with industry income and employment could be substantial. Recent levels of leasing and drilling activity in the CPA indicate that the closure areas considered are among the most productive in the entire GOM.[11] Given this, it is less likely that other GOM areas will offer equivalent alternative opportunities. As a result, the analyzed area closures have greater potential to reduce domestic oil and gas production, industry income, and related regional employment opportunities.

NRDC asks NMFS to conduct analyses that cannot be supported by existing data. Further, NRDC asks NMFS to speculate as to the impacts of restricting exploration activity outside the development of existing leases. However, such a restriction, while less impactful than a complete area-wide restriction, would necessarily foreclose the ability of both the government and industry to assess fair market value of leases already planned for sale. While NMFS believes that the evaluated restriction area would be beneficial for sperm whales and beaked whales, such restrictions are at this time not practicable. NRDC does not provide any information contradicting this conclusion, and provides no specific, viable alternatives for NMFS' evaluation.

Comment: NRDC states that NMFS should consider time-area closures for additional species.

Response: NMFS did consider habitat-based protections for species additional to those discussed in the time-area restrictions section of Mitigation. For all affected species, NMFS evaluated the environmental baseline (*i.e.,* other population-level stressors), the nature and degree of effects likely to be the result of the specified activities, and the information available to support the development of appropriate time-area restrictions. NMFS determined that the available information supported development of the measures described in the notice of proposed rulemaking for the Bryde's whale, sperm whales, and beaked whales. For other species, context does not justify additional protections and/or the available information does not support the designation of any specific area for protection, when considered in combination with practicability concerns.

NRDC asserts that ''marine mammal populations in the northern Gulf of Mexico can no longer be considered by the agency to be too 'data poor' or broadly distributed to justify specific mitigation measures for their protection, including time-area closures.'' This is not a representation NMFS made in the notice of proposed rulemaking. NRDC then erroneously claims that NMFS ''limits its analysis to two deep-diving species, sperm whales and beaked whales [. . .]. In doing so, however, it omitted other populations whose conservation status or modeled impacts pose particular concern.'' First, NMFS did conduct core abundance analyses for all GOM stocks. Second, NRDC declines to elaborate on which stocks they believe ''pose particular concern,'' other than noting that *Kogia* spp. may be subject to Level A harassment. However, despite NRDC's statement that species can no longer be considered to be too broadly distributed to justify specific time-area mitigation measures, our core abundance analysis for *Kogia* spp. shows exactly that. Based on the Roberts *et al.* (2016) models, the two species are broadly distributed in shelf-break waters essentially throughout the GOM, and there is no identified biologically important area or specific bathymetric feature that would allow us a more refined understanding of an area suitable for protection (if it were warranted). NRDC does not suggest any specific area for protection of *Kogia* spp.

NRDC also suggests that NMFS should prohibit seismic activity in the Flower Garden Banks National Marine Sanctuary (FGBNMS) but offers no strong justification other than stating that marine mammals occur there. In addition, BOEM and/or BSEE will consult with NOAA's Office of National Marine Sanctuaries when they receive an application that indicates that survey activity may occur within or near the FGBNMS.

Overall, NRDC offers no useful recommendation as to the designation of protections for additional species. NMFS' consideration of habitat-based protections was conducted appropriately in light of relevant information regarding the environmental baseline, expected effects of the specified activities, and information regarding species use of the GOM.

Comment: Several commenters recommended establishing wider buffer zones around the proposed time-area closures. The Associations state that no buffers should be required around any time-area restriction (if required; the Associations also disagree that any restrictions should be required, as discussed previously).

Response: NRDC indicates that NMFS' stated objective in establishing the proposed buffer zones around time-area restrictions was unclear in terms of evaluating the proposed buffer zone relative to the objective. The stated objective was to exclude noise that is likely to result in harassment, which NMFS interpreted to mean site-specific modeled distances to the 160-dB isopleth (*i.e.,* 50 percent midpoint of the Level B harassment risk probability function). Following review of public comments, NMFS provides further context here regarding the multi-step Level B harassment risk function employed for purposes of evaluating modeled noise exposures.

[11] Leases within the closure areas considered within the Central Planning Area accounted for approximately 50 percent of total oil production in the GOM between 2012 and 2016 and 24 percent of total gas production. Existing reserves within the closure areas represent 57 percent of estimated oil reserves and 37 percent of estimated gas reserves in the GOM.

With regard to the establishment of a buffer zone, NMFS agrees with certain commenters that it is generally appropriate to buffer an area to be avoided by some degree, as discussed in the notice of proposed rulemaking. However, we disagree that a buffer must be developed to fully eliminate the potential for Level B harassment, as some commenters may have inferred from our use of the distance to the 160-dB isopleth (*i.e.,* historically used as a 100 percent single-step function for evaluation of Level B harassment; here the 50 percent midpoint of the Level B harassment risk function). Rather, the buffer concept, as described in the notice of proposed rulemaking, serves to reasonably minimize the extent and severity of what limited harassment may occur as a result of acoustic exposure to relatively low received levels of noise.

The Associations asserted that NMFS did not consider the use of buffer areas in the practicability analyses and provides no biological basis for including buffers. We disagree. As noted earlier, the RIA analysis (which forms a substantial part of the practicability analysis for these measures) includes analysis of the economic impacts of the time-area restrictions *inclusive of the buffer.* As noted above, the logical biological rationale is to provide a buffer around an area determined to be of particular biological importance such that the effects of noise from outside the restriction area intruding within the area is minimized.

However, BOEM's update of the geographic scope for this rule eliminates the need for proposed time-area restrictions #3 and 4 (*i.e.,* the Bryde's whale core habitat area and the ''Dry Tortugas area'' designed for protection of beaked whales and sperm whales). Therefore, comments addressing the proposed buffers for those areas are no longer relevant. Regarding the coastal bottlenose dolphin restriction (Area #1), NMFS has determined that the addition of a buffer to this area is not warranted, based on the objectives of the restriction (described in detail in a previous response to comment) and on the manner in which the area was delineated. Areas #3 and 4 were delineated based on NMFS' review of the available scientific information and expert opinion and in order to denote areas expected to be of particular biological importance for particular species. In contrast, the coastal dolphin restriction area was based simply on the stock boundaries for coastal bottlenose dolphins (*i.e.,* the seaward extent of the area is set at the 20-m isobath). As this boundary does not mark an area of specific biological importance or high density for the stock, but is rather an approximation of stock presence, NMFS has determined following review of public comments, in which valid practicability concerns were raised, that the inclusion of a buffer to this area is not warranted.

Comment: Noting that the proposed ITR included requirements to conduct visual monitoring following conclusion of active shooting, the MMC recommends that NMFS require operators to also continue conducting acoustic monitoring following conclusion of active shooting.

Response: The proposed ITR stated that acoustic monitoring must occur for 30 minutes prior to and during all active firing of airguns for deep penetration surveys, but was silent on the issue of acoustic monitoring following the survey. However, visual monitoring is required to continue for 60 minutes following cessation of survey activity during good visibility. NMFS agrees with the MMC that ''both visual and acoustic monitoring should occur concurrently, as acoustic detections can provide additional information not readily available via visual detections alone regarding changes in foraging and social behavior during survey activities and after activities cease.'' Accordingly, acoustic monitoring is also required to continue following cessation of survey activity for a period of 60 minutes.

Comment: BP comments that they welcome use of industry standard PAM/operator software such as PAMGuard. Noting the operational challenges associated with accommodating increased numbers of PSOs on survey vessels, BP also comments that they would welcome the inclusion of an option to implement PAM during survey activities using remote shore-based operators.

Response: NMFS agrees that this may be appropriate, depending on various factors. While we are not currently aware of the state of existing technology towards achieving this end, NMFS would consider the use of remote PAM monitoring, assuming reliability and the ability to achieve the same performance as shipboard PAM monitoring. NMFS believes the adaptive management process will be an appropriate venue for further consideration of this approach.

Comment: BP comments that, while they recognize the value of prospective formal standards for PAM operations (*e.g.,* hardware, software, training), the standards have not yet been finalized. BP requests that the standards be considered for use only after an initial draft has been circulated via relevant standards development and issuance processes.

Response: NMFS may adopt elements of the prospective standards, as it deems appropriate (as discussed in Monitoring and Reporting). However, we agree that wholesale adoption of the standards would not be appropriate until appropriate review and other necessary processes are complete.

Comment: Industry commenters state that non-airgun high-resolution geophysical (HRG) surveys should not be subject to pre-clearance and shutdown requirements. Relatedly, BP and Chevron comment that exclusion zones should not be required for HRG surveys, as these surveys typically operate using acoustic sources deployed on an automated underwater vehicle (AUV) running 40 m above the seafloor. Therefore, they state that there is no environmental benefit to a requirement for a surface exclusion zone.

Response: The Associations note that the acoustic footprint of sources typically used in non-airgun HRG surveys are too small to warrant the proposed exclusion and buffer zone distances and that, more importantly, due to the typically highly directional nature of these acoustic sources, animals observed at the surface will generally not be exposed to the signal. NMFS agrees with these comments, and notes that the proposed shutdown and exclusion zone requirements were offered in accordance with BOEM's HRG survey protocols (Appendix B of BOEM, 2017). Following review of these comments, as well as the available scientific information regarding the typical interaction of these signals with the environment and likely lack of efficacy of typical standard operational protocols developed for omnidirectional sources, NMFS has eliminated these requirements. However, we also clarify that certain electromechanical sources may be subject to the pre-clearance and shutdown requirements associated with shallow penetration surveys. In addition, the exclusion and buffer zone distances for shallow penetration surveys have been reduced (while adding an extended distance shutdown zone for certain circumstances) in recognition of the typically smaller harassment zones associated with use of the acoustic sources considered here to be used in shallow penetration surveys.

As noted here, NMFS has eliminated the requirement for implementation of an exclusion zone during HRG surveys. We also agree with BP's comment that exclusion zones should not be required for surveys using an AUV-deployed acoustic source running at short distances above the seafloor.

Comment: NRDC states that NMFS fails to prescribe adequate mitigation for

HRG surveys and, relatedly, that NMFS must not issue LOAs for use of lower-frequency multibeam echosounders (MBES).

Response: As evidenced by the previous comment response, in which describing elimination of certain mitigation measures that were proposed for HRG surveys, NMFS disagrees with NRDC. NRDC provides no reasonable justification for the recommendation to consider additional mitigation requirements. They reference the 2008 Madagascar stranding of melon-headed whales, implying that a similar occurrence may be a reasonably anticipated outcome of HRG survey work in the GOM. Although it is correct that an investigation of the event indicated that use of a high-frequency mapping system (12-kHz MBES) was the most plausible and likely initial behavioral trigger of the event (with the caveat that there was no unequivocal and easily identifiable single cause), the panel also noted several site- and situation-specific secondary factors that may have contributed to the avoidance responses that led to the eventual entrapment and mortality of the whales (Southall *et al.,* 2013). Specifically, regarding survey patterns prior to the event and in relation to bathymetry, the vessel transited in a north-south direction on the shelf break parallel to the shore, ensonifying deep-water habitat prior to operating intermittently in a concentrated area offshore from the stranding site. This may have trapped the animals between the sound source and the shore, thus driving them towards the lagoon system. Shoreward-directed surface currents and elevated chlorophyll levels in the area preceding the event may also have played a role.

The relatively lower output frequency, higher output power, and complex nature of the system implicated in this event, in context of the other factors noted here, likely produced a fairly unusual set of circumstances that indicate that such events would likely remain rare and are not necessarily relevant to use of more commonly used lower-power, higher-frequency systems such as those evaluated for this analysis. The risk of similar events recurring is expected to be very low, given the extensive use of active acoustic systems used for scientific and navigational purposes worldwide on a daily basis and the lack of direct evidence of such responses previously reported. The only report of a stranding that may be associated with this type of sound source is the one reported in Madagascar.

NRDC also references Cholewiak *et al.* (2017), stating that virtually no beaked whale vocalizations were detected acoustically during the time that the shipboard echosounder was operational. NRDC mischaracterizes the literature, including a speculative description of what they imagine the beaked whales were doing while not vocalizing (''suggesting that the whales broke off their foraging behavior and engaged in [. . .] silent flight''). Cholewiak *et al.* (2017) do describe finding that beaked whales were significantly less likely to be detected acoustically while echosounders were active. However, it is not clear that this response should be considered as Level B harassment when considered in the context of what is likely a brief, transient effect, given the mobile nature of the surveys and the fact that some beaked whale populations are known to have high site fidelity. In support of this conclusion, Quick *et al.* (2017) describe an experimental approach to assess potential changes in short-finned pilot whale behavior during exposure to an echosounder. Tags attached to the animals recorded both received levels of noise as well as orientation of the animal. Results did not show an overt response to the echosounder or a change to foraging behavior of tagged whales, but the whales did increase heading variance during exposure. The authors suggest that this response was not a directed avoidance response but was more likely a vigilance response, with animals maintaining awareness of the location of the echosounder through increased changes in heading variance (Quick *et al.,* 2017). Visual observations of behavior did not indicate any dramatic response, unusual behaviors, or changes in heading, and cessation of biologically important behavior such as feeding was not observed. More recently, Varghese *et al.* (2020) reported the results of an investigation of the effects of a 12-kHz MBES system on beaked whale foraging behavior off of California. Echolocation clicks from Cuvier's beaked whales were detected and classified into foraging events called group vocal periods (GVP), and compared across exposure periods before, during, and after MBES activity. Of the metrics used to assess beaked whale foraging behavior, only the number of GVPs per hour was statistically different during MBES activity versus a non-MBES period. GVPs per hour increased during MBES activity compared with before MBES activity, demonstrating that beaked whales did not stop foraging and were not displaced by the activity. These results suggest that there was not a negative impact of MBES activity on foraging behavior of this sensitive species (Varghese *et al.,* 2020).

Finally, NRDC references the work of Deng *et al.* (2014) and Hastie *et al.* (2014) in describing ''leakage'' of ''substantial noise'' at frequencies within marine mammal hearing range during use of active acoustic systems that are operated at higher frequencies. The referenced studies reported some behavioral reaction by marine mammals to acoustic systems operating at user-selected frequencies above 200 kHz. This work was discussed in the notice of proposed rulemaking. In general, the referenced literature indicates only that sub-harmonics could be detectable by certain species at distances up to several hundred meters. As NMFS has noted elsewhere, behavioral response to a stimulus does not necessarily indicate that Level B harassment, as defined by the MMPA, has occurred. Source levels of the secondary peaks considered in these studies—those within the hearing range of some marine mammals—mean that these sub-harmonics would either be below the threshold for Level B harassment or would attenuate to such a level within a few meters. The work cited by the commenters is consistent with previously observed occurrences of sub-harmonics. Essentially, the first sub-harmonic's source level (*e.g.,* if the primary frequency is 200 kHz, the first sub-harmonic is 200/2 or 100 kHz, the second is 200/3 or 66.7 kHz) is at least 20–30 dB less than the primary frequency's source level, with each subsequent sub-harmonic's source level decreasing rapidly from there. These sub-harmonics are typically so reduced in source level that, for most side-scan and multi-beam sonar systems, they are not strong enough to produce impacts beyond tens of meters from the source (distances at which reactions to the vessel itself are likely to supersede reactions to an acoustic signal). Additionally, for any potential impacts to occur, an animal must be within this range and within the very narrow beams produced by the systems (for these sub-harmonic frequencies).

In addition, recent sound source verification testing of these and other similar systems did not observe any sub-harmonics in any of the systems tested under controlled conditions (Crocker and Fratantonio, 2016). While this can occur during actual operations, the phenomenon may be the result of issues with the system or its installation on a vessel rather than an issue that is inherent to the output of the system. As concluded in the notice of proposed rulemaking, there is no evidence to suggest that Level B harassment of marine mammals should be expected in

relation to use of active acoustic sources at frequencies exceeding 180 kHz. NRDC's comments did not address NMFS' prior statements regarding this topic.

NRDC fails to adequately support the claims of harm to marine mammals that are reasonably likely to occur as a result of HRG surveys and, thus, fails to justify their recommendation for enhanced mitigation. The recommended measures include ''extended safety zone and monitoring requirements'' and a ''bar on nighttime operations.'' Even when animals are receiving echosounder signals, they may not be harassed, as described above. However, given the directional nature of these sources, animals observed at the surface will almost certainly not be within the acoustic beam, thus negating the benefit of detection-based measures such as shutdowns. Any exposure to the echosounder would likely be only in the ensonified cone below the vessel, and responses to the vessel itself at such close ranges would influence likelihood of acoustic exposure. The package of active acoustic systems modeled as representative of a typical HRG survey included a 200-kHz echosounder. Regarding the suggestion that this bars use of any system with a lower frequency output, NMFS disagrees. NMFS' analysis also includes use of different lower-frequency sources (*i.e.,* single airguns and boomers). Moreover, the specific sources selected for analysis do not limit the actual sources that may be used, assuming the actual sources are reasonably similar to the full suite of analyzed sources, as is the case here.

Comment: The Associations and other industry commenters claim that the proposed PSO staffing requirements compromise personnel safety, cannot be effectively implemented, and are unnecessary and unsupported.

Response: In the notice of proposed rulemaking, NMFS described in detail the importance of detection-based mitigation as a component of standard operational mitigation protocols. Detection-based mitigation cannot occur effectively without both visual and acoustic monitoring, with the latter being the only effective method of detection during periods of poor visibility or at any time for cryptic species (*e.g.,* beaked whales) or species with high availability bias (*e.g.,* sperm whales). Therefore, visual monitoring is required during daylight hours and acoustic monitoring is required throughout the period of survey operations. When these monitoring techniques are required, two visual PSOs must be on duty in order to effectively monitor 360 degrees around the vessel, communicate with the operator as necessary, and record data, and an acoustic PSO must be on duty to monitor the PAM system. In order to effectively carry out monitoring duties, PSOs must have sufficient periods of rest to minimize fatigue that would compromise their performance. Based on these considerations, and in consideration of the literature relating to mitigation and monitoring requirements and standard practice for scientific surveys, NMFS proposed minimum duty requirements.

While NMFS agrees that there is likely to be some increased logistical burden associated with these requirements, which are expanded to some degree from current practice in the GOM in the absence of compliance with the MMPA, the Associations do not demonstrate that this burden is so large as to be impracticable. Similarly, they do not provide information supporting claims that these requirements would compromise personnel safety (and certainly do not support the claim that the requirements are ''unnecessary and unsupported''). The Associations' comment states that survey vessels are typically at maximum capacity. NMFS acknowledges that in some cases, increased PSO staffing may result in a need for operators to balance staffing in other areas, such as in the seismic crew (25 to 30) or the three to seven client representatives that the Associations state are typically aboard a survey vessel, in order to accommodate necessary PSO staffing while not exceeding a vessel's maximum capacity. However, assuming that a vessel's maximum capacity is not exceeded, the claim that increasing the number of people aboard necessarily increases ''the risk of injuries, illnesses, and evacuation for medical reasons'' is unsupported. The comment is inconsistent regarding the number of PSO staff that the requirements would add, at various places stating that the requirements would result in the addition of six to eight or three to five PSO staff. Overall, the Associations state that only three (and possibly up to four) PSOs should be allowed, without explaining how this may achieve the objective of the proposed detection-based mitigation requirements.

However, in recognition of the likely increase in logistical burden and the possibility that individual LOA applicants may be able to demonstrate legitimate practicability issues, NMFS allows for the potential that an exception may be obtained specifically for the requirement that PSOs may be on duty for a maximum period of two hours, followed by a minimum period of one hour off. If an exception is granted based on practicability, the historical practice of a maximum on-duty period of four hours, followed by a minimum period of two hours off, would be substituted.

Comment: The Associations and other industry commenters comment that the proposed requirement for visual observation before and during nighttime ramp-ups would be ineffective and potentially present safety concerns.

Response: NMFS agrees that reduced efficacy should be expected for visual monitoring at night and, in consideration of comments asserting that this may present a safety concern, we have eliminated this requirement (noting that passive acoustic monitoring is still required for all nighttime operations of large airgun arrays). NMFS also agrees with the Associations' comment that employment of a PSO for the dedicated purpose of documenting entanglements with ocean-bottom node (OBN) cables is unnecessary and has eliminated this requirement. Elimination of these requirements is expected to help somewhat in alleviating the logistical concerns expressed by the Associations.

Comment: The Associations suggest that entanglement avoidance requirements should be removed from the ITR. The MMC comments that they support these requirements, and that the requirements are consistent with best management practices developed for avoiding entanglements.

Response: The Associations' comment, offered only in a footnote, is unclear as to whether the Associations' suggestion is to remove all entanglement avoidance requirements or only the requirement to use negatively buoyant coated wire-core tether cable. (Note that NMFS does agree with the suggested elimination of a requirement for use of a dedicated PSO for purposes of documenting entanglement.) Regardless, the Associations' suggestion that this requirement should be removed is keyed only to concern regarding practicability. NMFS disagrees that this requirement is impracticable, and the Associations offer no information to the contrary. Moreover, this measure is designed to prevent serious injury or mortality, which cannot be authorized under this rule.

Here, no mortality was requested or proposed for authorization and, therefore, potential for death by entanglement must be avoided. There is demonstrated potential for entanglement of protected species in association with OBN survey operations. As described in the notice of proposed rulemaking, a GOM OBN

operator remarkably entangled three different protected species within a year—including an Atlantic spotted dolphin, as well as an ESA-listed turtle and a manta ray. BSEE subsequently issued two enforcement actions against the operator for incidents of non-compliance, indicating that it is appropriate to be stringent regarding requirements relating to entanglement avoidance. Specific appropriate measures were determined in consultation between NMFS, BOEM, and BSEE, including consultation with NMFS' gear engineering experts, and were subsequently included in permits issued by BOEM (*e.g.,* OCS Permit L17–009, issued July 11, 2017). NMFS proposed these specific measures for this ITR and no comments offering useful suggestions regarding potential modifications to the measures were received. A generic suggestion that no entanglement avoidance requirements are necessary is not credible.

Comment: NRDC claims that NMFS fails to consider mitigation to reduce ship strike, particularly within Bryde's whale habitat. Separately, NRDC states that NMFS should consider extending ship-speed requirements to all project vessels. The Associations state that vessel strike avoidance measures should not be required, or that there should be modifications and/or exemptions to the measures.

Response: NMFS disagrees with NRDC's contention. NMFS' required vessel strike avoidance protocol is expected to further minimize any potential interactions between marine mammals and survey vessels, relative to the already low likelihood of vessel strike in relation to the activities considered herein. Please see ''Vessel Strike Avoidance'' for a full description of requirements, which include: Vessel operators and crews must maintain a vigilant watch for all marine mammals and must take necessary actions to avoid striking a marine mammal; vessels must reduce speeds to 10 kn or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel; and vessels must maintain minimum separation distances.

We also note that NRDC's comment that ''vessels supporting the seismic operation are not similarly constrained'' is in error. All project vessels are required to adhere to vessel strike avoidance requirements, including speed requirements in certain circumstances. As stated clearly in the proposed and final regulatory text, ''[v]essel operators and crews must maintain a vigilant watch for all marine mammals and slow down or stop their vessel or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal [. . .].'' Regarding whether ship speed requirements are warranted for all project vessels in the Bryde's whale core habitat area to minimize risk of strike for Bryde's whales, the consideration is no longer relevant to this rule, as activity within the Bryde's whale core habitat area referenced by NRDC can no longer be considered through this rule following BOEM's update to the scope of action. Further, we disagree that similar risk exists for sperm whales and beaked whales, as would be necessary to warrant vessel speed restrictions in the Mississippi Canyon area. There are very few records of vessel strikes for sperm whales, as compared with mysticete whales in general, and Bryde's whales' dive behavior in particular makes them potentially more susceptible to vessel strike.

The Associations' comments state that they are not aware of any incidence of ship strike associated with a geophysical survey, implying that no strike avoidance measures are necessary. The lack of recorded incidents of strike does not mean that none have occurred and, more importantly, does not mean that none will occur. Therefore, it is NMFS' responsibility to prescribe measures that will achieve the least practicable adverse impact via avoidance of vessel strike. The comments go on to assert that there is ''no evidence'' that strike avoidance measures benefit marine mammals, despite the wealth of scientific evidence described in the notice of proposed rulemaking that slower vessel speeds result in fewer strikes and, if a strike does occur, a significantly lower likelihood of mortality. Separation requirements are common sense—a moving vessel should maintain some minimum distance from a whale to avoid striking it—and are similar to generic strike avoidance guidelines found elsewhere. The comments implying that these requirements are unwarranted and burdensome are unpersuasive, particularly given that BOEM has required essentially identical strike avoidance measures in the GOM via notices to lessees for many years (currently, via BOEM NTL No. 2016–G01).

Nevertheless, NMFS recognizes that there are legitimate concerns regarding vessels towing gear and human safety issues. We have clarified in the strike avoidance measures that vessel strike avoidance requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

Comment: The Associations and other industry commenters raise concerns regarding the PSO requirements, including that NMFS' requirements for PSOs will result in labor shortages, and make an accompanying recommendation that these be ''preferred'' training requirements that LOA-holders would not have to meet.

Response: NMFS disagrees with the comments. The Associations' statement that requirements for PSOs to have bachelor's degrees or to satisfy a positive experience requirement are ''difficult, if not impossible, to achieve'' is not persuasive. As explained in the notice of proposed rulemaking, NMFS discussed these PSO requirements with BSEE and with third-party observer providers. Both parties indicated that the requirements should not be expected to result in any labor shortage. We pointed out that during a period when a significantly greater amount of survey activity was occurring in the GOM than at present (*i.e.,* with as many as 30 source vessels), requirements similar to those proposed did not result in any labor shortage. Moreover, NMFS specifically requested comment on the assumption that the requirements would not result in any labor shortage. The Associations' expressed concern regarding the potential for a labor shortage, but do not provide any specific information to support the claims. We also clarify that not all PSOs must have a minimum of 90 days at-sea experience, with no more than 18 months elapsed since the conclusion of the most recent relevant experience. As described in the notice of proposed rulemaking and herein, a minimum of one visual PSO and two acoustic PSOs must have such experience (rather than all PSOs).

Comment: The Associations provide a list of specific proposed monitoring and reporting requirements that they assert are unreasonable or otherwise problematic. Some of these comments are echoed by other industry commenters.

Response: We address the specific issues raised by the Associations in turn.

1. The Associations state that bigeye binoculars should not be required, because they are expensive, require installation on the vessel, and are not appropriate for monitoring of the exclusion zone.

NMFS disagrees with this comment. While it is correct that procurement of bigeye binoculars will incur costs, these costs were analyzed in NMFS' RIA.

While bigeye binoculars may not be an individual PSO's tool of choice for observing marine mammals at close range to the vessel, they are an indispensable tool for observing marine mammals at greater distance upon initial detection, are a standard component of marine mammal observation (for scientific purposes, but also as a part of standard mitigation monitoring conducted aboard surveys for which incidental take authorizations are issued), and will be helpful in more accurately identifying animals at greater distances, such that the precautionary shutdowns of concern to the Associations are avoided.

2. The Associations state that PSOs should not report on factors that may be contributing to impaired observations, as such reporting may be speculative, unverifiable, and/or incorrect.

NMFS disagrees with this comment. Reporting on such conditions is not connected to any requirement for action, but it is important to understand whether visual observation is able to be conducted in an effective fashion, whether it be due to weather conditions or to conditions on the vessel.

3. The Associations suggest that the reporting requirement to estimate numbers of animals observed by cohort is overly complicated, and that the rule should require only recording of juveniles and adults.

NMFS agrees with this comment and has made corresponding edits to the regulatory text.

4. The Associations express some confusion regarding language addressing the information that visual PSOs should be compiling on a daily basis and whether these daily ''reports'' include estimates of actual animals taken.

NMFS clarifies that the language cited by the Associations was not intended to mean that PSOs should be estimating ''takes'' on a daily basis, and confirm that the Associations' statement that such information should be included only in annual reporting is correct.

5. Regarding NMFS' consideration of an approach recommended by the MMC to produce estimates of actual take from observations of animals during survey effort, the Associations express concern about the appropriate application of this process, and suggest that the protocol be applied at the end of a period long enough to accumulate sufficient data to adequately evaluate the appropriateness and proper application of the process as part of the adaptive management process.

NMFS shares many of the Associations' concerns on this subject and regarding the specific methodology proposed by the MMC. NMFS looks forward to working with the Associations (as well as BOEM and BSEE) towards the development of appropriate methods through the adaptive management process.

6. In reference to the requirement for the lead PSO to submit to NMFS a statement concerning mitigation and monitoring implementation and effectiveness, CGG adds that, because there is a lead PSO on each offshore rotation, the LOA-holder should submit collated statements.

NMFS agrees that this may be a more practical approach.

Comment: The MMC recommends that NMFS require LOA-holders to implement electronic reporting systems for field-based PSO data entry and expedited reporting.

Response: NMFS agrees that this would be appropriate and would better ensure expedited field entry and quality control checking of PSO data, as well as facilitate data transfer, quality control, data analysis, and automated report generation. Overall, such a requirement is helpful to ensure the efficient synthesis of data, as required by the comprehensive reporting process.

Comment: The Associations express support for NMFS' proposed approach to comprehensive monitoring and development of a structured adaptive management process, and highlight their support for efforts that improve the quantity and quality of information related to determining the nature and magnitude of the potential effects of offshore geophysical activities on marine mammals, including industry-supported independent third-party research.

Response: NMFS appreciates the comments and looks forward to continued engagement with the regulated community, as well as BOEM and BSEE, to improve the collection and use of the best available science consistent with the requirements and limits of the MMPA.

Comment: The MMC comments that they support an annual adaptive management process for the issuance of LOAs in the GOM and recommend that they be included in the process along with representatives from BOEM, BSEE, and industry.

Response: NMFS appreciates the comments and will ensure that the adaptive management process includes participation of the parties noted, where appropriate.

Comment: NRDC asserts that NMFS fails to prescribe requirements sufficient to monitor and report takings of marine mammals. The MMC recommends that NMFS and BOEM work together to develop a coordinated long-term monitoring and research plan, and further recommends that, to facilitate the completion of the plan, NMFS and BOEM establish a GOM scientific advisory group, composed of agency and industry representatives and independent scientists, to assist in the identification and prioritization of monitoring needs and hypothesis-driven research projects to better understand the short- and long-term effects of geophysical surveys on marine mammals in the GOM. Commenters also noted that there are many research gaps that need to be filled and suggested that NMFS should include monitoring requirements that fill those gaps.

Response: Section 101(a)(5)(A) of the MMPA indicates that any regulations NMFS issues shall include ''requirements pertaining to the monitoring and reporting of such taking.'' This broad requirement allows for a high degree of flexibility in what NMFS may accept or include as a monitoring requirement, but is not specific in identifying a threshold of what should be considered adequate monitoring. Contrary to NRDC's comments, except for IHAs in Arctic waters, NMFS' implementing regulations do not provide a specific standard regarding what required monitoring and reporting measures ''must'' accomplish. However, NMFS' implementing regulations require incidental take applications to include suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species, the level of taking, or impacts on populations of marine mammals that are expected to be present while conducting activities, as well as suggested means of minimizing burdens by coordinating such reporting requirements with other schemes already applicable to persons conducting such activity. 50 CFR 216.104(a)(13). The comment extracts pieces of this language to suggest that future LOA applicants are required to coordinate with each other's monitoring efforts, ignoring the fact that the relevant regulation points to this coordination only in support of minimizing the burden on the applicant and that it refers to coordination with ''schemes already applicable to persons conducting such activity.'' 50 CFR 216.104(a)(13). NRDC attempts to further the argument that coordination across projects is required by statute by referencing a monitoring plan that they state is in development by BOEM. The MMC also references development of a ''long-term monitoring plan'' that they

attribute to BOEM. NMFS is not aware that any such monitoring plan has been developed and, therefore, such a plan is not ''already applicable to persons conducting such activity.''

NRDC discusses a litigation settlement agreement related to the activities that are the subject of this rule, stating that ''BOEM must analyze 'the development of a long-term adaptive monitoring plan that addresse[s] cumulative and chronic impacts from seismic surveys on marine mammal populations in the Gulf of Mexico.' '' *NRDC et al.* v. *Bernhardt et al.,* 2:10–cv–1882, ECF No. 118 (E.D. La. June 18, 2013). NRDC also cites BOEM's PEIS in discussing this plan. That requirement in the settlement agreement does not pertain to NMFS' statutory authority under the MMPA, which does not provide authority for NMFS to require the development of a ''long-term monitoring plan'' via the promulgation of ITRs or as a condition of an incidental take authorization. As noted above, NMFS' statutory authority is to prescribe ''requirements pertaining to the monitoring and reporting of such taking.'' Although applicants that anticipate the need for consecutive periods of five-year regulations to cover ongoing activities may develop monitoring and reporting plans that extend past the five-year effectiveness period of a rule, section 101(a)(5)(A) requires only monitoring and reporting to cover the specified activities undertaken during the period of the rule. Were a long-term monitoring plan to be developed by BOEM, it would therefore be a voluntary undertaking on the part of participants, rather than a requirement under the MMPA. While certainly an exemplar of what a strong comprehensive monitoring plan can look like, the U.S. Navy's Integrated Comprehensive Monitoring Program (ICMP), which NRDC references as a relevant analogue to the monitoring plan that they assert is required in the GOM to satisfy the requirements of the MMPA, should not be hailed as a model that should always be copied or a standard that must be achieved for all MMPA ITRs. The Navy's ICMP was developed in close coordination with NMFS and reflects several factors that are not present for all ITRs (including these regulations) and that lay the groundwork for what is an exceptionally comprehensive program. Specifically, as the single entity for which take is authorized and that has the responsibility for implementing a monitoring program, the Navy has an existing organizational and funding structure that can support a truly integrated and comprehensive plan that would be far more difficult under a rule allowing for authorization of take by disparate applicants with varying activity levels, resource availability, and familiarity with regulatory requirements and marine mammal issues. Also, the Navy has an independent environmental stewardship mandate that influences their monitoring approach and supports a robust program intended to work in concert with the work funded through their Office of Naval Research and Living Marine Resources programs to create essentially full coverage of the science necessary to support vigorous environmental assessment and compliance across all Navy actions. Last, Navy training and testing utilize a large variety and number of platforms and sound sources, many of which can result in the take of marine mammals but cannot be monitored at the source. Accordingly, the Navy employs the robust, problem-based, often off-site monitoring program currently in place in order to answer targeted questions with controlled studies.

Although NMFS' authority with regard to the prescription of monitoring requirements does not include mandating long term monitoring, the MMPA does require an assessment of impacts from the total taking by all persons conducting the activity. Thus, meaningful monitoring and reporting for a specified activity under section 101(a)(5)(A) should be designed to help us better understand the total taking that is considered for authorization under the regulations for all persons conducting the specified activities under the five-year regulations. This necessitates coordination across applicants with regard to comprehensive analysis and reporting of information collected in relation to ''the level of taking or impacts on populations of marine mammals that are expected to be present while conducting activities.'' 50 CFR 216.104(a)(13). We discuss these comprehensive reporting requirements in greater detail in Monitoring and Reporting. These requirements are appropriate to the necessary function of informing the assessment of the overall impact of the incidental take allowable under the regulations and acknowledge the need to conduct aggregation and analysis of the data in a manner that directly informs the question of whether and the degree to which marine mammal populations addressed may be affected by the incidental take authorized by LOAs.

We appreciate the MMC's acknowledgement of the investments made by BOEM and industry (via the E&P Sound and Marine Life Joint Industry Program) towards better understanding of marine mammal abundance and distribution, the characterization of anthropogenic sound sources in the GOM, and the effects of sound on marine mammal hearing and behavior, among other initiatives. We also note that much of the research recommended by NRDC has been conducted via the BOEM-sponsored Gulf of Mexico Marine Assessment Program for Protected Species initiative. However, while these voluntary efforts are commendable, section 101(a)(5)(A) does not require hypothesis-driven, focused research pertaining to the impact and mitigation of chronic noise exposure on populations of special concern, nor does it require a ''coordinated long-term monitoring and research plan,'' as expressed by the commenters.

Regarding the MMC's recommendation that NMFS establish a GOM ''scientific advisory group, composed of agency and industry representatives and independent scientists, to assist in the identification and prioritization of monitoring needs and hypothesis-driven research projects,'' NMFS would be willing to explore with the MMC the appropriate mechanisms for convening such a group, including consideration of the MMC's authorities under the MMPA.

The monitoring approach described in this preamble includes LOA-specific monitoring and reporting set forth in the regulations and, separately, outlines a framework for potential data collection, analysis, research, or collaborative efforts that are not specified in these regulations but which work towards satisfying the information elements identified in our implementing regulations. NMFS is committed to working with industry and BOEM through the adaptive management process to ensure that LOA-specific monitoring and reporting will be used appropriately to help better understand the impacts of the total taking from the specified activity contemplated in this ITR on the affected populations, as well as how the more overarching voluntary efforts will be identified and carried out.

Comment: The Associations reiterate their belief that NMFS, as the regulating agency, has the responsibility to collect, organize, and assess all of the data reported to NMFS under the terms of issued LOAs.

Response: NMFS disagrees with this comment. The MMPA requires NMFS to prescribe regulations setting forth requirements pertaining to the monitoring and reporting of ''such

taking.'' 16 U.S.C. 1371(a)(5)(A)(i)(II)(bb). (In contrast, the other required component of activity-specific regulations, relating to mitigation requirements, refers to ''taking pursuant to such activity.'' 16 U.S.C. 1371(a)(5)(A)(i)(II)(aa). In NMFS' view, these monitoring and reporting requirements in our activity-specific regulations refer to the total taking from the specified activity as a whole, and they are requirements that can be imposed on those entities availing themselves of LOAs issued under the activity specific regulations. Therefore, it is incumbent upon LOA-holders, collectively, to provide this information to NMFS in a reasonably synthesized form such that NMFS may adequately assess the effects of the specified activity on an ongoing basis. This information may in some cases be essential to NMFS' ability to carry out 50 CFR 216.105(e) (''Letters of Authorization shall be withdrawn or suspended, *either on an individual or class basis,* as appropriate, if, after notice and opportunity for public comment, the Assistant Administrator determines that: (1) The regulations prescribed are not being substantially complied with; or (2) The taking allowed is having, or may have, more than a negligible impact on the species or stock or, where relevant, an unmitigable adverse impact on the availability of the species or stock for subsistence uses'' (emphasis added).) While NMFS recognizes that the Associations are not subject to the ITR (including any reporting requirements in the ITR or related LOAs), LOA-holders (many of which are likely to be Association members) will collectively be responsible for the comprehensive reporting requirements described herein. The Associations in their comment commit to participate in the annual assessment process, and NMFS welcomes that participation.

Comment: The MMC recommends that NMFS require industry operators to measure and report the horizontal leakage of their various airgun arrays and investigate options to minimize horizontal sound leakage from those array configurations.

Response: As stated in the notice of proposed rulemaking, NMFS encourages the minimization of unnecessary horizontal propagation. However, while the MMC's recommendation would likely lead to a better understanding of actual horizontal propagation (or ''leakage'') that does occur, it is not clear that the product of such measurements (termed ''waste ratios'' by the MMC) would necessarily lead to a viable path to reducing such leakage. In addition, the MMC does not specify what it recommends as a sufficient amount of data concerning waste ratios to allow consideration of a potential threshold. Thus, the comment implies that all operators would be required to conduct field measurements of the acoustic output of airgun arrays under this recommendation, which NMFS believes would not be practicable. NMFS appreciates the comment and will further consider the utility of the recommendation, and methods of implementation, through the adaptive management process.

We do note that BOEM currently requires operators to confirm through the permitting process that the airgun arrays used have been calibrated or tuned to maximize subsurface illumination and to minimize, to the extent practicable, horizontal propagation of noise.

Comment: NRDC suggests that NMFS should consider requiring use of thermal detection as a supplement to visual monitoring.

Response: NMFS appreciates the suggestion and agrees that relatively new thermal detection platforms have shown promising results. Following review of NRDC's letter, we considered these and other supplemental platforms as suggested. However, to our knowledge, there is no clear guidance available for operators regarding characteristics of effective systems, and the detection systems cited by NRDC are typically extremely expensive, and are therefore considered impracticable for use in most surveys. For example, one system cited by NRDC (Zitterbart *et al.,* 2013)—a spinning infrared camera and an algorithm that detects whale blows on the basis of their thermal signature—was tested through funding provided by the German government and, according to the author at a 2015 workshop concerning mitigation and monitoring for seismic surveys, the system costs hundreds of thousands of dollars. We are not aware of its use in any commercial application. Further, these systems have limitations, as performance may be limited by conditions such as fog, precipitation, sea state, glare, water- and air-temperatures and ambient brightness, and the successful results obtained to date reflect a limited range of environmental conditions and species. NRDC acknowledges certain of these limitations in their comment, including that the systems have lesser utility in warmer temperatures. The GOM, however, is a warm environment. NRDC does not provide specific suggestions with regard to recommended systems or characteristics of systems. NMFS does not consider requirements to use systems such as those recommended by NRDC to currently be practicable.

Comment: NRDC states that NMFS should prescribe requirements for use of ''noise-quieting'' technology. NRDC elaborates that in addition to requiring noise-quieting technology (or setting a standard for ''noise output''), NMFS should ''prescribe targets to drive research, development, and adoption of alternatives to conventional airguns.''

Response: NMFS agrees with NRDC that development and use of quieting technologies, or technologies that otherwise reduce the environmental impact of geophysical surveys, is a laudable objective and may be warranted in some cases. However, here the recommended requirements either are not practicable or are not within NMFS' authority to require. To some degree, NRDC misunderstands the discussion of this issue as presented in the notice of proposed rulemaking. NMFS recognizes, for example, that certain technologies, including the Bolt eSource airgun, are commercially available, and that certain techniques such as operation of the array in ''popcorn'' mode may reduce impacts when viable, depending on survey design and objectives. However, a requirement to use different technology from that planned or specified by an applicant—for example, a requirement to use the Bolt eSource airgun—would require an impracticable expenditure to replace the airguns planned for use. NRDC offers no explanation for why such a large cost imposition (in the millions of dollars) should be considered practicable.

Separately, NRDC appears to suggest that NMFS must require or otherwise incentivize the development of wholly new or currently experimental technologies. We note that BOEM's PEIS concluded that alternative technologies are in various stages of development, and that none of the systems with the potential to replace airguns as a seismic source are currently commercially available for use on a scale of activity such as that considered herein. Although some alternative technologies are available now, or will be in the next several years, for select uses, none are, or will likely be in the next five years, at a stage where they can replace airgun arrays outright. However, some may be used in select environments when commercially available. According to BOEM, the suggestion in this comment would not provide the oil and gas industry or the government with sufficiently accurate data on the location, extent, and properties of hydrocarbon resources or the character

of formation fluids or gases, or information on shallow geologic hazards and seafloor geotechnical properties, in order to explore, develop, produce, and transport hydrocarbons safely and economically. Such technologies may be evaluated in the future as they become commercially available and on a scale commensurate to the need. In summary, while NMFS agrees that noise quieting technology is beneficial, the suggestions put forward by NRDC are either impracticable or outside the authority provided to NMFS by the MMPA. However, NMFS would consider participating in or learning about related efforts by parties interested in investigating these technologies. We note that NMFS has described a process by which new and unusual technologies may be considered for use under this rule (see Letters of Authorization).

Comment: NRDC recommended that NMFS consider compensatory mitigation for the adverse impacts of the specified activity on marine mammals and their habitat that cannot be prevented or mitigated.

Response: NMFS has prescribed a robust comprehensive suite of measures that are expected to reduce the amount of Level A and Level B harassment take, as well as the severity of any incurred impacts on the species or stock and their habitat. Compensatory mitigation is not required under the MMPA. Importantly, NRDC did not recommend any specific measure(s), rendering it impossible to evaluate their recommendation. In addition, many of the methods of compensatory mitigation that have proven successful in terrestrial settings (*e.g.,* purchasing or preserving land with important habitat, improving habitat through plantings) are not applicable in a marine setting with such far-ranging species. NMFS concludes that the concept is too speculative at this time to warrant specific action.

Letters of Authorization

Comment: The Associations assert that it is ''arbitrary and inappropriate'' for NMFS to provide an opportunity for public notice and comment in the event that an LOA applicant wishes to deviate from the modeling approach used herein (which was subject to public review and comment). The Associations state that such a requirement is contrary to the legal requirement to base the authorization of incidental take under the MMPA on the best available science, as better information may become available during the period of effectiveness for the ITR.

Response: LOAs issued under the authority of section 101(a)(5)(A) and NMFS' implementing regulations must be preceded by both substantive findings (including a negligible impact finding) and a process that includes rulemaking after notice and comment. In the case of LOA applications whose take estimates are not based on the modeling used for the rulemaking, NMFS has determined that it may be appropriate to subject those to notice and comment in certain circumstances. Such a process requirement does not impede or contradict the requirement to use the best available information.

Comment: The Associations and other industry commenters assert that there is no legal justification for NMFS to use the ITR as a mechanism to limit the number of activities that may occur in the GOM, stating that authorization of the activities themselves are subject to BOEM's jurisdiction.

Response: NMFS clarifies that we do not intend to use the ITR in the manner suggested by the Associations, and that the language cited in the Associations' comment (''cap on the number of authorizations that could be issued'') was inartful. We also acknowledge BOEM's jurisdiction regarding the authorization of the subject activities themselves. However, the total taking analyzed in the negligible impact analysis necessarily bounds the taking that may be authorized under these activity-specific regulations, as described in the Estimated Take section.

Comment: Referencing a cap on the number of authorizations that could be issued, the MMC recommends that NMFS (1) provide details to the public on how NMFS plans to implement the proposed cap and the basis for it; and (2) allow for an additional 30-day comment period to review such details sufficiently in advance of issuing the final rule.

Response: As discussed in the preceding comment response, the language referenced by the MMC was meant only to affirm what is inherent in the regulations, *i.e.,* that the amount of take analyzed for making a finding of negligible impact necessarily bounds the amount of take that may be authorized through LOAs issued under this rule (provided they also satisfy the small numbers requirement). The MMC places undue emphasis on this aspect of rule implementation. In claiming a ''lack of transparency,'' the MMC assigns complexity that does not exist, and no additional details exist to give. Therefore, we do not implement the MMC's recommendation for additional public comment.

Comment: The Associations and other industry commenters express concern regarding the implementation of the ITR, including the evaluation and processing of LOA requests. The Associations recommend that the final ITR clearly address how NMFS plans to process LOA applications in a timely and efficient manner, and encourage NMFS to retain flexibility in the final ITR for the development of efficient and effective LOA processes through workshops or other engagement with BOEM and the regulated community.

Response: NMFS appreciates the concerns expressed by the commenters. We believe we have addressed these issues in the updated preamble to this ITR (see Letters of Authorization) and are committed to ongoing, proactive engagement with BOEM, BSEE, and the regulated community towards efficient implementation of the ITR.

Comment: BP comments that a low-frequency geophysical survey source they refer to as ''Wolfspar'' should be considered to be within the range of potential impacts modeled in the ITR and, therefore, able to be used under an LOA issued pursuant to the ITR.

Response: NMFS will look forward to evaluating the Wolfspar source according to the ''New and Unusual Technology'' review process detailed in the Letters of Authorization section of this preamble. Only upon review of additional information regarding the source can NMFS make a determination in this regard.

Regulatory Impact Analysis

Comment: The Associations provide a bulleted list of criticisms of the RIA. We summarize these here and provide brief responses below. For full detail, we refer the reader to the final RIA, available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* The Associations' critiques of the RIA are not accompanied by any specific recommendations regarding potential changes to the analysis or additional data.

- The Associations assert that the RIA assumes that the only indirect costs of closures are delays, and state that such measures ''may render some survey proposals economically unattractive to the point at which prospects will not be explored.'' The Associations also state that closures may be assumed to be permanent, thereby having an additional dampening impact on exploration activity.

Response: The RIA accompanying the proposed rule did not assume that the costs of closures are simply delays. The RIA stated that the ''closures have the potential to affect the overall levels of G&G [geological and geophysical]

activities that occur in the GOM over the five-year timeframe of the analysis. In the case that the closures delay or reduce the ability of industry to collect the necessary data to identify and recover oil and gas resources, the overall level of oil and gas production in the GOM may in turn be delayed or reduced.'' The RIA for the proposed rule discussed the possibility of both delays *and* reductions in activity due to the uncertainty surrounding rule impacts. In addition, NMFS reiterates that closures and any other measures are in effect only during the five-year period of effectiveness of the ITR. It is unclear why closures may be ''assumed to be permanent'' if the regulations requiring them are effective only for five years. We note here that two of the closure areas included in the proposed rule and evaluated in the RIA are no longer in the final rule because they fall outside the area considered for this rule, following BOEM's update of the rule's scope.

• The Associations assert that the RIA ''incorrectly assumes that the costs of closures are highly uncertain or even low because geologic potential of some areas is low,'' stating that geophysical surveys are essential to understanding the geologic potential of the areas.

Response: There is significant uncertainty regarding the development potential of the areas considered for closure, and the RIA did not simply assume that it is ''low.'' The RIA accompanying the proposed rule provided the best available information regarding lease activity and reserves in the proposed closure areas and characterized the associated uncertainty.

• The Associations assert that the RIA ''wrongly assumes that the GOMESA moratorium prevents exploration of the Eastern GOM,'' when in fact the moratorium is currently set to expire in 2022. The Associations go on to state that ''the RIA seriously misleads readers about the costs of closure and increased restrictions in the Eastern GOM,'' and that the potential cost of the closure should be considered equivalent to that of the closure considered for the Central GOM because ''high-potential resources may underlie'' the Eastern GOM closure.

Response: The RIA made no such assumption, and in fact acknowledged that the moratorium does not restrict exploration per se. However, the Eastern GOM closure referenced by the commenter is no longer part of the rule, as BOEM's update to the scope of the rule has removed the area from consideration.

• The Associations state that the RIA fails to account for the environmental benefit associated with avoiding unnecessary drilling via use of geophysical surveys. Chevron echoes this comment. Neither commenter provides any specific recommendation as to how they believe it should be considered.

Response: The RIA does acknowledge the benefit of geophysical technology. However, we note that the magnitude of this benefit depends on the extent to which exploration and development companies move forward with drilling in cases where they have less seismic data than they otherwise would because of the requirements of the ITR.

• The Associations assert that the RIA for the proposed rule incorrectly assumes current geophysical data in the Eastern GOM is suitable, stating that ''there is high demand for state-of-the-art new data for Eastern GOM frontier areas where older data is considered unsuitable to support new investment.''

Response: The RIA did not state that current geophysical data for the Eastern GOM is ''suitable.'' Rather, the RIA stated that ''the suitability of existing G&G data to direct oil and gas production in the closure areas is unknown.'' As noted herein, the area of concern to the commenter is no longer considered through this rule.

• The Associations assert that the RIA ''fails to account for possible increased industry interest in Eastern GOM geophysical surveys'' and, therefore, that the RIA inappropriately relies on old statistics on survey interest for estimating costs.

Response: The RIA acknowledged that industry interest in Eastern GOM geophysical surveys is likely to increase leading up to the expiration of the moratorium. As noted herein, the area of concern to the commenter is no longer considered through this rule.

Comment: Chevron comments that NMFS should ensure in the final ITRs that all costs are evaluated, including the cost of reduced environmental benefits from effective geophysical surveys. The Associations echo these concerns.

Response: NMFS has appropriately evaluated the regulatory impacts of the ITR according to the requirements of E.O. 12866. See section 5.3 of the Final RIA, which describes this benefit of geophysical technology. The magnitude of this benefit depends on the extent to which exploration and development companies move forward with drilling in cases where they have less seismic data than they otherwise would because of the rule.

National Environmental Policy Act

Comment: NRDC reiterates (and resubmitted) comments that it submitted on BOEM's draft PEIS, stating that as it relates to marine mammals, the PEIS is deficient on its face due to the range of alternatives and mitigation considered, significance criteria, take and impact estimates, and cumulative impacts analysis.

Response: As a cooperating agency, NMFS reviewed all responses to comments on the draft PEIS that were relevant to its management authorities and provided input where we deemed it appropriate. See Appendix M of the Final PEIS.

Comment: NRDC also states that NMFS cannot rely on the PEIS because it ''does not adequately address NMFS' own actions and responsibilities under the MMPA,'' given that BOEM's PEIS is ''framed around a fundamentally different purpose and need'' relating to its mandates under the Outer Continental Shelf Lands Act (OCSLA) that is ''incongruent with NMFS obligations under the MMPA.''

Response: The proposed action at issue is BOEM's issuance of permits or authorizations for G&G activities in the GOM. PEIS Chapter 1.1.1. The PEIS also recognizes that NMFS' proposed action is a decision on whether to approve BOEM's petition for incidental take regulations. NOAA is a cooperating agency on BOEM's PEIS, as NOAA has jurisdiction by law and special expertise over marine resources impacted by the proposed action, including marine mammals and federally listed threatened and endangered species. The PEIS explicitly recognizes that the PEIS would be used in support of NMFS' decision on BOEM's petition for incidental take regulations. See PEIS Appendix B.

Consistent with the Council on Environmental Quality's (CEQ's) regulations, it is accepted NEPA practice for NOAA to adopt a lead agency's NEPA analysis when, after independent review, NOAA determines the document to be sufficient in accordance with 40 CFR 1506.3. Specifically here, NOAA is satisfied that BOEM's PEIS adequately addresses the impacts of issuing the MMPA incidental take authorization and that NOAA's comments and concerns have been adequately addressed. There is no requirement in CEQ regulations that NMFS, as a cooperating agency, issue a separate purpose and need statement in order to ensure adequacy and sufficiency for adoption. Nevertheless, the statement of Purpose and Need in the PEIS explicitly acknowledges NMFS' own separate action of issuing an MMPA incidental take authorization, and the PEIS is replete with discussion of issues relating to the issuance of an MMPA authorization, including discussion of marine mammal impacts, mitigation, and take estimates. NMFS' early participation in the NEPA process and the agency's continuing role in shaping and informing analyses using its special expertise ensured that the analysis in the PEIS is sufficient for purposes of NMFS' own NEPA obligations related to its issuance of an incidental take authorization under the MMPA.

Regarding the alternatives, NMFS' early involvement in the development of the PEIS and role in evaluating the effects of incidental take under the MMPA ensured that the PEIS would include adequate analysis of a reasonable range of alternatives. The PEIS includes a no action alternative specifically to address what could happen if NMFS did not issue an MMPA authorization. Some of the alternatives explicitly reference marine mammals or mitigation designed for marine mammals in their title. More importantly, these alternatives fully analyze a comprehensive variety of mitigation measures for marine mammals. This mitigation analysis supported NMFS' evaluation of our options in potentially issuing an MMPA authorization. This approach to evaluating a reasonable range of alternatives is consistent with NMFS' policy and practice for issuing MMPA incidental take authorizations. NOAA independently reviewed and evaluated the PEIS, including the purpose and need statement and range of alternatives, and determined that the PEIS fully satisfies NMFS' NEPA obligations related to its decision to issue the MMPA final rule and associated Letters of Authorization. Accordingly, NMFS has adopted the PEIS.

Finally, we disagree with the notion that the district court's decision in *Conservation Council for Hawaii* v. *NMFS* somehow would preclude NMFS from adopting the PEIS here. In *Conservation Council,* the court concluded that the FEIS NMFS adopted was deficient because it did not consider a true ''no action'' alternative from NMFS' perspective, in that the ''no action'' alternative assumed continuation of Navy's baseline activities, and therefore avoided the task facing NMFS, *i.e.,* whether to authorize the requested take. 97 F. Supp. 3d at 1236. In contrast, the PEIS here for NMFS' rule for GOM geophysical surveys includes a ''no action'' alternative from the perspectives of both NMFS and BOEM. See PEIS, Chapter 2.9.1, pp. 2–20 to 2–22.

Information Quality Act

Comment: The CRE states that NMFS' Technical Guidance violates Information Quality Act (IQA) requirements, because it (1) does not include an IQA Pre-dissemination Review Certification; (2) relies heavily on models that have not been peer reviewed to determine whether they are validated and comply with the Environmental Protection Agency's Council for Regulatory Environmental Modeling (CREM) guidance; and (3) relies heavily on models that were not peer reviewed in compliance with the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review (70 FR 2664; January 14, 2005).

Response: The CRE is incorrect. NMFS performed appropriate pre-dissemination review and documentation according to relevant agency guidance (NMFS Policy Directive PD 04–108, Policy on the Data Quality Act; NMFS Instruction 04–108–03, Section 515 Pre-Dissemination Review and Documentation Guidelines). All aspects of development of the 2016 Technical Guidance were peer reviewed (*www.cio.noaa.gov/services_programs/prplans/ID43.html*). Also of note, the same information and methodology that supported development of NMFS' Technical Guidance (NMFS, 2016, 2018) were more recently published in a peer-reviewed journal (Southall *et al.,* 2019a).

Comment: CRE states that NMFS' use of models in the acoustic exposure modeling process for this rule violates the IQA because ''they are incomplete, unfinished, inaccurate, unreliable, have never been validated, and have never been peer reviewed.'' CRE also asserts that NMFS has not conducted pre-dissemination review and documentation as required by the IQA and implies that, because NMFS did not address the IQA in the notice of proposed rulemaking, we must be in violation of it.

Response: CRE is incorrect; NMFS is in compliance with the requirements of the IQA. NMFS conducted the required pre-dissemination review at both the proposed and final stages of this rulemaking and appropriate documentation is included in the administrative record for this action.

CRE asserts that the models used in NMFS' rulemaking process are not properly evaluated or validated. CRE asserts that as a result, NMFS ''grossly overestimate[s] exposures and takes.'' According to the CRE, the supposed failings of the modeling necessarily lead to the overestimation of takes, as opposed to error in potentially different directions and of different magnitude in association with the various components of the modeling process. CRE comments at length that NMFS should use only the relatively simple approach of ''Line Transect,'' which they believe will result in lower numbers of estimated takes (see more detailed response to these suggestions earlier in Comments and Responses).

In asserting that the models used in support of this rule have not been adequately validated or peer reviewed, CRE refers to a similarly sophisticated, proprietary modeling package (Marine Acoustics, Inc.'s Acoustic Integration Model (''AIM'')) that underwent a dedicated external peer review, stating that AIM is ''therefore properly validated and acceptable for regulatory use.'' However, the AIM package functions virtually the same as the models used for this analysis, and was used for an essentially identical modeling process developed in support of BOEM's 2014 PEIS for geological and geophysical survey activities on the Mid- and South Atlantic Outer Continental Shelf.

The IQA concerns expressed in the comment are unfounded. As stated in the NOAA Information Quality Guidelines, information quality is composed of three elements: Utility, integrity, and objectivity.

Utility means that disseminated information is useful to its intended users. The disseminated information at issue here—modeled exposures of marine mammals to underwater noise—is useful to NMFS in that it forms the basis for subsequent analysis allowing NMFS to make determinations

necessary under the MMPA. It is useful to the public in that it enables appropriate review of NMFS' action and supporting determinations. It is useful to the regulated entities in that it will allow for an efficient regulatory regime, in which potential LOA applicants may make use of the existing modeling effort (while being afforded the opportunity to engage in different modeling if desired) in service of a streamlined LOA application process.

Integrity refers to security, *i.e.,* the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. The integrity of the information disseminated herein was not questioned, but it meets all relevant standards for integrity (as demonstrated in the administrative record for this action).

Finally, objectivity ensures that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and unbiased manner. Objectivity consists of two distinct elements: Presentation and substance. The presentation element includes whether disseminated information is presented in an accurate, clear, complete, and unbiased manner and in a proper context. NMFS has appropriately presented the disseminated information, and CRE does not assert otherwise. The substance element involves a focus on ensuring accurate, reliable, and unbiased information. Disseminated information reflects the inherent uncertainty of the scientific process, which is inseparable from the concept of statistical variation. In assessing information for accuracy, the information is considered accurate if it is within an acceptable degree of imprecision or error appropriate to the particular kind of information at issue and otherwise meets commonly accepted scientific and statistical standards, as applicable. This concept is inherent in the definition of ''reproducibility,'' as used in the OMB IQA Guidelines and adopted by NOAA. Therefore, original and supporting data that are within an acceptable degree of imprecision, or an analytic result that is within an acceptable degree of imprecision or error, are by definition within the agency standard and are therefore considered correct. CRE does not assert that the modeling results disseminated by NMFS are outside the bounds of an acceptable degree of imprecision or error.

The modeling report goes into great detail regarding potential error associated with different facets of the modeling process, and provides specific analysis of uncertainty in both the acoustic and animal phases of the modeling process (discussed in detail in the notice of proposed rulemaking and in the modeling report). Uncertainty associated with all aspects of the modeling was clearly identified and evaluated as to the effect on the overall modeling results. In order to best represent the overall uncertainty associated with the modeling, the report presents the exposure estimates as a distribution. The exposure estimate distribution provides the public with an understanding of the probability of certain events occurring, including the probability that an operation would not result in any animals being exposed above a defined threshold.

Regarding reproducibility and transparency, the NOAA Information Quality guidelines state that ''reproducibility means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision [. . .] With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.'' We have no reason to believe that similar modeling (for example, using the AIM modeling package) using the same data inputs would not return similar analytic results, and CRE provides none. Transparency is not defined in the OMB Guidelines, but is at the heart of the reproducibility standard. At its most basic, transparency—and ultimately reproducibility—is a matter of showing how you got the results you got. NMFS has produced a painstakingly detailed accounting of the modeling process and decisions made, such that an independent party using a different set of models would be able to perform a similar modeling effort in order to evaluate the similarity of the results. The modeling report includes a full description of all assumptions and reference material used for both sound sources and species of interest. CRE provides no meaningful argument to the contrary.

The NOAA Information Quality guidelines expressly address and allow for the use of proprietary models and other supporting information which cannot be disclosed. In such cases, the guidelines call for ''especially rigorous robustness checks.'' As summarized below and described in detail in the notice of proposed rulemaking and modeling report, NMFS has conducted rigorous robustness checks of the proprietary models used in support of this rule.

The models used in estimating the acoustic exposures described herein have been appropriately validated and reviewed. As described in detail in the notice of proposed rulemaking and in the modeling report, the acoustic exposure modeling effort requires the use of a package of models. Acoustic exposure modeling in general is not novel, controversial, or precedent-setting, and similar modeling has been performed for various applications for over 15 years. This type of modeling requires modeling of the acoustic output of a source, in this case a specified airgun array (as well as a single airgun and certain electromechanical sources that were modeled separately). The output of the source model is an input to a model or models used to model underwater sound propagation as a function of range from the source. The output of this process is a 3D sound field. Subsequently, an animal movement model is used to simulate the behavior of virtual animats in relation to the modeled sound field. Each animat acts as a virtual dosimeter, producing individual records of exposure history. There were many animats in the simulations, and together their received levels represent the probability, or risk, of exposure for each survey.

In this case, the source model used was JASCO Applied Sciences' proprietary Airgun Array Source Model (AASM). The AASM accepts airgun volume, pressure, and depth and has internal parameters that must be fit to real signature data. The model was originally fit to a large library of empirical airgun data spanning a range of airgun volumes and operating depths. Subsequently, the model was improved to better predict airgun radiation at frequencies above 1 kHz. Development and validation of this improved version were made possible by high quality airgun source signature data from field studies conducted under the industry-sponsored Joint Industry Program on Sound and Marine Life. Desktop evaluation and validation of AASM have been conducted against commercial geophysical source models such as Gundalf and Nucleus.

JASCO's proprietary Marine Operations Noise Model (MONM) was used to generate the 3D sound fields necessary for sound exposure estimates. MONM is based on standard and proven acoustic propagation models. In this case, propagation at frequencies less than 2 kHz was computed using a version of the U.S. Naval Research Laboratory's Range-dependent Acoustic

Model (RAM), which is based on a parabolic equation (PE) solution to the wave equation and extensively verified and validated under the Navy Ocean and Atmospheric Master Library process. The PE method has been extensively benchmarked and is widely employed in the underwater acoustics community (Collins *et al.,* 1996), and RAM's predictions (as generated within the MONM infrastructure) have been validated against experimental data in several underwater acoustic measurement programs conducted by JASCO (*e.g.,* Aerts *et al.,* 2008; Funk *et al.,* 2008; Ireland *et al.,* 2009; Blees *et al.,* 2010; Warner *et al.,* 2010). At frequencies greater than 2 kHz, increased sound attenuation due to volume absorption at higher frequencies is accounted for with the widely-used BELLHOP Gaussian beam ray-trace propagation model (Porter and Liu, 1994). Both of these complementary, non-proprietary propagation models (RAM and BELLHOP) have been extensively tested over many years and are accepted by the acoustics community. Implementation of these codes within the MONM infrastructure has been evaluated and validated against other PE codes including RAMS, RAM-Geo and original RAM, and against normal mode or wavenumber integration (fast field) methods in standard codes. Finally, JASCO has conducted end-to-end validation of source and propagation modeling against field data collected in sound source verification experiments, demonstrating that the results of the acoustic field modeling are in agreement with field data. The comparison of model results and measurements show that MONM can produce reliable results in challenging acoustic propagation conditions (Hannay and Racca, 2005).

The non-proprietary, peer-reviewed Marine Mammal Movement and Behavior (3MB) model (Houser, 2006) was used to generate realistic paths of simulated animals (animats) in the modeled area. JASCO's Exposure Modeling System (JEMS) was used to combine animal movement data (*i.e.,* the output from 3MB), with pre-computed acoustic fields (*i.e.,* the output from MONM described above). The JEMS is a relatively simple piece of software that acts as an indexer that finds the sound level from the computed fields for the location of each animat through time. The numerous, rigorous robustness checks described for the multiple modeling components are sufficient to comply with the IQA requirements, and no additional peer review is required.

While certain components of the modeling process (AASM, MONM, and JEMS) are proprietary in the sense that JASCO does not make the code publicly available, they are all based on standard physics or mathematical models generally accepted in the field and based on peer-reviewed models (*e.g.,* 3MB). In addition, ample opportunity has been provided for public input and review of the underlying scientific information and modeling efforts contained herein (including by scientists, peer experts at other agencies, and non-governmental organizations). Relevant data is provided such that an entity using similar models could reproduce or challenge the results. While the modeling results disseminated here may reasonably be considered to be influential for purposes of the OMB Peer Review Bulletin—meaning that the information may reasonably be considered to have a clear and substantial impact on important public policies, such as this ITR—the modeling is not a ''highly influential scientific assessment,'' (HISA) which is defined as a scientific assessment that: (i) Could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest. As described above, similar approaches to acoustic exposure modeling have been performed by numerous disparate entities for multiple applications. In 2014, during the aforementioned modeling workshop co-sponsored by the American Petroleum Institute and International Association of Geophysical Contractors, at least a half-dozen expert presenters (representing private and governmental entities from both the United States and Europe) discussed various available packages that function much the same way as what is described here. There is nothing novel, controversial, or precedent-setting about the modeling described here, and the additional peer review requirements associated with HISAs are not applicable.

Miscellaneous

Comment: NRDC contends that NMFS must consider a standard requiring analysis and selection of minimum source levels. In furtherance of this overall quieting goal, NRDC also states that NMFS should consider requiring that all vessels employed in the survey activities undergo regular maintenance to minimize propeller cavitation and be required to employ the best ship-quieting designs and technologies available for their class of ship, and that NMFS should require these vessels to undergo measurement for their underwater noise output.

Response: An expert panel, convened by BOEM to determine whether it would be feasible to develop standards to determine a lowest practicable source level, determined that it would not be reasonable or practicable to develop such metrics (see Appendix L in BOEM, 2017). NMFS does not believe it appropriate to address disagreements with these conclusions to us. NRDC further claims that NMFS' deference to the findings of an expert panel convened specifically to consider this issue is ''arbitrary under the MMPA.'' The bulk of NRDC's comment appears to be addressed to BOEM, and NMFS encourages NRDC to engage with BOEM regarding these alleged shortcomings of the panel's findings. The subject matter is outside NMFS' expertise, and we have no basis upon which to doubt the panel's published findings.

With regard to the recommended requirements to measure or control vessel noise, or to make some minimum requirements regarding the design of vessels used in the surveys, NMFS disagrees that these requirements would be practicable. While NMFS agrees that vessel noise is of concern in a cumulative and chronic sense, it is not of substantial concern in relation to the MMPA's least practicable adverse impact standard for this specified activity, given the few vessels used in any given survey and relative to commercial shipping. NMFS looks forward to continued collaboration with NRDC and others towards ship quieting.

Comment: NRDC states that NMFS must consider mitigation that limits and reduces the amount of survey activity, including ''prohibit[ing]'' duplicative surveys, and should consider ''consolidating'' surveys. Similarly, the MMC recommends that NMFS ''work with BOEM'' to require industry operators to increase collaboration on seismic surveys whenever possible.

Response: NRDC states that NMFS should ''require and enforce a cap'' on surveys, without explaining how they believe this is within NMFS' statutory authority or suggesting ways to appropriately apportion the amount of effort that might be allowed. NMFS cannot arbitrarily limit planned effort and has no legitimate means of changing the specified activity absent a conclusion that the activity would have more than a negligible impact. However, NMFS has made the necessary findings under the MMPA for issuance of this rule. NRDC goes on to state that NMFS should ''require BOEM to eliminate unnecessary duplication of survey effort'' but does not explain how they

believe that this suggestion is within NMFS' statutory authority. As the permitting agency, BOEM has the authority to require permit applicants to submit statements indicating that existing data are not available to meet the data needs identified for the applicant's survey (*i.e.,* non-duplicative survey statement), but such requirements are not within NMFS' purview. NMFS may not demand that BOEM discharge its authority under OCSLA in any particular manner. As stated previously, NMFS considers the specified activity described by an applicant in reviewing a request for an incidental take authorization. Nothing in the statute provides authority to direct consolidation or removal of activities based on some presumption of duplication that NMFS is not qualified to judge. NRDC claims erroneously that NMFS ''has authority under the mitigation provision of the MMPA to consider directing the companies to consolidate their surveys,'' placing such a requirement under the auspices of practicability. Leaving aside that directing any given applicant to abandon their survey plans would not in fact be practicable, it is inappropriate to consider this suggested requirement through that lens.

The MMC specifically cites a number of collaborative surveys conducted in foreign waters and recommends that NMFS ''work with BOEM'' to require such collaboration. However, the MMC provides no useful recommendations as to how such collaboration might be achieved. Given the absence of appropriate statutory authority, NMFS is willing to explore with the MMC possible mechanisms for fostering such collaboration between geophysical data acquisition companies and relevant Federal agencies, within the context of our respective authorities.

NMFS also notes that, although surveys may be perceived as ''duplicative'' simply because other surveys have also occurred in the same location, they are in fact designed specifically to produce proprietary data that satisfies the needs of survey funders. As noted by NRDC, BOEM convened an expert panel to study the issue of duplicative surveys (see Appendix L in BOEM, 2017) and developed standards for consideration of what surveys are duplicative. NRDC provides extensive discussion of their thoughts regarding the insufficiency of BOEM's duplicative survey standard and its implementation. We respectfully suggest that these comments are more appropriately directed at BOEM.

Comment: Chevron states that NMFS ''must be mindful of the mandates under OCSLA to assess and then balance the costs and benefits of alternative restrictions on geophysical activities against a requirement for 'expeditious and orderly development' of GOM resources.''

Response: NMFS' statutory obligations arise under the Marine Mammal Protection Act (with associated requirements under the Endangered Species Act, National Environmental Policy Act, and Administrative Procedure Act, among others). NMFS has no statutory obligation relative to OCSLA.

Comment: CRE provides several comments relating to E.O. 12866. CRE reiterates their view that there is ''no harm from seismic,'' and therefore, that it is not surprising that NMFS has not produced a quantitative statement of benefits. They also conclude that ''[s]ince the benefits of the proposed rule are minimal at best, the resultant benefit-cost ratio is less than one, making the proposed rule non-compliant'' with E.O. 12866.

Response: NMFS disagrees with the commenter's premise that there is no potential for harm, and accordingly evaluated the impacts of the specified activity and prescribed appropriate mitigation in the ITR, as required under the MMPA. With respect to E.O. 12866, the RIA provides a qualitative description of potential ecological benefits and their economic implications due to uncertainty preventing quantification. Similar to the qualitative evaluation of costs associated with the proposed area closures, the qualitative treatment of benefits does not indicate a lesser magnitude, but rather more data limitations or uncertainty.

Comment: Regarding E.O. 13211, Chevron comments that NMFS has provided inconsistent statements that should be resolved.

Response: NMFS has clarified its discussion regarding E.O. 13211. Overall, within the five-year timeframe of the analysis, the ITR is not expected to constitute a significant adverse effect on energy supply, distribution or use, according to the thresholds described by E.O. 13211, given that the direct compliance costs represent a small fraction (on the order of less than one percent) of the total costs of exploration and development in the GOM.

Comment: Chevron notes that E.O. 13795 required evaluation of NMFS' 2016 Technical Guidance (review of which was ongoing at the time of publication of the notice of proposed rulemaking). Chevron also asserts that assumptions of the 2016 Technical Guidance ''are multiplied with those in other elements of the modeling to reach 'unrealistic' conclusions.'' Because the 2016 Technical Guidance was used in the modeling, Chevron asserts that the modeling is inconsistent with the requirements of E.O. 13795. The CRE also claims that use of the 2016 Technical Guidance is in violation of E.O. 13795 and that the guidance should be rescinded or substantially revised. CRE also states that NMFS must emphasize that use of the Technical Guidance is not required.

Response: Review of the Technical Guidance under E.O. 13795 was completed in 2018. In response to the feedback received during the public comment period and the Interagency Consultation meeting, the Secretary of Commerce approved NMFS to issue a 2018 Revised Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing: Acoustic Thresholds for Onset of Permanent and Temporary Threshold Shifts (2018 Revised Technical Guidance) (NOAA Technical Memorandum NMFS–OPR–59) (June 21, 2018). NMFS' use of the guidance is, therefore, in compliance with E.O. 13795.

The 2018 Revised Technical Guidance retains the thresholds and weighting functions presented in the original 2016 Technical Guidance. Chevron's comment that the Technical Guidance somehow contributes to what they characterize as ''unrealistic'' conclusions is, in context of industry's overall comments on the modeling effort, unpersuasive. The industry-funded supplementary modeling variable analysis (Zeddies *et al.,* 2017b) found that use of the Technical Guidance was the single most influential factor in reducing the modeled exposures (for Level A harassment).

We acknowledge that the Technical Guidance is indeed guidance, and its use is voluntary (as stated in the Executive Summary of the Technical Guidance). The Technical Guidance provides more detail on if/when an alternative approach may be used.

Description of Marine Mammals in the Area of the Specified Activities

Sections 3 and 4 of the petition summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS refers the reader to those descriptions, descriptions of the affected environment in Appendix E of BOEM's PEIS, as well as NMFS' Stock Assessment Reports (SAR; *www.fisheries.noaa.gov/national/*

marine-mammal-protection/marine-mammal-stock-assessments), incorporated here by reference, instead of reprinting the information. Additional general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*www.fisheries.noaa.gov/find-species*).

Table 4 lists all species with expected potential for occurrence in the GOM and summarizes information related to the population or stock, including potential biological removal (PBR). For taxonomy, we follow Committee on Taxonomy (2020). PBR, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population, is considered in concert with known sources of ongoing anthropogenic mortality (as described in NMFS' SARs). For status of species, we provide information regarding U.S. regulatory status under the MMPA and ESA.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. Survey abundance (as compared to stock or species abundance) is the total number of individuals estimated within the survey area, which may or may not align completely with a stock's geographic range as defined in the SARs. These surveys may also extend beyond U.S. waters. For many GOM stocks, information regarding distribution and range-wide abundance is limited, as available data are generally limited to U.S. waters of the northern GOM. Abundance and distribution for GOM stocks occurring in the Mexican EEZ or the high seas are poorly understood. As discussed in additional detail below, U.S. waters only comprise about 40 percent of the entire GOM, and 65 percent of GOM oceanic waters are south of the U.S. EEZ. Studies based on abundance and distribution surveys restricted to U.S. waters are unable to detect temporal shifts in distribution beyond U.S. waters that might account for any changes in abundance within U.S. waters.

In some cases, species are treated as guilds. In general ecological terms, a guild is a group of species that have similar requirements and play a similar role within a community. However, for purposes of stock assessment or abundance prediction, certain species may be treated together as a guild because they are difficult to distinguish visually and many observations are ambiguous. For example, NMFS' GOM SARs assess stocks of *Mesoplodon* spp. and *Kogia* spp. as guilds. Here, we consider beaked whales and *Kogia* spp. as guilds. In the following discussion, reference to ''beaked whales'' includes the Cuvier's, Blainville's, and Gervais beaked whales, and reference to ''*Kogia* spp.'' includes both the dwarf and pygmy sperm whale.

Twenty-one species (with 24 managed stocks) have the potential to co-occur with the prospective survey activities. Extralimital species or stocks unlikely to co-occur with survey activity include 31 estuarine bottlenose dolphin stocks, the blue whale (*Balaenoptera musculus*), fin whale (*B. physalus*), sei whale (*B. borealis*), minke whale (*B. acutorostrata*), humpback whale (*Megaptera novaeangliae*), North Atlantic right whale (*Eubalaena glacialis*), and the Sowerby's beaked whale (*Mesoplodon bidens*). All mysticete species listed here (as well as Sowerby's beaked whale) are considered only of accidental occurrence in GOM and are generally historically known only from a very small number of strandings and/or sightings (Würsig *et al.,* 2000; Würsig, 2017). In addition, following BOEM's update to the scope of activity considered through this rule, the eastern coastal stock of bottlenose dolphin, which was considered in the notice of proposed rulemaking, would no longer be potentially impacted by activities that may be authorized under this rule. For detailed discussion of these species, please see the notice of proposed rulemaking (83 FR 29212; June 22, 2018). In addition, the West Indian manatee (*Trichechus manatus latirostris*) may be found in coastal waters of the GOM. However, manatees are managed by the U.S. Fish and Wildlife Service and are not considered further in this document. All managed stocks in this region are assessed in NMFS' U.S. Atlantic SARs.

All values presented in Table 4, which are available in the most recent final SARs (Hayes *et al.,* 2020) and have not changed since the proposed rule was published, are the most recent available at the time the analyses for this final rule were completed. We also reviewed new information for many GOM stocks in unpublished draft 2020 SARs. The unpublished draft SARs include updates to most GOM stocks, including to abundance estimates, PBR values, and annual mortality and serious injury (M/SI) estimates. The most notable change is that, through the introduction of M/SI estimates related to the Deepwater Horizon (DWH) oil spill, M/SI values are generally larger than in past SARs and in some cases are larger than the PBR values. NMFS has considered this information and determined that it is previously accounted for as part of the baseline, through our existing analysis of the effects of the DWH oil spill. We have fully considered the underlying information in our analysis and have determined that the unpublished draft SAR updates do not impact our conclusions.

TABLE 4—MARINE MAMMALS POTENTIALLY PRESENT IN THE SPECIFIED GEOGRAPHICAL REGION

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	NMFS stock abundance (CV, N_{min}, most recent abundance survey)[2,7]	Predicted mean (CV)/maximum abundance [3]	PBR	Annual M/SI (CV) [4]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)							
Family Balaenopteridae (rorquals):							
Bryde's whale	*Balaenoptera edeni*	Gulf of Mexico	E/D; Y	33 (1.07; 16; 2009)	44 (0.27)/n/a	0.03	0.8
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)							
Family Physeteridae:							
Sperm whale	*Physeter macrocephalus*	GOM	E/D; Y	763 (0.38; 560; 2009)	2,128 (0.08)/2,234.	1.1	0

TABLE 4—MARINE MAMMALS POTENTIALLY PRESENT IN THE SPECIFIED GEOGRAPHICAL REGION—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; Strategic (Y/N) [1]	NMFS stock abundance (CV, N_{min}, most recent abundance survey)[2,7]	Predicted mean (CV)/ maximum abundance [3]	PBR	Annual M/SI (CV) [4]
Family Kogiidae:							
Pygmy sperm whale	*Kogia breviceps*	GOM	-; N	186 (1.04; 90; 2009) [5]	2,234 (0.19)/ 6,117 [5].	0.9	0.3 (1.0)
Dwarf sperm whale	*K. sima*	GOM	-; N				
Family Ziphiidae (beaked whales):							
Cuvier's beaked whale:.	*Ziphius cavirostris*	GOM	-; N	74 (1.04; 36; 2009)	2,910 (0.16)/ 3,958 [5].	0.4	0
Gervais beaked whale.	*Mesoplodon europaeus*	GOM	-; N	149 (0.91; 77; 2009) [5]		0.8	0
Blainville's beaked whale.	*M. densirostris*	GOM	-; N				
Family Delphinidae:							
Rough-toothed dolphin.	*Steno bredanensis*	GOM	-; N	624 (0.99; 311; 2009)	4,853 (0.19)/n/a.	2.5	0.8 (1.0)
Common bottlenose dolphin.	*Tursiops truncatus truncatus.*	GOM Oceanic	-; N	5,806 (0.39; 4,230; 2009)	138,602 (0.06)/ 192,176 [5].	42	6.5 (0.65)
		GOM Continental Shelf	-; N	51,192 (0.10; 46,926; 2011–12).		469	0.8
		GOM Coastal, Northern	-; N	7,185 (0.21; 6,044; 2011–12).		60	0.4
		GOM Coastal, Western	-; N	20,161 (0.17; 17,491; 2011–12).		175	0.6
Clymene dolphin	*Stenella clymene*	GOM	-; N	129 (1.00; 64; 2009)	11,000 (0.16)/ 12,115.	0.6	0
Atlantic spotted dolphin	*S. frontalis*	GOM	-; N	37,611 (0.28; 29,844; 2000–01)[6].	47,488 (0.13)/ 85,108.	Undet.	42 (0.45)
Pantropical spotted dolphin.	*S. attenuata attenuata*	GOM	-; N	50,880 (0.27; 40,699; 2009).	84,014 (0.06)/ 108,764.	407	4.4
Spinner dolphin	*S. longirostris longirostris*	GOM	-; N	11,441 (0.83; 6,221; 2009).	13,485 (0.24)/ 31,341.	62	0
Striped dolphin	*S. coeruleoalba*	GOM	-; N	1,849 (0.77; 1,041; 2009)	4,914 (0.17)/ 5,323.	10	0
Fraser's dolphin	*Lagenodelphis hosei*	GOM	-; N	726 (0.7; 427; 1996–2001)[6].	1,665 (0.73)/n/a.	Undet.	0
Risso's dolphin	*Grampus griseus*	GOM	-; N	2,442 (0.57; 1,563; 2009)	3,137 (0.10)/ 4,153.	16	7.9 (0.85)
Melon-headed whale	*Peponocephala electra*	GOM	-; N	2,235 (0.75; 1,274; 2009)	6,733 (0.30)/ 7,105.	13	0
Pygmy killer whale	*Feresa attenuata*	GOM	-; N	152 (1.02; 75; 2009)	2,126 (0.30)/n/a.	0.8	0
False killer whale	*Pseudorca crassidens*	GOM	-; N	777 (0.56; 501; 2003–04)[6].	3,204 (0.36)/n/a.	Undet.	0
Killer whale	*Orcinus orca*	GOM	-; N	28 (1.02; 14; 2009)	185 (0.41)/n/a	0.1	0
Short-finned pilot whale	*Globicephala macrorhynchus.*	GOM	-; N	2,415 (0.66; 1,456; 2009)	1,981 (0.18)/n/a.	15	0.5 (1.0)

[1] ESA status: Endangered (E)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[3] This information represents species- or guild-specific abundance predicted by habitat-based cetacean density models (Roberts *et al.,* 2016). These models provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. Gulf of Mexico, and we provide the corresponding abundance predictions as a point of reference. Total abundance estimates were produced by computing the mean density of all pixels in the modeled area and multiplying by its area.

[4] These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[5] Abundance estimates are in some cases reported for a guild or group of species when those species are difficult to differentiate at sea. Similarly, the habitat-based cetacean density models produced by Roberts *et al.* (2016) are based in part on available observational data which, in some cases, is limited to genus or guild in terms of taxonomic definition. NMFS' SARs present pooled abundance estimates for *Kogia* spp. and *Mesoplodon* spp., while Roberts *et al.* (2016) produced density models to genus level for *Kogia* spp. and as a guild for beaked whales (*Ziphius cavirostris* and *Mesoplodon* spp.). Finally, Roberts *et al.* (2016) produced a density model for bottlenose dolphins that does not differentiate between oceanic, shelf, and coastal stocks. The modeled abundance estimate provided here for all bottlenose dolphins includes abundance that may be attributed to the eastern coastal stock.

[6] NMFS' abundance estimates for these species are not considered current. PBR is therefore considered undetermined, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimate.

[7] We note that Dias and Garrison (2016) present abundance estimates for oceanic stocks that were calculated for use in DWH oil spill injury quantification. For most stocks, these estimates are based on pooled observations from shipboard surveys conducted in 2003, 2004, and 2009 and corrected for detection bias. Estimates for beaked whales and *Kogia* spp. were based on density estimates derived from passive acoustic data collection (Hildebrand *et al.,* 2012). The abundance estimate for Bryde's whales incorporated the results of additional shipboard surveys conducted in 2007, 2010, and 2012. Here we retain NMFS' official SAR information for comparison with model-predicted abundance (Roberts *et al.,* 2016).

For the majority of species potentially present in the specified geographical region, NMFS has designated only a single generic stock (*i.e.,* ''Gulf of Mexico'') for management purposes, although there is currently no information to differentiate the stock from the Atlantic Ocean stock of the same species, nor information on whether more than one stock may exist in the GOM (Hayes *et al.,* 2020).

For the bottlenose dolphin, NMFS defines an oceanic stock, a continental shelf stock, and three coastal stocks. As in the northwestern Atlantic Ocean, there are two general bottlenose dolphin ecotypes: ''coastal'' and ''offshore.''

These ecotypes are genetically and morphologically distinct (Hoelzel *et al.,* 1998; Waring *et al.,* 2016), though ecotype distribution is not clearly defined and the stocks are delineated primarily on the basis of management rather than ecological boundaries. The offshore ecotype is assumed to correspond to the oceanic stock, with the stock boundary (and thus the de facto delineation of offshore and coastal ecotypes) defined as the 200-m isobath. The continental shelf stock is defined as between two typical survey strata: The 20- and 200-m isobaths. While the shelf stock is assumed to consist primarily of coastal ecotype dolphins, offshore ecotype dolphins may also be present. There is expected to be some overlap with the three coastal stocks as well, though the degree is unknown and it is not thought that significant mixing or interbreeding occurs between them (Waring *et al.,* 2016). The coastal stocks are defined as being in waters between the shore, barrier islands, or presumed outer bay boundaries out to the 20-m isobath and, as a working hypothesis, NMFS has assumed that dolphins occupying habitats with dissimilar climatic, coastal, and oceanographic characteristics might be restricted in their movements between habitats, thus constituting separate stocks (Waring *et al.,* 2016). Shoreward of the 20-m isobath, the eastern coastal stock extends from Key West, FL to 84° W longitude; the northern coastal stock from 84° W longitude to the Mississippi River delta; and the western coastal stock from the Mississippi River delta to the Mexican border. The latter is assumed to be a trans-boundary stock, though no information is available regarding abundance in Mexican waters. As noted above, the eastern coastal stock will not be affected by activities considered through this rule.

At the time of publication of the notice of proposed rulemaking, the GOM Bryde's whale was proposed for listing as an endangered species under the ESA (81 FR 88639; December 8, 2016). Since that time, NMFS has listed the GOM Bryde's whale as endangered under the ESA, effective on May 15, 2019 (84 FR 15446; April 15, 2019). The proposed listing was based largely on NMFS' status review of Bryde's whales in the GOM (Rosel *et al.,* 2016), and no significant new information has become available since that time. No critical habitat has yet been designated for the species, and no recovery plan has yet been developed. NMFS' analysis related to the GOM Bryde's whale in the notice of proposed rulemaking was conducted in context of the same information that informed the proposal to list the GOM Bryde's whale and, therefore, the final listing decision itself does not introduce new information for consideration in the analysis for this final rulemaking.

In Table 4 above, NMFS reports two sets of abundance estimates: Those from NMFS' SARs and those predicted by Roberts *et al.* (2016)—for the latter, we provide both the annual mean and the monthly maximum (where applicable). Please see footnotes 2–3 of Table 4 for more detail. NMFS' SAR estimates are typically generated from the most recent shipboard and/or aerial surveys conducted. GOM oceanography is dynamic, and the spatial scale of the GOM is small relative to the ability of most cetacean species to travel. As an example, no groups of Fraser's dolphins were observed during dedicated cetacean abundance surveys during 2003–2004 or 2009, yet the SAR states that it is probable that Fraser's dolphins were present in the northern GOM but simply not encountered, and therefore declines to present an abundance estimate of zero (Waring *et al.,* 2013). U.S. waters only comprise about 40 percent of the entire GOM, and 65 percent of GOM oceanic waters are south of the U.S. EEZ. Studies based on abundance and distribution surveys restricted to U.S. waters are unable to detect temporal shifts in distribution beyond U.S. waters that might account for any changes in abundance within U.S. waters. NMFS' SAR estimates also typically do not incorporate correction for detection bias. Therefore, they should generally be considered underestimates, especially for cryptic or long-diving species (*e.g.,* beaked whales, *Kogia* spp., sperm whales). Dias and Garrison (2016) state, for example, that current abundance estimates for *Kogia* spp. may be considerably underestimated due to the cryptic behavior of these species and difficulty of detection in Beaufort sea state greater than one, and density estimates for certain species derived from long-term passive acoustic monitoring are much higher than are estimates derived from visual observations (Mullin and Fulling, 2004; Mullin, 2007; Hildebrand *et al.,* 2012).

The Roberts *et al.* (2016) abundance estimates represent the output of predictive models derived from multi-year observations and associated environmental parameters and which incorporate corrections for detection bias. Incorporating more data over multiple years of observation can yield different results in either direction, as the result is not as readily influenced by fine-scale shifts in species habitat preferences or by the absence of a species in the study area during a given year. NMFS' abundance estimates show substantial year-to-year variability in some cases. For example, NMFS-reported estimates for the Clymene dolphin vary by a maximum factor of more than 100 (2009 estimate of 129 versus 1996–2001 estimate of 17,355), indicating that it may be more appropriate to use the model prediction versus a point estimate, as the model incorporates all available data (from 1992–2009). The latter factor—incorporation of correction for detection bias—should systematically result in greater abundance predictions. For these reasons, the Roberts *et al.* (2016) estimates are generally more realistic and, for these purposes, represent the best available information. For purposes of assessing estimated exposures relative to abundance—used in this case to understand the scale of the predicted takes compared to the population—NMFS generally believes that the Roberts *et al.* (2016) abundance predictions are most appropriate because they were used to generate the exposure estimates and therefore provide the most relevant comparison. Roberts *et al.* (2016) represents the best available scientific information regarding marine mammal occurrence and distribution in the Gulf of Mexico.

As a further illustration of the distinction between the SARs and model-predicted abundance estimates, the current NMFS stock abundance estimates for most GOM species are based on direct observations from shipboard surveys conducted in 2009 (from the 200-m isobath to the edge of the U.S. EEZ) and not corrected for detection bias, whereas the exposure estimates presented herein for those species are based on the abundance predicted by a density surface model informed by observations from surveys conducted over approximately 20 years and covariates associated at the observation level. To directly compare the estimated exposures predicted by the outputs of the Roberts *et al.* (2016) model to NMFS' SAR abundance would therefore not be meaningful.

Biologically Important Areas (BIA)—As part of our description of the environmental baseline, we discuss any known areas of importance as marine mammal habitat. These areas may include designated critical habitat for ESA-listed species (as defined by section 3 of the ESA) or other known areas not formally designated pursuant to any statute or other law. Important areas may include areas of known importance for reproduction, feeding, or migration, or areas where small and

resident populations are known to occur.

Although there is no designated critical habitat for marine mammal species in the specified geographical region, BIAs for marine mammals are recognized. For example, the GOM Bryde's whale is a very small population that is genetically distinct from other Bryde's whales and not genetically diverse within the GOM (Rosel and Wilcox, 2014). Further, the species is typically observed only within a narrowly circumscribed area within the eastern GOM. Therefore, this area is described as a year-round BIA by LaBrecque *et al.* (2015). Although survey effort has covered all oceanic waters of the U.S. GOM, whales were observed only between approximately the 100- and 300-m isobaths in the eastern GOM from the head of the De Soto Canyon (south of Pensacola, Florida) to northwest of Tampa Bay, Florida (Maze-Foley and Mullin, 2006; Waring *et al.,* 2016; Rosel and Wilcox, 2014; Rosel *et al.,* 2016). NOAA subsequently conducted a status review of the GOM Bryde's whale (Rosel *et al.,* 2016). The review expanded this description by stating that, due to the depth of some sightings, the area is more appropriately defined to the 400-m isobath and westward to Mobile Bay, Alabama, in order to provide some buffer around the deeper sightings and to include all sightings in the northeastern GOM. However, the recorded Bryde's whale shipboard and aerial survey sightings between 1989 and 2015 have mainly fallen within the BIA described by LaBreque *et al.* (2015). The entirety of this area is now excluded from the scope of this rule following BOEM's update to that scope.

LaBrecque *et al.* (2015) also described eleven year-round BIAs for small and resident BSE bottlenose dolphin populations in the GOM. Additional study would likely allow for identification of additional BIAs associated with other GOM BSE dolphin stocks.

Deepwater Horizon Oil Spill—In 2010 the *Macondo* well blowout and explosion aboard the *Deepwater Horizon* drilling rig (also known as the *Deepwater Horizon* explosion, oil spill, and response; hereafter referred to as the DWH oil spill) caused oil, natural gas, and other substances to flow into the GOM for 87 days before the well was sealed. Total oil discharge was estimated at 3.19 million barrels (134 million gallons), resulting in the largest marine oil spill in history (DWH NRDA Trustees, 2016). In addition, the response effort involved extensive application of dispersants at the seafloor and at the surface, and controlled burning of oil at the surface was also used extensively as a response technique. The oil, dispersant, and burn residue compounds present ecological challenges in the region. NMFS discussed the impacts of the DWH oil spill on marine mammals in detail in the notice of proposed rulemaking (83 FR 29212; June 22, 2018) and we refer the reader to that document for additional detail.

At its maximum extent, oil covered over 40,000 km^2 of ocean. Cumulatively, over the course of the spill, oil was detected on over 112,000 km^2 of ocean. Currents, winds, and tides carried these surface oil slicks to shore, fouling more than 2,100 km of shoreline, including beaches, bays, estuaries, and marshes from eastern Texas to the Florida Panhandle. In addition, some lighter oil compounds evaporated from the slicks, exposing air-breathing organisms like marine mammals to noxious fumes at the sea surface.

The Oil Pollution Act requires that a natural resource damage assessment (NRDA) be conducted following oil pollution incidents. An injury assessment undertaken as part of the NRDA first requires a determination of whether an incident injured natural resources. Trustees assessing natural resource injuries must establish that a pathway existed from the oil discharge to the resource, confirm that resources were exposed to the discharge, and evaluate the adverse effects that occurred as a result of the exposure (or response activities). Subsequently, the assessment requires injury quantification (including degree and spatiotemporal extent), essentially by comparing the post-event conditions with the pre-event baseline. For a fuller overview of the injury assessment process in this case, please see Takeshita *et al.* (2017). Critical pathways of exposure for marine mammals included the contaminated water column, where they swim and capture prey; the surface slick at the air to water interface, where they breathe, rest, and swim; and contaminated sediment, where they forage and capture prey.

DWH oil was found to cause problems with the regulation of stress hormone secretion from adrenal cells and kidney cells, which will affect an animal's ability to regulate body functions and respond appropriately to stressful situations, thus leading to reduced fitness. Bottlenose dolphins living in habitats contaminated with DWH oil showed signs of adrenal dysfunction, and dead, stranded dolphins from areas contaminated with DWH oil had smaller adrenal glands (Schwacke *et al.,* 2014a; Venn-Watson *et al.,* 2015b). Other factors were ruled out as a primary cause for the high prevalence of adverse health effects, reproductive failures, and disease in stranded animals. When all of the data were considered together, the DWH oil spill was determined to be the only reasonable cause for the full suite of observed adverse health effects.

Due to the difficulty of investigating marine mammals in pelagic environments and across the entire region impacted by the event, the injury assessment focused on health assessments conducted on bottlenose dolphins in nearshore habitats and used these populations as case studies for extrapolating to coastal and oceanic populations that received similar or worse exposure to DWH oil, with appropriate adjustments made for differences in behavior, anatomy, physiology, life histories, and population dynamics among species. Investigators then used a population modeling approach to capture the overlapping and synergistic relationships among the metrics for injury, and to quantify the entire scope of DWH marine mammal injury to populations into the future, expressed as ''lost cetacean years'' due to the DWH oil spill (which represents years lost due to premature mortality as well as the resultant loss of reproductive output). This approach allowed for consideration of long-term impacts resulting from immediate losses and reproductive failures in the few years following the spill, as well as expected persistent impacts on survival and reproduction for exposed animals well into the future (Takeshita *et al.,* 2017). For a more detailed overview of the injury quantification for these stocks and their post-DWH population trajectory, please see Schwacke *et al.* (2017), and for full details of the overall injury quantification, see DWH MMIQT (2015).

The results of the quantification exercise for each affected shelf and oceanic stock, and for northern and western coastal stocks of bottlenose dolphin, are presented in Table 5. This is likely a conservative estimate of impacts, because: (1) Shelf and oceanic species experienced long exposures (up to 90 days) to very high concentrations of fresh oil and a diverse suite of response activities, while estuarine dolphins were not exposed until later in the spill period and to weathered oil products at lower water concentrations; (2) oceanic cetaceans dive longer and to deeper depths, and it is possible that the types of lung injuries observed in estuarine dolphins may be more severe for oceanic cetaceans; and (3) cetaceans

in deeper waters were exposed to very high concentrations of volatile gas compounds at the water's surface near the wellhead. No analysis was performed for Fraser's dolphins or killer whales; although they are present in the GOM, sightings are rare and there were no historical sightings in the oil spill footprint during the surveys used in the quantification process. These stocks were likely injured, but no information is available on which to base a quantification effort.

TABLE 5—SUMMARY OF MODELED EFFECTS OF DWH OIL SPILL

Common name	% Population exposed to oil (95% CI)	% Population killed (95% CI)	% Females with reproductive failure (95% CI)	% Population with adverse health effects (95% CI)	% Maximum population reduction (95% CI)	Years to recovery (95% CI) [b]
Bryde's whale	48 (23 – 100)	17 (7 – 24)	22 (10 – 31)	18 (7 – 28)	– 22	69
Sperm whale	16 (11 – 23)	6 (2 – 8)	7 (3 – 10)	6 (2 – 9)	– 7	21
Kogia spp.	15 (8 – 29)	5 (2 – 7)	7 (3 – 10)	6 (2 – 9)	– 6	11
Beaked whales	12 (7 – 22)	4 (2 – 6)	5 (3 – 8)	4 (2 – 7)	– 6	10
Rough-toothed dolphin	41 (16 – 100)	14 (6 – 20)	19 (9 – 26)	15 (6 – 23)	– 17	54
Bottlenose dolphin, oceanic	10 (5 – 10)	3 (1 – 5)	5 (2 – 6)	4 (1 – 6)	– 4	n/a
Bottlenose dolphin, northern coastal	82 (55 – 100)	38 (26 – 58)	37 (17 – 53)	30 (11 – 47)	– 50 (32 – 73)	39 (23 – 76)
Bottlenose dolphin, western coastal	23 (16 – 32)	1 (1 – 2)	10 (5 – 15)	8 (3 – 13)	– 5 (3 – 9)	n/a
Shelf dolphins [a]	13 (9 – 19)	4 (2 – 6)	6 (3 – 8)	5 (2 – 7)	– 3	n/a
Clymene dolphin	7 (3 – 15)	2 (1 – 4)	3 (2 – 5)	3 (1 – 4)	– 3	n/a
Pantropical spotted dolphin	20 (15 – 26)	7 (3 – 10)	9 (4 – 13)	7 (3 – 11)	– 9	39
Spinner dolphin	47 (24 – 91)	16 (7 – 23)	21 (10 – 30)	17 (6 – 27)	– 23	105
Striped dolphin	13 (8 – 22)	5 (2 – 7)	6 (3 – 9)	5 (2 – 8)	– 6	14
Risso's dolphin	8 (5 – 13)	3 (1 – 4)	3 (2 – 5)	3 (1 – 4)	– 3	n/a
Melon-headed whale	15 (6 – 36)	5 (2 – 7)	7 (3 – 10)	6 (2 – 9)	– 7	29
Pygmy killer whale	15 (7 – 33)	5 (2 – 8)	7 (3 – 10)	6 (2 – 9)	– 7	29
False killer whale	18 (7 – 48)	6 (3 – 9)	8 (4 – 12)	7 (3 – 11)	– 9	42
Short-finned pilot whale	6 (4 – 9)	2 (1 – 3)	3 (1 – 4)	2 (1 – 3)	– 3	n/a

Modified from DWH NRDA Trustees (2016).
CI = confidence interval. No CI was calculated for population reduction or years to recovery for shelf or oceanic stocks.
[a] "Shelf dolphins" includes Atlantic spotted dolphins and the shelf stock of bottlenose dolphins (20–200 m water depth). These two species were combined because the abundance estimate used in population modeling was derived from aerial surveys and the species could not generally be distinguished from the air.
[b] It is not possible to calculate YTR for stocks with maximum population reductions of less than or equal to 5 percent.

Coastal and oceanic marine mammals were injured by exposure to oil from the DWH spill. Nearly all of the stocks that overlap with the oil spill footprint have demonstrable, quantifiable injuries, and the remaining stocks (for which there is no quantifiable injury) were also likely injured, though there is not currently enough information to make a determination. Injuries included elevated mortality rates, reduced reproduction, and disease. Due to these effects, affected populations may require decades to recover absent successful efforts at restoration (*e.g.,* DWH NRDA Trustees, 2017). The ability of the stocks to recover and the length of time required for that recovery are tied to the carrying capacity of the habitat, and to the degree of other population pressures. NMFS treats the effects of the DWH oil spill as part of the baseline in considering the likely resilience of these populations to the effects of the activities considered in this regulatory framework.

Unusual Mortality Events (UME)—A UME is defined under Section 410(6) of the MMPA as "a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response." From 1991 to the present, there have been fourteen formally recognized UMEs affecting marine mammals in the region and involving species under NMFS' jurisdiction. These have primarily impacted coastal bottlenose dolphins, with multiple UMEs determined to have resulted from biotoxins and one from infectious disease. One relevant UME was declared since publication of the notice of proposed rulemaking and is discussed below.

Most significantly, a UME affecting multiple cetacean species in the northern GOM occurred from 2010–2014. NMFS discussed this UME in the notice of proposed rulemaking (83 FR 29212; June 22, 2018). Please see that document for additional information regarding the 2010–2014 UME. Additional information on the UME is also available online at: *www.fisheries.noaa.gov/national/marine-life-distress/2010-2014-cetacean-unusual-mortality-event-northern-gulf-mexico.* In summary, the event included all cetaceans stranded during this time in Alabama, Mississippi, and Louisiana and all cetaceans other than bottlenose dolphins stranded in the Florida Panhandle (Franklin County through Escambia County), with a total of 1,141 cetaceans stranded or reported dead offshore. For reference, the same area experienced a normal average of 75 strandings per year from 2002–09 (Litz *et al.,* 2014). The majority of stranded animals were bottlenose dolphins, though at least ten additional species were reported as well. Since not all cetaceans that die wash ashore where they may be found, the number reported stranded is likely a fraction of the total number of cetaceans that died during the UME. There was also an increase in strandings of stillborn and newborn dolphins (Colegrove *et al.,* 2016). The UME investigation and the *Deepwater Horizon* Natural Resource Damage Assessment determined that the DWH oil spill (discussed above) is the most likely explanation of the persistent, elevated stranding numbers in the northern GOM after the 2010 spill. The evidence to date supports that exposure to hydrocarbons released during the DWH oil spill was the most likely explanation of adrenal and lung disease in dolphins, which has contributed to increased deaths of dolphins living within the oil spill footprint and increased fetal loss. The longest and

most prolonged stranding cluster was in Barataria Bay, Louisiana in 2010–11, followed by Mississippi and Alabama in 2011, consistent with timing and spatial distribution of oil, while the number of deaths was not elevated for areas that were not as heavily oiled. Subsequent health assessments of live dolphins from Barataria Bay and comparison to a reference population found significantly increased adrenal disease, lung disease, and poor health, while histological evaluations of samples from dead stranded animals from within and outside the UME area found that UME animals were more likely to have lung and adrenal lesions and to have primary bacterial pneumonia, which caused or contributed significantly to death (Schwacke *et al.,* 2014a, 2014b; Venn-Watson *et al.,* 2015b). The chronic adrenal gland and lung diseases identified in stranded UME dolphins are consistent with exposure to petroleum compounds (Venn-Watson *et al.,* 2015b). Colegrove *et al.* (2016) found that the increase in perinatal strandings resulted from late-term pregnancy failures and development of *in utero* infections likely caused by chronic illnesses in mothers who were exposed to oil.

While the number of dolphin mortalities in the area decreased after the peak from March 2010-July 2014, it does not indicate that the effects of the oil spill on these populations have ended. Researchers still saw evidence of chronic lung disease and adrenal impairment four years after the spill (in July 2014) and saw evidence of failed pregnancies in 2015 (Smith *et al.,* 2017). These follow-up studies found a yearly mortality rate for Barataria Bay dolphins of roughly 13 percent (as compared to annual mortality rates of 5 percent or less that have been previously reported for other dolphin populations) and found that only 20 percent of pregnant dolphins produced viable calves (compared with 83 percent in a reference population) (Lane *et al.,* 2015; McDonald *et al.,* 2017). In addition, compromised health may make dolphins more susceptible to additional environmental stressors.

Since the publication of the proposed rule, another UME involving bottlenose dolphins in the northern GOM was declared. Elevated bottlenose dolphin strandings occurred in Louisiana, Mississippi, Alabama, and the panhandle of Florida (Alabama border through Taylor County) from February 1, 2019, through November 30, 2019. A total of 337 confirmed strandings were documented, with a majority occurring from February through May. Excluding prior UMEs, the annual average for February through May in the affected area is 57 dolphins; at least 260 standings were documented during this period in 2019. The cause of the UME was determined to be environmentally driven by exposure to low salinity waters resulting from extreme freshwater discharge from watersheds that drain into the GOM, including rivers in Florida, Alabama, Mississippi and Louisiana. This unprecedented amount of freshwater discharge during the winter, spring, and summer months of 2019 resulted in a drop in salinity levels across the coastally associated waters in the region. Prolonged exposure to low salinity water has been documented to have harmful health impacts on bottlenose dolphins, ranging from skin lesions and serum electrolyte abnormalities to acute mortality. The location of the UME and the dolphin stocks affected, including the western and northern coastal stocks of bottlenose dolphin, are the same as those impacted by the 2010–2014 UME. For additional information, please visit *www.fisheries.noaa.gov/national/marine-life-distress/2019-bottlenose-dolphin-unusual-mortality-event-along-northern-gulf.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges that marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). NMFS (2018) describes generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera *Kogia* and *Cephalorhynchus;* including two members of the genus *Lagenorhynchus,* on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Twenty-one species of cetacean have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 4. Of the cetacean species that may be present, one is classified as a low-frequency cetacean (*i.e.,* the Bryde's whale), 18 are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and two are classified as high-frequency cetaceans (*i.e., Kogia* spp.).

Potential Effects of the Specified Activities on Marine Mammals and Their Habitat

In NMFS' notice of proposed rulemaking (83 FR 29212; June 22, 2018), this section included a comprehensive summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat, including general background information on sound and specific discussion of potential effects to marine mammals from noise produced through use of airgun arrays. We incorporate by reference that information and do not repeat that discussion here, instead referring the reader to the notice of proposed rulemaking.

The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by the specified activity. The Negligible Impact Analysis and Determinations section includes an analysis of how these

activities will impact marine mammals and considers the content of this section, the Estimated Take section, and the Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations.

Description of Active Acoustic Sound Sources

In the notice of proposed rulemaking, this section contained a brief technical background on sound, the characteristics of certain sound types, and on metrics used in the proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. Here, we summarize key information relating to terminology used in this notice.

Amplitude (or ''loudness'') of sound is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)). The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures. Sound exposure level (SEL; represented as dB re 1 $\mu Pa^2 - s$) represents the total energy contained within a pulse, and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0–p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (pk-pk), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately 6 dB higher than peak pressure (Southall *et al.,* 2007).

As described in more detail in the notice of proposed rulemaking, airgun arrays are in a general sense considered to be omnidirectional sources of pulsed noise. Pulsed sound sources (as compared with non-pulsed sources) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Airguns produce sound with energy in a frequency range from about 10–2,000 Hz, with most energy radiated at frequencies below 200 Hz. Although the amplitude of the acoustic wave emitted from the source is equal in all directions (*i.e.,* omnidirectional), airgun arrays do possess some directionality due to different phase delays between guns in different directions. Airgun arrays are typically tuned to maximize functionality for data acquisition purposes, meaning that sound transmitted in horizontal directions and at higher frequencies is minimized to the extent possible.

Acoustic sources used for high-resolution geophysical (HRG) surveys generally produce higher frequency signals with highly directional beam patterns. These sources are generally considered to be intermittent, with typically brief signal durations. Boomers, considered to be impulsive sources, generate a high-amplitude broadband (100 Hz-10 kHz) acoustic pulse with high downward directivity, though may be considered omnidirectional at frequencies below 1 kHz. Other typical HRG sources are considered non-impulsive. Sub-bottom profiler systems generally project a chirp pulse spanning an operator-selectable frequency band, usually between 1 to 20 kHz, with a single beam directed vertically down. Multibeam echosounders use an array of transducers that project a high-frequency, fan-shaped beam under the hull of a survey ship and perpendicular to the direction of motion. Side-scan sonars use two transducers to project high-frequency beams that are usually wide in the vertical plane (50°–70°) and very narrow in the horizontal plane (less than a few degrees). Other, similar impulsive or non-impulsive sources may be used in conducting shallow penetration or HRG surveys.

Acoustic Habitat

NMFS also included a detailed discussion and analysis of potential impacts to acoustic habitat. Acoustic habitat is the soundscape—which encompasses all of the sound present in a particular location and time, as a whole—when considered from the perspective of the animals experiencing it. Animals listen for sounds produced by conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

That discussion summarized a report titled ''*Cumulative and Chronic Effects in the Gulf of Mexico: Estimating Reduction of Listening Area and Communication Space due to Seismic Activities,*'' (''Cumulative and Chronic Effects report'') as well as a subsequent addendum to the report presenting additional analysis relating to sperm whales. The initial report (originally presented as Appendix K in BOEM (2017)) as well as the addendum ((hereafter, ''the CCE report''), are available online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* The CCE report presented a first-order cumulative and chronic effects assessment for noise produced by oil and gas exploration activities in the U.S. GOM.

The term ''listening area'' refers to the region of ocean over which sources of sound can be detected by an animal at the center of the space. Loss of communication space concerns the area over which a specific animal signal, used to communicate with conspecifics in biologically-important contexts (*e.g.,* foraging, mating), can be heard, in noisier relative to quieter conditions (Clark *et al.,* 2009). Lost listening area concerns the more generalized contraction of the range over which animals would be able to detect a variety of signals of biological importance, including eavesdropping on predators and prey (Barber *et al.,* 2009). Implications for acoustic masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold; see notice of

proposed rulemaking at 29239 for explanation of masking) and reduced communication space resulting from noise produced by airgun surveys in the GOM are expected to be particularly heightened for animals that actively produce low-frequency sounds or whose hearing is attuned to lower frequencies (*i.e.,* Bryde's whales).

Acoustic modeling was conducted for ten locations (''receiver sites'') within the study area to examine aggregate noise produced over a full, generic year. The locations of the receiver sites were chosen to reflect areas of biological importance to cetaceans, areas of high densities of cetaceans, and areas of key biological diversity. The CCE report analyzed multiple scenarios, including a baseline scenario in which no geophysical surveys are conducted and noise consists of natural sounds and a minimum estimate of commercial vessel noise; a survey activity scenario in which projected activities were uniformly distributed throughout the study area, with the exception of coastal waters from February to May; and a closure scenario in which no activities are conducted in certain restriction areas, 25 percent of the activity that would have occurred in the restriction areas is redistributed into non-restriction areas of the same activity zone, and 75 percent of the activities that would have occurred in the restriction areas are not conducted at all. For additional methodological details, see discussion in the notice of proposed rulemaking or the CCE report.

Regarding sperm whales, the analysis shows that the survey activities do not significantly contribute to the soundscape in the frequency band relevant for their lower-frequency slow-clicks, and that there will be no significant change in communication space for sperm whales. Because other sperm whale calls are higher-frequency, they would not be expected to be affected. Please see the CCE report for further discussion of the findings for sperm whales. The remaining discussion that follows is in reference to the findings for Bryde's whales and to general findings for other hearing groups.

The methods used in the CCE report were meant to average the conditions generated by low-frequency dominant noise sources throughout a full year, during which animals of key management interest rely on habitats within the study area. Considered as a complement to assessments of the acute effects of the same types of noise sources in the same region (discussed below in the *Estimated Take* section), the CCE assessment estimates noise produced by the same sources over much larger spatial scales, and considers how the summation of noise from these sources relates to levels without the proposed activity (ambient). The lost listening area method calculates a fractional reduction in listening area due to the addition of anthropogenic noise to ambient noise. Results are presented as a percentage of the original listening area remaining due to the increase in noise levels relative to no activity and between activity scenarios. The communication space assessment provides relative losses of communication space (in both areas and percentages) between the activity scenarios.

At most sites, lost listening area was greater for deeper waters than for shallower waters, which is attributed to the downward-refracting sound speed profile near the surface, caused by the thermocline, which steers sound to deeper depths. Shallow water noise levels were reduced due to surface interactions that increase transmission loss, particularly for low frequencies. Listening area reductions were also generally most severe when weighted for low-frequency hearing cetaceans. Both low- and mid-frequency weighted losses were high in the Mississippi Canyon, while only low-frequency weighted values were high for the De Soto Canyon. Both of these sites are considered important to sperm whales as well as other deep-diving odontocetes. These modeling results suggest that accumulations of noise from survey activities below 5 kHz and often heightened at depth could be degrading the ability of animals that forage at great depths in the GOM to use acoustic cues to find prey as well as to maintain conspecific contact.

Comparison between results provided for the two metrics applied in the CCE report highlights important interpretive differences for evaluating the biological implications of background noise. The strength of the communication space approach is that it evaluates potential contractions in the availability of a signal of documented importance to a population of animals of key management interest in the region. In this case, losses of communication space for Bryde's whales were estimated to be higher in eastern and central GOM canyons and shelf break areas. In contrast, relative maintenance of listening area and communication space was seen within the Bryde's whale core habitat area in the eastern GOM (an area that has since been removed from consideration through this rule). In areas where larger amounts of survey activity were projected, significant loss of low-frequency listening area and communication space for Bryde's whale calls was estimated, though we emphasize that these are not areas where Bryde's whales are expected to occur.

The CCE report is described here in order to summarize information presented in the proposed rule regarding potential longer-term and wider-range noise effects from sources such as airguns. Please see the notice of proposed rulemaking, as well as the CCE report and addendum, for additional information.

Estimated Take

This section provides an estimate of the number and type of incidental takes that may be expected to occur under the specified activity (as it has been revised in scope), which informed NMFS' negligible impact determination. Realized incidental takes would be determined by the actual levels of activity at specific times and places that occur under any issued LOAs.

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment). Harassment is the only type of take expected to result from these activities.

Anticipated takes would primarily be by Level B harassment, as use of the described acoustic sources, particularly airgun arrays, is likely to disrupt behavioral patterns of marine mammals. There is also some potential for auditory injury (Level A harassment) to result for low- and high-frequency species due to the size of the predicted auditory injury zones for those species. NMFS does not expect auditory injury to occur for mid-frequency species, as discussed in greater detail on the notice of proposed rulemaking (83 FR 29212; June 22, 2018) and in responses to public comments. The required mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable. It is unlikely that lethal takes would occur even in the absence of the mitigation and monitoring measures, and no such takes are anticipated or will be authorized. Below we summarize how the take that may be authorized was estimated using acoustic thresholds, sound field modeling, and

marine mammal density data. Detailed discussion of all facets of the take estimation process was provided in the notice of proposed rulemaking (83 FR 29212; June 22, 2018), and nothing has changed since that time. Therefore, that full discussion is not repeated. Please see that notice, and associated companion documents available online, for additional detail.

Acoustic Thresholds

NMFS uses acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals generally would be reasonably expected to exhibit disruption of behavioral patterns (Level B harassment) or to incur permanent threshold shift (PTS) of some degree (Level A harassment).

Level B Harassment—Although available data are consistent with the basic concept that louder sounds evoke more significant behavioral responses than softer sounds, defining precise sound levels that will potentially disrupt behavioral patterns is difficult because responses depend on the context in which the animal receives the sound, including an animal's behavioral mode when it hears sounds (*e.g.,* feeding, resting, or migrating), prior experience, and biological factors (*e.g.,* age and sex). Some species, such as beaked whales, are known to be more highly sensitive to certain anthropogenic sounds than other species. Other contextual factors, such as signal characteristics, distance from the source, duration of exposure, and signal to noise ratio, may also help determine response to a given received level of sound. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict (Southall *et al.,* 2007; Ellison *et al.,* 2012; Bain and Williams, 2006). Typically, and especially in cases where PTS is predicted, NMFS anticipates that some number of individuals may incur temporary threshold shift (TTS) (considered Level B harassment). However, it is not necessary to separately quantify those takes, as it is unlikely that an individual marine mammal would be exposed at the levels and duration necessary to incur TTS without also being exposed to the levels associated with behavioral harassment and, therefore, NMFS expects any potential TTS takes to be captured by the estimated takes by behavioral harassment.

Based on the practical need to use a relatively simple threshold based on available information that is both predictable and measurable for most activities, NMFS has historically used a generalized acoustic threshold based on received level to estimate the onset of Level B harassment. These thresholds are 160 dB rms (intermittent sources, which include impulsive sources) and 120 dB rms (continuous sources). Airguns are impulsive sound sources and electromechanical sources used for HRG surveys are intermittent sources. Therefore, the 160 dB rms threshold has typically been used in evaluating effects from the sources planned for use in the specified activities. However, in the notice of proposed rulemaking, NMFS identified a more complex probabilistic risk function for use in evaluating the potential effects of the specified activity considered herein. That function, described in Wood *et al.* (2012), is better reflective of available scientific information (as discussed in detail in the notice of proposed rulemaking, as well as in comment responses provided earlier in this preamble). Such an approach takes the fundamental step of acknowledging the potential for Level B harassment at exposures to received levels below 160 dB rms (as well as the potential that animals exposed to received levels above 160 dB rms will not respond in ways constituting Level B harassment). The approach described by Wood *et al.* (2012) also accounts for differential hearing sensitivity by incorporating frequency-weighting functions. The analysis of Gomez *et al.* (2016) indicates that behavioral responses in cetaceans are best explained by the interaction between sound source type and functional hearing group. Southall *et al.* (2007) proposed auditory weighting functions for species groups based on known and assumed hearing ranges (Type I). Although newer filters are better designed to predict the onset of auditory injury (as discussed below and used for evaluation of potential Level A harassment), the broader Type I filters were retained for use in evaluating potential behavioral disturbance in conjunction with the Wood *et al.* (2012) probabilistic response function.

NMFS received public comments on this topic, including some criticizing the proposed use of the Wood *et al.* (2012) risk function. We responded to all comments received on this topic and, in addition to the more detailed discussion provided in the Estimated Take section of the notice of proposed rulemaking, we provide detailed discussion of these concerns in the responses to comments, provided earlier in this preamble. NMFS retains use of the Wood *et al.* (2012) approach as the basis for estimating take and considering the effects of the specified activity on marine mammal behavior. The Level B harassment criteria upon which the analysis presented herein is based are presented in Table 6.

TABLE 6—BEHAVIORAL EXPOSURE CRITERIA

Group	Probability of response to frequency-weighted rms SPL			
	120 (%)	140 (%)	160 (%)	180 (%)
Beaked whales	50	90	n/a	n/a
All other species	n/a	10	50	90

Level A Harassment—NMFS' *Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing* (NMFS, 2018) (2018 Revised Technical Guidance) identifies dual criteria to assess the potential for auditory injury (Level A harassment) to occur for different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise. The 2018 Revised Technical Guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for all underwater anthropogenic sound sources and reflects the best available science on the potential for noise to affect auditory sensitivity by:

- Dividing sound sources into two groups (*i.e.,* impulsive and non-impulsive) based on their potential to affect hearing sensitivity;
- Choosing metrics that best address the impacts of noise on hearing sensitivity, *i.e.,* peak sound pressure level (peak SPL) (reflects the physical properties of impulsive sound sources to affect hearing sensitivity) and

cumulative sound exposure level (cSEL) (accounts for not only level of exposure but also duration of exposure); and

• Dividing marine mammals into hearing groups and developing auditory weighting functions based on the science that indicates that not all marine mammals hear and use sound in the same manner.

The premise of the dual criteria approach is that, while there is no definitive answer to the question of which acoustic metric is most appropriate for assessing the potential for injury, both the received level and duration of received signals are important to an understanding of the potential for auditory injury. Therefore, peak SPL is used to define a pressure criterion above which auditory injury is predicted to occur, regardless of exposure duration (*i.e.,* any single exposure at or above this level is considered to cause auditory injury), and cSEL is used to account for the total energy received over the duration of sound exposure (*i.e.,* both received level and duration of exposure) (Southall *et al.,* 2007, 2019a; NMFS, 2018). As a general principle, whichever criterion is exceeded first (*i.e.,* results in the largest isopleth) would be used as the effective injury criterion (*i.e.,* the more precautionary of the criteria). Note that cSEL acoustic threshold levels incorporate marine mammal auditory weighting functions, while peak pressure thresholds do not (*i.e.,* flat or unweighted). Weighting functions for each hearing group (*e.g.,* low-, mid-, and high-frequency cetaceans) are described in NMFS (2018).

The 2018 Revised Technical Guidance recommends 24 hours as a maximum accumulation period relative to cSEL thresholds. These thresholds were developed by compiling and synthesizing the best available science, and are provided in Table 7 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS (2018), and more information is available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 7—EXPOSURE CRITERIA FOR AUDITORY INJURY

Hearing group	Peak pressure [1] (dB)	Cumulative sound exposure level [2]	
		Impulsive (dB)	Non-impulsive (dB)
Low-frequency cetaceans	219	183	199
Mid-frequency cetaceans	230	185	198
High-frequency cetaceans	202	155	173

[1] Referenced to 1 μPa; unweighted within generalized hearing range.
[2] Referenced to 1 μPa^2-s; weighted according to appropriate auditory weighting function. Airguns and the boomer are treated as impulsive sources; other HRG sources are treated as non-impulsive.

NMFS considers these updated thresholds and associated weighting functions to be the best available information for assessing whether exposure to specific activities is likely to result in changes in marine mammal hearing sensitivity.

Modeling Overview

Zeddies *et al.* (2015, 2017a) (*i.e.,* ''the modeling report'') provides estimates of the annual marine mammal acoustic exposure caused by sounds from geophysical survey activity in the GOM for ten years of notional activity levels. Here we provide a brief overview of key modeling elements, with more detail provided in the notice of proposed rulemaking (83 FR 29212; June 22, 2018). For full details of the modeling effort, the interested reader should see the report (available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico*).

Initial phases of the modeling effort involved preliminary modeling of a typical 3D WAZ survey, which was simulated at two locations in order to establish the basic methodological approach and to provide results used to evaluate test scenarios that could influence exposure estimates. We discussed each of the six evaluated test scenarios in the notice of proposed rulemaking. Please see that discussion and the modeling report for full details.

The modeling effort produced exposure estimates computed from modeled sound levels as received by simulated animals (animats) in a specific modeling area. The GOM was divided into seven modeling zones with six survey types simulated within each zone to estimate the potential effects of each survey. The zones were designed as described previously (Description of the Specified Activity; Figure 3)—shelf and slope waters were divided into eastern, central, and western zones, plus a single deep-water zone—to account for both the geospatial dependence of acoustic fields and the geographic variations of animal distributions. The selected boundaries considered sound propagation conditions and species distribution to create regions of optimized uniformity in both acoustic environment and animal density. Survey types included deep penetration surveys using a large airgun array (2D, 3D NAZ, 3D WAZ, and coil survey types), shallow penetration surveys using a single airgun (which were assumed to be a reasonable proxy for surveys conducted using a boomer), and high resolution surveys concurrently using a CHIRP sub-bottom profiler, side-scan sonar, and multibeam echosounder. The results from each zone were summed to provide GOM-wide estimates of take for each marine mammal species for each survey type for each notional year. To get these annual aggregate exposure estimates, 24-hr average exposure estimates from each survey type were multiplied by the number of expected survey days from BOEM's effort projections. Because these projections are not season-specific, surveys were assumed to be equally likely to occur at any time of the year and at any location within a given zone.

Acoustic source emission levels and directivity of a single airgun and an airgun array were modeled using JASCO Applied Sciences' Airgun Array Source Model (AASM). AASM is capable of predicting airgun source levels at frequencies up to 25 kHz, and produces a set of notional signatures for each array element based on array layout; volume, tow depth, and firing pressure for each element; and interactions between different elements in the array. The signatures are summed to obtain the far-field source signature of the entire array in the horizontal plane, which is then filtered into one third-octave frequency bands to compute the source

levels of the array as a function of frequency band and azimuthal angle in the horizontal plane (at the source depth), after which it is considered to be an azimuth-dependent directional point source in the far field. Source levels for high-resolution sources were obtained from manufacturer's specifications for representative sources. Electromechanical sources were modeled on the basis of transducer beam theory, which is often used to estimate beam pattern of the source in the absence of field measurements, and which is described in detail in the modeling report.

Underwater sound propagation (*i.e.,* transmission loss) as a function of range from each source was modeled using JASCO's Marine Operations Noise Model (MONM) for multiple propagation radials centered at the source to yield 3D transmission loss fields in the surrounding area. The MONM computes received per-pulse SEL for directional sources at specified depths. MONM uses two separate models to estimate transmission loss. At frequencies less than 2 kHz, MONM computes acoustic propagation via a wide-angle parabolic equation (PE) solution to the acoustic wave equation (Collins, 1993), based on a version of the U.S. Naval Research Laboratory's Range-dependent Acoustic Model (RAM) modified to account for an elastic seabed (Zhang and Tindle, 1995). MONM–RAM incorporates bathymetry, underwater sound speed as a function of depth, and a geoacoustic profile based on seafloor composition, and accounts for source horizontal directivity. At frequencies greater than 2 kHz, MONM accounts for increased sound attenuation due to volume absorption at higher frequencies (Fisher and Simmons, 1977) with the widely-used BELLHOP Gaussian beam ray-trace propagation model (Porter and Liu, 1994). This component incorporates bathymetry and underwater sound speed as a function of depth with a simplified representation of the sea bottom, as sub-bottom layers have a negligible influence on the propagation of acoustic waves with frequencies above 1 kHz. MONM–BELLHOP accounts for horizontal directivity of the source and vertical variation of the source beam pattern. Both propagation models account for full exposure from a direct acoustic wave, as well as exposure from acoustic wave reflections and refractions (*i.e.,* multi-path arrivals at the receiver).

In order to accurately estimate exposure, a simulation must adequately cover the various location- and season-specific environments. The surveys may be conducted at any location within the planning area and occur at any time of the year, so simulations must adequately cover each area and time period. The seven zones within which potential exposures were modeled, corresponding with shelf and slope environments subdivided into western, central, and eastern areas, as well as a single deep zone, were previously introduced (Figure 3). The subdivision depth definitions are: Shelf, 0–200 m; slope, 200–2,000 m; and deep, greater than 2,000 m. Within each of the seven zones, a set of representative survey-simulation rectangles for each of the survey types was defined, with larger areas for the ''large-area'' surveys (*i.e.,* deep penetration airgun) and smaller areas for the ''small-area'' surveys (*i.e.,* shallow penetration airgun and HRG). In Figure 3, the smaller numbered boxes represent the survey area extents for the different survey types. The stars represent acoustic modeling sites along western, central, and eastern transects (Figure 3).

A set of 30 sites was selected to calculate acoustic propagation loss grids as functions of source, range from the source, azimuth from the source, and receiver depth. These were then used as inputs to the acoustic exposure model. The environmental parameters and acoustic propagation conditions represented by these 30 modeling sites were chosen to be representative of the prevalent acoustic propagation conditions within the survey extents. To account for seasonal variation in propagation, winter (most conservative) and summer (least conservative) were both used to calculate exposure estimates. Propagation during spring and fall was found to be almost identical to the results for summer, so those seasons were represented with the summer results. The primary seasonal influence on transmission loss is the presence of a sound channel, or duct, near the surface in winter.

Marine Mammal Density Information

The best available scientific information was considered in conducting marine mammal exposure estimates (the basis for estimating take). Roberts *et al.* (2016) provided several key improvements over information previously available for the GOM, by incorporating NMFS aerial and shipboard survey data collected over the period 1992–2009; controlling for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting; and modeling density from an expanded set of eight physiographic and 16 dynamic oceanographic and biological covariates. There are multiple reasons why marine mammals may be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (*e.g.,* Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. Therefore, failure to correct for these biases may lead to underestimates of cetacean abundance (as is the case for NMFS' SAR abundance estimates for the GOM). Additional data was used to improve detection functions for taxa that were rarely sighted in specific survey platform configurations. The degree of underestimation would likely be particularly high for species that exhibit long dive times or are cryptic, such as sperm whales, beaked whales, or *Kogia* spp. In summary, consideration of additional survey data and an improved modeling strategy allowed for an increased number of taxa modeled and better spatiotemporal resolutions of the resulting predictions. More information concerning the Roberts *et al.* (2016) models, including the model results and supplementary information for each model, is available online at *seamap.env.duke.edu/models/Duke-EC-GOM-2015/.*

Description of Exposure Estimates

The sound received by an animal when near a sound source is a function of the animal's position relative to the source, and both source and animals may be moving. To a reasonable approximation, we know, predict, or specify the location of the sound source, a 3D sound field around the source, and the expected occurrence of animals within 100 km^2 grid cells (Roberts *et al.,* 2016). However, because the specific location of animals within the modeled sound field is unknown, agent-based animal movement modeling is necessary to complete the assessment of potential acoustic exposure. Realistic animal movement within the sound field can be simulated, and repeated random sampling (Monte Carlo)—achieved by simulating many animals within the operations area—used to estimate the sound exposure history of animals during the operation. Animats are randomly placed, or seeded, within the simulation boundary at a specified density, and the probability of an event's occurrence is determined by the frequency with which it occurs in the simulation. Higher densities provide a finer resolution for an estimate of the probability distribution function (PDF),

but require greater computational resources. To ensure good representation of the PDF, the animat density is set as high as is practical, with the resulting PDF then scaled using the real-world animal density (Roberts *et al.,* 2016) to obtain the real-world number of modeled acoustic exposures.

Several models for marine mammal movement have been developed (*e.g.,* Frankel *et al.,* 2002, Gisiner *et al.,* 2006; Donovan *et al.,* 2013). Animats transition from one state to another, with user-specified parameters representing simple states, such as the speed or heading of the animal, or complex states, such as likelihood of an animal foraging, playing, resting, or traveling. This analysis uses the Marine Mammal Movement and Behavior (3MB) model (Houser, 2006). Parameter values to control animat movement are typically determined using available species-specific behavioral studies, but the amount and quality of available data varies by species. While available data often provides a detailed description of the proximate behavior expected for real individual animals, species with more available information must be used as surrogates for those without sufficient available information. In this study, pantropical spotted dolphins are used as a surrogate for Clymene, spinner, and striped dolphins; short-finned pilot whales are surrogates for Fraser's dolphins, *Kogia* spp., and melon-headed whales; and rough-toothed dolphins are surrogates for false killer whales and pygmy killer whales. Observational data for all remaining species in the study were sufficient to determine animat movement.

Species-specific animats were created with programmed behavioral parameters describing dive depth, surfacing and dive durations, swimming speed, course change, and behavioral aversions (*e.g.,* water too shallow). The programmed animats were then randomly distributed over a given bounded simulation area. Because the exact positions of sound sources and animals are not known in advance for proposed activities, multiple runs of realistic predictions are used to provide statistical validity to the simulated scenarios. Each species-specific simulation was seeded with approximately 0.1 animats/km^2 which, in most cases, represents a higher density of animats in the simulation than occurs in the real environment. A separate simulation was created and run for each combination of location, survey movement pattern, and marine mammal species. Animats were only allowed to be 'taken' once during a 24-hour evaluation period. That is, an animat whose received level exceeds the peak SPL threshold more than once during an evaluation period was only counted once. Energy accumulation for SEL occurred throughout the 24-hour integration period and was reset at the beginning of each period. Similarly, the maximum received rms SPL was determined for the entirety of the evaluation period and reset at the beginning of each period.

The JASCO Exposure Modeling System (JEMS) combined animal movement data (*i.e.,* the output from 3MB), with pre-computed acoustic fields. The JEMS output was the time-history of received levels and slant ranges (the three-dimensional distance between the animat and the source) for all animats of the 3MB simulation. Animat received levels and slant ranges are used to determine the risk of acoustic exposure. There were many animats in the simulations and together their received levels represent the probability, or risk, of exposure for each survey.

All survey simulations were for 7 days and a sliding 4-hr window approach was used to get the average 24-hr exposure. In this sliding-window approach, 42 exposure estimate samples are obtained for each seven-day simulation, with the mean value then used as the 24-hr exposure estimate for that survey. The 24-hr exposure levels were then scaled by the projected level of effort for each survey type (*i.e.,* multiplied by the number of days) to calculate associated annual exposure levels. The number of individual animals expected to exceed threshold during the 24-hr window is the number of animats exposed to levels exceeding threshold multiplied by the ratio of real-world animal density to model animat density.

Injury—To evaluate the likelihood an animal might experience auditory injury as a result of accumulated sound energy, the cSEL for each animat in the simulation was calculated. To obtain that animat's cSEL, the SEL an animat received from each source over the 24-hr integration window was summed, and the number of animats whose cSEL exceeded the specified thresholds (Table 7) during the integration window was counted. To evaluate the likelihood an animal might be injured via exposure to peak SPL, the range at which the specific peak SPL threshold (Table 7) occurs for each source based on the broadband peak SPL source level was estimated. For each 24-hr integration window, the number of animats that came within this range of the source was counted.

Behavior—To evaluate the likelihood an animal might experience disruption of behavioral patterns (*i.e.,* a ''take''), the number of animats that received a maximum rms SPL exposure within the specified step ranges (Table 6) was calculated. The number of animats with a maximum rms SPL received level categorized into each bin of the step function was multiplied by the probability of the behavioral response specific to that range (Table 6). Specifically, 10 percent of animals exposed to received levels from 140–159 dB rms would be assumed as ''takes,'' while 50 percent exposed to levels between 160–179 dB rms and 90 percent exposed to levels of 180 dB rms and above would be. The totals within each bin were then summed as the total estimated number of exposures above Level B harassment thresholds. This process was repeated for each 24-hr integration window. For beaked whales, for which lower behavioral harassment thresholds are designated, 50 percent of animals exposed to received levels from 120–149 dB rms would be assumed as ''takes,'' while 90 percent exposed to levels of 140 dB rms and above would be.

Take Estimates

In summary, BOEM provided estimated levels of effort for geophysical survey activity in the GOM for a notional ten-year period. Exposure estimates were then computed from modeled sound levels received by animats for several representative types of geophysical surveying. Because animals and acoustic sources move relative to the environment and each other, and the sound fields generated by the sources are shaped by various physical parameters, the sound levels received by an animal are a complex function of location and time. The basic modeling approach was to use acoustic models to compute the 3D sound fields and their variations in time. Animats were modeled moving through these fields to sample the sound levels in a manner similar to how real animals would experience these sounds. From the time histories of the received sound levels of all animats, the numbers of animals exposed to levels exceeding effects threshold criteria were determined and then adjusted by the number of animals expected in the area, based on density information, to estimate the potential number of real-world marine mammal exposures to levels above the defined criteria. The acoustic exposure history of many simulated animals (animats) allows for the estimation of potential exposures due to operations. These modeled exposures are summed and represent the aggregate exposures that may result

from future surveys given the specified levels of effort for each survey type in each year and may vary according to the statistical distribution associated with these mean annual exposures.

Exposure estimates above Level A and Level B harassment criteria, developed by Zeddies *et al.* (2015, 2017a) in association with the activity projections for the various annual effort scenarios, were generated based on the specific modeling scenarios (including source and survey geometry), *i.e.,* 2D survey (1 × 8,000 in^3 array), 3D NAZ survey (2 × 8,000 in^3 array), 3D WAZ survey (4 × 8,000 in^3 array), coil survey (4 × 8,000 in^3 array), shallow penetration survey (either single 90 in^3 airgun or boomer), and HRG surveys (side-scan sonar, multibeam echosounder, and sub-bottom profiler). Annual effort scenario-based pooled exposure estimates are therefore available by species.

NMFS presented BOEM's original 10-year activity projections in Table 1 of the notice of proposed rulemaking under ''Detailed Description of Activities.'' For purposes of analysis in the notice of proposed rulemaking, NMFS identified representative ''high,'' ''moderate,'' and ''low'' effort years. Because the duration of these regulations are limited to five years, NMFS needed to determine a reasonable basis for evaluating acoustic exposures that might occur during that timeframe (rather than ten years). Therefore, for the proposed rule, in recognition of relatively low recent levels of geophysical survey activity, from the ten notional years of projected survey effort provided by BOEM, NMFS selected five representative years representing three different potential levels of survey effort as the basis for the assessment. These included one ''high-activity'' year, two separate ''moderate-activity'' years, and two separate ''low-activity'' years. Because the first 5 years of BOEM's original effort projections were relatively high-effort years, NMFS' level-of-effort selections for the proposed rule corresponded with the detailed per-survey type effort projections given for Years 1, 4, 5, 8, and 9, respectively. Exposure estimates resulting from the process summarized here and corresponding with those activity scenarios were shown in Table 8 of the notice of proposed rulemaking. These exposure estimates were then further evaluated to provide an estimate of takes of marine mammals that could occur as a result of a reasonably expected level of geophysical survey activity in the GOM over the course of five years. Take estimates associated with those scenarios, which informed the analysis in the proposed rule, are shown in Table 8 of this document for reference. These values have been updated from those shown in Table 8 of the notice of proposed rulemaking by correctly incorporating discounted estimates of Level A harassment into the estimates of Level B harassment (as pointed out by public commenters).

Level A Harassment

As we explain here, the modeled exposure estimates for onset of permanent threshold shift (*i.e.,* Level A harassment), are not expected to represent realistic results for any species. Overall, there is a low likelihood of take by Level A harassment for any species, though the degree of this low likelihood is primarily influenced by the specific hearing group. For mid- and high-frequency cetaceans, potential auditory injury would be expected to occur on the basis of instantaneous exposure to peak pressure output from an airgun array while, for low-frequency cetaceans, potential auditory injury would occur on the basis of the accumulation of energy output over time by an airgun array. Importantly, the modeled exposure estimates do not account for either aversion or the beneficial impacts of the required mitigation measures.

Of even greater import for mid-frequency cetaceans is that the small calculated Level A harassment zone size in conjunction with the properties of sound fields produced by arrays in the near field versus far field leads to a logical conclusion that Level A harassment is so unlikely for species in this hearing group as to be discountable. As stated in the notice of proposed rulemaking, for all mid-frequency cetaceans, following evaluation of the available scientific literature regarding the auditory sensitivity of mid-frequency cetaceans and the properties of airgun array sound fields, NMFS does not expect any reasonable potential for Level A harassment to occur. We discussed this issue in detail earlier in the response to public comments. NMFS expects the potential for Level A harassment of mid-frequency cetaceans to be discountable, even before the likely moderating effects of aversion are considered. When considering potential for aversion, NMFS does not believe that Level A harassment is a likely outcome for any mid-frequency cetacean (as reflected in Table 9).

As discussed in greater detail in the notice of proposed rulemaking, NMFS and BOEM considered the possibility of incorporating quantitative adjustments within the modeling process to account for the effects of mitigation and/or aversion, as both of these factors would lead to a reduction in likely injurious exposure. However, these factors were ultimately not quantified in the modeling because, in summary, there is too much inherent uncertainty regarding the effectiveness of detection-based mitigation to support any reasonable quantification of its effect in reducing injurious exposure and there is too little information regarding the likely level of onset and degree of aversion to quantify this behavior in the modeling process. This does not mean that mitigation is not effective (to some degree) in avoiding incidents of Level A harassment, nor does it mean that aversion is not a meaningful real-world effect of noise exposure that should be expected to reduce the number of incidents of Level A harassment. However, certain public commenters misconstrued statements in the notice of proposed rulemaking regarding the strictly modeling-related investigations of aversion (*i.e.,* that there is not sufficient quantitative data to inform decisions regarding the programming of animats as far as received levels of noise that provoke aversive response, and the degree of response, for relevant species) as meaning that there is not sufficient information to support that aversion happens at all. To the contrary, there is ample evidence in the literature that aversion is one of the most common responses to noise exposure across varied species, though the onset and degree may be expected to vary across individuals and in different contexts. Therefore, NMFS proposed to incorporate a reasonable adjustment to modeled Level A harassment exposure estimates to account for aversion for low- and high-frequency species. That adjustment is retained here, as discussed in greater detail in the responses to public comments. Specifically, NMFS assumes here that an eighty percent reduction in modeled exposure estimates for Level A harassment for low- and high-frequency cetaceans is reasonable and likely conservative in terms of the overall numbers of actual incidents of Level A harassment for these species, as the adjustment does not explicitly account for the effects of mitigation.

As discussed previously, BOEM provided an update to the scope of their proposed action through removal of the area subject to leasing moratorium under GOMESA from consideration in the rule. In support of this revision, BOEM provided revised 5-year level of effort predictions and associated acoustic exposure estimates. BOEM's process for developing this information,

described in detail in ''Revised Modeled Exposure Estimates,'' available online, was straightforward. Rather than using the PEIS's 10-year period, BOEM provided revised levels of effort for a 5-year period, using Years 1–5 of the original level of effort projections. BOEM stated that the first five years were selected to be carried forward ''because they were contiguous, they included the three years with the most activity, and they were the best understood in relation to the historical data upon which they are based.'' NMFS concurs with this choice. Levels of effort were revised based on the basic assumption that if portions of areas are removed from consideration, then the corresponding effort previously presumed to occur in those areas also is removed from consideration. The revised levels of effort are shown in Table 2. Associated revised take estimates, which were generated utilizing the methods described above and in the proposed rule and inform the analysis in this final rule, are shown in Table 9. These estimates have been modified from the values provided by BOEM (available online; ''Revised Modeled Exposure Estimates'') in that we have correctly accounted for the type of taking expected, *i.e.,* for mid-frequency cetaceans, Level A harassment is not expected to occur and the calculated takes have been shifted into the totals for Level B harassment. No incidents of Level A harassment for Bryde's whales were predicted under the revised effort scenarios, which exclude the area where most Bryde's whales would be expected to be found. For *Kogia* spp., estimates of Level A harassment were adjusted as discussed previously to account for likely aversion, and the portion of estimated Level A harassment events not expected to occur were shifted into the totals for Level B harassment for these species.

Estimated instances of take, *i.e.,* scenario-specific acoustic exposure estimates incorporating the adjustments to Level A harassment exposure estimates discussed here, are shown in Table 9. This information regarding total number of takes (with Level A harassment takes based on assumptions relating to mid-frequency cetaceans in general as well as aversion), on an annual basis for five years, provides the bounds within which incidental take authorizations may be issued in association with this regulatory framework.

Typically, and especially in cases where PTS is predicted, NMFS anticipates that some number of individuals may incur TTS. However, it is not necessary to separately quantify those takes, as it is unlikely that an individual marine mammal would be exposed at the levels and duration necessary to incur TTS without also being exposed to the levels associated with behavioral disruption and, therefore, NMFS expects any potential TTS takes to be captured by the estimated takes by behavioral disruption (discussed below).

TABLE 8—SCENARIO-SPECIFIC INSTANCES OF TAKE (BY LEVEL A AND LEVEL B HARASSMENT) AND MEAN ANNUAL TAKE LEVELS EVALUATED IN THE PROPOSED RULE [1]

Species	Survey effort scenario [2]											
	High		Moderate #1		Moderate #2		Low #1		Low #2		Mean annual take	
	A	B	A	B	A	B	A	B	A	B	A	B
Bryde's whale	3	572	2	422	2	510	2	395	2	411	2	462
Sperm whale	0	43,549	0	27,300	0	33,378	0	26,681	0	27,689	0	31,719
Kogia spp.	728	19,101	475	13,328	636	16,188	472	12,629	562	13,414	575	14,932
Beaked whale	0	235,667	0	162,172	0	190,824	0	151,745	0	156,622	0	179,406
Rough-toothed dolphin	0	37,816	0	30,306	0	31,231	0	28,775	0	26,420	0	30,910
Bottlenose dolphin	0	655,345	0	979,905	0	598,607	0	941,001	0	581,121	0	751,196
Clymene dolphin	0	111,211	0	73,225	0	87,995	0	69,913	0	73,051	0	83,079
Atlantic spotted dolphin	0	133,758	0	175,128	0	116,988	0	165,221	0	110,126	0	140,244
Pantropical spotted dolphin	0	609,653	0	421,786	0	513,572	0	401,568	0	421,856	0	473,687
Spinner dolphin	0	83,041	0	59,818	0	73,259	0	56,735	0	59,448	0	66,460
Striped dolphin	0	44,232	0	30,069	0	36,431	0	28,652	0	30,023	0	33,881
Fraser's dolphin	0	13,910	0	9,690	0	11,438	0	9,162	0	9,426	0	10,725
Risso's dolphin	0	27,165	0	18,197	0	22,005	0	17,380	0	18,166	0	20,583
Melon-headed whale	0	69,152	0	47,719	0	57,004	0	45,011	0	46,801	0	53,137
Pygmy killer whale	0	18,112	0	12,335	0	14,859	0	11,733	0	12,198	0	13,847
False killer whale	0	25,622	0	17,708	0	20,922	0	16,849	0	17,239	0	19,668
Killer whale	0	1,498	0	1,034	0	1,262	0	987	0	1,039	0	1,164
Short-finned pilot whale	0	19,326	0	12,198	0	14,214	0	11,565	0	11,942	0	13,849

[1] A and B refer to expected scenario-based instances of take by Level A and Level B harassment, respectively. For the Bryde's whale and *Kogia* spp., expected takes by Level A harassment represent modeled exposures adjusted to account for aversion. For *Kogia* spp., exposures above Level A harassment criteria were predicted by the peak SPL metric. For the Bryde's whale, exposures above Level A harassment criteria were predicted by the cSEL metric.

[2] High survey effort scenario corresponds with level of effort projections given previously for Year 1 (see Table 1 of the notice of proposed rulemaking). Moderate #1 and #2 and Low #1 and #2 correspond with Years 4, 5, 8, and 9, respectively.

TABLE 9—REVISED INSTANCES OF TAKE (BY LEVEL A AND LEVEL B HARASSMENT) (YEARS 1–5) AND MEAN ANNUAL TAKE LEVELS [1]

Species	Year 1		Year 2		Year 3		Year 4		Year 5		Mean annual take	
	A	B	A	B	A	B	A	B	A	B	A	B
Bryde's whale	0	10	0	8	0	8	0	6	0	7	0	8
Sperm whale	0	16,405	0	14,205	0	13,603	0	9,496	0	12,388	0	13,219
Kogia spp.	371	10,383	337	9,313	310	8,542	209	6,238	314	8,318	308	8,559
Beaked whale	0	191,566	0	162,301	0	158,328	0	111,415	0	142,929	0	153,308
Rough-toothed dolphin	0	30,640	0	27,024	0	25,880	0	19,620	0	23,219	0	25,277
Bottlenose dolphin	0	603,649	0	973,371	0	567,962	0	1,001,256	0	567,446	0	742,737
Clymene dolphin	0	85,828	0	67,915	0	73,522	0	47,332	0	60,379	0	66,995
Atlantic spotted dolphin	0	128,299	0	183,717	0	112,120	0	191,495	0	111,305	0	145,387
Pantropical spotted dolphin	0	478,490	0	436,047	0	391,363	0	311,316	0	395,987	0	402,641
Spinner dolphin	0	75,953	0	71,873	0	61,098	0	48,775	0	64,357	0	64,411
Striped dolphin	0	33,573	0	29,275	0	27,837	0	20,136	0	26,056	0	27,375
Fraser's dolphin	0	4,522	0	3,843	0	3,792	0	2,726	0	3,455	0	3,668
Risso's dolphin	0	21,859	0	18,767	0	18,218	0	12,738	0	16,634	0	17,643
Melon-headed whale	0	55,813	0	47,784	0	46,584	0	32,581	0	42,224	0	44,997
Pygmy killer whale	0	8,079	0	6,964	0	6,764	0	4,970	0	6,277	0	6,611
False killer whale	0	16,165	0	13,710	0	13,604	0	9,664	0	12,269	0	13,082
Killer whale	0	60	0	56	0	50	0	42	0	52	0	52
Short-finned pilot whale	0	15,045	0	9,824	0	13,645	0	7,459	0	8,959	0	10,986

[1] A and B refer to expected instances of take by Level A and Level B harassment, respectively, for Years 1–5. For *Kogia* spp., expected takes by Level A harassment represent modeled exposures adjusted to account for aversion. For the Bryde's whale, no takes by Level A harassment are predicted to occur. Therefore, no adjustment to modeled exposures to account for aversion was necessary. For *Kogia* spp., exposures above Level A harassment criteria were predicted by the peak SPL metric. For the Bryde's whale, the cSEL metric is used to evaluate the potential for Level A harassment.

Level B Harassment

NMFS has determined the estimated values shown in Table 9 are a reasonable representation of the potential instances of take that may occur (more specifically, each of these ''takes'' representing a day in which one individual is exposed above the Level B harassment criteria, even if only for seconds). However, these take numbers do not represent the number of individuals expected to be taken, given they are higher than the estimated abundance for all species. Accordingly, as described in the notice of proposed rulemaking, NMFS references Test Scenario 1 in the modeling report (''*Long-Duration Surveys and Scaling Methods*'') to inform two important parts of the analyses. Comparing the results of modeling simulations that more closely match longer survey durations (30 days) to the results of 24-hour take estimates scaled up to 30 days (as the instances of take in Table 9 were calculated) provides the comparative ratios of number of individuals taken/calculated (within a 30-day survey) and instances of take, in order to better understand the comparative distribution of exposures across individuals of different species. First, in NMFS' analyses in this rule, the ratio and its inverse are used to inform a better understanding of the nature in which individuals are taken across the multiple days of a longer duration survey given the different behaviors that are represented in the animat modeling, *i.e.,* looking at the ratio of (number of individuals taken in 30-day modeling scenario)/(number of instances of take when 1-day average multiplied by 30 days), if all else is equal within one survey, for the species with a smaller ratio (larger inverse), fewer individuals will be taken but each will be exposed above the threshold on a higher number of days (see Table 16). Second, this ratio may be appropriately be used in combination with the calculated instances of take to predict the number of individuals taken for surveys of similar duration (noting that for surveys of notably longer than 30-day duration, it will still likely result in some degree of overestimate of individuals), in order to support evaluation of take estimates in requests for Letters of Authorization, given the need to meet the ''small numbers of marine mammals'' standard, which is based on the number of individuals taken. A summary of this, which was included in the notice of proposed rulemaking along with a description of the other Test Scenarios and how they inform this analysis, is included below.

Although some survey operations may continue for months, survey simulations were conducted for seven days in order to derive mean 24-hr exposure averages, with these averages then used to scale according to the total number of survey days projected by BOEM. This approach was necessary due to the more computationally-intensive modeling required to model more realistic durations (*i.e.,* 30 days). As summarized above and discussed in detail in the notice of proposed rulemaking, a test scenario was used to evaluate methods for scaling results from shorter-duration simulations to longer duration operations. Results from test modeling conducted for a suite of six representative species over 30-day simulations of a hypothetical 3D WAZ survey were compared to the results of a shorter 5-day simulation, *i.e.,* the number of animats exposed to levels exceeding threshold for 24-hr time periods multiplied by the number of days in the simulations was compared to the number of animats exposed to levels exceeding threshold for the entire duration of the simulations. The results of the test scenario indicated that undesired systematic biases in the modeling procedure, if present, were small relative to the survey design and would not affect scaling up the results in time (*i.e.,* the shorter 7-day simulations ultimately used in the modeling would provide unbiased results). However, the results also indicated that scaling up the 24-hr average SPL exposure estimates to 30 days greatly overestimates the number of notional marine mammals (*i.e.,* animats) exposed to levels exceeding threshold when determined over the entire simulation (although the estimated instances of exposure are reasonably accurate). This occurs because animats were commonly exposed to levels exceeding these thresholds, and the relatively short reset period of 24 hours means that individual animats were, in effect, counted several times during the scale-up (*i.e.,* on multiple days) whereas they would only have been counted once when evaluating over the entire simulation. When a real-world survey extends over longer durations within the same region, it is most likely that the same individuals are repeatedly exposed to survey noise. However, the modeling assumption that populations of animals were reset for each 24-hr period is equivalent to an assumption that each survey day is a completely independent event, *i.e.,* that new individuals are impacted on each subsequent day.

In order to determine more realistic exposure probabilities for individuals across multiple days, modeled results were compared for a 30-day period versus the aggregation of 24-hr population reset intervals (the investigation described above) to determine a species-typical offset of modeled daily exposures. When conducting computationally-intensive modeling over the full assumed 30-day survey period (versus aggregating the smaller 24-hr periods for 30 days), results showed about 10–45 percent of the total number of takes calculated using a 24-hr reset of the population, with differences relating to species-typical movement and residency patterns. Given that many of the evaluated survey activities occur for 30-day or longer periods, particularly some of the larger surveys for which the majority of the modeled exposures occur, using such a scaling process is appropriate in order to evaluate the likely severity of the predicted exposures. This approach is also discussed in more detail in the EWG report (Southall *et al.,* 2017), available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.*

The test scenario modeled six representative GOM species/guilds: Bryde's whale, sperm whale, beaked whales, bottlenose dolphin, *Kogia* spp., and short-finned pilot whale. For purposes of this analysis, bottlenose dolphin was used as a proxy for other small dolphin species, and short-finned pilot whale was used as a proxy for other large delphinids. Tables 22–23 in the modeling report provide information regarding the number of modeled animals receiving exposure above criteria for average 24-hr sliding windows scaled to the full 30-day duration and percent change in comparison to the same number evaluated when modeling the full 30-day duration. This information was used to derive 30-day scalar ratios which, when applied to the total instances of take given in Table 9, captures repeated takes of individuals at a 30-day sampling level. Scalar ratios are as follows: Bryde's whale, 0.189; sperm whale, 0.423; beaked whales, 0.101; bottlenose dolphin, 0.287; *Kogia* spp., 0.321; and short-finned pilot whale, 0.295. Application of the re-scaling method reduced the overall magnitude of modeled takes for all species by slightly more than double to up to ten-fold (Table 10).

These adjusted take numbers (shown in Table 10) provide a more realistic basis upon which to evaluate severity of

the expected taking. Please see the Negligible Impact Analysis and Determinations section, later in this document, for additional detail. It is important to recognize that while these scaled numbers better reflect the number of individuals likely to be taken within a single 30-day survey than the number of instances in Table 9, they will still overestimate the number of individuals taken across the aggregated GOM activities, because they do not correct for (*i.e.,* further reduce take to account for) individuals exposed to multiple surveys or fully correct for individuals exposed to surveys significantly longer than 30 days.

As noted in the beginning of this section and in the Small Numbers section, using modeled instances of take (Table 9) and the method described here to scale those numbers (based on Test Scenario 1) allows one to more accurately predict the number of individuals that will be taken as a result of exposure to one survey and, therefore, these scaled predictions should be considered in requests for LOAs to assess whether a resulting LOA would meet the small numbers standard. However, for the purposes of ensuring that the take authorized pursuant to all issued LOAs is within the scope of the analysis conducted to support the negligible impact finding in this rule, authorized instances of take (which are the building blocks of the analysis) also must be assessed. Specifically, reflecting Table 9 and what has been analyzed, the total take authorized for any given species or stock over the course of the five years covered under these regulations should not exceed the sum of the five years of take indicated for the five scenarios in that table, and in any given year, the take of any species should not exceed the highest annual take listed for any of the five scenarios.

TABLE 10—EXPECTED TOTAL TAKE NUMBERS, SCALED [1]

Species	Year 1	Year 2	Year 3	Year 4	Year 5
Bryde's whale	2	2	2	1	1
Sperm whale	6,939	6,009	5,754	4,017	5,240
Kogia spp.	3,452	3,098	2,841	2,069	2,771
Beaked whale	19,348	16,392	15,991	11,253	14,436
Rough-toothed dolphin	8,794	7,756	7,428	5,631	6,664
Bottlenose dolphin	173,247	279,357	163,005	287,360	162,857
Clymene dolphin	24,633	19,492	21,101	13,584	17,329
Atlantic spotted dolphin	36,822	52,727	32,178	54,959	31,945
Pantropical spotted dolphin	137,327	125,145	112,321	89,348	113,648
Spinner dolphin	21,799	20,628	17,535	13,998	18,470
Striped dolphin	9,635	8,402	7,989	5,779	7,478
Fraser's dolphin	1,298	1,103	1,088	782	992
Risso's dolphin	6,448	5,536	5,374	3,758	4,907
Melon-headed whale	16,465	14,096	13,742	9,611	12,456
Pygmy killer whale	2,383	2,054	1,995	1,466	1,852
False killer whale	4,769	4,044	4,013	2,851	3,619
Killer whale	18	17	15	12	15
Short-finned pilot whale	4,438	2,898	4,025	2,200	2,643

[1] Scalar ratios were applied to values in Table 9 as described in preceding text to derive scaled take numbers shown here.

Mitigation

''*Least Practicable Adverse Impact*'' *Standard*

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses (hereinafter referred to as ''LPAI'' or ''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. However, NMFS' implementing regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)). We note that in some cases, certain mitigation may be necessary in order to make a ''negligible impact'' finding for an affected species or stock, which is a fundamental requirement of issuing an authorization—in these cases, consideration of practicability may be a lower priority for decision-making if impacts to marine mammal species or stocks would not be negligible in the measure's absence.

In *Conservation Council for Hawaii* v. *NMFS,* 97 F. Supp. 3d 1210, 1229 (D. Haw. 2015), the district court stated that NMFS ''appear[s] to think [it satisfies] the statutory 'least practicable adverse impact' requirement with a 'negligible impact' finding.'' Later, expressing similar concerns in a challenge to an incidental take rule for U.S. Navy Operation of Surveillance Towed Array Sensor System Low Frequency Active (SURTASS LFA) Sonar (77 FR 50290, August 20, 2012), the Ninth Circuit in *Natural Resources Defense Council (NRDC)* v. *Pritzker,* 828 F.3d 1125, 1134 (9th Cir. 2016), stated, ''[c]ompliance with the 'negligible impact' requirement does not mean there [is] compliance with the 'least practicable adverse impact' standard.'' NMFS is in full agreement that the ''negligible impact'' and ''least practicable adverse impact'' requirements are distinct, even though both statutory standards refer to species and stocks. With that in mind, we provide further explanation of NMFS' interpretation of least practicable adverse impact and explain what distinguishes it from the negligible impact standard. This discussion is consistent with, and expands upon, previous rules issued by NMFS, such as the Navy Gulf of Alaska rule (82 FR 19530; April 27, 2017); the Navy Atlantic Fleet Testing and Training rule (83 FR 57076; November 14, 2018); the Navy Hawaii-Southern California Training and Testing rule (83 FR 66846; December 27, 2018); and the SURTASS

LFA sonar rule (84 FR 40132; August 13, 2019).

Before NMFS can issue incidental take regulations under section 101(a)(5)(A) of the MMPA, it must make a finding that the total taking will have a ''negligible impact'' on the affected ''species or stocks'' of marine mammals. NMFS' and the U.S. Fish and Wildlife Service's implementing regulations for section 101(a)(5) both define ''negligible impact'' as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103 and 50 CFR 18.27(c)). Recruitment (*i.e.,* reproduction) and survival rates are used to determine population growth rates [12] and, therefore, are considered in evaluating population level impacts.

As NMFS stated in the preamble to the final rule for the incidental take implementing regulations, not every population-level impact violates the negligible impact requirement. The negligible impact standard does not require a finding that the anticipated take will have ''no effect'' on population numbers or growth rates: ''The statutory standard does not require that the same recovery rate be maintained, rather that no significant effect on annual rates of recruitment or survival occurs. [T]he key factor is the significance of the level of impact on rates of recruitment or survival.'' (54 FR 40338, 40341–42; September 29, 1989).

While some level of impact on population numbers or growth rates of a species or stock may occur and may still satisfy the negligible impact requirement—even without consideration of mitigation—the least practicable adverse impact provision separately requires NMFS to prescribe means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, 50 CFR 216.102(b), which are typically identified as mitigation measures.[13]

The negligible impact and least practicable adverse impact standards in the MMPA both call for evaluation at the level of the ''species or stock.'' The MMPA does not define the term ''species.'' However, Webster's New Collegiate Dictionary (1981) defines ''species'' to include ''a group of intimately related and physically similar organisms that actually or potentially interbreed [. . .], that ordinarily comprise differentiated *populations* limited geographically [. . .] or ecologically [. . .]'' (emphasis added). See also Merriam-Webster Dictionary, which defines ''species'' to include ''related organisms or *populations* potentially capable of interbreeding.'' *www.merriam-webster.com/dictionary/species* (emphasis added). The MMPA defines ''stock'' as a group of marine mammals of the same species or smaller taxa in a common spatial arrangement that interbreed when mature (16 U.S.C. 1362(11)). The definition of ''population'' includes ''a group of interbreeding biotypes that represents the level of organization at which speciation begins.'' Webster's New Collegiate Dictionary (1981). See also *www.merriam-webster.com/dictionary/population,* which defines population as ''a group of interbreeding organisms that represents the level of organization at which speciation begins.'' The definition of ''population'' is strikingly similar to the MMPA's definition of ''stock,'' with both involving groups of individuals that belong to the same species and are located in a manner that allows for interbreeding. In fact, the term ''stock'' in the MMPA is interchangeable with the statutory term ''population stock.'' (16 U.S.C. 1362(11)). Both the negligible impact standard and the least practicable adverse impact standard call for evaluation at the level of the species or stock, and the terms ''species'' and ''stock'' both relate to populations. Therefore, it is appropriate to view both the negligible impact standard and the least practicable adverse impact standard as having a population-level focus.

This interpretation is consistent with Congress's statutory findings for enacting the MMPA, nearly all of which are most applicable at the species or stock (*i.e.,* population) level. See 16 U.S.C. 1361 (finding that it is species and population stocks that are or may be in danger of extinction or depletion; that it is species and population stocks that should not diminish beyond being significant functioning elements of their ecosystems; and that it is species and population stocks that should not be permitted to diminish below their optimum sustainable population level). Annual rates of recruitment (*i.e.,* reproduction) and survival are the key biological metrics used in the evaluation of population-level impacts, and accordingly these same metrics are also used in the evaluation of population-level impacts for the least practicable adverse impact standard.

Recognizing this common focus of the least practicable adverse impact and negligible impact provisions on the ''species or stock'' does not mean that NMFS conflates the two standards; despite some common statutory language, we recognize the two provisions are different and have different functions.

First, a negligible impact finding is required before NMFS can issue an incidental take authorization. Although it is acceptable to use mitigation measures to reach a negligible impact finding (see 50 CFR 216.104(c)), no amount of mitigation can enable NMFS to issue an incidental take authorization for an activity that would not meet the negligible impact standard.

Second, even where NMFS can reach a negligible impact finding—which we emphasize does allow for the possibility of some ''negligible'' population-level impact—the agency must still prescribe measures that will effect the least practicable amount of adverse impact upon the affected species or stock.

Section 101(a)(5)(A)(i)(II) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions (in the form of regulations) setting forth how the activity must be conducted, thus ensuring the activity has the ''least practicable adverse impact'' on the affected species or stocks and their habitat. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(A)(i)(II) also provides a mechanism for ensuring compliance with the ''negligible impact'' requirement.

Finally, as noted above, the least practicable adverse impact standard requires consideration of measures for marine mammal habitat, with particular attention to rookeries; mating grounds; and other areas of similar significance, and for subsistence impacts. By contrast, the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.[14]

In *NRDC* v. *Pritzker,* the Ninth Circuit stated, ''[t]he statute is properly read to mean that even if population levels are not threatened *significantly,* still the agency must adopt mitigation measures aimed at protecting *marine mammals* to

[12] A growth rate can be positive, negative, or flat.

[13] For purposes of this discussion, we omit reference to the language in the standard for least practicable adverse impact that says that NMFS also must mitigate for subsistence impacts, because subsistence impacts are not at issue in this action.

[14] Mitigation may also be appropriate to ensure separate compliance with the ''small numbers'' language and negligible impact standard in MMPA sections 101(a)(5)(A) and (D).

the greatest extent practicable in light of military readiness needs.'' *Pritzker,* 828 F.3d at 1134 (emphases added). This statement is consistent with our understanding stated above that even when the effects of an action satisfy the negligible impact standard (*i.e.,* in the court's words, ''population levels are not threatened significantly''), still the agency must prescribe mitigation under the least practicable adverse impact standard. However, as the statute indicates, the focus of both standards is ultimately the impact on the affected ''species or stock''; the standards are not solely focused on or directed at the impact on individual marine mammals.

NMFS has carefully considered the Ninth Circuit's opinion in *NRDC* v. *Pritzker* in its entirety. While the court's reference to ''marine mammals'' rather than ''marine mammal species or stocks'' in the italicized language above might be construed as a holding that the least practicable adverse impact standard applies at the individual ''marine mammal'' level, *i.e.,* that NMFS must require mitigation to minimize impacts to each individual marine mammal unless impracticable, we believe that such an interpretation reflects an incomplete appreciation of the court's decision. In NMFS' view, the decision as a whole turned on the court's determination that the agency had not given separate and independent meaning to the least practicable adverse impact standard apart from the negligible impact standard. NMFS further believes that the court's use of the term ''marine mammals'' was not addressing the question of whether the standard applies to individual animals as opposed to the species or stock as a whole. We recognize that while consideration of mitigation can play a role in a negligible impact determination, consideration of mitigation measures extends beyond that analysis. In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the specified activity, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures, as described below.

Implementation of Least Practicable Adverse Impact Standard

In light of the *NRDC* v. *Pritzker* decision, we discuss here how NMFS determines whether a measure or set of measures meets the ''least practicable adverse impact'' standard. Our separate analysis of whether the take anticipated to result from the specified activities meets the ''negligible impact'' standard appears in the Negligible Impact Analysis and Determinations section below.

NMFS' evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (where relevant). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation.

(2) The practicability of the measures for applicant implementation. Practicability of implementation may consider such things as cost, impact on activities, personnel safety, and practicality of implementation.

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks and their habitat, NMFS recognizes that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS' analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals that are likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the environment, and the affected species or stocks. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks. NMFS also acknowledges that there is always the potential that new information, or a new recommendation that had not previously been considered, becomes available and necessitates re-evaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability) and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species and practicability of implementation are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability, can vary widely. For example, a time-area restriction could be of very high value for reducing the potential for, or severity of, population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less firmly established biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the operator's ability to acquire necessary data (higher impact), or it could mean incremental delays that increase operational costs but still allow the activity to be conducted (lower impact). A responsible evaluation of ''least practicable adverse impact'' will consider the factors along these realistic scales. Expected effects of the activity and of the mitigation as well as status of the stock all weigh into these considerations. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stock or their habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. Consideration of these factors is discussed in greater detail below.

1. *Reduction of adverse impacts to marine mammal species or stocks and their habitat.*[15]

[15] NMFS recognizes the least practicable adverse impact standard requires consideration of measures that will address minimizing impacts on the availability of the species or stocks for subsistence uses where relevant. Because subsistence uses are not implicated for this action, we do not discuss them. However, a similar framework would apply

Continued

The emphasis given to a measure's ability to reduce the impacts on a species or stock considers the degree, likelihood, and context of the anticipated reduction of impacts to individuals (and how many individuals) as well as the status of the species or stock.

The ultimate impact on any individual from a disturbance event (which informs the likelihood of adverse species- or stock-level effects) is dependent on the circumstances and associated contextual factors, such as duration of exposure to stressors. Though any proposed mitigation needs to be evaluated in the context of the specific activity and the species or stocks affected, measures with the following types of effects have greater value in reducing the likelihood or severity of adverse species- or stock-level impacts: Avoiding or minimizing injury or mortality; limiting interruption of known feeding, breeding, mother/young, or resting behaviors; minimizing the abandonment of important habitat (temporally and spatially); minimizing the number of individuals subjected to these types of disruptions; and limiting degradation of habitat. Mitigating these types of effects is intended to reduce the likelihood that the activity will result in energetic or other types of impacts that are more likely to result in reduced reproductive success or survivorship. It is also important to consider the degree of impacts that are expected in the absence of mitigation in order to assess the added value of any potential measures. Finally, because the least practicable adverse impact standard gives NMFS discretion to weigh a variety of factors when determining appropriate mitigation measures and because the focus of the standard is on reducing impacts at the species or stock level, the least practicable adverse impact standard does not compel mitigation for every kind of take, or every individual taken, if that mitigation is unlikely to meaningfully contribute to the reduction of adverse impacts on the species or stock and its habitat, even when practicable for implementation by the applicant.

The status of the species or stock is also relevant in evaluating the appropriateness of potential mitigation measures in the context of least practicable adverse impact. The following are examples of factors that may (either alone, or in combination) result in greater emphasis on the importance of a mitigation measure in reducing impacts on a species or stock: the stock is known to be decreasing or status is unknown, but believed to be declining; the known annual mortality (from any source) is approaching or exceeding the PBR level; the affected species or stock is a small, resident population; or the stock is involved in a UME or has other known vulnerabilities, such as recovering from an oil spill.

Habitat mitigation, particularly as it relates to rookeries, mating grounds, and areas of similar significance, is also relevant to achieving the standard and can include measures such as reducing impacts of the activity on known prey utilized in the activity area or reducing impacts on physical habitat. As with species- or stock-related mitigation, the emphasis given to a measure's ability to reduce impacts on a species or stock's habitat considers the degree, likelihood, and context of the anticipated reduction of impacts to habitat. Because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat.

NMFS considers available information indicating the likelihood of any measure to accomplish its objective. If evidence shows that a measure has not typically been effective nor successful, then either that measure should be modified or the potential value of the measure to reduce effects should be lowered.

2. *Practicability.*

Factors considered may include those costs, impact on activities, personnel safety, and practicality of implementation.

In carrying out the MMPA's mandate for this action, NMFS applies the previously described context-specific balance between the manner in which and the degree to which measures are expected to reduce impacts to the affected species or stocks and their habitat and practicability for operators. The effects of concern (*i.e.,* those with the potential to adversely impact species or stocks and their habitat), addressed previously in the Potential Effects of the Specified Activity on Marine Mammals and Their Habitat section of the notice of proposed rulemaking, include auditory injury, severe behavioral reactions, disruptions of critical behaviors, and to a lesser degree, masking and impacts on acoustic habitat (see discussion of this concept in the ''Anticipated Effects on Marine Mammal Habitat'' section in the notice of proposed rulemaking). Here, we focus on measures with proven or reasonably presumed ability to avoid or reduce the intensity of acute exposures that have potential to result in these anticipated effects with an understanding of the drawbacks or costs of these requirements, as well as time-area restrictions that would avoid or reduce both acute and chronic impacts. To the extent of the information available to NMFS, we considered practicability concerns, as well as potential undesired consequences of the measures, *e.g.,* extended periods using the acoustic source due to the need to reshoot lines. NMFS also recognizes that instantaneous protocols, such as shutdown requirements, are not capable of avoiding all acute effects, and are not suitable for avoiding many cumulative or chronic effects and do not provide targeted protection in areas of greatest importance for marine mammals. Therefore, in addition to a basic suite of seismic mitigation protocols, we also consider measures that may or may not be appropriate for other activities (*e.g.,* time-area restrictions specific to the surveys discussed herein), but that are warranted here given the spatial scope of these specified activities, potential for population-level effects and/or high magnitude of take for certain species in the absence of such mitigation (see Negligible Impact Analysis and Determinations), and the information we have regarding habitat for certain species.

In order to satisfy the MMPA's least practicable adverse impact standard, NMFS evaluated a suite of basic mitigation protocols that are required regardless of the status of a stock. Additional or enhanced protections are required for species whose stocks are in particularly poor health and/or are subject to some significant additional stressor that lessens that stock's ability to weather the effects of the specified activities without worsening its status. NMFS reviewed the mitigation measures proposed in the petition, the requirements specified in BOEM's PEIS, seismic mitigation protocols required or recommended elsewhere (*e.g.,* HESS, 1999; DOC, 2013; IBAMA, 2018; Kyhn *et al.,* 2011; JNCC, 2017; DEWHA, 2008; BOEM, 2016; DFO, 2008; GHFS, 2015; MMOA, 2016; Nowacek *et al.,* 2013; Nowacek and Southall, 2016), recommendations received during the public comment period, and the available scientific literature. NMFS also considered recommendations given in a number of review articles (*e.g.,* Weir and Dolman, 2007; Compton *et al.,* 2008; Parsons *et al.,* 2009; Wright and Cosentino, 2015; Stone, 2015b). Certain changes from the mitigation measures described in the notice of proposed

for evaluating those measures, taking into account both the MMPA's directive that we make a finding of no unmitigable adverse impact on the availability of the species or stocks for taking for subsistence, and the relevant implementing regulations.

rulemaking were made on the basis of additional information and following review of public comments. The required suite of mitigation measures differs in some cases from the measures proposed in the petition and/or those specified by BOEM in the preferred alternative identified in their PEIS in order to reflect what NMFS believes to be the most appropriate suite of measures to satisfy the requirements of the MMPA. Additionally, two geographic mitigation measures discussed in the proposed rule are no longer applicable because of the change in the scope of the rule.

For purposes of defining mitigation requirements, we differentiate here between requirements for two classes of airgun survey activity: Deep penetration and shallow penetration, with surveys using arrays greater than 1,500 in^3 total airgun volume considered deep penetration. This delineation is discussed further below, under ''Changes from the Proposed Regulations.'' Shallow penetration surveys also include those using single airguns, boomers, or equivalent sources. A third general class of surveys is also considered, referred to here as high-resolution geophysical (HRG) surveys and including those surveys using the other electromechanical sources described previously. HRG surveys are treated differentially on the basis of water depth, with 200 m as the divider between shallow and deep HRG. Water depth is used as an indicator for surveys (shallow) that should be expected to have less potential for impacts to marine mammals, because HRG sources used in shallow waters are typically higher-frequency, lower power, and/or having some significant directionality to the beam pattern. Finally, HRG surveys using only sources operating at frequencies greater than or equal to 180 kHz are exempt from the mitigation requirements described herein, with the exception of adherence to vessel strike avoidance protocols. (Note that this has been changed from 200 kHz to reflect the best available scientific information regarding generalized hearing ranges for affected marine mammal hearing groups (NMFS, 2018).) No distinction in standard required mitigations is made on the basis of BOEM's planning areas (*i.e.,* Western Planning Area (WPA), Central Planning Area (CPA), Eastern Planning Area (EPA)).

First, we summarize notable changes made to the mitigation requirements as a result of review of public comments and/or new information and then describe mitigation prescribed in the regulations. For additional detail regarding mitigation considerations, including expected efficacy and/or practicability, or descriptions of mitigation considered but not required, please see the notice of proposed rulemaking. Where the practicability analysis was described in the notice of proposed rulemaking and nothing has changed, we do not repeat the description.

Changes to Mitigation From the Proposed Regulations

Here we summarize substantive changes to mitigation requirements from the proposed regulations. All changes were made on the basis of review of public comments received and/or review of new information.

Delineation of Airgun Activity Tiers

In the notice of proposed rulemaking, for purposes of prescribing mitigation, NMFS proposed to define ''deep penetration'' surveys as those using arrays greater than 400 in^3 total volume. As stated in that notice, NMFS had little information upon which to base such a delineation for purposes of defining appropriate mitigation, but considered 400 in^3 as a reasonable cutoff based on descriptions of airgun surveys provided in BOEM's petition. We also noted that the Associations stated in their comments on the petition that deep penetration array volumes used in the GOM range from approximately 2,000 to 8,400 in^3. BOEM has subsequently provided information to NMFS supporting a cutoff at 1,500 in^3. In support of section 3(c) of E.O. 13795, BOEM analyzed available data for single airguns and airgun arrays, including arrays with known characteristics used by the National Science Foundation and U.S. Geological Survey and arrays evaluated through BOEM NEPA analyses. See *e.g.,* Richardson *et al.* (1995); NSF and USGS (2011). These data suggest that the output of an array, in terms of peak source level, increases at a greater rate at volumes above approximately 1,500 in^3. No public comments addressing this issue were received. Therefore, NMFS has elected to redefine the transition from ''shallow penetration'' to ''deep penetration'' from 400 to 1,500 in^3 total volume of the array.

Time-Area Restrictions

Bryde's Whale Core Habitat Area: The proposed regulatory text included a seasonal restriction within an area we termed Bryde's whale core habitat, and the preamble for the proposed rule presented several alternatives to the seasonal restriction for consideration by the public (83 FR 29281; 29302) including a year-round closure for this area, which was considered in the analysis for the preliminary determination of negligible impact. See 83 FR 29280–29281; 83 FR 29297.

However, the entirety of this area is now excluded from consideration through this rule following BOEM's update to the scope of activity (*i.e.,* removal of the GOMESA moratorium area from the geographic scope of the rulemaking). Therefore, consideration of a time-area restriction for the Bryde's whale core habitat area (including the alternatives described above) is moot, and no restriction is included in this final rule.

Dry Tortugas Area: As with the Bryde's whale core habitat area, the entirety of the Dry Tortugas area is now excluded from consideration through this rule following BOEM's update to the scope of activity (*i.e.,* removal of the GOMESA moratorium area from the geographic scope of the rulemaking). Therefore, consideration of a time-area restriction for the biologically important area for sperm whales and beaked whales in the EPA is moot, and no restriction is included in this final rule.

Coastal Restriction: NMFS proposed a GOM-wide restriction within coastal waters inside the 20-m isobath, to be in effect from February through May. For this final rule, NMFS contracted the proposed coastal time-area restriction spatially and expanded it temporally. The restriction has been reduced to cover the same coastal waters (20-m isobath) but between 90° W and the eastern extent of the coastal waters portion of BOEM's updated specified geographic region, while expanding temporally to include the month of January. NMFS received informative public comment on both sides of this issue. Some commenters provided information indicating practicability concerns regarding the proposed restriction, while other commenters supported the importance of the restriction and provided information supporting the temporal expansion of the restriction to include January. As described in the notice of proposed rulemaking, the stock most heavily impacted by the DWH oil spill (of those that may be affected by the specified activities) was the northern coastal stock of bottlenose dolphin. Since publication of the proposed regulations, an additional UME occurred in the area largely overlapping the range of this stock. Therefore, while NMFS appreciates the practicability concerns raised by commenters, we contracted the restriction spatially but did not eliminate the restriction, while expanding it temporally to encompass January through May. The change is

described in more detail under Comments and Responses as well as later in this section where the details of the specific closure area is discussed.

Restriction Area Buffer Zones: The proposed regulations included buffer zones specific to each time-area restriction that corresponded with modeled distances to the 160-dB isopleth (*i.e.,* the midpoint of the Level B harassment risk function). These distances were 6 km around the EPA Bryde's whale core habitat area (Area #2), 13 km around the coastal waters restriction (Area #1), and 9 km around the southern EPA area (Area #3). Following BOEM's update to the geographic scope of activity considered through this rule, Areas 2 and 3 are excluded from consideration. Therefore, consideration of buffer zone size around these areas is not relevant. Upon review of public comment, in which commenters raised concerns about practicability among others, and re-evaluation of the nature and extent of mitigation Area #1 as it relates to the necessity of an additional buffer area, NMFS determined it appropriate to not include a buffer for this area. The rationale for the change is described in more detail under Comments and Responses.

Shutdown Requirements

Delphinid Exception: NMFS does not require shutdown or power-down for certain delphinid species. In the notice of proposed rulemaking, we proposed an exception to the general shutdown requirements for certain species of dolphins in relation to airgun surveys, in which the acoustic source would be powered down to the smallest single element of the array. Power-down conditions would be maintained until the animal(s) is observed exiting the exclusion zone or for 15 minutes beyond the last observation of the animal, following which full-power operations may be resumed without ramp-up. NMFS also provided an alternative proposal for consideration by the public, in which no shutdown or power-down would be required upon observation of the same species of dolphins. While we are careful to note that the reasons for and potential effects of dolphin interaction with vessels, including working survey vessels, are not fully understood, we also understand that dolphins are unlikely to incur any degree of threshold shift due to their relative lack of sensitivity to the frequency content in an airgun signal (as well as because of potential coping mechanisms). NMFS also recognizes that, although dolphins do in fact react to airgun noise in ways that may be considered take (Barkaszi *et al.,* 2012; Barkaszi and Kelly, 2018), there is a lack of notable adverse dolphin reactions to airgun noise despite a large body of observational data. Therefore, the removal of the power-down measure for small delphinids, in favor of the no-shutdown or power-down alternative, is warranted in consideration of the available information regarding the effectiveness of such measures in mitigating impacts to small delphinids and the practicability of such measures. No shutdown or power-down is required for these species.

Distance of Extended Shutdowns: NMFS limits extended distance shutdowns to within 1,500 m. We proposed a number of shutdown requirements on the basis of detections of certain species deemed particularly sensitive (*e.g.,* beaked whales) or of particular circumstances deemed to warrant particular caution (*e.g.,* whales with calves). These were all conditioned upon observation or detection of these species or circumstances at any distance from the vessel. However, NMFS also included as an alternative proposal for public consideration a distance limit of 1,000 m for these extended distance shutdown requirements. We received several comments challenging the value of extended distance shutdown requirements at all and, while NMFS disagrees with these comments, we agree that some reasonable distance limit should be placed on these requirements in order to better focus the observational effort of protected species observers (PSO) and to avoid the potential for numerous shutdowns based on uncertain detections at great distance. Therefore, as described in greater detail later in this section, NMFS determined that a limit on such extended distance shutdown zones for relevant species or circumstances was appropriate. However, upon consideration of additional information (discussed later in this section), NMFS determined it appropriate to limit extended distance shutdown zones to 1,500 m, rather than 1,000 m.

Sperm Whale Shutdowns: The proposed regulatory text included an extended distance shutdown upon acoustic detection of sperm whales, and this final ITR explicitly expands that requirement to include any detection of sperm whales (*i.e.,* including visual detection) at extended distance (*i.e.,* within 1,500 m). As discussed in Comments and Responses, NMFS received some comments showing that there was a lack of clarity regarding the extended distance shutdowns for acoustic detections of sperm whales. NMFS also received comments indicating that the proposed division (*i.e.,* extended distance shutdown upon acoustic detection of sperm whales but not visual detection) did not make sense given the available information regarding both the status of the GOM sperm whale population and the potential impacts of airgun noise on sperm whale foraging activity. While this measure does not avoid such impacts—the observed impacts on foraging behavior were at even greater distances (Miller *et al.,* 2009)—it may be expected to practicably reduce the occurrence and severity of impacts on foraging behavior.

Shallow Penetration Surveys: NMFS has reduced the standard exclusion zone from 200 m to 100 m, and included an extended distance shutdown requirement that mirrors the requirements for deep penetration surveys but out to a distance of 500 m. The 200-m shutdown distance was proposed on the basis of BOEM's HRG survey protocol (Appendix B of BOEM, 2017). However, practicability concerns were raised by public commenters and 100-m shutdown zones have been effectively applied in the past to afford protection from potential Level A harassment and more severe behavioral responses from these types of activities. Therefore, rather than defer to BOEM's HRG survey protocol, NMFS re-evaluated the same information informing development of the proposed rule, as well as public comment, and determined that the 200-m shutdown distance is not warranted and we reduce the distance accordingly. Regarding the extended distance shutdown in special circumstances, NMFS proposed this mitigation concept in context of deep penetration surveys in the notice of proposed rulemaking. Airgun (and equivalent) surveys are considered to have similar effects on exposed marine mammals, and the sensitive species for which the extended distance shutdown measure was proposed are similarly susceptible to disturbance from shallow penetration surveys, if exposed. Therefore, NMFS expands the extended distance shutdown measure to shallow penetration surveys in addition to deep penetration surveys.

HRG Surveys: NMFS eliminates shutdown requirements for HRG surveys (defined here as surveys using electromechanical sources such as multi-beam echosounders, side-scan sonars, and chirp sub-bottom profilers). The proposed regulations required shutdown for marine mammals within the proposed exclusion zone for surveys operating in water depths greater than 200 m. As discussed above for shallow penetration surveys, this proposal was

modeled after BOEM's HRG survey protocol. However, NMFS re-evaluated the available information, as well as public comment, and has determined the requirement to not be warranted. These sources are typically higher-frequency and lower-power, and have highly directional beam patterns. Effects to marine mammals due to use of these sources, if any, are expected to be of very low severity and, therefore, the benefits of the proposed shutdown requirement would be minimal (especially given that animals observed at the surface are necessarily not ensonified by the downward-directed beams from the source at the time they are observed).

Monitoring

Nighttime Ramp-Up: NMFS eliminates the requirement for visual observation during nighttime ramp-up and pre-clearance. Public commenters indicated that this measure is not likely to be effective, and that there are safety concerns associated with PSOs working on deck at night. NMFS concurs with this assessment, as described in detail in Comments and Responses.

PSOs for Node Retrieval: The proposed requirement for third-party PSOs aboard node retrieval vessels is eliminated due to practicability concerns expressed through public comment. NMFS concurs with this assessment, as described in detail in Comments and Responses.

Below, mitigation requirements are described in detail.

Mitigation-Related Monitoring

Monitoring by dedicated, trained marine mammal observers is required in all water depths and, for certain surveys, observers must be independent. Additionally, for some surveys, NMFS requires that some PSOs [16] have prior experience in the role. Independent observers are employed by a third-party observer provider; vessel crew may not serve as PSOs when independent observers are required. Dedicated observers are those who have no tasks other than to conduct observational effort, record observational data, and communicate with and instruct the survey operator (*i.e.,* vessel captain and crew) with regard to the presence of marine mammals and mitigation requirements. Communication with the operator may include brief alerts regarding maritime hazards. Trained PSOs have successfully completed an approved PSO training course (see Monitoring and Reporting), and experienced PSOs have additionally gained a minimum of 90 days at-sea experience working as a PSO during a deep penetration seismic survey, with no more than 18 months having elapsed since the conclusion of the relevant at-sea experience. Training and experience is specific to either visual or acoustic PSO duties (where required). An experienced visual PSO must have completed approved, relevant training and must have gained the requisite experience working as a visual PSO. An experienced acoustic PSO must have completed a passive acoustic monitoring (PAM) operator training course and must have gained the requisite experience working as an acoustic PSO. Hereafter, we also refer to acoustic PSOs as PAM operators, whereas when we use ''PSO'' without a qualifier, the term refers to either visual PSOs or PAM operators (acoustic PSOs).

NMFS does not formally administer any PSO training program or endorse specific providers but will approve PSOs that have successfully completed courses that meet the curriculum and trainer requirements specified herein (see Monitoring and Reporting). NMFS will provide PSO approvals in the context of the need to ensure that PSOs have the necessary training to carry out their duties competently while also approving applicant staffing plans quickly. In order for PSOs to be approved, NMFS must review and approve PSO resumes indicating successful completion of an acceptable training course. Although PSOs must be approved by NMFS, third-party observer providers and/or companies seeking PSO staffing should expect that observers having satisfactorily completed acceptable training and with the requisite experience (if required) will be quickly approved and, if NMFS does not respond within one week of having received the required information, such PSOs shall be considered to have received de facto approval. A PSO may be trained and/or experienced as both a visual PSO and PAM operator and may perform either duty, pursuant to scheduling requirements. Where multiple PSOs are required and/or PAM operators are required, PSO watch schedules shall be devised in consideration of the following restrictions: (1) A maximum of two consecutive hours on watch followed by a break of at least one hour between watches for visual PSOs (periods typical of observation for research purposes and as used for airgun surveys in certain circumstances (Broker *et al.,* 2015)); (2) a maximum of four consecutive hours on watch followed by a break of at least two consecutive hours between watches for PAM operators; and (3) a maximum of 12 hours observation per 24-hour period. NMFS may grant an exception for the requirement that visual PSOs be limited to a maximum of two consecutive hours on watch followed by a break of at least one hour between watches if requested on the basis of practicability concerns by LOA applicants. If an exception is granted, visual PSOs would instead be limited to a maximum of four consecutive hours on watch followed by a break of at least two hours between watches. Further information regarding PSO requirements may be found in the Monitoring and Reporting section, later in this document.

Deep Penetration Surveys—During deep penetration survey [17] operations (*e.g.,* any day on which use of the acoustic source is planned to occur; whenever the acoustic source is in the water, whether activated or not), a minimum of two independent PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). PSOs should use NOAA's solar calculator (*www.esrl.noaa.gov/gmd/grad/solcalc/*) to determine sunrise and sunset times at their specific location. NMFS recognizes that certain daytime conditions (*e.g.,* fog, heavy rain) may reduce or eliminate effectiveness of visual observations. However, on-duty PSOs shall remain alert for marine mammal observational cues and/or a change in conditions.

All source vessels must carry a minimum of one experienced visual PSO, who shall be designated as the lead PSO, coordinate duty schedules and roles,[18] and serve as the primary point of contact for the operator. However, while it is desirable for all PSOs to be qualified through experience, NMFS is also mindful of the need to expand the workforce by allowing opportunity for newly trained PSOs to gain experience. Therefore, the lead PSO shall devise the duty schedule such that experienced PSOs are on duty with trained PSOs (*i.e.,* those PSOs with appropriate training but who have not yet gained relevant experience) to the maximum extent practicable in order to provide necessary mentorship.

[16] Note that, although we discuss requirements related only to observation of marine mammals, we use the generic term ''protected species observer.''

[17] Deep penetration surveys are defined as those surveys using airgun arrays with total volume greater than 1,500 in^3.

[18] The coordination of PSO duty schedules and roles may alternatively be performed by a third-party, shore-based Monitoring Coordinator.

With regard to specific observational protocols, NMFS largely follows those described in Appendix B of BOEM's PEIS (BOEM, 2017). The lead PSO shall determine the most appropriate observation posts that will not interfere with navigation or operation of the vessel while affording an optimal, elevated view of the sea surface. These should be the highest elevation available on each vessel, with the maximum viewable range from the bow to 90 degrees to port or starboard of the vessel. PSOs shall coordinate to ensure 360° visual coverage around the vessel, and shall conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. All source vessels must be equipped with pedestal-mounted ''bigeye'' binoculars that will be available for PSO use. Within these broad outlines, the lead PSO and PSO team will have discretion to determine the most appropriate vessel- and survey-specific system for implementing effective marine mammal observational effort. Any observations of marine mammals by crew members aboard any vessel associated with the survey, including receiver or chase vessels, should be relayed to the source vessel(s) and to the PSO team.

All source vessels must use a towed PAM system for potential detection of marine mammals at all times when operating the sound source in waters deeper than 100 m. The term ''towed PAM system'' refers to any combination of hardware and software that uses a towed array for operations. The array can be physically separate from other in-water hardware, or embedded into other equipment, such as seismic streamers. The system must be monitored at all times during use of the acoustic source, and acoustic monitoring must begin at least 30 minutes prior to ramp-up. PAM operators must be independent, and all source vessels shall carry a minimum of two experienced PAM operators. PAM operators shall communicate all detections to visual PSOs, when visual PSOs are on duty, including any determination by the PSO regarding species identification, distance and bearing, and the degree of confidence in the determination. Further detail regarding PAM system requirements may be found in the Monitoring and Reporting section, later in this document. The effectiveness of PAM depends to a certain extent on the equipment and methods used and competency of the PAM operator, but no formal standards are currently in place regarding PAM system hardware/software requirements, or regarding PAM operator training.

Visual monitoring must begin at least 30 minutes prior to ramp-up (described below) and must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. If any marine mammal is observed at any distance from the vessel, a PSO would record the observation and monitor the animal's position (including latitude/longitude of the vessel and relative bearing and estimated distance to the animal) until the animal dives or moves out of visual range of the observer. A PSO would continue to observe the area to watch for the animal to resurface or for additional animals that may surface in the area. Visual PSOs shall communicate all observations to PAM operators, including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination.

As noted previously, all source vessels must carry a minimum of one experienced visual PSO and two experienced PAM operators. The observer designated as lead PSO (including the full team of visual PSOs and PAM operators) must have experience as a visual PSO. The applicant may determine how many additional PSOs are required to adequately fulfill the requirements specified here. To summarize, these requirements are: (1) 24-hour acoustic monitoring during use of the acoustic source in waters deeper than 100 m; (2) visual monitoring during use of the acoustic source by two PSOs during all daylight hours; (3) maximum of two consecutive hours on watch followed by a minimum of one hour off watch for visual PSOs and a maximum of four consecutive hours on watch followed by a minimum of two consecutive hours off watch for PAM operators; and (4) maximum of 12 hours of observational effort per 24-hour period for any PSO, regardless of duties.

Shallow Penetration Surveys—During shallow penetration surveys,[19] operators must follow the same requirements described above for deep penetration surveys, with one notable exception. The use of PAM is not required.

HRG Surveys—HRG survey protocols differ from the previously described protocols for deep and shallow penetration surveys, and we differentiate between deep-water (greater than 100 m) and shallow-water HRG surveys. Water depth in the GOM provides a reliable indicator of the marine mammal fauna that may be encountered and, therefore, the complexity of likely observations and concern related to potential effects on deep-diving and/or sensitive species.

Deep-water HRG surveys are required to employ a minimum of one independent visual PSO during all daylight operations, in the same manner as was described for deep and shallow penetration surveys. Shallow-water HRG surveys are required to employ a minimum of one visual PSO, which may be a crew member. PSOs employed during shallow-water HRG surveys are only required during a pre-clearance period. PAM is not required for any HRG survey.

PAM Malfunction—Emulating sensible protocols described by the New Zealand Department of Conservation for airgun surveys conducted in New Zealand waters (DOC, 2013), survey activity may continue for brief periods of time when the PAM system malfunctions or is damaged. Activity may continue for 30 minutes without PAM while the PAM operator diagnoses the issue. If the diagnosis indicates that the PAM system must be repaired to solve the problem, operations may continue for an additional two hours without acoustic monitoring under the following conditions:

- Daylight hours and sea state is less than or equal to Beaufort sea state (BSS) 4;
- No marine mammals (excluding delphinids; see below) detected solely by PAM in the exclusion zone (see below) in the previous two hours;
- NMFS is notified via email as soon as practicable with the time and location in which operations began without an active PAM system; and
- Operations with an active acoustic source, but without an operating PAM system, do not exceed a cumulative total of four hours in any 24-hour period.

Exclusion Zone and Buffer Zone

An exclusion zone is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce the potential for certain outcomes such as auditory injury or more severe disruption of behavioral patterns. For deep penetration surveys, the PSOs shall establish and monitor a 500-m exclusion zone and additional 500-m buffer zone (total 1,000 m) during the pre-clearance period (see below) and a 500-m exclusion zone during the ramp-up and operational periods (see below for description of extended 1,500-m zone in

[19] Shallow penetration surveys are defined as those using airgun arrays with total volume less than or equal to 1,500 in^3, single airguns, boomers, or equivalent sources.

special circumstances). PSOs should generally focus their observational effort within a 1.5-km zone, to the extent possible, with animals observed at greater distances recorded and mitigation action taken as necessary (see below). For shallow penetration surveys, the PSOs shall establish and monitor a 100-m exclusion zone with additional 100-m buffer (total 200-m zone) during the pre-clearance period and a 100-m exclusion zone during the ramp-up (for small arrays only, versus single airguns) and operational periods (see below for description of extended 500-m zone in special circumstances). PSOs should generally focus their observational effort within a 500-m zone, to the extent possible, with animals observed at greater distances recorded and mitigation action taken as necessary (see below). These zones shall be based upon radial distance from any element of the airgun array (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source, occurrence of marine mammals within the buffer zone (but outside the exclusion zone) should be communicated to the operator to prepare for the potential shutdown of the acoustic source. Use of the buffer zone in relation to ramp-up is discussed below under ''Ramp-up.'' Further detail regarding the exclusion zone and shutdown requirements is given under ''Exclusion Zone and Shutdown Requirements.''

Ramp-Up

Ramp-up of an acoustic source is intended to provide a gradual increase in sound levels, enabling animals to move away from the source if the signal is sufficiently aversive prior to its reaching full intensity. We infer on the basis of behavioral avoidance studies and observations that this measure results in some reduced potential for auditory injury and/or more severe behavioral reactions. Although this measure is not proven and some arguments have been made that use of ramp-up may not have the desired effect of aversion (which is itself a potentially negative impact but assumed to be better than the alternative), ramp-up remains a relatively low-cost, common-sense component of standard mitigation for surveys using airgun arrays. Ramp-up is most likely to be effective for more sensitive species (*e.g.,* beaked whales) with known behavioral responses at greater distances from an acoustic source (*e.g.,* Tyack *et al.,* 2011; DeRuiter *et al.,* 2013; Miller *et al.,* 2015). Ramp-up is required for all surveys using airgun arrays. While non-airgun acoustic sources are not typically amenable to ''ramping up'' the acoustic output in the way that multi-element airgun arrays are, power to these sources should be increased as feasible in order to effect a ramp-up.

The ramp-up procedure involves a step-wise increase in the number of airguns firing and total array volume until all operational airguns are activated and the full volume is achieved. Ramp-up is required at all times as part of the activation of the acoustic source (including source tests; see ''Miscellaneous Protocols'' for more detail) and may occur at times of poor visibility, assuming appropriate acoustic monitoring with no detections in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at night where operational planning cannot reasonably avoid such circumstances. For example, a nighttime initial ramp-up following port departure is reasonably avoidable and may not occur. Ramp-up must occur at night following acoustic source deactivation due to line turn or mechanical difficulty. The operator must notify a designated PSO of the planned start of ramp-up as agreed-upon with the lead PSO; the notification time should be at least 60 minutes prior to the planned ramp-up. A designated PSO must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed.

Ramp-up procedures follow the recommendations of IAGC (2015). Ramp-up begins by activating a single airgun (*i.e.,* array element) of the smallest volume in the array. Ramp-up continues in stages by doubling the number of active elements at the commencement of each stage, with each stage of approximately the same duration. Total duration should not be less than approximately 20 minutes but maximum duration is not prescribed and will vary depending on the total number of stages. Von Benda-Beckmann *et al.* (2013), in a study of the effectiveness of ramp-up for sonar, found that extending the duration of ramp-up did not have a corresponding effect on mitigation benefit. There will generally be one stage in which doubling the number of elements is not possible because the total number is not even. This should be the last stage of the ramp-up sequence. The operator must provide information to the PSO documenting that appropriate procedures were followed. Ramp-ups should be scheduled so as to minimize the time spent with the source activated prior to reaching the designated run-in. This approach is intended to ensure a perceptible increase in sound output per increment while employing increments that produce similar degrees of increase at each step.

For deep penetration surveys, PSOs must monitor a 1,000-m zone (or to the distance visible if less than 1,000 m) for a minimum of 30 minutes prior to ramp-up (*i.e.,* pre-clearance). For shallow penetration surveys, PSOs must monitor a 200-m zone (or to the distance visible if less than 200 m) for a minimum of 30 minutes prior to ramp-up or start-up (for single airgun or non-airgun surveys). (Note that extended distance shutdowns, discussed below, may be required if certain species or circumstances are detected within greater distances: 1.5 km for deep penetration surveys and 500 m for shallow penetration surveys). The pre-clearance period may occur during any vessel activity (*i.e.,* transit, line turn). Ramp-up must be planned to occur during periods of good visibility when possible; operators may not target the period just after visual PSOs have gone off duty. Following deactivation of the source for reasons other than mitigation, the operator must communicate the near-term operational plan to the lead PSO with justification for any planned nighttime ramp-up. Any suspected patterns of abuse by the operator must be reported by the lead PSO to be investigated by NMFS. Ramp-up may not be initiated if any marine mammal is within the designated zone. If a marine mammal is observed within the zone during the pre-clearance period, ramp-up may not begin until the animal(s) has been observed exiting the zone or until an additional time period has elapsed with no further sightings (*i.e.,* 15 minutes for small delphinids and 30 minutes for all other species). PSOs will monitor the exclusion zone during ramp-up, and ramp-up must cease and the source shut down upon observation of marine mammals within or approaching the zone.

Exclusion Zone and Shutdown Requirements

Deep Penetration Surveys—The PSOs must establish a minimum exclusion zone with a 500-m radius as a perimeter around the outer extent of the airgun array (rather than being delineated around the center of the array or the vessel itself). If a marine mammal (other than the small delphinid species discussed below) appears within or enters this zone, the acoustic source must be shut down (*i.e.,* power to the acoustic source must be immediately turned off). If a marine mammal is detected acoustically, the acoustic source must be shut down, unless the PAM operator is confident that the

animal detected is outside the exclusion zone or that the detected species is not subject to the shutdown requirement (see below).

The 500-m radial distance of the standard exclusion zone is expected to contain sound levels exceeding peak pressure injury criteria for all hearing groups other than, potentially, high-frequency cetaceans, while also providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. Although significantly greater distances may be observed from an elevated platform under good conditions, NMFS believes that 500 m is likely regularly attainable for PSOs using the naked eye during typical conditions. In addition, an exclusion zone is expected to be helpful in avoiding more severe behavioral responses. Behavioral response to an acoustic stimulus is determined not only by received level but by context (*e.g.,* activity state) including, importantly, proximity to the source (*e.g.,* Southall *et al.,* 2007; Ellison *et al.,* 2012; DeRuiter *et al.,* 2013). In prescribing an exclusion zone, NMFS seeks not only to avoid most potential auditory injury but also to reduce the likely severity of the behavioral response at a given received level of sound.

As discussed in the notice of proposed rulemaking, use of monitoring and shutdown measures within defined exclusion zone distances is inherently an essentially instantaneous proposition—a rule or set of rules that requires mitigation action upon detection of an animal. This indicates that defining an exclusion zone on the basis of thresholds related to the accumulation of energy (*i.e.,* cumulative SEL), which require that an animal accumulate some level of sound energy exposure over some period of time (*e.g.,* 24 hours), has questionable relevance as a standard protocol for mobile sources, given the relative motion of the source and the animals. A PSO aboard a mobile source will typically have no ability to monitor an animal's position relative to the acoustic source over relevant time periods for purposes of understanding whether auditory injury is likely to occur on the basis of cumulative sound exposure and, therefore, whether action should be taken to avoid such potential.

Cumulative SEL (cSEL) thresholds are more relevant for purposes of modeling the potential for auditory injury than they are for dictating real-time mitigation, though they can be informative (especially in a relative sense). NMFS recognizes the importance of the accumulation of sound energy to an understanding of the potential for auditory injury and that it is likely that, at least for low-frequency cetaceans, some potential auditory injury may be impossible to fully avoid, depending on survey location in relation to the areas where these species occur, and should be considered for authorization.

Considering both the dual-metric thresholds described previously (and shown in Table 7) and hearing group-specific marine mammal auditory weighting functions in the context of airgun sources, auditory injury zones indicated by the peak pressure metric are expected to be predominant for both mid- and high-frequency cetaceans, while zones indicated by cSEL criteria are expected to be predominant for low-frequency cetaceans. Assuming a source level of 255.2 dB 0-pk SPL for the notional 8,000 in^3 array and spherical spreading propagation, distances for exceedance of group-specific peak injury thresholds are as follows: 65 m (LF), 18 m (MF), and 457 m (HF) (for high-frequency cetaceans, although the notional source parameters indicate a zone less than 500 m, we recognize that actual isopleth distances will vary based on specific array characteristics and site-specific propagation characteristics, and that it is therefore possible that a real-world distance to the injury threshold could exceed 500 m). Assuming a source level of 227.7 dB 0-pk SPL for the notional 90 in^3 single airgun and spherical spreading propagation, these distances would be 3 m (LF) and 19 m (HF) (the source level is lower than the threshold criterion value for mid-frequency cetaceans). These specific modeled source level values were discussed in the notice of proposed rulemaking, and additional information may be found in the modeling report.

Consideration of auditory injury zones based on cSEL criteria is dependent on the animal's generalized hearing range and how it overlaps with the frequencies produced by the sound source of interest in relation to marine mammal auditory weighting functions (NMFS, 2018). As noted above, zones based on the cSEL threshold are expected to be predominant for low-frequency cetaceans because their most susceptible hearing range overlaps the low frequencies produced by airguns, while the modeling indicates that zones based on peak pressure criteria dominate for mid- and high-frequency cetaceans. As described in detail in the notice of proposed rulemaking, NMFS obtained unweighted spectrum data (modeled in 1 Hz bands) for a reasonably equivalent acoustic source (*i.e.,* a 36-airgun array with total volume of 6,600 in^3) in order to evaluate notional zone sizes and to incorporate NMFS' Technical Guidance weighting functions over an airgun array's full acoustic band. Using NMFS' associated User Spreadsheet with hearing group-specific weighted source levels, and inputs assuming a 231.8 dB SEL source level for the notional 8,000 in^3 array, spherical spreading propagation, a source velocity of 4.5 kn, pulse duration of 100 ms, and a 25-m shot interval (shot intervals may vary, with longer shot intervals resulting in smaller calculated zones), distances for group-specific threshold criteria are as follows: 574 m (LF), 0 m (MF), and 1 m (HF). NMFS also assessed the potential for injury based on the accumulation of energy resulting from use of the single airgun and, assuming a source level of 207.8 dB SEL, there would be no realistic zone within which injury would occur.

Therefore, the 500-m exclusion zone contains the entirety of any potential injury zone for mid-frequency cetaceans (realistically, there is no such zone, as discussed above in Estimated Take and in Comments and Responses), while the zones within which injury could occur may be larger for high-frequency cetaceans (on the basis of peak pressure and depending on the specific array) and for low-frequency cetaceans (on the basis of cumulative sound exposure).

In summary, NMFS' goal in prescribing a standard exclusion zone distance is to (1) encompass zones for most species within which auditory injury could occur on the basis of instantaneous exposure; (2) provide protection from the potential for more severe behavioral reactions (*e.g.,* panic, antipredator response) for marine mammals at relatively close range to the acoustic source; (3) enable more effective implementation of required mitigation by providing consistency and ease of implementation for PSOs, who need to monitor and implement the exclusion zone; and (4) define a distance within which detection probabilities are reasonably high for most species under typical conditions. NMFS' use of 500 m as the zone is not based directly on any quantitative understanding of the range at which auditory injury would be entirely precluded or any range specifically related to disruption of behavioral patterns. Rather, we believe it is a reasonable combination of factors. This zone has been proven as a feasible measure through past implementation by operators in the GOM. In summary, a practicable criterion such as this has the advantage of familiarity and simplicity while still providing in most

cases a zone larger than relevant auditory injury zones, given realistic movement of source and receiver. Increased shutdowns, without a firm idea of the outcome the measure seeks to avoid, simply displace survey activity in time and increase the total duration of acoustic influence as well as total sound energy in the water (due to additional ramp-up and overlap where data acquisition was interrupted). The shutdown requirement described here would be required for most marine mammals, with certain differences. Small delphinids are excepted from the shutdown requirement, as described in the following section. Certain species are subject to an extended distance shutdown zone, as described in the subsequent section entitled ''Other Shutdown Requirements.''

Dolphin Exception—The shutdown requirement described above is in place for all marine mammals, with the exception of small delphinids. As defined here, the small delphinid group is intended to encompass those members of the Family Delphinidae most likely to voluntarily approach the source vessel for purposes of interacting with the vessel and/or airgun array (*e.g.,* bow-riding). (Here we refer to ''large delphinids'' and ''small delphinids'' as shorthand for generally deep-diving versus surface-dwelling/bow-riding groups, respectively, as the important distinction is their dive behavior rather than their size.) This exception to the shutdown requirement applies solely to specific genera of dolphins—*Steno, Tursiops, Stenella,* and *Lagenodelphis* (see Table 4)—and applies under all circumstances, regardless of what the perception of the animal(s) behavior or intent may be. The proposed regulations included a requirement to conduct a power-down upon detection of these species within the exclusion zone. However, in the preamble to the proposed regulations, NMFS also included an alternative proposal for public review and comment in which no shutdown or power-down would be required. We requested comment on both proposals and other variations of those proposals, including NMFS' interpretation of the data and any other data that support the necessary findings regarding dolphins for no shutdown and no power-down or no shutdown but a power-down. Upon review of the public comments received, as well as the scientific information summarized below, NMFS has determined that the alternative proposal of no shutdown or power-down is appropriate, and satisfies the least practicable adverse impact requirement.

Variations of this measure that include exceptions based on animal behavior—*e.g.,* ''bow-riding'' dolphins, or only ''traveling'' dolphins, meaning that the intersection of the animal and exclusion zone may be due to the animal rather than the vessel—have been proposed by both NMFS and BOEM and have been criticized, in part due to the subjective on-the-spot decision-making this scheme would require of PSOs. If the mitigation requirements are not sufficiently clear and objective, the outcome may be differential implementation across surveys as informed by individual PSOs' experience, background, and/or training. The exception described here is based on several factors: The lack of evidence of or presumed potential for the types of effects to these species of small delphinid that our shutdown requirement for other species seeks to avoid, the uncertainty and subjectivity introduced by such a decision framework, and the practicability concern presented by the operational impacts. Despite a large volume of observational effort during airgun surveys, including in locations where dolphin shutdowns have not previously been required (*i.e.,* the U.S. GOM and United Kingdom (UK) waters), we are not aware of accounts of notable adverse dolphin reactions to airgun noise (Stone, 2015a; Barkaszi *et al.,* 2012; Barkaszi and Kelly, 2018) other than one isolated incident (Gray and Van Waerebeek, 2011). Dolphins have a relatively high threshold for the onset of auditory injury (*i.e.,* PTS) and more severe adverse behavioral responses seem less likely given the evidence of purposeful approach and/or maintenance of proximity to vessels with operating airguns.

The best available scientific evidence indicates that auditory injury as a result of airgun sources is extremely unlikely for mid-frequency cetaceans, primarily due to a relative lack of sensitivity and susceptibility to noise-induced hearing loss at the frequency range output by airguns (*i.e.,* most sound below 500 Hz) as shown by the mid-frequency cetacean auditory weighting function (NMFS, 2018). Criteria for TTS in mid-frequency cetaceans for impulsive sounds were derived by experimental measurement of TTS in beluga whales exposed to pulses from a seismic watergun. Dolphins exposed to the same stimuli in this study did not display TTS (Finneran *et al.,* 2002). Moreover, when the experimental watergun signal was weighted appropriately for mid-frequency cetaceans, less energy was filtered than would be the case for an airgun signal. More recently, Finneran *et al.* (2015) exposed bottlenose dolphins to repeated pulses from an airgun and measured no TTS.

NMFS cautions that, while dolphins are observed voluntarily approaching source vessels (*e.g.,* bow-riding or interacting with towed gear), the reasons for the behavior are unknown. In context of an active airgun array, the behavior cannot be assumed to be harmless. Although bow-riding comprises approximately 30 percent of behavioral observations in the GOM, there is a much lower incidence of the behavior when the acoustic source is active (Barkaszi *et al.,* 2012), and this finding was replicated by Stone (2015a) for surveys occurring in UK waters. Some studies have found evidence of aversive behavior by dolphins during firing of airguns. Barkaszi *et al.* (2012) found that the median closest distance of approach to the acoustic source was at significantly greater distances during times of full-power source operation when compared to silence, while Stone (2015a) and Stone and Tasker (2006) reported that behavioral responses, including avoidance and changes in swimming or surfacing behavior, were evident for dolphins during firing of large arrays. Goold and Fish (1998) described a ''general pattern of localized disturbance'' for dolphins in the vicinity of an airgun survey. However, while these general findings—typically, dolphins will display increased distance from the acoustic source, decreased prevalence of ''bow-riding'' activities, and increases in surface-active behaviors—are indicative of adverse or aversive responses that may rise to the level of ''take'' (as defined by the MMPA), they are not indicative of any response of a severity such that the need to avoid it outweighs the impact on practicability for the industry and operators.

Additionally, increased shutdowns resulting from such a measure would require source vessels to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Therefore, the removal of such measures for small delphinids is warranted in consideration of the available information regarding the effectiveness of such measures in mitigating impacts to small delphinids and the practicability of such measures.

Although other mid-frequency hearing specialists (*e.g.,* large delphinids) are considered no more likely to incur auditory injury than are small delphinids, they are more

typically deep divers, meaning that there is some increased potential for more severe effects from a behavioral reaction, as discussed in greater detail in Comments and Responses. Therefore, NMFS anticipates benefit from a shutdown requirement for large delphinids, in that it is likely to preclude more severe behavioral reactions for any such animals in close proximity to the source vessel as well as any potential for physiological effects.

At the same time, large delphinids are much less likely to approach vessels. Therefore, a shutdown requirement for large delphinids would not have similar impacts as a small delphinid shutdown in terms of either practicability for the applicant or corollary increase in sound energy output and time on the water.

Other Surveys—Shutdown protocols for shallow penetration surveys are similar to those described for deep penetration surveys, except that the exclusion zone is defined as a 100-m radial distance around the perimeter of the acoustic source. The dolphin exception described above for deep penetration surveys would apply. As described previously, no shutdowns would be required for HRG surveys.

Extended Shutdown Requirements for Special Circumstances—Shutdown of the acoustic source is also required in the event of certain other detections beyond the standard exclusion zones. In the proposed regulatory text, NMFS conditioned these shutdowns upon detection of the relevant species or circumstances at any distance. However, in the preamble to the proposed regulations, we also included an alternative proposal for public review and comment in which shutdown of the acoustic source would occur in the circumstances listed below, but only within 1 km of the source (for deep penetration surveys). We requested comment on both proposals and other variations of those proposals, including NMFS' interpretation of the data and any other data that support the necessary findings regarding initiating shutdown for certain circumstances at any distance or within 1 km. Following review of public comments and the relevant scientific information, NMFS determined that it is appropriate to limit such shutdown requirements. However, as discussed in the next paragraph, we also determined that the relevant scientific information better supports 1.5 km as a reasonable detection radius (versus 1 km). Placement of a distance limit on these requirements maintains the intent of the measures as originally proposed, *i.e.,* to provide for additional real-time protection by limiting the intensity and duration of acoustic exposures for certain species or in certain circumstances, while reducing the area over which PSOs must maintain observational effort. As for normal shutdowns within the standard exclusion zone, shutdowns at extended distance should be made on the basis of confirmed detections (visual or acoustic) within the zone.

For deep penetration surveys, NMFS determined an appropriate distance on the basis of available information regarding detection functions for relevant species, but notes that, while based on quantitative data, the distance is an approximate limit that is merely intended to encompass the region within which we would expect a relatively high degree of success in sighting certain species while also improving PSO efficacy by removing the potential that a PSO might interpret these requirements as demanding a focus on areas further from the vessel. The appropriate distance limit may vary for different regions, depending on the species to which it may apply. For each modeled taxon, Roberts *et al.* (2016) fitted detection functions that modeled the detectability of the taxon according to distance from the trackline and other covariates (*i.e.,* the probability of detecting an animal given its distance from the transect). These functions were based on nearly 1.1 million linear km of line-transect survey effort conducted from 1992–2014, with surveys arranged in aerial and shipboard hierarchies and further grouped according to similarity of observation protocol and platform. Where a taxon was sighted infrequently, a detection function was fit to pooled sightings of suitable proxy species. For example, for the Bryde's whale and shipboard binocular surveys (*i.e.,* the relevant combination of platform and protocol), a detection function was fit using pooled sightings of Bryde's whales and other mysticete species (Roberts *et al.,* 2015c). The resulting detection function shows a slightly more than 20 percent probability of detecting whales at 2 km, with a mean effective strip half-width (ESHW) (which provides a measure of how far animals are seen from the transect line; Buckland *et al.,* 2001) of 1,309 m (Roberts *et al.,* 2015c). Similarly, Barlow *et al.* (2011) reported mean ESHWs for various mysticete species ranging from approximately 1.5–2 km. The detection function used in modeling density for beaked whales provided mean ESHWs of 1,462 m and 2,258 m for two NOAA vessels on which visual surveys have historically been conducted (Roberts *et al.,* 2015b). Therefore, NMFS set the shutdown radius for special circumstances (described below) at 1.5 km for deep penetration surveys. The shutdown radius for special circumstances is set at 500 m for shallow penetration surveys.

Comments disagreeing with the proposal to require shutdowns upon certain detections at any distance also suggested that the measures did not have commensurate benefit for the relevant species. However, it must be noted that any such observations would still be within range of where behavioral disturbance of some form and degree would be likely to occur. While visual PSOs should focus observational effort within the vicinity of the acoustic source and vessel, this does not preclude them from periodic scanning of the remainder of the visible area or from noting observations at greater distances, and there is no reason to believe that such periodic scans by professional PSOs would hamper the ability to maintain observation of areas closer to the source and vessel. Circumstances justifying shutdown at extended distance (*e.g.,* within 1.5 km) include:

- *Upon detection of a Bryde's whale.* On the basis of the findings of NMFS' status review (Rosel *et al.,* 2016), NMFS has listed the GOM Bryde's whale as an endangered species pursuant to the ESA (April 15, 2019; 84 FR 15446). These whales form a small and resident population in the northeastern GOM, with a highly restricted geographic range and a very small population abundance (fewer than 100)—recently determined by a status review team to be ''at or below the near-extinction population level'' (Rosel *et al.,* 2016). The review team stated that, aside from the restricted distribution and small population, the whales face a significant suite of anthropogenic threats, one of which is noise produced by geophysical surveys. NMFS believes it appropriate to eliminate potential effects to individual Bryde's whales to the extent practicable. There may be rare sightings of vagrant baleen whales of other species in the GOM, and the PSO may order a shutdown when observed in the applicable exclusion zone.
- *Upon detection of a sperm whale.* NMFS provided an expanded discussion of the available evidence that supports this measure in the notice of proposed rulemaking. In summary, the sperm whale's primary means of locating prey is echolocation (Miller *et al.,* 2004), and multiple studies have shown that noise can disrupt feeding behavior and/or significantly reduce foraging success for sperm whales at relatively low levels of exposure (*e.g.,* Miller *et al.,* 2009, 2012; Isojunno *et al.,*

2016; Sivle *et al.,* 2012; Cure *et al.,* 2016). Effects on energy intake with no immediate compensation, as is suggested by disruption of foraging behavior without corollary movements to new locations, would be expected to result in bioenergetics consequences to individual whales. Farmer *et al.* (2018a) developed a stochastic life-stage structured bioenergetic model to evaluate the consequences of reduced foraging efficiency in sperm whales, finding that individual resilience to foraging disruptions is primarily a function of size (*i.e.,* reserve capacity) and daily energetic demands, and that the ultimate effects on reproductive success and individual fitness are largely dependent on the duration and frequency of disturbance. The bioenergetic simulations of Farmer *et al.* (2018a) show that frequent disruptions in foraging, as might be expected when large amounts of survey activity overlap with areas of importance for sperm whales, can have potentially severe fitness consequences. In addition, the GOM sperm whale population was heavily impacted by the DWH oil spill. Therefore, in consideration of the potential energetic impacts of survey activity on individual sperm whales and the environmental baseline for the GOM sperm whale population, NMFS determined that meaningful measures must be taken to minimize disruption of foraging behavior. As described earlier in this section, the proposed regulations limited this extended distance shutdown requirement to acoustic detections of sperm whales. However, while stating that NMFS preliminarily did not believe the addition of shutdowns for sperm whales based on visual detections at any distance were warranted, we also requested any information from the public that would be relevant to that determination. NMFS' review of the comments and information provided by the public indicates that expansion of this requirement to include all sperm whale detections, rather than only acoustic detections (as was proposed), is warranted. Please see Comments and Responses for further discussion.

• *Upon detection of a beaked whale or Kogia spp.* These species are behaviorally sensitive deep divers and it is possible that disturbance could provoke a severe behavioral response leading to fitness consequences (*e.g.,* Wursig *et al.,* 1998; Cox *et al.,* 2006). NMFS recognizes that there are generally low detection probabilities for beaked whales and *Kogia* spp., meaning that many animals of these species may go undetected. Barlow (1999) estimates such probabilities at 0.23 to 0.45 for Cuvier's and Mesoplodont beaked whales, respectively. However, Barlow and Gisiner (2006) predict a roughly 24–48 percent reduction in the probability of detecting beaked whales during seismic mitigation monitoring efforts as compared with typical research survey efforts, and Moore and Barlow (2013) noted a decrease in $g(0)$ for Cuvier's beaked whales from 0.23 at BSS 0 (calm) to 0.024 at BSS 5. Similar detection probabilities have been noted for *Kogia* spp., though they typically travel in smaller groups and are less vocal, thus making detection more difficult (Barlow and Forney, 2007). As discussed previously in this document (see the Estimated Take section), there are high levels of predicted exposures for beaked whales in particular. Because it is likely that only a small proportion of beaked whales and *Kogia* spp. potentially affected by the proposed surveys would actually be detected, it is important to avoid potential impacts when practicable. Additionally for *Kogia* spp.—the one species of high-frequency cetacean likely to be encountered—auditory injury zones relative to peak pressure thresholds are significantly greater than for other cetaceans—approximately 500 m from the acoustic source, depending on the specific real world array characteristics (NMFS, 2018).

Shutdown Implementation Protocols—Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch; hand-held UHF radios are recommended. When both visual PSOs and PAM operators are on duty, all detections must be immediately communicated to the remainder of the on-duty team for potential verification of visual observations by the PAM operator or of acoustic detections by visual PSOs and initiation of dialogue as necessary. When there is certainty regarding the need for mitigation action on the basis of either visual or acoustic detection alone, the relevant PSO(s) must call for such action immediately.

Upon implementation of shutdown, the source may be reactivated after the animal(s) has been observed exiting the exclusion zone or following a 30-minute clearance period with no further detection of the animal(s).

If the acoustic source is shut down for reasons other than mitigation (*e.g.,* mechanical difficulty) for brief periods (*i.e.,* less than 30 minutes), it may be activated again without ramp-up if PSOs have maintained constant observation (including acoustic observation, where required) and no visual detections of any marine mammal have occurred within the exclusion zone and no acoustic detections have occurred (when required). NMFS defines ''brief periods'' in keeping with other clearance watch periods and to avoid unnecessary complexity in protocols for PSOs. For any longer shutdown (*e.g.,* during line turns), pre-clearance watch and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required but if the shutdown period was brief and constant observation maintained, pre-clearance watch is not required.

Miscellaneous Protocols

The acoustic source must be deactivated when not acquiring data or preparing to acquire data, except as necessary for testing. Unnecessary use of the acoustic source should be avoided. Firing of the acoustic source at any volume above the stated production volume would not be authorized. The operator must provide information to the lead PSO at regular intervals confirming the firing volume. Notified operational capacity (not including redundant backup airguns) must not be exceeded during the survey, except where unavoidable for source testing and calibration purposes. All occasions where activated source volume exceeds notified operational capacity must be noticed to the PSO(s) on duty and fully documented for reporting. The lead PSO must be granted access to relevant instrumentation documenting acoustic source power and/or operational volume.

Testing of the acoustic source involving all elements requires normal mitigation protocols (*e.g.,* ramp-up). Testing limited to individual source elements or strings does not require ramp-up but does require pre-clearance.

Restriction Areas

Discussion of various time-area restrictions was provided in the notice of proposed rulemaking. NMFS proposed two time-area restrictions located within the area covered by the current GOMESA moratorium. As discussed previously, BOEM subsequently updated the scope of the specified activity that was the subject of

the petition for the ITR, removing the area subject to the current GOMESA moratorium from consideration through this rule. Therefore, consideration of those two proposed restrictions (Areas 2–3 in Figure 4 below), and any alternatives, is no longer relevant. Figure 4 depicts the time-area restrictions, absent consideration of BOEM's removal of the GOMESA moratorium area. Areas 2 and 3 are entirely within that area, and the eastern extent of Area 1 is functionally reduced through the removal of the GOMESA moratorium area.

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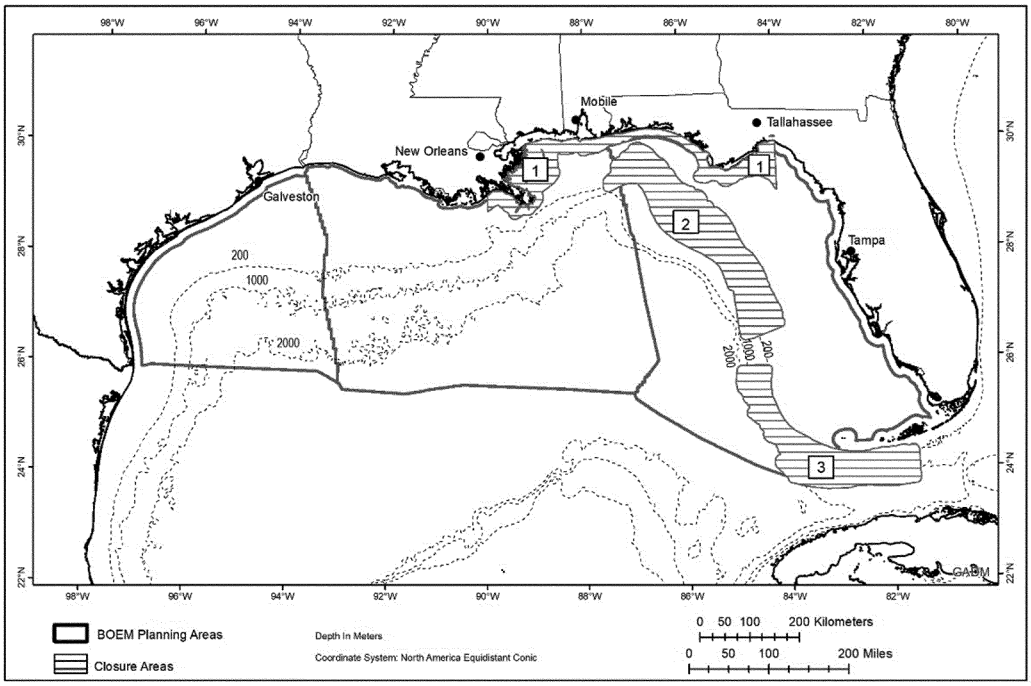

Figure 4. Time-area Restrictions as Originally Proposed. Areas 2 and 3 are not within the area covered by the final rule, which was updated and reduced.

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Coastal Restriction—No airgun surveys may occur from 90–84° W (as truncated through removal of the GOMESA moratorium area) and shoreward of a line indicated by the 20-m isobath, during the months of January through May (Area 1; Figure 4). Waters shoreward of the 20-m isobath, where coastal dolphin stocks occur, represent the areas of greatest abundance for bottlenose dolphins (Roberts *et al.,* 2016). As discussed above, and in greater detail in Comments and Responses, this requirement was modified from the proposed regulations by contracting the area spatially while expanding the restriction temporally by one month, in order to more practicably minimize potential impacts on the potentially affected stock most heavily impacted by the DWH oil spill (*i.e.,* the northern coastal stock of bottlenose dolphins).

The restriction is intended specifically to avoid additional stressors to the northern coastal stock of bottlenose dolphins during the time period believed to be of greatest importance as a reproductive period. As described previously, NOAA estimates that potentially 82 percent of northern coastal dolphins were exposed to DWH oil, resulting in an array of long-term health impacts (including reproductive failure) and possible population reductions of 50 percent for the stock (DWH MMIQT, 2015). The same analysis estimated that these population-level impacts could require 39 years to recovery, in the absence of other additional stressors. More recently, the stock has been subject to another declared UME; further discussion of this UME is provided under Description of Marine Mammals in the Area of the Specified Activity.

The January–May timeframe is intended to best encompass the most important reproductive period for bottlenose dolphins in these coastal waters, when additional stress is most likely to have serious impacts on pregnancy and/or survival of neonates. Expert interpretation of the long-term data for neonate strandings is that February–April are the primary months that animals are born in the northern GOM, and that fewer but similar numbers are born in January and May. This refers to long-term averages and in any particular year the peak reproductive period can shift earlier or later.

Bryde's Whale—The ''Bryde's whale core habitat area'' considered in the notice of proposed rulemaking was designated as between the 100- and 400-m isobaths, from 87.5° W to 27.5° N (Area 2; Figure 4). As summarized at the beginning of this section, and discussed in greater detail in Comments and Responses, the proposed regulatory text included a seasonal restriction within the same area. The preamble to the proposed regulations also included alternative proposals for public review and comment. This area is entirely

located in the GOMESA moratorium area, which is now removed from consideration through this rule.

As described previously, NOAA's status review team determined the status of the GOM Bryde's whale to be precarious (Rosel *et al.,* 2016). These findings formed, in part, the basis for the analysis presented in the preamble to the proposed regulations and subsequently supported NMFS' listing of the GOM Bryde's whale as an endangered species pursuant to the ESA (84 FR 15446; April 15, 2019). These whales form a small and resident population in the northeastern GOM, with a highly restricted geographic range and a very small population abundance—determined by the status review team to be ''at or below the near-extinction population level'' (Rosel *et al.,* 2016). Aside from the restricted distribution and small population, the whales face a significant suite of anthropogenic threats, one of which is noise produced by airgun surveys.

While various population abundance estimates are available (*e.g.,* Waring *et al.,* 2016; Roberts *et al.,* 2016; Dias and Garrison, 2016), the population abundance was almost certainly less than 100 prior to the DWH oil spill. NOAA estimated that, as a result of that event, 48 percent of the population may have been exposed to DWH oil, with 17 percent killed and 22 percent of females experiencing reproductive failure. The best estimate for maximum population reduction was 22 percent, with an estimated 69 years to recovery (to the precarious status prior to the DWH oil spill) (DWH MMIQT, 2015). It is considered likely that Bryde's whale habitat previously extended to shelf and slope areas of the western and central GOM similar to where they are found now in the eastern GOM, and that anthropogenic activity—largely energy exploration and production—concentrated in those areas could have resulted in habitat abandonment (Reeves *et al.,* 2011; Rosel and Wilcox, 2014). Further, the population exhibits very low levels of genetic diversity and significant genetic mitochondrial DNA divergence from other Bryde's whales worldwide (Rosel and Wilcox, 2014).

The small population size, restricted range, and low genetic diversity alone place these whales at significant risk of extinction (IWC, 2017), which has been exacerbated by the effects of the DWH oil spill. Additionally, Bryde's whale dive and foraging behavior places them at heightened risk of being struck by vessels and/or entangled in fishing gear (Soldevilla *et al.,* 2017). NMFS considered a restriction in this core habitat area to protect Bryde's whales because of their hearing sensitivity in the lower frequency range (which makes them generally more susceptible to incurring effects from airgun noise than other taxa in the GOM); the potential impacts to important behavioral functions such as feeding, breeding, and raising young; their dangerously low population size; and other issues discussed previously. The absence of survey activity in the area would be expected to protect Bryde's whales and their habitat through the alleviation or minimization of a range of airgun effects, both acute and chronic, that could otherwise accrue to impact the reproduction or survival of individuals in the core habitat area. The absence of survey activity in the area would not only largely avoid Level B harassment of Bryde's whales, but also very importantly minimize other acoustic effects such as masking and loss of communication space. Based on Roberts *et al.,* 2016, this core habitat area is expected to encompass approximately 92 percent of Bryde's whales in the Gulf of Mexico. The update of the scope of the rule eliminates this core area and the corresponding impacts of concern from consideration in the analysis.

Although this area is no longer relevant under the updated geographic scope of the specified activity and this rule, the discussion above is still important to provide a picture of the species' distribution in the GOM and NMFS' work to identify appropriate mitigation in this rulemaking. Because NMFS acknowledges that some whales may be present at locations other than within this core habitat area, we considered additional information in order to evaluate whether a different closure area may be warranted. For example, a NOAA survey reported observation of a Bryde's whale in the western GOM in 2017 (NMFS, 2018). There had not previously been a verified sighting of a Bryde's whale in the western GOM and, given the importance of this observation, additional survey effort was conducted in an attempt to increase effort in the area. However, no additional sightings were recorded. Overall, Bryde's whales observations have been consistently located within the eastern GOM core habitat area, with few whales sighted elsewhere despite a large amount of dedicated cetacean survey effort that covered both continental shelf and oceanic waters. Whales have been sighted in the core habitat area in all seasons, and all indications are that the whales inhabit this area year-round as a resident population. A tagged whale remained within the area for 38 days, the entire time the tag was active. Therefore, while it is possible that Bryde's whales occur outside the core habitat area, or that whales from the eastern GOM occasionally travel outside the area, the few existing observations outside the eastern GOM do not affect NMFS' determination that the area considered in the proposed rule represents core habitat, or identify any additional important habitat that may appropriately be subject to a restriction on survey activity.

Entanglement Avoidance

The use of ocean-bottom nodes (OBN) or similar equipment requiring the use of tethers or connecting lines poses an entanglement risk. In order to avoid incidents of entanglement, NMFS requires the same measures included for the same purpose in permits issued by BOEM. These measures apply to operators conducting OBN surveys (or surveys using similar equipment), and include: (1) Use negatively buoyant coated wire-core tether cable (*e.g.,* ¾'' polyurethane-coated cable with ½'' wire core); (2) retrieve all lines immediately following completion of the survey; and (3) attach acoustic pingers directly to the coated tether cable. Acoustic releases should not be used. No unnecessary release lines or lanyards may be used and nylon rope may not be used for any component of the system. Pingers must be attached directly to the nodal tether cable via shackle, with cables retrieved via grapnel. If a lanyard is required it must be as short as possible and made as stiff as possible, *e.g.,* by placing inside a hose sleeve. The notice of proposed rulemaking also included a proposed requirement to require operators to employ a third-party PSO aboard the node retrieval vessel in order to document any unexpected marine mammal entanglement. In consideration of the information provided by public commenters, NMFS has determined that this measure is unnecessary and eliminates it from the final ITR. Use of a third-party PSO in this capacity would not help to avoid entanglement events, and operators would be required to report any such events to BSEE. Therefore, the requirement provides little benefit while imposing costs on operators.

Vessel Strike Avoidance

These measures apply to all vessels associated with any survey activity (*e.g.,* source vessels, streamer vessels, chase vessels, supply vessels). However, NMFS notes that these requirements do not apply in any case where compliance would create an imminent and serious

threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply. These measures include the following:

1. Vessel operators and crews must maintain a vigilant watch for all marine mammals and must slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel (distances stated below). Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to (1) distinguish protected species from other phenomena and (2) broadly to identify a marine mammal as a baleen whale, sperm whale, or other marine mammal;

2. Vessel speeds must be reduced to 10 kn or less when mother/calf pairs, pods, or large assemblages of any marine mammal are observed near a vessel;

3. All vessels must maintain a minimum separation distance of 500 m from baleen whales;

4. All vessels must maintain a minimum separation distance of 100 m from sperm whales;

5. All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.,* for animals that approach the vessel); and

6. When marine mammals are sighted while a vessel is underway, the vessel shall take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area). If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

NMFS has carefully evaluated the suite of mitigation measures described here and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of these measures, we have determined that the required mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an LOA for an activity, Section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of the authorized taking. NMFS' MMPA implementing regulations further describe the information that an applicant should provide when requesting an authorization (50 CFR 216.104(a)(13)), including the means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and the level of taking or impacts on populations of marine mammals. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Section 101(a)(5)(A) allows that incidental taking may be authorized only if the total of such taking contemplated over the course of five years will have a negligible impact on affected species or stocks (a finding based on impacts to annual rates of recruitment and survival) and, further, section 101(a)(5)(B) requires that authorizations issued pursuant to 101(a)(5)(A) be withdrawn or suspended if the total taking is having, or may have, more than a negligible impact (or such information may inform decisions on requests for LOAs under the specific regulations). Therefore, the necessary requirements pertaining to monitoring and reporting must address the total annual impacts to marine mammal species or stocks. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

These requirements are described below under ''Data Collection'' and ''LOA Reporting.'' Additional comprehensive reporting, across LOA-holders on an annual basis, is also required and is described below under ''Comprehensive Reporting.''

More specifically, monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species in action area (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Changes To Monitoring and Reporting From the Notice of Proposed Rulemaking

Here we summarize substantive changes to monitoring and reporting requirements from the notice of proposed rulemaking. All changes were made on the basis of review of public comments received and/or review of new information.

- Although NMFS recognizes the importance of producing the most accurate estimates of actual take possible, we agree that the specific approach described in the proposed rule for correcting observations to produce estimates of actual takes is novel in that it has not been previously required of applicants conducting similar activities and, therefore, its appropriateness for application to observations conducted from working source vessels (versus research vessels) is unknown. As suggested through public comment, NMFS will continue to evaluate the best method for producing accurate estimates of actual take, based on marine mammal detections, through the adaptive management process, including consideration of the Marine Mammal Commission-recommended method included in the proposed regulations.
- NMFS has revised requirements relating to reporting of injured or dead marine mammals and has added newly crafted requirements relating to actions that should be taken in response to notification of live stranding events in

certain circumstances, in order to reflect current best practice.

PSO Eligibility and Qualifications

All PSO resumes must be submitted to NMFS and PSOs must be approved by NMFS after a review of their qualifications. These qualifications include whether the individual has successfully completed the necessary training (see ''Training,'' below) and, if relevant, whether the individual has the requisite experience (and is in good standing). PSOs should provide a current resume and information indicating successful completion of an acceptable PSO training course; submitted resumes should not include superfluous information. In order for a PSO training course to be deemed acceptable by NMFS (in consultation with BOEM/BSEE), the agencies must, at minimum, review a course information packet that includes the name and qualifications (*e.g.,* experience, training, or education) of the instructor(s), the course outline or syllabus, and course reference material. Absent a waiver (discussed below), PSOs must be trained biologists, with the following minimum qualifications:

- A bachelor's degree from an accredited college or university with a major in one of the natural sciences and a minimum of 30 semester hours or equivalent in the biological sciences and at least one undergraduate course in math or statistics; and
- Successful completion of relevant training (described below), including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program.

In addition, it is recommended that PSOs meet the following requirements:

- Experience and ability to conduct field observations and collect data according to assigned protocols (may include academic experience) and experience with data entry on computers;
- Visual acuity in both eyes (vision correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target (required for visual PSOs only);
- Experience or training in the field identification of marine mammals, including the identification of behaviors (required for visual PSOs only);
- Sufficient training, orientation, or experience with the survey operation to ensure personal safety during observations;
- Writing skills sufficient to prepare a report of observations (*e.g.,* description, summary, interpretation, analysis) including but not limited to the number and species of marine mammals observed; marine mammal behavior; and descriptions of activity conducted and implementation of mitigation; and
- Ability to communicate orally, by radio or in person, with survey personnel to provide real-time information on marine mammals detected in the area as necessary.

The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver must include written justification, and prospective PSOs granted waivers must satisfy training requirements described below. Alternate experience that may be considered includes, but is not limited to, the following:

- Secondary education and/or experience comparable to PSO duties;
- Previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; and
- Previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

Training—NMFS does not formally administer any PSO training program or endorse specific providers but will approve PSOs that have successfully completed courses that meet the curriculum and trainer requirements specified herein and, therefore, are deemed acceptable. To be deemed acceptable, training should adhere generally to the recommendations provided by ''*National Standards for a Protected Species Observer and Data Management Program: A Model Using Geological and Geophysical Surveys*'' (Baker *et al.,* 2013). Those recommendations include the following topics for training programs:

- Life at sea, duties, and authorities;
- Ethics, conflicts of interest, standards of conduct, and data confidentiality;
- Offshore survival and safety training;
- Overview of oil and gas activities (including geophysical data acquisition operations, theory, and principles) and types of relevant sound source technology and equipment;
- Overview of the MMPA and ESA as they relate to protection of marine mammals;
- Mitigation, monitoring, and reporting requirements as they pertain to geophysical surveys;
- Marine mammal identification, biology and behavior;
- Background on underwater sound;
- Visual surveying protocols, distance calculations and determination, cues, and search methods for locating and tracking different marine mammal species (visual PSOs only);
- Optimized deployment and configuration of PAM equipment to ensure effective detections of cetaceans for mitigation purposes (PAM operators only);
- Detection and identification of vocalizing species or cetacean groups (PAM operators only);
- Measuring distance and bearing of vocalizing cetaceans while accounting for vessel movement (PAM operators only);
- Data recording and protocols, including standard forms and reports, determining range, distance, direction, and bearing of marine mammals and vessels; recording GPS location coordinates, weather conditions, Beaufort wind force and sea state, etc.;
- Proficiency with relevant software tools;
- Field communication/support with appropriate personnel, and using communication devices (*e.g.,* two-way radios, satellite phones, internet, email, facsimile);
- Reporting of violations, noncompliance, and coercion; and
- Conflict resolution.

PAM operators should regularly refresh their detection skills through practice with simulation-modeling software and should keep up to date with training on the latest software/hardware advances.

Visual Monitoring

The lead PSO is responsible for establishing and maintaining clear lines of communication with vessel crew. The vessel operator shall work with the lead PSO to accomplish this and shall ensure any necessary briefings are provided for vessel crew to understand mitigation requirements and protocols. While on duty, PSOs will continually scan the water surface in all directions around the acoustic source and vessel for presence of marine mammals, using a combination of the naked eye and high-quality binoculars, from optimum vantage points for unimpaired visual observations with minimum distractions. PSOs will collect observational data for all marine mammals observed, regardless of distance from the vessel, including species, group size, presence of calves, distance from vessel and direction of travel, and any observed behavior (including an assessment of behavioral responses to survey activity). Upon observation of marine mammal(s), a

PSO will record the observation and monitor the animal's position (including latitude/longitude of the vessel and relative bearing and estimated distance to the animal) until the animal dives or moves out of visual range of the observer, and a PSO will continue to observe the area to watch for the animal to resurface or for additional animals that may surface in the area. PSOs will also record environmental conditions at the beginning and end of the observation period and at the time of any observations, as well as whenever conditions change significantly in the judgment of the PSO on duty.

For all deep penetration surveys, the vessel operator must provide bigeye binoculars of appropriate quality (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) solely for PSO use. These should be pedestal-mounted on the deck at the most appropriate vantage point that provides for optimal sea surface observation, PSO safety, and safe operation of the vessel. Other required equipment, which should be made available to PSOs by the third-party observer provider, includes reticle binoculars of appropriate quality (*e.g.,* 7 x 50), GPS, digital camera with a telephoto lens (the camera or lens should also have an image stabilization system) that is at least 300 mm or equivalent on a full-frame single-lens reflex, compass, and any other tools necessary to adequately perform the tasks described above, including accurate determination of distance and bearing to observed marine mammals.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Specifically, implementation of shutdown requirements will be made on the basis of the PSO's best professional judgment. While PSOs should not insert undue precaution into decision-making, it is expected that PSOs may call for mitigation action on the basis of reasonable certainty regarding the need for such action, as informed by professional judgment. Any modifications to protocol will be coordinated between NMFS and the applicant.

Acoustic Monitoring

Use of towed PAM is required for deep penetration surveys. Monitoring of a towed PAM system is required at all times for these surveys, from 30 minutes prior to ramp-up, throughout all use of the acoustic source, and for 60 minutes following cessation of survey activity. Towed PAM systems should consist of hardware (*e.g.,* hydrophone array, recorder, cables) and software (*e.g.,* data processing program and algorithm). Some type of automated detection software must be used. Acoustic signals are processed for output to the PAM operator with software designed to detect marine mammal vocalizations. Current PAM technology has some limitations (*e.g.,* limited directional capabilities and detection range, detection of signals due to vessel and flow noise, low accuracy in localization) and there are no formal guidelines currently in place regarding specifications for hardware, software, or operator training requirements.

NMFS' requirement to use PAM refers to the use of calibrated hydrophone arrays with full system redundancy to detect, identify, and estimate distance and bearing to vocalizing cetaceans, to the extent possible. With regard to calibration, the PAM system should have at least one calibrated hydrophone, sufficient for determining whether background noise levels on the towed PAM system are sufficiently low to meet performance expectations. Additionally, if multiple hydrophone types occur in a system (*i.e.,* monitor different bandwidths), then one hydrophone from each such type shall be calibrated, and whenever sets of hydrophones (of the same type) are sufficiently spatially separated such that they would be expected to experience ambient noise environments that differ by 6 dB or more across any integrated species cluster bandwidth, then at least one hydrophone from each set should be calibrated. In terms of calibrating the rest of the system, the signal route to the data recorder and monitoring software shall be calibrated so that the binary amplitude data written to hard disk can be converted into units of acoustic pressure. The configuration of hardware should be coupled with appropriate software to aid monitoring and listening by a PAM operator skilled in bioacoustics analysis and computer system specifications capable of running appropriate software. GPS data acquisition is recommended for all PAM operations. If the PAM plan (see below) claims an ability to localize, every localization estimate obtained from a PAM system must be accompanied by some estimate of uncertainty and ambiguity.

In the absence of formal standards addressing any of these three facets of PAM technology, all applicants must provide a PAM plan including description of the hardware and software proposed for use prior to proceeding with any survey where PAM is required. Following the survey, a validation document must be submitted as part of required reporting (see below). The purpose of the PAM plan is to demonstrate that the PAM system being proposed for use is adequate for addressing the mitigation goals. The plan shall include methodology and documentation requirements for all stages of the project. As recommended by Thode *et al.* (2017), PAM plans should, at minimum, adequately address and describe (1) the hardware and software planned for use, including a hardware performance diagram demonstrating that the sensitivity and dynamic range of the hardware is appropriate for the operation; (2) deployment methodology, including target depth/tow distance; (3) definitions of expected operational conditions, used to summarize background noise statistics; (4) proposed detection-classification-localization methodology, including anticipated species clusters (using a cluster definition table), target minimum detection range for each cluster, and the proposed localization method for each cluster; (5) operation plans, including the background noise sampling schedule; (6) array design considerations for noise abatement; and (7) cluster-specific details regarding which real-time displays and automated detectors the operator would monitor. Where relevant, the plan should address the potential for PAM deployment on a receiver vessel or other associated vessel separate from the acoustic source.

Species clusters—The plan shall list the species of concern during the upcoming operation. While some species may be listed individually for special attention, in many circumstances it is expected that for the purposes of a PAM operation multiple species can be grouped together in a ''cluster'' that shares similar acoustic and behavioral characteristics (*e.g.,* sperm whale, beaked whales). The plan must specify a target minimum detection (and possibly localization) range for each species cluster used in the document. Different ranges can be defined for different operational conditions. The PAM system may exceed this detection range, but shall always be capable of achieving this minimum detection range.

Hardware and software specifications—The plan shall have a section dedicated to demonstrating that the PAM hardware is sensitive enough to detect signals from the species clusters of concern at the target minimum detection ranges specified. The plan should include a hardware

specification table and hardware performance diagram. The diagram will show the sensitivity and bandwidth of the combined array hardware and recording system, as well as the received levels required for a given species cluster to be detectable at the target minimum detection range. The overall goal of the diagram is to visually demonstrate that the planned PAM array/recording system would have the capability of detecting various species clusters at required target ranges, provided that background noise levels are not an issue.

Operational conditions—The validation document should demonstrate whether the PAM system has been compromised by excessive background noise, whether that noise is electronic interference, flow, platform, or environmental noise. Therefore, the plan shall define a set of ''operational conditions'' under which detection statistics (background noise profiles) will be categorized during the project. Operational conditions consist of three categories: Platform activity and status, mitigation (activity) status, and environmental status.

Operating procedures—The plan shall describe the level of effort that is reasonably expected to occur for the monitoring requirements. For every species cluster, the plan should detail which part of the PAM display would be used for detecting that cluster. For example, if a scrolling spectrogram display is being used for a species cluster, then the spectrogram's fast Fourier transform sample size, frequency bandwidth, and their refresh rate shall be specified. Similar details would be provided for other software tools, such as click detectors and other automated detectors and classifiers. The plan shall also provide a screenshot of the expected monitor display.

In coordination with vessel crew, the lead PAM operator will be responsible for deployment, retrieval, and testing and optimization of the hydrophone array. While on duty, the PAM operator must diligently listen to received signals and/or monitoring display screens in order to detect vocalizing cetaceans, except as required to attend to PAM equipment. The PAM operator must use appropriate sample analysis and filtering techniques and must report all cetacean detections. While not required prior to development of formal standards for PAM use, NMFS recommends that vessel self-noise assessments be undertaken during mobilization in order to optimize PAM array configuration according to the specific noise characteristics of the vessel and equipment involved, and to refine expectations for distance/bearing estimations for cetacean species during the survey. Copies of any vessel self-noise assessment reports must be included with the summary trip report.

Data Collection

PSOs must use standardized electronic data forms. PSOs will record detailed information about any implementation of mitigation requirements, including the distance of animals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source to resume survey. If required mitigation was not implemented, PSOs should submit a description of the circumstances. NMFS requires that, at a minimum, the following information be reported:

- Vessel names (source vessel and other vessels associated with survey), vessel size and type, maximum speed capability of vessel, port of origin, and call signs;
- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Dates and participants of PSO briefings;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort begins and ends and vessel location at beginning and end of visual PSO duty shifts;
- Vessel location at 30 second intervals (if software capability allows) or 5 minute intervals (if location must be manually recorded);
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort scale and any other relevant weather conditions including cloud cover, fog, sun glare, night, and overall visibility to the horizon;
- Vessel location when environmental conditions change significantly;
- Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions);
- Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in an array, tow depth of an acoustic source, and any other notes of significance (*i.e.,* pre-clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.);
- If a marine mammal is sighted, the following information should be recorded:
  - Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
  - PSO who sighted the animal and PSO location (including height above water) at time of sighting;
  - Time of sighting;
  - Vessel location at time of sighting;
  - Water depth;
  - Direction of vessel's travel (compass direction);
  - Direction of animal's travel relative to the vessel;
  - Pace of the animal;
  - Estimated distance to the animal (and method of estimating distance) and its heading relative to vessel at initial sighting;
  - Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and PSO confidence in identification; also note the composition of the group if there is a mix of species;
  - Estimated number of animals (high/low/best);
  - Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
  - Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);
  - Detailed behavior observations (*e.g.,* number of blows, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
  - Animal's closest point of approach (CPA) and/or closest distance from the acoustic source;
  - Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and
  - Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up); time and location of the action should also be recorded;
- If a marine mammal is detected while using the PAM system, the following information should be recorded:
  - An acoustic encounter identification number, and whether the detection was linked with a visual sighting;

○ Time when first and last heard;

○ Types and nature of sounds heard (*e.g.,* clicks, whistles, creaks, burst pulses, continuous, sporadic, strength of signal, etc.); and

○ Any additional information recorded such as water depth of the hydrophone array, bearing of the animal to the vessel (if determinable), species or taxonomic group (if determinable), spectrogram screenshot, and any other notable information.

LOA Reporting

PSO effort, survey details, and sightings data should be recorded continuously during surveys. Reports must include all information described above under ''Data Collection,'' including amount and location of line-kms surveyed and all marine mammal observations with closest approach distance. Reports must be submitted to NMFS within 90 days of survey completion or following expiration of an issued LOA. In the event that an LOA is issued for a period exceeding one year, annual reports must be submitted during the period of validity. The draft report must be accompanied by a certification from lead PSOs as to the accuracy of the report. A final report must be submitted within 30 days following resolution of any comments on the draft report.

The report must describe the operations conducted and sightings of marine mammals near the operations; provide full documentation of methods, results, and interpretation pertaining to all monitoring; summarize the dates and locations of survey operations, and all marine mammal sightings (dates, times, locations, activities, associated survey activities); and provide information regarding locations where the acoustic source was used. The LOA-holder shall provide geo-referenced time-stamped vessel tracklines for all time periods in which airguns (full array or single) were operating. Tracklines should include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off). GIS files shall be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates should be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available to NMFS.

This report must also include a validation document concerning the use of PAM (if PAM was required), which should include necessary noise validation diagrams (NVD) and demonstrate whether background noise levels on the PAM deployment limited achievement of the planned detection goals. A separate diagram shall be produced for every background noise percentile chosen for analysis. Background noise percentiles, rather than a simple average of the data, are required because the highly non-stationary characteristics of many background noise profiles cannot be described by a simple mean. For example, data collected during a seismic survey will have short periods of time containing high-intensity pulses and longer periods of time dominated by lower levels of reverberation. Taking a simple mean of these noise data would imply background noise levels substantially higher than what may actually have been present between seismic pulses. A validation report would typically contain between three to five diagrams, depending on the number of percentiles analyzed. At a minimum, the validation report should contain three diagrams that include the 50th percentile (median), 5th percentile, and 95th percentile. The 25th percentile and 75th percentile may also be included. In each percentile diagram, a separate background noise curve shall be drawn for each defined operational condition. In general, the NVD should be generated from the data stream that is used for detecting the presence of marine mammal signals. For example, if beamforming or some other form of array gain has been applied before invoking signal detection, then the NVD should be generated using the beamformed data, and not omnidirectional data. The complete set of NVDs, one for each percentile of interest, combined with a table that lists the fraction of time the activity was in each operational state, provides a means of reviewing the background noise-limitations encountered by the PAM system during various operational conditions. Actual marine mammal detections should be plotted on this diagram for a reasonableness check on the expected received levels. Overall, the validation document should reiterate all the goals and parameters stated in the planning document and verify that goals were/were not met, why, changes, etc. Also, the validation document should state whether the planning was suited to the needs of the survey and met the required mitigation standards.

There are multiple reasons why marine mammals may be present and yet be undetected by observers. Animals are missed because they are underwater (availability bias) or because they are available to be seen, but are missed by observers (perception and detection biases) (*e.g.,* Marsh and Sinclair, 1989). Negative bias on perception or detection of an available animal may result from environmental conditions, limitations inherent to the observation platform, or observer ability. In this case, we do not have prior knowledge of any potential negative bias on detection probability due to observation platform or observer ability. Therefore, it may be appropriate to make observational data corrections with respect to assumed species-specific detection probability as evaluated through consideration of environmental factors (*e.g., f*(0)). Appropriate methods will be considered through the adaptive management process.

The report must include a post-survey estimate of the instances of take of each species utilizing the line miles of survey actually conducted and the same methods used to initially predict the estimated take in the LOA application. Depending on the length and dates of the survey, LOA-holders may be required to segment take estimates into specific years to support the administration of the rule.

Comprehensive Reporting

Individual LOA-holders will be responsible for collecting and submitting monitoring data to NMFS, as described above. In addition, on an annual basis, LOA-holders will also collectively be responsible for compilation and analysis of those data for inclusion in subsequent annual synthesis reports. Individual LOA-holders may collaborate to produce this report or may elect to have their trade associations support the production of such a report. These reports would summarize the data presented in the individual LOA-holder reports, provide analysis of these synthesized results, discuss the implementation of required mitigation, and present any recommendations. This comprehensive annual report would be the basis of an annual adaptive management process (described below in Adaptive Management). The following topics will be described in comprehensive reporting:

- Summary of geophysical survey activity by survey type, geographic zone (*i.e.,* the seven zones described in the modeling report), month, and acoustic source status (*e.g.,* inactive, ramp-up, full-power, power-down);
- Summary of monitoring effort (on-effort hours and/or distance) by acoustic source status, location, and visibility conditions (for both visual and acoustic monitoring);
- Summary of mitigation measures implemented (*e.g.,* delayed ramp-ups,

shutdowns, course alterations for vessel strike avoidance) by survey type and location;

- Sighting rates of marine mammals during periods with and without acoustic source activities and other variables that could affect detectability of marine mammals, such as:
  - Initial sighting distances of marine mammals relative to source status;
  - Closest point of approach of marine mammals relative to source status;
  - Observed behaviors and types of movements of marine mammals relative to source status;
  - Distribution/presence of marine mammals around the survey vessel relative to source status; and
  - Analysis of the effects of various factors influencing the detectability of marine mammals (*e.g.,* wind speed, sea state, swell height, presence of glare or fog).
- Estimates of total take across all activities for which take is authorized based on actual survey effort and original estimation method;
- Summary and conclusions from monitoring in previous year; and
- Recommendations for adaptive management.

Each annual comprehensive report should cover one full year of monitoring effort and must be submitted for review each year. Each report should analyze survey and monitoring effort described in reports submitted by individual LOA-holders during a given one-year period, beginning from the date of effectiveness of these regulations. Each annual comprehensive report must be submitted for review 90 days following conclusion of the annual reporting period.

Reporting Injured or Dead Marine Mammals

Discovery of Injured or Dead Marine Mammal—In the event that personnel involved in the survey activities covered by the authorization discover an injured or dead marine mammal, the LOA-holder shall report the incident to the Office of Protected Resources (OPR), NMFS and to the regional stranding network as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel Strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, the LOA-holder shall report the incident to OPR, NMFS and to the regional stranding network as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Species identification (if known) or description of the animal(s) involved;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Estimated size and length of animal that was struck;
- Description of the behavior of the marine mammal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Actions To Minimize Additional Harm to Live-Stranded (or Milling) Marine Mammals

For deep penetration surveys, in the event of a live stranding (or near-shore atypical milling) event within 50 km of the survey operations, where the NMFS stranding network is engaged in herding or other interventions to return animals to the water, the Director of OPR, NMFS (or designee) will advise the LOA-holder of the need to implement shutdown procedures for all active acoustic sources operating within 50 km of the stranding. Shutdown procedures for live stranding or milling marine mammals include the following:

- If at any time, the marine mammals die or are euthanized, or if herding/intervention efforts are stopped, the Director of OPR, NMFS (or designee) will advise the LOA-holder that the shutdown around the animals' location is no longer needed.
- Otherwise, shutdown procedures will remain in effect until the Director of OPR, NMFS (or designee) determines and advises the LOA-holder that all live animals involved have left the area (either of their own volition or following an intervention).
- If further observations of the marine mammals indicate the potential for re-stranding, additional coordination with the LOA-holder will be required to determine what measures are necessary to minimize that likelihood (*e.g.,* extending the shutdown or moving operations farther away) and to implement those measures as appropriate.

Shutdown procedures are not related to the investigation of the cause of the stranding and their implementation is not intended to imply that the specified activity is the cause of the stranding. Rather, shutdown procedures are intended to protect marine mammals exhibiting indicators of distress by minimizing their exposure to possible additional stressors, regardless of the factors that contributed to the stranding.

Additional Information Requests—If NMFS determines that the circumstances of any marine mammal stranding found in the vicinity of the activity suggest investigation of the association with survey activities is warranted (example circumstances noted below), and an investigation into the stranding is being pursued, NMFS will submit a written request to the LOA-holder indicating that the following initial available information must be provided as soon as possible, but no later than 7 business days after the request for information.

- Status of all sound source use in the 48 hours preceding the estimated time of stranding and within 50 km of the discovery/notification of the stranding by NMFS; and
- If available, description of the behavior of any marine mammal(s) observed preceding (*i.e.,* within 48 hours and 50 km) and immediately after the discovery of the stranding.

Examples of circumstances that could trigger the additional information request include, but are not limited to, the following:

- Atypical nearshore milling events of live cetaceans;
- Mass strandings of cetaceans (two or more individuals, not including cow/calf pairs);
- Beaked whale strandings; or,
- Necropsies with findings of pathologies that are unusual for the species or area.

In the event that the investigation is still inconclusive, the investigation of the association of the survey activities is still warranted, and the investigation is still being pursued, NMFS may provide additional information requests, in writing, regarding the nature and location of survey operations prior to the time period above.

Negligible Impact Analysis and Determinations

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base a negligible impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the type of take, the likely nature of any behavioral responses (*e.g.,* intensity, duration), the context of any such responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into these analyses via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality).

For each potential activity-related stressor, NMFS considers the potential effects to marine mammals and the likely significance of those effects to the species or stock as a whole. Potential risk due to vessel collision and related mitigation measures, as well as potential risk due to entanglement and contaminant spills, was addressed under Mitigation and in the Potential Effects of the Specified Activity on Marine Mammals section of this notice and the notice of proposed rulemaking and are not discussed further, as there are minimal risks expected from these potential stressors.

The ''specified activity'' for these regulations is a broad program of geophysical survey activity that could occur at any time of year in U.S. waters of the GOM, within the specified geographical region as updated by BOEM (*i.e.,* excluding the GOMESA leasing moratorium area). In recognition of the broad scale of this activity in terms of geographic and temporal scales, we use a new analytical methodology—first described by Ellison *et al.* (2015) and proposed for use and discussed in detail in the notice of proposed rulemaking—through which an explicit, systematic risk assessment framework is applied to evaluate potential effects of aggregated discrete acoustic exposure events (*i.e.,* proposed geophysical survey activities) on marine mammals. This risk assessment framework is one component of the overall negligible impact analysis. Development of the approach was supported collaboratively by BOEM and NMFS, which together provided guidance to an expert working group (EWG) in terms of application to relevant regulatory processes. The risk assessment framework (or EWG framework) is described by Southall *et al.* (2017), which is available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-oil-and-gas.* That document is a companion to this analysis, and is referred to hereafter as the ''EWG report.'' The risk assessment framework is also described below. It was developed and implemented by the EWG in relation to the specified activity described in the proposed rule, provided for public review in association with the notice of proposed rulemaking (Southall *et al.,* 2017), and subsequently refined in response to public comment and in consideration of the updated scope of the activity. We incorporate the framework and its results into this analysis.

The EWG framework described below comprehensively considers the aggregate impacts to marine mammal populations from the activities addressed in this rule in the context of both (1) the severity of the impacts and (2) the vulnerability of the affected species. However, it does not consider the effects of the mitigation required through these regulations in identifying risk ratings for the affected species. In addition, while the EWG framework comprehensively considers the spatial and temporal overlay of the activities and the marine mammals in the GOM, as well as the number of takes predicted by the described modeling (both in the proposed rule, and as updated in this final rule), there are details about the nature of any ''take'' anticipated to result from these activities that were not considered directly in the EWG framework analysis that warrant explicit consideration in the negligible impact determination. Last, the EWG framework analysis addresses impacts to guilds in some cases where there is not specific information to further support species-specific findings. Accordingly, following the description of the EWG framework below, NMFS highlights a few factors regarding the nature of the predicted ''takes'' and then brings together the results of implementation of the EWG framework, these additional factors, and the anticipated effects of the mitigation to summarize the negligible impact analysis for each of the affected species or stocks.

EWG Risk Assessment

The acoustic exposure modeling (Zeddies *et al.,* 2015, 2017a) provided marine mammal noise exposure estimates based on BOEM-provided projections of future survey effort and best available modeling of sound propagation, animal distribution, and animal movement. This provided a conservative but reasonable best estimate of potential acute noise exposure events that may result from the described suite of activities, and formed the basis for the analysis in the proposed rule. BOEM subsequently updated the scope of its activity, which reduced the amount of activity overall through removal of projected activity in the eastern GOM (see Table 1 and Figure 2). Acoustic exposure estimates were updated by BOEM accordingly (based on the same modeling presented in the proposed rule) and these revised estimates form the basis for this updated analysis.

The primary goal of this new analytical effort was to develop a systematic risk assessment framework that would use the modeling results to put into biologically-relevant context the level of potential risk of injury and/or disturbance to marine mammals. The risk assessment framework considers both the aggregation of acute effects and the broad temporal and spatial scales over which chronic effects may occur. Previously, Wood *et al.* (2012) conducted an analysis of a proposed airgun survey, in which the authors derived a qualitative risk assessment method of considering the biological significance of exposures predicted to be consistent with the onset of physical injury and behavioral disturbance. Subsequently, Ellison *et al.* (2015) described development of a more systematic and (in some cases)

quantitative basis for a risk assessment approach to assess the biological significance and potential population consequences of predicted noise exposures. The approach for this final rule, which incorporates the revised acoustic exposure modeling results as an input, includes certain modifications to and departures from the conceptual approach described by Ellison *et al.* (2015). These are described in greater detail in the EWG report.

Generally, this approach is a relativistic risk assessment that provides an interpretation of the exposure estimates within the context of key biological and population parameters (*e.g.,* population size, life history factors, compensatory ability of the species, animal behavioral state, aversion), as well as other biological, environmental, and anthropogenic factors. This analysis as updated since BOEM revised the scope of its action was performed on a species-specific basis within each modeling zone (Figure 3) for a high-effort scenario (represented by Year 1 of BOEM's revised effort projections) and a moderate-effort scenario (represented by Year 4 of BOEM's revised effort projections). (For most species, the maximum annual take occurs under the Year 1 scenario. The two exceptions are the bottlenose dolphin and Atlantic spotted dolphin, for which the maximum annual take occurs under the Year 4 scenario.) The end result provides an indication of the biological significance of these exposure numbers for each affected marine mammal stock (*i.e.,* yielding the severity of impact and vulnerability of stock/population information), and forecasts the likelihood of any such impact. This result is expressed as relative impact ratings of overall risk that couple potential severity of effect on a stock and likely vulnerability of the population to the consequences of those effects, given biologically relevant information (*e.g.,* compensatory ability).

Spectral, temporal, and spatial overlaps between survey activities and animal distribution are the primary factors that drive the type, magnitude, and severity of potential effects on marine mammals, and these considerations are integrated into both the severity and vulnerability assessments. In discussion with BOEM and NMFS, the EWG developed a strategic approach to balance the weight of these considerations between the two assessments, specifying and clarifying where and how the interactions between potential disturbance and species within these dimensions are evaluated. Overall ratings are then considered in conjunction with the required mitigation (and any additional relevant contextual information) to ultimately inform our determinations. Elements of this approach are subjective and relative within the context of this program of projected actions and, overall, the analysis necessarily requires the application of professional judgment.

Severity of Effect

Level A Harassment—In order to evaluate the potential severity of the expected potential takes by Level A harassment (accounting for aversion) (Table 9) on the species or stock, the EWG framework uses a potential biological removal (PBR)-equivalent metric. As described previously, PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population. To be clear, NMFS does not expect any of the potential occurrences of injury (*i.e.,* permanent threshold shift (PTS)) that may be authorized under this rule to result in mortality of marine mammals, nor should Level A harassment be considered a ''removal'' in the context of PBR when used to inform a negligible impact determination. PTS is not appropriately considered equivalent to serious injury. However, PBR can serve as a gross indicator of the status of the species and a good surrogate for population vulnerability/health and, accordingly, PBR or a related metric can be used appropriately to inform a separate analysis to evaluate the potential relative severity to the population of a permanent impact such as PTS on a given number of individuals. This analysis is used to assess relative risks to populations as a result of PTS; NMFS does not expect that Level A harassment could directly result in mortality and our use of the PBR metric in this context should not be interpreted as such.

However, exposure estimates generated using habitat-based density models (Roberts *et al.,* 2016) cannot appropriately be directly related to the PBR values found in NMFS' SARs. Therefore, a modified PBR value was derived on the basis of the typical pattern for NMFS' PBR values, where the value varies between approximately 0.6–0.9 percent of the minimum population abundance depending upon population confidence limits (higher with increasing confidence). For endangered species, PBR values are typically ⅕ of the values for non-endangered species due to assumption of a lower recovery factor—endangered species are typically assigned recovery factors of 0.1, while species of unknown status relative to the optimum sustainable population level (*i.e.,* most species) are typically assigned factors of 0.5. This basic relationship of population size relative to PBR was used to define the following relative risk levels due to Level A harassment.

- Very high—Level A harassment greater than 1.5 or 0.3 percent (the latter figure is used for endangered species) of zone-specific estimated population abundance.
- High—0.75–1.5 or 0.15–0.3 percent of zone-specific population.
- Moderate—0.375–0.75 or 0.075–0.15 percent of zone-specific population.
- Low—0.075–0.375 or 0.015–0.075 percent of zone-specific population.
- Very low—less than 0.075 or less than 0.015 percent of zone-specific population.

Relative severity scores by zone (Figure 3) and species were determined for high and moderate annual effort scenarios. As described previously, we do not believe that Level A harassment is likely to actually occur for mid-frequency cetaceans and therefore do not predict (nor will we authorize) any take by Level A harassment for these species (*i.e.,* most species in the GOM).

Bryde's whales (a low-frequency cetacean species) are expected to be present primarily in Zones 1 and 4 (though may be present to a lesser extent in Zones 2 and 5). BOEM's update to the geographic scope of its action removed the entirety of Zone 1 and the majority of Zone 4 from consideration in this rule. Altogether, no incidents of Level A harassment are predicted for Bryde's whales.

Kogia spp. (high-frequency cetacean species) are primarily present in Zones 4–7. We assess the relative severity resulting from injury for *Kogia* spp. to be ''very high'' in Zones 5–7 under both evaluated activity scenarios. In Zone 4, relative severity is ''high'' under the moderate effort scenario, and no activity is projected in Zone 4 under the high effort scenario.

In summary, we assess that there is no risk of Level A harassment for any mid-frequency cetacean species. Overall severity associated with take by Level A harassment is expected to be very high for *Kogia* spp. and very low for Bryde's whales, as no incidents of Level A harassment are predicted for the stock.

We note that regardless of the relative risk assessed in this framework, because of the anticipated received levels and duration of sound exposure expected for any marine mammals exposed above Level A harassment criteria, no individuals of any species or stock are

expected to receive more than a relatively minor degree of PTS, which would not be expected to meaningfully increase the likelihood or severity of any potential population-level effects. See ''Loss of Hearing Sensitivity,'' below, for additional discussion.

Level B Harassment—As described above in Estimated Take, a significant model assumption was that populations of animals were reset for each 24-hr period. Exposure estimates for the 24-hr period were then aggregated across all assumed survey days as completely independent events, assuming populations turn over completely within each large zone on a daily basis. In order to evaluate modeled daily exposures and determine more realistic exposure probabilities for individuals across multiple days, we used information on species-typical movement behavior to determine a species-typical offset of modeled daily exposures, using the exploratory analysis discussed under Estimated Take (*i.e.,* Test Scenario 1). In this test scenario, modeled results were compared for a 30-day period versus the aggregation of 24-hr population reset intervals. When conducting computationally-intensive modeling over the full assumed 30-day survey period (versus aggregating the smaller 24-hr periods for 30 days), results showed about 10–45 percent of the total number of takes calculated using a 24-hr reset of the population, with differences relating to species-typical movement and residency patterns. Given that many of the evaluated survey activities occur for 30-day or longer periods, particularly some of the larger surveys for which the majority of the modeled exposures occur, using such a scaling process is appropriate in order to evaluate the likely severity of the predicted exposures and to estimate take for the purposes of LOA applications and predicting the number of individual marine mammals taken during the course of a single survey (although, as noted previously, for surveys significantly longer than 30 days, the take numbers with this scaling applied would still be expected to overestimate the number of individuals, given the greater degree of repeat exposures that would be expected the longer the survey goes on). This output was used in a severity assessment. This approach is also discussed in more detail in the EWG report.

Similar to the evaluation of severity for Level A harassment, the scaled Level B harassment takes were rated through a population-dependent binning system. For each species, scaled takes were divided by the zone-specific predicted abundance, and these proportions were used to evaluate the relative severity of modeled exposures based on the distribution of values across species to evaluate risk associated with behavioral disruption across species—a simple, logical means of evaluating relative risk across species and areas. Relative risk ratings using percent of area population size were defined as follows:

- Very high—Adjusted Level B harassment takes greater than 800 percent of zone-specific population;
- High—Adjusted Level B harassment takes 401–800 percent of zone-specific population;
- Moderate—Adjusted Level B harassment takes 201–400 percent of zone-specific population;
- Low—Adjusted Level B harassment takes 100–200 percent of zone-specific population; and
- Very low—Adjusted Level B harassment takes less than 100 percent of zone-specific population.

Vulnerability of Affected Population

Vulnerability rating seeks to evaluate the relative risk of a predicted effect given species-typical and population-specific parameters (*e.g.,* species-specific life history, population factors) and other relevant interacting factors (*e.g.,* human or other environmental stressors). The assessment includes consideration of four categories within two overarching risk factors (species-specific biological and environmental risk factors). These values were selected to capture key aspects of the importance of spatial (geographic), spectral (frequency content of noise in relation to species-typical hearing and sound communications), and temporal relationships between sound and receivers. Explicit numerical criteria for identifying scores were specified where possible, but in some cases qualitative judgments based on a reasonable interpretation of given aspects of the proposed activity and how it relates to the species in question and the environment within the specified area were required. Factors considered in the vulnerability assessment were detailed in Southall *et al.* (2017) and are reproduced here (Table 11). Note that the effects of the Deepwater Horizon oil spill are accounted for through the non-noise chronic anthropogenic risk factor identified below, while the effects to acoustic habitat and on individual animal behavior via masking (summarized in Potential Effects of the Specified Activity on Marine Mammals and Their Habitat and described in detail in that section of the notice of proposed rulemaking) are accounted for through the masking and chronic anthropogenic noise risk factors. Species-specific vulnerability scoring according to this scheme is shown in Table 12. Zone-specific vulnerability ratings corresponding with the scores given in Table 12 below are provided in Tables 8–10 of the EWG report.

TABLE 11—VULNERABILITY ASSESSMENT FACTORS

	Score
Masking: Degree of spectral overlap between biologically important acoustic signals and predominant noise source of proposed activity (max: 7 out of 30):	
Communication masking: Predominant noise energy directly/partially overlaps[1] species-specific signals utilized for communication.	+3/+1
Foraging masking: Predominant noise energy directly/partially overlaps[1] species-specific signals utilized in foraging (including echolocation and other foraging coordination signals).	+2/+1
Navigation/Orientation signal masking: Predominant noise energy directly/partially overlaps[1] signals likely utilized in spatial orientation to which species is well capable of hearing.	+2/+1
Species population: Stock status, trend, and size (max: 7 out of 30):	
Population status: Endangered (ESA) and/or depleted (MMPA) (Y/N)	+3/0
Trend rating: Decreasing/unknown or data deficient/stable (*i.e.,* within 5 percent)/increasing (last three SARs for which new population estimates were updated).	+2/+1/0/−1
Population size: Small (less than 2,500)	+2
Species habitat use and compensatory abilities: Degree to which activity within a specified area[2] overlaps with species habitat and distribution (max: 7 out of 30):	
Habitat use: Survey area contains greater than 30/15–30/5–15/less than 5 percent of total region-wide estimated population (during defined survey period).	+4/+2/+1/0

TABLE 11—VULNERABILITY ASSESSMENT FACTORS—Continued

	Score
Temporal sensitivity: Survey overlaps temporally with well-defined species-specific biologically-important period (*e.g.,* calving).	Up to +3
Other (chronic) noise and non-noise stressors: Magnitude of other potential sources of disturbance or other stressors that may influence a species response to additional noise and disturbance of the proposed activity (max: 9 out of 30):	
Chronic anthropogenic noise: Species subject to high/moderate degree of current or known future (overlapping activity) chronic anthropogenic noise.	+2/+1
Chronic anthropogenic risk factors (non-noise): Species subject to high/moderate degree of current or known future risk from other chronic, non-noise anthropogenic activities (*e.g.,* fisheries interactions, ship strike).	Up to +4/+2
Chronic biological risk factors (non-noise): Known presence of disease, parasites, prey limitation, or high predation pressure.	Up to +3

[1] Direct or partial overlap means that the predominant spectral content of received noise exposure from activity specific sources is expected to occur at identical frequencies as signals of interest, or that secondary (lower-level) spectral content of received noise exposure from activity specific sources is expected to occur at identical frequencies as signals of interest.
[2] This is the area over which an activity is evaluated and a local population is determined, in this case the seven modeling zones.

TABLE 12—VULNERABILITY ASSESSMENT SCORING [1]

Species	Communication	Foraging	Navigation	Status	Trend	Size	Habitat	Time	Chronic noise	Chronic other	Biological risk	Total score range
Bryde's whale	3	2	2	3	2	2	0–4	0–1	1–2	0–3	0	16–23
Sperm whale	1	1	2	3	2	2	0–4	0–1	1–2	0–3	0	14–18
Kogia spp.	0	0	1	0	2	2	0–4	0–1	1–2	0–3	0	8–13
Beaked whale	0	0	1	0	1	0	0–4	0–1	1–2	0–3	1	6–13
Rough-toothed dolphin	0	0	1	0	2	0	1–4	0–1	1–2	0–3	0	6–10
Bottlenose dolphin	1	0	1	0	−1	0	0–4	0–1	1–2	0–3	0	2–10
Clymene dolphin	0	0	1	0	2	0	0–4	0–1	1–2	0–3	0	6–10
Atlantic spotted dolphin	1	0	1	0	1	0	0–4	0–1	1–2	0–3	2	6–14
Pantropical spotted dolphin	0	0	1	0	2	0	0–4	0–1	1–2	0–3	0	6–10
Spinner dolphin	0	0	1	0	0	0	0–4	0–1	1–2	0–3	0	3–9
Striped dolphin	0	0	1	0	2	0	0–4	0–1	1–2	0–3	0	6–10
Fraser's dolphin	0	0	1	0	1	2	0–4	0–1	1–2	0–3	0	7–11
Risso's dolphin	0	0	1	0	−1	0	0–4	0–1	1–2	0–3	1	4–9
Melon-headed whale	0	0	1	0	2	0	0–4	0–1	1–2	0–3	0	6–10
Pygmy killer whale	0	0	1	0	2	2	0–4	0–1	1–2	0–3	0	8–12
False killer whale	0	0	1	0	−1	0	0–4	0–1	1–2	0–3	0	3–7
Killer whale	1	0	1	0	2	2	0–4	0–1	1–2	0–3	0	9–12
Short-finned pilot whale	1	0	1	0	0	2	0–4	0–1	1–2	0–3	1	7–13

[1] Factors with a single value presented are those that remain constant across zones; other factors vary based on zone and a range of values is presented.

TABLE 13—VULNERABILITY RATING SCHEME

Total score	Risk probability (% of total)	Vulnerability rating
24–30	80–100	Very high.
18–23	60–79	High.
12–17	40–59	Moderate.
6–11	20–39	Low.
0–5	0–19	Very low.

Risk

In the final step of the framework, severity and vulnerability ratings are integrated to provide relative impact ratings of overall risk. Severity and vulnerability assessments each produce a numerical rating (1–5) corresponding with the qualitative rating (*i.e.,* very low, low, moderate, high, very high). A matrix is then used to integrate these two scores to provide an overall risk assessment. The matrix is shown in Table 2 of Southall *et al.* (2017).

The likely severity of effect was assessed as the percentage of total population affected based on scaled modeled Level B harassment takes relative to zone population size. There is no risk due to the effects of survey activity when there is no survey activity in a given zone for a given effort scenario. However, a stock's inherent zone-specific vulnerability score drives the risk rating in those zones (Zone 1 under any activity scenario and Zone 4 under the high effort scenario), and risk ratings for all zones are considered

together in generating scenario-specific GOM-wide risk ratings for each species. Also, zones predicted to contain abundance of less than 0.05 percent of the GOM-wide population for a species were considered to have *de minimis* risk and are not included in derivation of the stock-specific GOM-wide rating.

Table 14 provides relative impact ratings by zone, and Table 15 provides GOM-wide relative impact ratings, for overall risk associated with predicted takes by Level B harassment, for representative high and moderate effort scenarios.

TABLE 14—OVERALL EVALUATED RISK BY ZONE AND ACTIVITY SCENARIO

Species	Zone 1 [1]		Zone 2		Zone 3		Zone 4 [1]		Zone 5		Zone 6		Zone 7	
	H	M	H	M	H	M	H	M	H	M	H	M	H	M
Bryde's whale	L	L	L	L	n/a	n/a	L	L	L	L	n/a	n/a	n/a	n/a
Sperm whale	n/a	n/a	n/a	n/a	n/a	n/a	L	L	VH	VH	M	L	L	L
Kogia spp.	VL	VL	n/a	n/a	n/a	n/a	L	L	H	M	L	VL	VL	VL
Beaked whale	n/a	n/a	n/a	n/a	n/a	n/a	VL	VL	VH	VH	H	M	M	L
Rough-toothed dolphin	VL	VL	L	M	VL	VL	VL	VL	H	M	M	L	VL	VL
Bottlenose dolphin	VL	VL	H	H	VL	VL	VL	VL	VL	VL	n/a	n/a	n/a	n/a
Clymene dolphin	n/a	n/a	n/a	n/a	n/a	n/a	VL	VL	H	M	M	L	VL	VL
Atlantic spotted dolphin	L	L	H	VH	VL	VL	VL	VL	M	L	n/a	n/a	n/a	n/a
Pantropical spotted dolphin	VL	VL	n/a	n/a	n/a	n/a	VL	VL	H	M	L	VL	L	L
Spinner dolphin	VL	VL	n/a	n/a	n/a	n/a	VL	VL	H	M	n/a	n/a	VL	VL
Striped dolphin	n/a	n/a	n/a	n/a	n/a	n/a	VL	VL	H	M	L	VL	L	VL
Fraser's dolphin	VL	VL	VL	VL	VL	VL	VL	VL	M	L	L	VL	VL	VL
Risso's dolphin	VL	VL	n/a	n/a	n/a	n/a	VL	VL	H	M	M	VL	VL	VL
Melon-headed whale	VL	VL	n/a	n/a	n/a	n/a	VL	VL	H	M	M	VL	VL	VL
Pygmy killer whale	VL	VL	n/a	n/a	n/a	n/a	VL	VL	M	L	L	VL	VL	VL
False killer whale	VL	VL	VL	VL	VL	VL	VL	VL	H	M	L	VL	VL	VL
Killer whale	VL	VL	VL	VL	VL	VL	VL	VL	L	L	VL	VL	L	L
Short-finned pilot whale	n/a	n/a	n/a	n/a	n/a	n/a	VL	VL	M	M	M	VL	VL	VL

H = Year 1 (representative high effort scenario); M = Year 4 (representative moderate effort scenario).
n/a = less than 0.05% of GOM-wide population predicted in zone.
VL = very low; L = low; M = moderate; H = high; VH = very high.
[1] No activity would occur in Zone 1, and no activity is projected in Zone 4 under the high effort scenario.

TABLE 15—OVERALL EVALUATED RISK BY ACTIVITY SCENARIO, GOM-WIDE

Species	High effort scenario (Year 1)	Moderate effort scenario (Year 4)
Bryde's whale	Low	Low.
Sperm whale	Moderate [1]	Low.
Kogia spp.	Low	Very low.
Beaked whales	High [1]	Moderate.[1]
Rough-toothed dolphin	Very low	Very low.
Bottlenose dolphin (shelf/coastal)	Very low	Very low.
Bottlenose dolphin (oceanic)	Very low	Very low.
Clymene dolphin	Low	Low.[1]
Atlantic spotted dolphin	Low	Low.
Pantropical spotted dolphin	Low	Very low.
Spinner dolphin	Very low	Very low.
Striped dolphin	Low	Very low.
Fraser's dolphin	Very low	Very low.
Risso's dolphin	Very low	Very low.
Melon-headed whale	Very low	Very low.
Pygmy killer whale	Very low	Very low.
False killer whale	Very low	Very low.
Killer whale	Very low	Very low.
Short-finned pilot whale	Low	Low.[1]

[1] For these ratings, the median value across zones for the scenario fell between two ratings, and the higher rating is presented.

In order to characterize the relative risk for each species across their entire range in the GOM, the EWG analysis used the median of the seven zone-specific risk ratings for each activity scenario (high and moderate effort), not counting those in which less than 0.05 percent of the GOM-wide abundance occurred, to describe a GOM-wide risk rating for each of the representative activity scenarios (Table 15).

Overall, the results of the risk assessment show that (as expected), risk is highly correlated with effort and density. Areas where little or no survey activity is predicted to occur or areas within which few or no animals of a particular species are believed to occur have very low or no potential risk of negatively affecting marine mammals, as seen across activity scenarios in Zones 1, 3, and 4. Areas with consistently high levels of effort (Zones 2, 5, 6, and 7) are generally predicted to have higher overall evaluated risk across all species. However, fewer species of animals are expected to be present in Zone 2, where we primarily expect shelf species such as bottlenose and Atlantic spotted dolphins. In Zone 7, animals are expected to be subject to less other chronic noise and non-noise stressors, which is reflected in the vulnerability scoring for that zone. Therefore, despite consistently high levels of projected effort, overall rankings for that zone are lower than for Zones 5 and 6.

Zones 2 and 5 were the only zones with ''very high'' levels of risk due to behavioral disturbance, identified for two species of particular concern in Zone 5 (beaked and sperm whales) and for Atlantic spotted dolphins in Zone 2 (moderate effort scenario only). As particularly sensitive species, beaked whales and sperm whales consistently receive relatively high severity scores. For sperm whales, this sensitivity is manifest through typically higher vulnerability scoring, whereas the assumed sensitivity of beaked whales to

noise exposure is expressed through the application of behavioral harassment criteria (Table 6) and, therefore, relatively high assumed take numbers. Bottlenose dolphins and Atlantic spotted dolphin are generally the only species expected to commonly occur in relatively shallow waters of the continental shelf (Zones 1–3) and relatively high risk is assessed for these species in Zone 2, across activity scenarios. Relatively moderate levels of risk were also identified for other species in some contexts, and these are generally explained by the interaction of specific factors related to survey effort concentration and areas of heightened geographic distribution or specific factors related to population trends or zone-related differences in vulnerability. Overall, following BOEM's update to the geographic scope of activity (with the entirety of Zone 1, most of Zone 4, and one-third of Zone 7 removed from consideration here; see Table 1) the greatest relative risk across species is generally seen in Zones 5 and 6.

When considered across both representative activity scenarios (Table 15), only beaked whales are considered to have relatively high risk (under the high effort scenario only). Relatively moderate risk is assessed for beaked whales under the moderate effort scenario. Relatively moderate risk is also assessed for sperm whales under the high effort scenario. The rest of the species have no more than low to very low risk under either scenario. Shelf/coastal and oceanic bottlenose dolphin stocks, rough-toothed dolphins, spinner dolphins, Fraser's dolphins, Risso's dolphins, melon-headed whales, pygmy killer whales, false killer whales, and killer whales are assessed as having no greater than very low relative risk under any scenario.

Although the scores generated by the EWG framework and further aggregated across zones (as described above) are species-specific, additional stock-specific information can be gleaned through the zone-specific nature of the analysis. For example, with some bottlenose dolphin stocks, the zones align with stock range edges. The oceanic stock of bottlenose dolphins occurs within Zones 4–7, while coastal and shelf stocks occur within Zones 1–3 (sufficient information is not available to attribute takes on a stock-specific basis in Zones 1–3). These species-specific risk ratings are broadly applied in NMFS' negligible impact analysis to all of the multiple stocks that are analyzed in this rule (Table 4). However, NMFS is also considering additional stock-specific information in our analysis, where appropriate, as indicated in our Description of Marine Mammals in the Area of the Specified Activity, Potential Effects of the Specified Activity on Marine Mammals and Their Habitat, and Mitigation sections (*e.g.,* coastal bottlenose dolphins were heavily impacted by the DWH oil spill, and we have therefore required a time/area restriction to reduce impacts).

Duration of Level B Harassment Exposures

In order to more fully place the predicted amount of take into meaningful context, it is useful to understand the duration of exposure at or above a given level of received sound, as well as the likely number of repeated exposures across days. While a momentary exposure above the criteria for Level B harassment counts as an instance of take, that accounting does not make any distinction between fleeting exposures and more severe encounters in which an animal may be exposed to that received level of sound for a longer period of time. Yet this information is meaningful to an understanding of the likely severity of the exposure, which is relevant to the negligible impact evaluation and not directly incorporated into the risk assessment framework described above. For example, for bottlenose dolphins exposed to noise from 3D WAZ surveys in Zone 6, the modeling report shows that approximately 72 takes (Level B harassment) would be expected to occur in a 24-hr period. However, each animat modeled has a record or time history of received levels of sound over the course of the modeled 24-hr period. The 50th percentile of the cumulative distribution function indicates that the time spent exposed to levels of sound above 160 dB rms SPL (*i.e.,* the 50 percent midpoint for Level B harassment) would be only 1.8 minutes—a minimal amount of exposure carrying little potential for significant disruption of behavioral activity. We provide summary information regarding the total average time in a 24-hr period that an animal would spend with received levels above 160 dB and between 140 and 160 dB in Table 16.

Additionally, as we discussed in the Estimated Take section of the notice of proposed rulemaking for Test Scenario 1 (and summarized above), by comparing exposure estimates generated by multiplying 24-hr exposure estimates by the total number of survey days versus modeling for a full 30-day survey duration for six representative species, we were able to refine the exposure estimates to better reflect the number of individuals exposed above threshold within a single survey. Using this same comparison and scalar ratios described above, we are able to predict an average number of days each of the representative species modeled in the test scenario were exposed above the Level B harassment thresholds within a single survey. As with the duration of exposures discussed above, the number of repeated exposures is important to an understanding of the severity of effects. For example, the ratio for beaked whales indicates that the 30-day modeling showed that approximately 10 percent as many individual beaked whales (compared to the results produced by multiplying average 24-hr exposure results by the 30-day survey duration) could be expected to be exposed above harassment thresholds. However, the approach of scaling up the 24-hour exposure estimates appropriately reflects the instances of exposure above threshold (which cannot be more than 1 in 24 hours), so the inverse of the scalar ratio suggests the average number of days in the 30-day modeling period that beaked whales are exposed above threshold is approximately ten. It is important to remember that this is an average and that it is likely some individuals would be exposed on fewer days and some on more. Table 16 reflects the average days exposed above threshold for the indicated species having applied the scalar ratios described previously.

TABLE 16—TIME IN MINUTES (PER DAY) SPENT ABOVE THRESHOLDS (50TH PERCENTILE) AND AVERAGE NUMBER OF DAYS INDIVIDUALS TAKEN DURING 30-DAY SURVEY

Species	Survey type and time (min/day) above 160 dB rms (50% take)				Survey type and time (min/day) above 140 dB rms (10% take)				Average number of days "taken" during 30-day survey
	2D	3D NAZ	3D WAZ	Coil	2D	3D NAZ	3D WAZ	Coil	
Bryde's whale	7.6	18.2	6.8	21.4	61.7	163.5	55.4	401.1	5.3
Sperm whale	5.2	10.3	4.0	20.7	12.0	31.8	10.7	25.2	2.4

TABLE 16—TIME IN MINUTES (PER DAY) SPENT ABOVE THRESHOLDS (50TH PERCENTILE) AND AVERAGE NUMBER OF DAYS INDIVIDUALS TAKEN DURING 30-DAY SURVEY—Continued

Species	Survey type and time (min/day) above 160 dB rms (50% take)				Survey type and time (min/day) above 140 dB rms (10% take)				Average number of days "taken" during 30-day survey
	2D	3D NAZ	3D WAZ	Coil	2D	3D NAZ	3D WAZ	Coil	
Kogia spp.	3.2	7.9	2.8	15.3	7.6	19.0	6.7	13.9	3.1
Beaked whale [1]	6.0	12.4	4.4	24.0	16.2	39.7	14.1	31.1	9.9
Rough-toothed dolphin	3.0	6.3	2.5	11.4	11.2	27.6	10.2	20.9	3.5
Bottlenose dolphin	4.5	11.7	4.0	16.8	22.0	54.6	19.7	53.2	3.5
Clymene dolphin	1.8	3.9	1.6	8.7	8.0	21.1	7.2	20.4	3.5
Atlantic spotted dolphin	7.0	16.0	6.5	25.7	23.4	58.1	20.9	49.3	3.5
Pantropical spotted dolphin	1.8	4.1	1.6	8.7	8.1	21.0	7.1	22.2	3.5
Spinner dolphin	3.2	8.5	2.7	16.4	12.4	31.0	10.8	22.8	3.5
Striped dolphin	1.8	4.0	1.6	8.5	8.0	21.0	7.2	21.3	3.5
Fraser's dolphin	2.8	6.4	2.4	13.8	9.4	24.2	8.4	24.0	3.5
Risso's dolphin	3.4	8.4	2.9	15.3	13.8	37.7	12.2	31.5	3.5
Melon-headed whale	2.6	5.9	2.2	13.1	9.3	24.2	8.3	24.0	3.4
Pygmy killer whale	1.8	3.6	1.4	7.1	7.3	18.5	6.6	17.3	3.4
False killer whale	2.4	4.9	1.9	9.3	8.8	22.0	8.0	17.8	3.4
Killer whale	2.7	6.1	3.3	12.0	16.8	46.1	14.9	73.6	3.4
Short-finned pilot whale	3.3	8.1	2.9	17.5	10.9	27.4	9.8	20.8	3.4

[1] Beaked whales are evaluated according to a different scale where 90% of the population exposed above 140 dB rms is considered taken and 50% of the population exposed above 120 dB rms is considered taken.

Loss of Hearing Sensitivity

In general, NMFS expects that noise-induced hearing loss, whether temporary (temporary threshold shift, equivalent to Level B harassment) or permanent (PTS, the only form of Level A harassment that may result from this action), is only possible as a result of airgun survey activity for low-frequency and high-frequency cetaceans. The best available scientific information indicates that low-frequency cetacean species (*i.e.,* mysticete whales, including the Bryde's whale) have heightened sensitivity to frequencies in the range output by airguns, as shown by their auditory weighting function, whereas high-frequency cetacean species (including *Kogia* spp.) have heightened sensitivity to noise in general (as shown by their lower threshold for the onset of PTS) (NMFS, 2018). However, no instances of Level A harassment are predicted to occur for Bryde's whales, and Level A harassment of Bryde's whales will not be authorized under this rule.

Level A harassment is predicted to occur for *Kogia* spp. (as indicated in Table 9 and evaluated in the ''Level A harassment'' subsection above). However, the degree of injury (hearing impairment) is expected to be mild. If permanent hearing impairment occurs, it is most likely that the affected animal would lose a few dB in its hearing sensitivity, which in most cases would not be expected to affect its ability to survive and reproduce. Hearing impairment that occurs for these individual animals would be limited to at or slightly above the dominant frequency of the noise sources. In particular, the predicted PTS resulting from airgun exposure is not likely to affect their echolocation performance or communication, as *Kogia* spp. likely produce acoustic signals at frequencies above 100 kHz (Merkens *et al.,* 2018), well above the frequency range of airgun noise. Further, modeled exceedance of Level A harassment criteria typically resulted from being near an individual source once, rather than accumulating energy from multiple sources. Overall, the modeling indicated that exceeding the SEL threshold is a rare event, and having four vessels close to each other (350 m between tracks) did not cause appreciable accumulation of energy at the ranges relevant for injury exposures. Accumulation of energy from independent surveys is expected to be negligible. This is relevant for *Kogia* spp. because based on their expected sensitivity, we expect that aversion may play a stronger role in avoiding exposures above the peak pressure PTS threshold than we have accounted for.

For both Bryde's whales and *Kogia* spp., some subset of the individual marine mammals predicted to be taken by Level B harassment may incur some TTS in addition to being behaviorally harassed. For Bryde's whales, TTS is more likely to occur at frequencies important for communication. However, any TTS incurred would be expected to be of a relatively small degree and short duration. This is due to the low likelihood of sound source approaches of the proximity or duration necessary to cause more severe TTS, given the fact that both sound source and marine mammals are continuously moving, the anticipated effectiveness of shutdowns, and general avoidance by marine mammals of louder sources.

For these reasons, and in conjunction with the required mitigation, NMFS does not believe that Level A harassment (here, PTS) or Level B harassment in the form of TTS will play a meaningful role in the overall degree of impact experienced by marine mammal populations as a result of the projected survey activity. Further, the impacts of any TTS incurred are addressed along with behavioral disruption through the broader analysis of Level B harassment.

Impacts to Habitat

Potential impacts to marine mammal habitat, including to marine mammal prey, were discussed in detail in the notice of proposed rulemaking and summarized herein (see Potential Effects of the Specified Activities on Marine Mammals and Their Habitat as well as responses to comments concerning these issues).

Regarding impacts to prey species such as fish and invertebrates, NMFS' review of the available information leads to a conclusion that the most likely impact of survey activity would be temporary avoidance of an area, with a rapid return to pre-survey distribution and behavior, and minimal impacts to recruitment or survival anticipated. Therefore, the specified activities are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to prey species are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Regarding potential impacts to acoustic habitat, NMFS previously summarized a detailed analysis of

potential cumulative and chronic effects to marine mammals (found in the CCE report available online at *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico*). That analysis focused on potential effects to sperm whales (which also provides a conservative proxy regarding potential effects to other mid- and high-frequency cetacean species) and to Bryde's whales. Regarding sperm whales, the analysis shows that the survey activities do not significantly contribute to the soundscape in the frequency band relevant for their lower-frequency slow-clicks, and that there will be no significant change in communication space for sperm whales. Similar conclusions may be assumed for other mid- and high-frequency cetacean species.

Implications for acoustic masking and reduced communication space resulting from noise produced by airgun surveys in the GOM are expected to be particularly heightened for animals that actively produce low-frequency sounds or whose hearing is attuned to lower frequencies (*i.e.,* Bryde's whales). The strength of the communication space approach used here is that it evaluates potential contractions in the availability of a signal of documented importance to a population of animals of key management interest in the region. In this case, losses of communication space for Bryde's whales were estimated to be higher in eastern and central GOM canyons and shelf break areas. In contrast, relative maintenance of listening area and communication space was seen within the Bryde's whale core habitat area in the eastern GOM. The result was heavily influenced by the projected lack of survey activity in that region, which underscores the importance of maintaining this important habitat for the Bryde's whale. Following BOEM's update to the scope of activity considered herein, no survey activity will occur under this rule within Bryde's whale core habitat, or within the broader eastern GOM. In areas where larger amounts of survey activity were projected, significant loss of low-frequency listening area and communication space for Bryde's whale calls was estimated. However, these are areas where Bryde's whales are unlikely to occur (*i.e.,* deeper waters of the central and western GOM).

Species and Stock-Specific Negligible Impact Analysis Summaries

In this section, we consider the relative impact ratings described above in conjunction with the required mitigation and other relevant contextual information in order to produce a final assessment of impact to the stock or species, *i.e.,* the negligible impact determinations. The effects of the DWH oil spill are accounted for through the vulnerability scoring (Table 12). NMFS developed mitigation requirements for consideration in the proposed rule, including time-area restrictions, designed specifically to provide benefit to certain populations for which a relatively high amount of risk is predicted in relation to exposure to survey noise. The required time-area restrictions, described in detail in Proposed Mitigation in the notice of proposed rulemaking and depicted in Figure 4, were designed specifically to provide benefit to the bottlenose dolphin, Bryde's whale, and beaked and sperm whales, with additional benefits to *Kogia* spp., which are often found in higher densities in the same locations of greater abundance for beaked and sperm whales. Two of the three time-area restrictions in the proposed rule—the Bryde's whale core habitat area and the Dry Tortugas area (Areas #2 and 3; Figure 4)—are eliminated from consideration as a result of BOEM's update to the geographic scope of action, as these two areas are entirely within the portion of the GOM removed from consideration. The bottlenose dolphin area, as revised herein (see Mitigation), is included in this final rule.

Although the Bryde's whale core habitat and Dry Tortugas areas are not the subject of restrictions on survey activity, as the updated scope of activity considered here does not include those two areas, the beneficial effect for animals in those areas, and the stocks of which they are a part, remains the same. No survey activity in those areas can be considered for LOAs issued under this rule. In addition, we expect the lack of survey activity in those areas to provide some subsidiary benefit to additional species that may be present, as indicated in the sections below and reflected in the updated take estimates.

The absence of survey activity in those two areas benefits both the primary species for which they were designed and species that may benefit secondarily by likely reducing the portion of a stock likely exposed to survey noise and avoiding impacts to certain species in areas of importance for them. These areas are discussed more specifically in the context of the species and stocks they were designed to protect in the Proposed Mitigation section of the notice of proposed rulemaking, and are summarized in the sections below.

Bryde's Whale

First, we note that the estimated (and allowable) take of Bryde's whales has been reduced as compared to the proposed rule as a result of the change in scope. Specifically, both the maximum annual take and the average annual take decreased by approximately 98 percent. The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for Bryde's whales are low, regardless of activity scenario. We note that, although the evaluated severity of take for Bryde's whales is very low in all zones where take could occur, vulnerability for the species is assessed as high in all zones where the species occurs. When integrated through the risk framework as described above, overall risk for the species is therefore assessed as low for both the high and moderate effort scenarios. Evaluated risk is lower than what was considered in the proposed rule, where analysis of the prior take estimates resulted in a risk rating of moderate for both scenarios.

We further consider the likely severity of any predicted behavioral disruption of Bryde's whales in the context of the likely duration of exposure above Level B harassment thresholds. Specifically, the average modeled time per day spent at received levels above 160 dB rms (where 50 percent of the exposed population is considered taken) ranges from 6.8–21.4 minutes for deep penetration survey types. The average time spent exposed to received levels between 140 and 160 dB rms (where 10 percent of the exposed population is considered taken) ranges from 55–164 minutes for 2D, 3D NAZ, and 3D WAZ surveys, and 401 minutes for coil surveys (which comprise approximately 10 percent of the total activity days).

Importantly, no survey activity will occur within the Bryde's whale core habitat area pursuant to this rule. The absence of survey activity in the area is expected to benefit Bryde's whales and their habitat by minimizing a range of potential effects of airgun noise, both acute and chronic, that could otherwise accrue to impact the reproduction or survival of individuals in this area. Absence of survey activity in this area will minimize disturbance of the species in the place most important to them for critical behaviors such as foraging and socialization. Based on Roberts *et al.* (2016), the area encompasses approximately 92 percent of the predicted abundance of Bryde's whales in the GOM. Intensive survey effort in

the region has not resulted in any confirmed Bryde's whale sightings outside this core habitat area (aside from a single anomalous sighting in the western GOM). Although some sound from airguns may still propagate into the Bryde's whale core habitat area from surveys that may occur outside of the area (in certain locations where separation distance between the core habitat area and the area considered for survey activity through this rule is less; see Figure 2), exposure of Bryde's whales to sound levels that may be expected to result in Level B harassment will be eliminated or reduced for animals within the Bryde's whale core area. The absence of survey activity in this area and significant reduction in associated exposure of Bryde's whales to seismic airgun noise is expected to eliminate the likelihood of auditory injury of Bryde's whales. Finally, the absence of survey activity in the eastern GOM will reduce chronic exposure of Bryde's whales to higher levels of anthropogenic sound and the associated effects including masking, disruption of acoustic habitat, long-term changes in behavior such as vocalization, and stress.

As described in the preceding ''Loss of Hearing Sensitivity'' section, we have analyzed the likely impacts of potential temporary hearing impairment and do not expect that they would result in impacts on reproduction or survival of any individuals. The extended shutdown zone for Bryde's whales (1,500 m)—to be implemented in the unlikely event that a Bryde's whale is encountered outside of the core habitat area—is expected to further minimize the severity of any hearing impairment incurred as well as reducing the likelihood of more severe behavioral responses. Similarly, application of this extended distance shutdown requirement when calves are present will minimize the potential for and degree of disturbance during this sensitive life stage.

No mortality of Bryde's whales is anticipated or authorized. It is possible that Bryde's whale individuals in this stock, if encountered in areas not typically considered to be Bryde's whale habitat, will be impacted briefly on one or more days during a year of activity by one type of survey or another and some subset of those exposures above thresholds may be of comparatively long duration within a day. However, the significant and critical protection afforded through the absence of survey activity in the core habitat area and the associated reduction in estimated take ensures that the impacts of the expected takes from these activities are not likely to adversely affect the GOM stock of Bryde's whales through impacts on annual rates of recruitment or survival.

Sperm Whale

First, we note that the estimated (and allowable) take of sperm whales has been reduced as compared to the proposed rule as a result of the change in scope. Specifically, the maximum annual take decreased by approximately 62 percent and the average annual take decreased by approximately 58 percent. The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for sperm whales were between moderate and low (equivalent to a 2.5 on a 5-point scale, with a 3 equating to ''moderate'') (for the high effort scenario) or low (for the moderate effort scenario). Evaluated risk is reduced from the proposed rule, where the high effort scenario resulted in a very high risk rating and the moderate effort scenario resulted in a high risk rating. We further consider the likely severity of any predicted behavioral disruption of sperm whales in the context of the likely duration of exposure above Level B harassment thresholds. Specifically, the average modeled time per day spent at received levels above 160 dB rms (where 50 percent of the exposed population is considered taken) ranges from 4–10.3 minutes for 2D, 3D NAZ, and 3D WAZ surveys and up to 20.7 minutes for coil surveys (which comprise less than 10 percent of the total projected activity days) and the average time spent between 140 and 160 dB rms (where 10 percent of the exposed population is considered taken) is 12–31.8 minutes.

Odontocetes echolocate to find prey, and while there are many different strategies for hunting, one common pattern, especially for deeper-diving species, is to conduct multiple repeated deep dives within a feeding bout, and multiple bouts within a day, to find and catch prey. While exposures of the short durations noted above could potentially interrupt a dive or cause an individual to relocate to feed, such a short-duration interruption would typically be unlikely to have significant impacts on an individual's energy budget. However, the moderate risk rating for the high effort scenario reflects the higher number of total days across which these singularly more minor impacts may occur, as well as other factors, and points to the need for the consideration of additional reduction of impacts where possible. In years when less effort occurs, as represented by the moderate effort scenario, risk will be less.

Importantly, no survey activity is expected within the Dry Tortugas Mitigation Area, which was analyzed and proposed for implementation in the proposed rule. The area provides preferred habitat for comparatively high densities of sperm whales and is thought to be used as a calving area. The absence of survey activity in the area is expected to alleviate some of the previous impacts of concern to sperm whales (as well as beaked whales and *Kogia* spp.) and their habitat by minimizing a range of potential effects of airgun noise, both acute and chronic, that could otherwise accrue to impact the reproduction or survival of individuals in this area. Absence of survey activity in this area will minimize disturbance of the species in a place of importance for critical behaviors such as foraging and socialization and, overall, helps to reduce evaluated risk to the stock as a whole.

Additionally, we note that the extended distance shutdown zone for sperm whales (1,500 m) is expected to further reduce the likelihood and minimize the severity of more severe behavioral responses. Similarly, application of this extended distance shutdown requirement when calves are present will minimize the potential for and degree of disturbance during this sensitive life stage.

No mortality or Level A harassment of sperm whales is anticipated or authorized. While it is likely that the majority of the individual sperm whales will be impacted briefly on one or more days during a year of activity by one type of survey or another, based on the nature of the individual exposures (shorter duration) and takes, as well as the aggregated scale of the impacts across the GOM in consideration of the mitigation discussed here, the impacts of the expected takes from these activities are not likely to adversely affect the GOM stock of sperm whales through adverse impacts on annual rates of recruitment or survival.

Beaked Whales

In consideration of the similarities in the nature and scale of impacts, we consider the GOM stocks of Cuvier's, Gervais', and Blainville's beaked whales together in this section. First, we note that the estimated (and allowable) take of beaked whales has been reduced as compared to the proposed rule as a result of the change in scope. Specifically, the maximum annual take decreased by approximately 19 percent and the average annual take decreased

by approximately 15 percent. The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for beaked whales were between high and moderate (equivalent to a 3.5 on a 5-point scale, with a 4 equating to ''high'') for the high effort scenario and between moderate and low (equivalent to a 2.5 on a 5-point scale, with a 3 equating to ''moderate'') for the moderate effort scenario. Evaluated risk is reduced from the proposed rule, where the high effort scenario resulted in a very high risk rating and the moderate effort scenario resulted in a high risk rating. We further consider the likely severity of any predicted behavioral disruption of beaked whales in the context of the likely duration of exposure above Level B harassment thresholds. Beaked whales are considered more behaviorally sensitive to sound than most other species, and therefore we utilize different thresholds to predict behavioral disturbance. However, this means that beaked whales are evaluated as ''taken'' upon exposure to received sound levels as low as 120 dB (where 50 percent of the exposed beaked whale population is considered taken). These received levels are typically reached at extreme distance from the acoustic source (*i.e.,* greater than 50 km from the source). Behavioral responses to noise are significantly correlated with distance from the source (*e.g.,* Gomez *et al.,* 2016); and potential responses to these relatively low received levels at such great distances, while conservatively evaluated here as take under the MMPA, are unlikely to result in any response of such a severity as to carry any cost to the animal. (Additionally, in certain circumstances, noise from the surveys at these distances may be indistinguishable from other low-frequency background noise). Therefore, as for other species, we consider only the average modeled time per day spent at received levels above 140 dB rms (where 90 percent of the exposed beaked whale populations are considered taken) and 160 dB rms (where, potentially, all exposed beaked whales are taken). The average time spent in a state of exposure above 160 dB rms is only 6–12.4 minutes for 2D, 3D NAZ, and 3D WAZ surveys and 24 minutes for coil surveys. The average time spent in a state of exposure above 140 dB rms is 14.1 minutes for 3D WAZ surveys, 16.2 minutes for 2D surveys, 31.1 minutes for coil surveys, and 39.7 minutes for 3D NAZ surveys.

Odontocetes echolocate to find prey, and while there are many different strategies for hunting, one common pattern, especially for deeper-diving species, is to conduct multiple repeated deep dives within a feeding bout, and multiple bouts within a day, to find and catch prey. As we noted, while some of the exposures of the durations noted above could interrupt a dive or cause an individual to relocate to feed because of the lower thresholds combined with the way exposures are distributed across received levels, a higher proportion of the total takes (as compared to other taxa) are at the lower end of the received levels at which take would be expected to occur and at great distance from the acoustic source, where responses (if any) should be assumed to be minor. All else being equal, exposures to lower received levels and, separately, at greater distances might be expected to result in less severe responses, even given longer durations (*e.g.,* DeRuiter *et al.,* 2013). Considered individually or infrequently, these sorts of feeding interruptions would be unlikely to have significant impacts on an individual's energy budget, especially given the likely availability of adequate alternate feeding areas relatively nearby. However, the high risk rating for the high effort scenario reflects the higher number of total days across which these singularly more minor impacts may occur, as well as other factors, and points to the need for the consideration of additional reduction of impacts where possible. In years when less effort occurs, as represented by the moderate effort scenario, risk will be less.

Importantly, no survey activity is expected within the Dry Tortugas Mitigation Area, which was analyzed and proposed for implementation in the proposed rule. The area provides preferred habitat for comparatively high densities of beaked whales. The absence of survey activity in this important area is expected to alleviate some of the previous impacts of concern to beaked whales (as well as sperm whales and *Kogia* spp.) and their habitat by minimizing a range of potential effects of airgun noise, both acute and chronic, that could otherwise accrue to impact the reproduction or survival of individuals in this area. Absence of survey activity in this area will minimize disturbance of the species in a place of importance for critical behaviors such as foraging and socialization and, overall, helps to reduce evaluated risk to the stocks as a whole.

Additionally, we note that the extended distance shutdown zone for beaked whales (1,500 m) is expected to further reduce the likelihood of, and minimize the severity of, more severe behavioral responses.

Despite the nature and duration of the exposures anticipated, which at a smaller scale might not be expected to meaningfully impact individual fitness, given the high to moderate EWG risk rating and the relatively high number of predicted beaked whale takes (increasing the likelihood of some subset of individuals accruing a fair number of repeated takes over sequential days—albeit assuming takes at low received levels and at distances from the source where responses, if any, should be expected to be minor), it is more likely that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending energy to find alternative feeding options) could cause them to forego reproduction for a year. Energetic impacts to males are generally meaningless to population rates unless they cause death, and extreme energy deficits (beyond what could be considered reasonably likely to result from these activities) are required to cause the death of an adult marine mammal. As noted previously, however, foregone reproduction (especially for one year, which is the maximum predicted because the relatively small number anticipated in any one year makes the probability that any individual would be impacted in this way twice in five years very low) has far less of an impact on population rates than mortality. And a small number of instances of foregone reproduction would not be expected to adversely affect these stocks through effects on annual rates of recruitment or survival.

It is worth noting that in similar situations, *i.e.,* where individual beaked whales may be exposed to noise above harassment thresholds regularly, populations appear to be stable based on multiple studies and lines of evidence (*e.g.,* Falcone and Schorr, 2014; DiMarzio *et al.,* 2018). In research done at the Navy's fixed tracking range in the Bahamas, animals were observed to leave the immediate area of an anti-submarine warfare training exercise but return within a few days after the event ended (Claridge and Durban, 2009; McCarthy *et al.,* 2011; Moretti *et al.,* 2009, 2010; Tyack *et al.,* 2010, 2011). It is important to note that in these contexts, beaked whales were exposed to noise stimuli to which they are significantly more acoustically sensitive (*i.e.,* mid-frequency active sonar versus low-frequency airgun noise).

Of note, due to their pelagic distribution, typical high availability bias due to deep-diving behavior and cryptic nature when at the surface, beaked whales are rarely sighted during at-sea surveys and difficult to distinguish between species when visually observed in the field. Accordingly, abundance estimates in NMFS SARs are recorded for *Mesoplodon* spp. Available sightings data, including often unresolved sightings of beaked whales, must be combined in order to develop habitat-based density models for beaked whales, as were used to inform our acoustic exposure modeling effort. Therefore, density and take estimates in this rule are similarly lumped for the three species of beaked whales, and there is no additional information by which NMFS could appropriately apportion impacts other than equally/proportionally across the three species.

No mortality or Level A harassment of any of these three species of beaked whales is anticipated or authorized. It is likely that the majority of the individual beaked whales will be impacted on one or more days during a year of activity by one type of survey or another. It is possible that some small number of female beaked whales may experience a year of foregone reproduction. However, based on the nature of the majority of the individual exposures and the overall scale of the aggregate impacts and risk rating in consideration of the mitigation discussed here, and noting the continued presence of beaked whales in the GOM given the many years of high activity levels and the evidence that beaked whales maintain stable or increasing populations in other areas with high levels of acoustic activity, the impacts of the expected takes from these activities are not likely to adversely affect the GOM stocks of Cuvier's, Gervais', or Blainville's beaked whales through adverse impacts on annual rates of recruitment or survival.

Kogia spp.

First, we note that the estimated (and allowable) take of *Kogia* spp. has been reduced as compared to the proposed rule as a result of the change in scope. Specifically, the maximum annual take by Level B harassment decreased by approximately 46 percent and the average annual take decreased by approximately 43 percent. (These reductions are 49 and 46 percent, respectively, for Level A harassment.) The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for *Kogia* spp. were low (for the high effort scenario) and very low (for the moderate effort scenario). Evaluated risk is reduced from the proposed rule, where the high effort scenario resulted in a moderate risk rating and the moderate effort scenario resulted in a low risk rating. We further consider the likely severity of any predicted behavioral disruption of *Kogia* spp. in the context of the likely duration of exposure above Level B harassment thresholds. Specifically, the average modeled time per day spent at received levels above 160 dB rms (where 50 percent of the exposed population is considered taken) ranges from 2.8–7.9 minutes for 2D, 3D NAZ, and 3D WAZ surveys and up to 15.3 minutes for coil surveys (which comprise less than 10 percent of the total projected activity days), and the average time spent between 140 and 160 dB rms (where 10 percent of the exposed population is considered taken) is 6.7–19 minutes.

Odontocetes echolocate to find prey, and while there are many different strategies for hunting, one common pattern, especially for deeper diving species, is to conduct multiple repeated deep dives within a feeding bout, and multiple bouts within a day, to find and catch prey. While exposures of the short durations noted above could potentially interrupt a dive or cause an individual to relocate to feed, such a short-duration interruption would be unlikely to have significant impacts on an individual's energy budget and, further, for these species and this open-ocean area, there are no specific known reasons (*i.e.,* these species range GOM-wide beyond the continental slope and there are no known biologically important areas) to expect that there would not be adequate alternate feeding areas relatively nearby, especially considering the anticipated absence of survey activity in the eastern GOM.

As described above, no survey activity is expected within the Dry Tortugas Mitigation Area, which was analyzed and proposed for implementation in the proposed rule. The absence of survey activity in the area is expected to afford additional reduction of impacts to *Kogia* spp., in addition to sperm and beaked whales, given their relatively high density in that area. Importantly, the absence of survey activity in the area will reduce disturbance of these species in places of importance to them for critical behaviors such as foraging and socialization and, overall, help to reduce evaluated risk to the stocks as a whole.

NMFS has analyzed the likely impacts of potential hearing impairment, including the estimated upper bounds of permanent threshold shift (Level A harassment) that could be authorized under the rule, and do not expect that they would result in impacts on reproduction or survival of any individuals. As described in the previous section, the degree of injury for individuals would be expected to be mild, and the predicted PTS resulting from airgun exposure is not likely to affect echolocation performance or communication for *Kogia* spp. Additionally, the extended distance shutdown zone for *Kogia* spp. (1,500 m) is expected to further minimize the severity of any hearing impairment incurred and also to further reduce the likelihood of, and minimize the severity of, more severe behavioral responses.

Of note, due to their pelagic distribution, small size, and cryptic behavior, pygmy sperm whales and dwarf sperm whales are rarely sighted during at-sea surveys and difficult to distinguish between when visually observed in the field. Accordingly, abundance estimates in NMFS SARs are recorded for *Kogia* spp. only, density and take estimates in this rule are similarly lumped for the two species, and there is no additional information by which NMFS could appropriately apportion impacts other than equally/proportionally across the two species.

No mortality of *Kogia* spp. is anticipated or authorized. While it is likely that the majority of the individuals of these two species will be impacted briefly on one or more days during a year of activity by one type of survey or another, based on the nature of the individual exposures and takes, as well as the aggregated scale of the impacts across the GOM, and in consideration of the mitigation discussed here, the impacts of the expected takes from these activities are not likely to adversely impact the GOM stocks of dwarf or pygmy sperm whales through adverse impacts on annual rates of recruitment or survival.

Bottlenose Dolphins

The change in scope did not result in any appreciable change to estimated (and allowable) take of bottlenose dolphins compared to the proposed rule. Specifically, the maximum annual take increased slightly (by approximately 2 percent), while the average annual take decreased slightly (by approximately 1 percent). The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for both oceanic

bottlenose dolphins and coastal/shelf bottlenose dolphins are very low for both scenarios. In the proposed rule, risk was evaluated for bottlenose dolphins GOM-wide (here we have refined the risk evaluation to differentiate between oceanic and coastal/shelf stocks). Evaluated risk is reduced from the proposed rule, where the high effort scenario resulted in a low risk rating and the moderate effort scenario resulted in a moderate risk rating. We further considered the likely severity of any predicted behavioral disruption of bottlenose dolphins in the context of the likely duration of exposure above Level B harassment thresholds. Specifically, the average modeled time per day spent at received levels above 160 dB rms (where 50 percent of the exposed population is considered taken) ranges from 4–11.7 minutes for 2D, 3D NAZ, and 3D WAZ surveys and up to 16.8 minutes for coil surveys (which comprise less than 10 percent of the total projected activity days) and the average time spent between 140 and 160 dB rms is 19.7–54.6 minutes. While exposures of the short durations noted above could potentially interrupt a dive or cause an individual to relocate to feed, among other impacts, such a short-duration interruption would be unlikely to have significant impacts on an individual's energy budget or otherwise impact reproduction or survival.

As described earlier in this preamble, the northern coastal stock of bottlenose dolphin was particularly severely impacted by the DWH oil spill, and was additionally affected by a recent UME. Importantly, as described in Mitigation, NMFS is requiring a seasonal time-area restriction on airgun survey activity within the coastal waters where this stock is likely to be found. The closure area is expected to protect coastal bottlenose dolphins and their habitat through the alleviation or minimization of a range of potential effects of airgun noise, both acute and chronic, that could otherwise accrue to impact the reproduction or survival of individuals in this area. The timing of the restriction provides protection during the times of year thought to be most important for bottlenose dolphin calving and nursing of young. Although some sound from airguns may still propagate into the area from surveys that may occur outside of the area, exposure of bottlenose dolphins to sound levels that would result in Level B harassment will be alleviated or reduced for animals within the closure area. Any exposure to noise that may increase stress levels and exacerbate health problems in bottlenose dolphins still recovering from the effects of the DWH spill will be minimized during this important reproductive period. This important mitigation results in a reduction in the scale of aggregate effects (which, among other things, suggests the comparative number of days across which individual bottlenose dolphins might be taken within a year) and associated risk assessment.

Of note, bottlenose dolphins cannot be identified to stock when visually observed in the field. Abundance estimates in NMFS SARs are based strictly on the location where animals are observed, and available sightings data must be combined in order to develop habitat-based density models for bottlenose dolphins, as were used to inform our acoustic exposure modeling effort. Therefore, density and take estimates in this rule are provided for bottlenose dolphins as a GOM-wide species. However, based on NMFS' stock delineations, we can reasonably assume that dolphins occurring within Zones 4–7 would be from the oceanic stock, while dolphins occurring within Zones 1–3 would be from the shelf stock and/or coastal stocks. Therefore, for the oceanic stock, we are able to draw stock-specific conclusions in this analysis. For coastal/shelf stocks, there is no additional information by which NMFS could appropriately apportion impacts other than equally/proportionally across the stocks, with the exception of predicting reduced impacts to the northern coastal stock as described above. We note that, as a result of BOEM's update to the scope of activity, the eastern coastal stock will not experience any impacts and is accordingly no longer considered in this rule.

No mortality or Level A harassment of bottlenose dolphins is anticipated or authorized. While it is likely that the majority of individual dolphins may be impacted briefly on one or more days during a year of activity by one type of survey or another, based on the nature of the individual exposures (shorter duration) and takes, as well as the aggregated scale of the impacts across the GOM in consideration of the mitigation discussed here, the impacts of the expected takes from these activities are not likely to adversely affect any affected GOM stock of bottlenose dolphins through adverse impacts on annual rates of recruitment or survival.

All Other Stocks

In consideration of the similarities in the nature and scale of impacts, we consider the GOM stocks of the following species together in this section: Rough-toothed dolphin, Clymene dolphin, Atlantic spotted dolphin, pantropical spotted dolphin, striped dolphin, spinner dolphin, Fraser's dolphin, Risso's dolphin, melon-headed whale, pygmy killer whale, false killer whale, killer whale, and short-finned pilot whale. Estimated (and allowable) take of these stocks (including both the maximum annual take and the average annual take) has been reduced as compared to the proposed rule as a result of the change in scope (with the exception of the Atlantic spotted dolphin). For the Atlantic spotted dolphin, the change in scope resulted in increases compared to the proposed rule. Specifically, the maximum annual take increased by approximately 9 percent, while the average annual take increased by approximately 4 percent. These slight increases do not impact our analysis for the stock.

The EWG analysis, which evaluated the relative significance of the aggregated impacts of the survey activities across seven GOM zones in the context of the vulnerability of each species, concluded that the GOM-wide risk ratings for high and moderate effort scenarios ranged from very low to low for these species. For all stocks, there was a trend of decreased or static risk ratings compared to the proposed rule, where the GOM-wide risk ratings for high and moderate effort scenarios ranged from low to moderate.

We further considered the likely severity of any predicted behavioral disruption of the individuals of these species in the context of the likely duration of exposure above Level B harassment thresholds. Specifically, the average modeled time per day spent at received levels above 160 dB rms (where 50 percent of the exposed population is considered taken) ranges from 1.4–11.7 minutes for 2D, 3D NAZ, and 3D WAZ surveys and up to 25.7 minutes for coil surveys (which comprise less than 10 percent of the total projected activity days). The average time per day spent between 140 and 160 dB rms for individuals that are taken is from 8–58.1 minutes, with the one exception of killer whales exposed to noise from coil surveys, which average 73.6 minutes (though we note that the overall risk rating for the species is very low).

Odontocetes echolocate to find prey, and there are many different strategies for hunting. One common pattern for deeper-diving species is to conduct multiple repeated deep dives within a feeding bout, and multiple bouts within a day, to find and catch prey. While

exposures of the shorter durations noted above could potentially interrupt a dive or cause an individual to relocate to feed, such a short-duration interruption would be unlikely to have significant impacts on an individual's energy budget and, further, for these species and this open-ocean area, there are no specific known reasons (*i.e.,* these species range GOM-wide beyond the continental slope and there are no known biologically important areas) to expect that there would not be adequate alternate feeding areas relatively nearby, especially considering the anticipated absence of survey activity in the eastern GOM. For those species that are more shallow feeding species, it is unlikely that the noise exposure considered herein would result in minimal significant disruption of foraging behavior and, therefore, the concomitant energetic effects would similarly be minimal.

Of note, the Atlantic spotted dolphin would benefit (via lessening of both number and severity of takes) from the coastal waters time-area restriction developed to benefit bottlenose dolphins and several additional species experience notably reduced effects from the absence of survey activity in important eastern GOM habitat. Specifically, multiple shelf-break associated and pelagic species (such as Risso's dolphin, melon-headed whales, and rough-toothed dolphins) experience a reduction estimated take from the absence of survey activity in both the Bryde's whale core habitat and Dry Tortugas Areas. Maximum annual and average annual take decreased for these species compared with the proposed rule by 20 and 14 percent, 19 and 15 percent, and 19 and 18 percent, respectively. Numerous other species would be expected to be present in varying numbers at various times.

No mortality or Level A harassment of these species is anticipated or authorized. It is likely that the majority of the individuals of these 13 species will be impacted briefly on one or more days during a year of activity by one type of survey or another. Based on the nature of the individual exposures and takes, as well as the very low to low aggregated scale of the impacts across the GOM and considering the mitigation discussed here, the impacts of the expected takes from these activities are not likely to adversely impact the GOM stocks of any of these 13 GOM stocks of these species through adverse impacts on annual rates of recruitment or survival.

Determination

Based on the analysis contained herein of the likely effects of the specified activities on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the specified activities will have a negligible impact on all affected marine mammal species and stocks.

Small Numbers

The sections below provide an explanation of how NMFS interprets and applies the small numbers standard and remain substantively unchanged from the discussion provided in the notice of proposed rulemaking. Additional discussion appears in Comments and Responses to address specific comments, questions, or recommendations received from the public.

What are small numbers?

The term ''small numbers'' appears in section 101(a)(5)(A) of the MMPA as follows:

(5)(A)(i) Upon request therefor by citizens of the United States who engage in a specified activity (other than commercial fishing) within a specified geographical region, the Secretary shall allow, during periods of not more than five consecutive years each, the incidental, but not intentional, taking by citizens while engaging in that activity within that region of *small numbers* of marine mammals of a species or population stock if the Secretary, after notice (in the **Federal Register** and in newspapers of general circulation, and through appropriate electronic media, in the coastal areas that may be affected by such activity) and opportunity for public comment—

(I) finds that the total of such taking during each five-year (or less) period concerned will have a negligible impact on such species or stock and will not have an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses [. . .] and

(II) prescribes regulations setting forth—

(aa) permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses; and

(bb) requirements pertaining to the monitoring and reporting of such taking.

(Emphasis added.)

In addition to section 101(a)(5)(A), the MMPA as amended in 1994 includes a similar provision in section 101(a)(5)(D), which provides for the issuance of incidental take authorizations for small numbers of marine mammals without the need for regulations, effective for up to one year, where the taking is limited to harassment:

(5)(D)(i) Upon request therefor by citizens of the United States who engage in a specified activity (other than commercial fishing) within a specific geographic region, the Secretary shall authorize, for periods of not more than 1 year, subject to such conditions as the Secretary may specify, the incidental, but not intentional, taking by harassment of *small numbers* of marine mammals of a species or population stock by such citizens while engaging in that activity within that region if the Secretary finds that such harassment during each period concerned—

(I) will have a negligible impact on such species or stock, and

(II) will not have an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses[.]

(Emphasis added.)

The MMPA does not define ''small numbers.'' NMFS' and the U.S. Fish and Wildlife Service's 1989 implementing regulations defined small numbers as a portion of a marine mammal species or stock whose taking would have a negligible impact on that species or stock. This definition was invalidated in *Natural Resources Defense Council* v. *Evans,* 279 F.Supp.2d 1129 (2003) (N.D. Cal. 2003), based on the court's determination that the regulatory definition of small numbers was improperly conflated with the regulatory definition of ''negligible impact,'' which rendered the small numbers standard superfluous. As the court observed, ''the plain language indicates that small numbers is a separate requirement from negligible impact.'' Since that time, NMFS has not applied the definition found in its regulations. Rather, consistent with Congress' pronouncement that small numbers is not a concept that can be expressed in absolute terms (House Committee on Merchant Marine and Fisheries Report No. 97–228 (September 16, 1981)), NMFS makes its small numbers findings based on an analysis of whether the number of individuals authorized to be taken annually from a specified activity is small relative to the stock or population size. The Ninth Circuit has upheld a similar approach. See *Center for Biological Diversity* v. *Salazar,* 695 F.3d 893 (9th Cir. 2012).

However, NMFS has not historically indicated what the agency believes to be the upper limit of small numbers.

To maintain an interpretation of small numbers as a proportion of a species or stock that does not conflate with negligible impact, NMFS uses a simple approach that establishes equal bins corresponding to small, medium, and large proportions of the population abundance. NMFS then compares the number of individuals estimated and authorized to be taken against the best available abundance estimate for that species or stock.

It can be challenging to predict the numbers of individual marine mammals that will be taken by an activity. Many models calculate instances of take but are unable to account for repeated exposures of individual marine mammals, though the instances of take necessarily represent the upper bound of the number of individuals. In some of those cases, such as for this rule (see Estimated Take), we are able to generate a more refined estimate of the numbers of individuals predicted to be taken utilizing a combination of quantitative tools and qualitative information. When an acceptable estimate of the individual marine mammals taken is available,[20] the small numbers determination is based directly upon whether these estimates exceed one-third of the stock abundance. In other words, consistent with past practice, when the estimated number of individual animals taken (which may or may not be assumed as equal to the total number of takes, depending on the available information) is up to, but not greater than, one-third of the most appropriate species or stock abundance, NMFS will determine that the numbers of marine mammals taken of a species or stock are small.

Another circumstance in which NMFS considers it appropriate to make a small numbers finding is in the case of a species or stock that may potentially be taken but is either rarely encountered or only expected to be taken on rare occasions. In that circumstance, one or two assumed encounters with a group of animals (meaning a group that is traveling together or aggregated, and thus exposed to a stressor at the same approximate time) should reasonably be considered small numbers, regardless of consideration of the proportion of the stock, as infrequent or rare encounters resulting in take of one or two groups should be considered small relative to the range and distribution of any stock.

In summary, when quantitative take estimates of individual marine mammals are available or inferable through consideration of additional factors, and the number of animals taken is one-third or less of the best available abundance estimate for the species or stock, NMFS considers it to be of small numbers. NMFS may also appropriately find that one or two predicted group encounters will result in small numbers of take relative to the range and distribution of a species, regardless of the estimated proportion of the abundance.

Is the small numbers standard evaluated based on total take under incidental take regulations or within the context of an individual letter of authorization?

Neither the MMPA nor NMFS' implementing regulations address whether the small numbers determination should be based upon the total annual taking for (1) all activities occurring under specific incidental take regulation or (2) to individual LOAs issued thereunder. The MMPA does not define small numbers or explain how to apply the term in either paragraph (A) or (D) of section 101(a)(5), including how to apply the term in a way that allows for consistency between those two very similar provisions in the statute. Whether to apply the small numbers finding to each individual LOA under regulations that cover multiple concurrent LOA holders is a matter of first impression for NMFS.

Specifically, section 101(a)(5)(A)(i)(I) explicitly states that the negligible impact determination for a specified activity must take into account the total taking over the five-year period, but the small numbers language is not tied explicitly to the same language. Rather, the small numbers provision appears in section 101(a)(5)(A)(i) as a limitation on what the Secretary may allow. The regulatory vehicle for authorizing (*i.e.,* ''allowing'') the take of marine mammals is the LOA.

Given NMFS' discretion in light of the ambiguities in the statute regarding how to apply the small numbers standard, we have determined that the small numbers finding should be applied to the annual take authorized per individual LOA, rather than to the total annual taking for all activities potentially occurring under the incidental take regulations. This per-LOA approach harmonizes section 101(a)(5)(A) with the per-IHA application in section 101(a)(5)(D) of the MMPA.[21] This per-LOA approach is not only permissible but also preferable to the total annual taking approach because NMFS' per-LOA approach to small numbers in section 101(a)(5)(A) affords greater regulatory flexibility to utilize section 101(a)(5)(A) when there are benefits to doing so for the resource (marine mammals), the public, prospective applicants, and administrative efficiency:

- From a resource protection standpoint, it is better to conduct a comprehensive negligible impact analysis that considers all of the activities covered under the rule (versus considering them independently pursuant to individual IHAs) and ensures that the total combined taking from those activities will have a negligible impact on the affected marine mammal species or stocks and no unmitigable adverse impact on subsistence uses. Furthermore, mitigation and monitoring are more effective when considered across all activity and years covered under regulations.
- From an agency resource standpoint, it ultimately will save significant time and effort to cover multi-year activities under a rule instead of multiple incidental harassment authorizations (IHAs). While regulations require more analysis up front, additional public comment and internal review, and additional time to promulgate compared to a single IHA, they are effective for up to five years (for non-military readiness activities) and can cover multiple actors within a year. The process of issuing individual LOAs under incidental take regulations utilizes the analysis, public comment, and review that was conducted for the regulations, and takes significantly less time than it takes to issue independent IHAs.
- From an applicant standpoint, incidental take regulations offer more regulatory certainty than IHAs (five years versus one year) and significant cost savings, both in time and environmental compliance analysis and documentation. This is especially true for situations like here, where multiple applicants will be applying for individual LOAs under regulations. In the case of this rule, the certainty afforded by the promulgation of a regulatory framework (*e.g.,* by using previously established take estimates, mitigation and monitoring

[20] We note that although NMFS' implementing regulations require applications for incidental take to include an estimate of the marine mammals to be taken, there is nothing in section 101(a)(5)(A) (or (D)) that requires NMFS to quantify or estimate numbers of marine mammals to be taken for purposes of evaluating whether the number is small. (See *CBD* v. *Salazar.*)

[21] As the court observed in *Native Village of Chickaloon* v. *NMFS,* 947 F. Supp. 2d 1031, 1049 n.123 (D. Alaska 2013) ''the same statutory standards apply'' to incidental take authorization under both provisions.

requirements, and procedures for requesting and obtaining an LOA) is a significant benefit for prospective applicants.

NMFS' evaluation of past IHAs suggests that bundling together the activities covered by two or three IHAs that might be ideal subjects for a combined incidental take regulation (*e.g.,* for ongoing maintenance construction activities, or seismic surveys in the Arctic by different entities) may exceed the taking of small numbers of a species if NMFS were to apply the small numbers standard across all taking contemplated by the regulation in a year. In other words, if the small numbers standard is applied to the total annual taking under a rule, NMFS may not be able to make the necessary small numbers finding, which would preclude the use of section 101(a)(5)(A) for multiple activities, thereby eliminating the opportunity to derive the resource and streamlining benefits outlined above. Also, application of the small numbers standard across the total annual taking covered by an incidental take regulation, inasmuch as prospective applicants can see that the total annual take may exceed one-third of species or stock abundance, would create an incentive for applicants to pursue individual IHAs (again, precluding the ability to gain the benefits outlined above).

Our conclusion is that NMFS can appropriately elect to make a ''small numbers'' finding based on the estimated annual take in individual LOAs issued under the rule. This approach does not affect the negligible impact analysis for a rule, which is the biologically relevant inquiry and based on the total annual estimated taking for all activities the regulations will govern. Making the small numbers finding based on the estimated annual take in individual LOAs allows NMFS to take advantage of the associated administrative and environmental benefits of utilizing section 101(a)(5)(A) that would be precluded in many cases if small numbers were required to be applied to the total annual taking under the regulations. NMFS finds this method of making a small numbers determination to be a permissible interpretation of the relevant MMPA provisions.

Although this application of small numbers may be argued as being less protective of marine mammals, NMFS disagrees. As noted previously, the small numbers standard has less biological significance as compared to the substantive and contextually-specific analysis necessary to support the negligible impact determination. The negligible impact determination is still controlling, and the maximum total annual taking that may be authorized across all LOAs under an incidental take regulation still could not exceed the overall amount analyzed for the negligible impact determination. Thus, under this option, the negligible impact analysis for the rulemaking still would have to be conducted for the time period explicitly specified in the statute (*i.e.,* up to five years), but the small numbers analysis would attach to the instrument itself that authorizes the taking, *i.e.,* the LOA.

How will small numbers be evaluated under this GOM rule?

In this rule, up-to-date species information is available, and sophisticated models have been used to estimate take in a manner that will allow for quantitative comparison of the take of individuals versus the best available abundance estimates for the species or stocks. Specifically, while the modeling effort utilized in the rule enumerates the estimated instances of takes that will occur across days as the result of the operation of certain survey types in certain areas, the modeling report also includes the evaluation of a test scenario that allows for a reasonable modification of those generalized take estimates to better estimate the number of individuals that will be taken within one survey. LOA applicants using modeling results from the rule to inform their applications will be able to reasonably estimate the number of marine mammal individuals taken by their activities. LOA applications that do not use the modeling provided in the rule to estimate take for their activities will need to be reviewed, and applicants will be required to ensure that their estimates adequately inform the small numbers finding. If applicants use the modeling provided by this rule to estimate take, additional review will not be deemed necessary (unless other conditions necessitating review exist, as described in the Letters of Authorization section). If applicants do not use the modeling provided by the rule, however, NMFS may publish a notice in the **Federal Register** soliciting public comment, if the model or inputs differ substantively from those that have been reviewed by NMFS and the public previously, if the model or inputs differ substantively from those that have been reviewed by NMFS and the public previously. The estimated take of marine mammals for each species will then be compared against the best available scientific information on species or stock abundance estimate as determined by NMFS, and estimates that do not exceed one-third of that estimate will be considered small numbers.

Adaptive Management

The regulations governing the take of marine mammals incidental to geophysical survey activities contain an adaptive management component. The comprehensive reporting requirements associated with this rule (see the Monitoring and Reporting section) are designed to provide NMFS with monitoring data from the previous year to allow consideration of whether any changes are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the LOA-holders regarding practicability) on a regular (*e.g.,* annual or biennial) basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammal species or stocks or their habitat and if the measures are practicable. The adaptive management process and associated reporting requirements would serve as the basis for evaluating performance and compliance.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized through these regulations and subsequent LOAs or that the specified activity may be having more than a negligible impact on affected stocks.

Under this rule, NMFS plans to implement an annual adaptive management process including BOEM, BSEE, industry operators (including geophysical companies as well as exploration and production companies), and others as appropriate. Industry operators may elect to be represented in this process by their respective trade associations. NMFS, BOEM, and BSEE (*i.e.,* the regulatory agencies) and industry operators who have conducted or contracted for survey operations in the GOM in the prior year (or their representatives) will provide an agreed-upon description of roles and responsibilities, as well as points of contact, in advance of each year's

adaptive management process. The foundation of the adaptive management process will be the annual comprehensive reports produced by LOA-holders (or their representatives), as well as the results of any relevant research activities, including research supported voluntarily by the oil and gas industry and research supported by the Federal government. Please see the Monitoring Contribution Through Other Research section in the notice of proposed rulemaking for a description of representative past research efforts. The outcome of the annual adaptive management process would be an assessment of effects to marine mammal populations in the GOM relative to NMFS' determinations under the MMPA and ESA, recommendations related to mitigation, monitoring, and reporting, and recommendations for future research (whether supported by industry or the regulatory agencies).

Data collection and reporting by individual LOA-holders will occur on an ongoing basis, per the terms of issued LOAs. In a given annual cycle, the comprehensive annual report will summarize and synthesize all LOA-specific reports received, with report development (supported through collaboration of individual LOA-holders or by their representatives) occurring for 90 days following the end of a given one-year period. Review and revision of the report, followed by a joint meeting of the parties, will occur within 90 days following receipt of the annual report. Any agreed-upon modifications will occur through the process for modifications and/or adaptive management described in the regulatory text following this preamble.

Monitoring Contribution Through Other Research

NMFS' MMPA implementing regulations require that applicants for incidental take authorizations describe the suggested means of coordinating research opportunities, plans, and activities relating to reducing incidental taking and evaluating its effects (50 CFR 216.104(a)(14)). Such coordination can serve as an effective supplement to the monitoring and reporting required pursuant to issued LOAs and/or incidental take regulations. NMFS expects that relevant research efforts will inform the annual adaptive management process described above, and that levels and types of research efforts will change from year to year in response to identified needs and evolutions in knowledge, emerging trends in the economy and available funding, and available scientific and technological resources. In the notice of proposed rulemaking, NMFS described examples of relevant research efforts (83 FR 29300–29301). We do not repeat that information here, but refer the reader to that notice for more information. The described efforts may not be predictive of any future levels and types of research efforts. Research occurring in locations other than the GOM may be relevant to understanding the effects of geophysical surveys on marine mammals or marine mammal populations or the effectiveness of mitigation. NMFS also refers the reader to the industry Joint Industry Program (JIP) website (*www.soundandmarinelife.org*), which hosts a database of available products funded partially or fully through the JIP, and to BOEM's Environmental Studies Program (ESP), which develops, funds, and manages scientific research to inform policy decisions regarding outer continental shelf resource development (*www.boem.gov/studies).*

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by these actions. Therefore, NMFS has determined that the total taking of affected species or stocks will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7 of the ESA requires Federal agencies to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or adversely modify or destroy their designated critical habitat. Federal agencies must consult with NMFS for actions that may affect such species under NMFS' jurisdiction or critical habitat designated for such species.

At the conclusion of consultation, the consulting agency provides an opinion stating whether the Federal agency's action is likely to jeopardize the continued existence of ESA-listed species or destroy or adversely modify designated critical habitat.

NMFS's issuance of this final rule, and any subsequent LOAs, is subject to the requirements of Section 7 of the ESA. Therefore, NMFS' Office of Protected Resources (OPR), Permits and Conservation Division requested initiation of a formal consultation with the NMFS OPR, ESA Interagency Cooperation Division on the proposed issuance of the rule and subsequent LOAs on July 19, 2018. The formal consultation concluded and a final Biological Opinion (BiOp) was issued on March 13, 2020. The BiOp concluded that the Permits and Conservation Division's proposed action is not likely to jeopardize the continued existence of sperm whales or the GOM Bryde's whale.

National Environmental Policy Act

In 2017, BOEM produced a final Programmatic Environmental Impact Statement (PEIS) to evaluate the direct, indirect, and cumulative impacts of geological and geophysical survey activities on the GOM OCS, pursuant to requirements of NEPA. These activities include geophysical surveys in support of hydrocarbon exploration, as are described in the MMPA petition before NMFS. The PEIS is available online at: *www.boem.gov/Gulf-of-Mexico-Geological-and-Geophysical-Activities-Programmatic-EIS/.* NOAA, through NMFS, participated in preparation of the PEIS as a cooperating agency due to its legal jurisdiction and special expertise in conservation and management of marine mammals, including its responsibility to authorize incidental take of marine mammals under the MMPA.

NEPA, Council on Environmental Quality (CEQ) regulations, and NOAA's NEPA implementing procedures (NOAA Administrative Order (NAO) 216–6A) encourage the use of programmatic NEPA documents to streamline decision-making. NMFS reviewed the Final PEIS and determined that it meets the requirements of the CEQ regulations (40 CFR part 1500–1508) and NAO 216–6A. NMFS further determined, after independent review, that the Final PEIS satisfied NMFS' comments and suggestions in the NEPA process. In the notice of proposed rulemaking, NMFS stated its intention to adopt BOEM's analysis in order to assess the impacts to the human environment of issuance of the subject ITR, and that we would review all comments submitted in response to the notice as we completed the NEPA process, including a final decision of whether to adopt BOEM's PEIS and sign a Record of Decision related to issuance of the ITR and subsequent LOAs. Following review of public comments received, NMFS confirmed that it would be appropriate to adopt BOEM's analysis in order to support assessment of the impacts to the human environment of issuance of the subject ITR and subsequent LOAs. Therefore NMFS prepared a Record of Decision for the following purposes: (1) To adopt the Final PEIS to support NMFS' analysis associated with issuance of incidental take authorizations pursuant to section 101(a)(5)(A) or (D) of the MMPA and the regulations governing the taking and

importing of marine mammals (50 CFR part 216); and (2) in accordance with 40 CFR 1505.2, to announce and explain the basis for NMFS' decision to review and potentially issue incidental take authorizations under the MMPA on a case-by-case basis, if appropriate.

Letters of Authorization

Under these incidental take regulations, industry operators may apply for and obtain LOAs, as described in NMFS' MMPA implementing regulations (50 CFR 216.106). LOAs may be issued for any time period that does not exceed the effective duration of the final rule, provided the description of the activity in the request includes a sufficient degree of specificity with which to evaluate whether the activity falls within the scope of the rule. Because the specified activity described herein does not provide actual specifics of the timing, location, and survey design for activities that would be the subject of issued LOAs, such requests must include, at minimum, the information described at 50 CFR 216.104(a)(1) and (2), and should include an affirmation of intent to adhere to the mitigation, monitoring, and reporting requirements described in the regulations. The level of effort proposed by an operator would be used to develop an LOA-specific take estimate based on the results of Zeddies *et al.* (2015, 2017a).

The proposed rule indicated that LOA applications with take estimates based on modeling other than that specifically included in the modeling report used to support the EIS and the proposed rule (Zeddies *et al.,* 2015, 2017a) would be published for public comment prior to the issuance of an LOA. However, upon further consideration of the ''*Gulf of Mexico Acoustic Exposure Model Variable Analysis*'' (Zeddies *et al.,* 2017b; ''Acoustic Exposure Model Variable Analysis'') provided by IAGC and API to NMFS prior to the publication of the proposed rule and made available to the public with the proposed rule and the Associations' public comments, which extensively referenced the Acoustic Exposure Model Variable Analysis, the final rule more flexibly provides that if applicants do not use the modeling provided by the rule, NMFS may publish a notice in the **Federal Register** soliciting public comment, if the model or inputs differ substantively from those that have been reviewed by NMFS and the public previously. Specifically, the Acoustic Exposure Model Variable Analysis includes the results (*i.e.,* take estimates) of a supplemental analysis of the same modeling effort used in Zeddies *et al.* (2015, 2017a) to support the proposed rule, but evaluating the effects on the modeling results of different variables. One analyzed variable of particular utility was the use of a smaller airgun array that could serve as a reasonable representative for some of the smaller arrays that are commonly used in the GOM. This specific applicable example, in which the model and inputs of this Acoustic Exposure Model Variable Analysis have been reviewed by NMFS and the public previously (both in that they mirror Zeddies *et al.* (2015, 2017a) and in that NMFS also explicitly made the Acoustic Exposure Model Variable Analysis available to the public during the comment period), illustrates the need to provide flexibility and make efficient use of previous public and agency review. NMFS has, therefore, determined it appropriate to allow that additional public review is not needed unless the model or inputs differ substantively from those that have been reviewed by NMFS and the public previously. Further, we explicitly note the utility of the modeling and results presented in the Acoustic Exposure Model Variable Analysis report for representing smaller airgun arrays that are commonly used in the GOM and affirm that further public comment on that report should not be necessary prior to the use of its results to support the issuance of LOAs.

Technologies continue to evolve to meet the technical, environmental, and economic challenges of oil and gas development. The use of ''new and unusual technologies'' (NUT), *i.e.,* technologies other than those described herein, will be evaluated on a case-by-case basis and may require public review. Some seemingly new technologies proposed for use by operators are often extended applications of existing technologies and interface with the environment in essentially the same way as well-known or conventional technologies. For such evaluations, NMFS will follow the existing process used by BOEM, by using the following considerations:

- Has the technology or hardware been used previously or extensively in the U.S. GOM under operating conditions similar to those anticipated for the activities proposed by the operator? If so, the technology would not be considered a NUT;
- Does the technology function in a manner that potentially causes different impacts to the environment than similar equipment or procedures did in the past? If so, the technology would be considered a NUT;
- Does the technology have a significantly different interface with the environment than similar equipment or procedures did in the past? If so, the technology would be considered a NUT; and
- Does the technology include operating characteristics that are outside established performance parameters? If so, the technology would be considered a NUT.

NMFS will consult with BOEM as well as with NMFS' ESA Interagency Cooperation Division regarding the level of review necessary for issuance of an LOA in which a NUT is proposed for use.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget (OMB) has determined that this rule is economically significant. Accordingly, a regulatory impact analysis (RIA) was prepared and made available for review by the public. Following review of public comments, a final RIA has been prepared and is available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* Appendix B of the RIA provides a final regulatory flexibility analysis (FRFA, discussed below), while Appendix C addresses other compliance requirements.

The RIA evaluates the potential costs and benefits of these incidental take regulations against two baselines, a baseline corresponding with regulatory conditions in place since 2013 pursuant to a settlement agreement, as amended through stipulated agreement, involving a stay of litigation (*NRDC et al.* v. *Bernhardt et al.,* Civil Action No. 2:10 cv–01882 (E.D. La.)), and a baseline corresponding to conditions prior to the 2013 settlement agreement. Under the settlement agreement that is in effect, industry trade groups representing operators agreed to include certain mitigation requirements for geophysical surveys in the GOM.

OMB Circular A–4 provides that agencies may present multiple baselines where this would provide additional useful information to the public on the projected effects of the regulation. NMFS presented both baselines for public information and comment, consistent with the Circular A–4 provision allowing agencies to present multiple baselines. No information or comments regarding the economic baselines were received.

These regulations require new mitigation measures relative to the settlement baseline and, thus, new costs for survey operators. However, the rule

also alleviates the burden of implementing minimum separation distance requirements for deep penetration airgun surveys, as required under the settlement agreement. The rule also results in certain indirect (but non-monetized) costs. However, the RIA analysis demonstrates that these costs are not likely to be significant. Moreover, as described in the RIA, total costs related to compliance for survey activities are small compared with expenditures on other aspects of oil and gas industry operations, and direct compliance costs of the regulatory requirements are unlikely to result in materially reduced oil and gas activities in the GOM.

The rule also results in certain non-monetized benefits. The protection of marine mammals afforded by this rule (pursuant to the requirements of the MMPA) benefits the regional economic value of marine mammals via tourism and recreation to some extent, as mitigation measures applied to geophysical survey activities in the GOM region are expected to benefit the marine mammal populations that support this economic activity in the GOM. In addition, some degree of benefits can be expected to accrue solely via ecological benefits to marine mammals and other wildlife as a result of the regulatory requirements. The published literature (described in the RIA) is clear that healthy populations of marine mammals and other co-existing species benefit regional economies and provide social welfare benefits to people. However, the literature does not provide a basis for quantitatively valuing the cost of anticipated incremental changes in environmental disturbance and marine mammal harassment associated with the rule.

Notably, the rule also affords significant benefit to the regulated industry by providing regulatory certainty through an efficient framework within which to achieve compliance with the MMPA. In particular, cost savings may be generated by the reduced administrative effort required to obtain an LOA under the framework established by a rule compared to what would be required to obtain an incidental harassment authorization (IHA) under section 101(a)(5)(D). Absent the rule, to attain equivalent compliance with the MMPA, survey operators in the GOM would need to apply for an IHA. Although not monetized in the RIA, NMFS' analysis indicates that the upfront work associated with the rule (*e.g.,* analyses, modeling, process for obtaining LOA) likely saves significant time and money for operators. A conservative cost savings calculation, based on estimates of the costs for IHA applications relative to LOA application costs and an assumption of the number of likely authorizations based on total annual survey days and survey estimates included in the RIA, ranges from $500,000 to $1.5 million annually. In terms of timing, NMFS recommends that IHA applicants contact the agency six to nine months in advance of the planned activity, whereas NMFS anticipates a timeframe of three months or less (depending upon the content of the request and the activities covered) for LOA applications under this rule.

Details regarding cost estimation are available in the RIA. A qualitative evaluation of indirect costs related to the regulations is also provided in the RIA. Note that these costs would be diffused across all operators receiving LOAs.

NMFS prepared a FRFA, as required by Section 603 of the Regulatory Flexibility Act (RFA), for this rule. The FRFA describes the economic effects this rule will have on small entities. A description of this action, why it is being considered, the objectives of the action, and the legal basis for the action are contained in the preamble of this rule. A copy of the full analysis is available as an appendix to the RIA. The MMPA provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. A detailed summary of the initial regulatory flexibility analysis was provided at the proposed rule stage. No comments or information regarding this analysis were received.

This final rule is expected to directly regulate businesses that conduct geophysical surveys in the GOM with the potential to incidentally take marine mammals. Some of these businesses may be defined as small entities. The FRFA is summarized below.

The FRFA focuses on identifying small businesses that would bear the incremental survey costs associated with the rule. These may include entities undertaking, commissioning, or purchasing surveys. In order to estimate the number of small entities to which the rule will apply, permit applications between 2006 and 2015 were analyzed to understand what industries were involved in permit applications for geophysical surveys in the Gulf of Mexico and to identify U.S.-based permit applicants that would be classified as small according to Small Business Administration definitions and the most recent revenue or employment data available. In total, 34 U.S.-based small businesses applied for geophysical survey permits in the Gulf of Mexico between 2006 and 2015. By assuming that the same proportion of international, large, and small companies will undertake the surveys over the next five years as occurred during 2006 to 2015, the likely number of future surveys that will include small entity applicants may be estimated. Accordingly, NMFS estimates that small entities would apply for approximately 32 to 53 surveys over the next five years, or approximately six to 11 surveys annually. Historically, there was a ratio of approximately 2.2 surveys applied for per small entity. Using this ratio, NMFS estimates that approximately 15 to 24 small companies will likely apply for permits over the next five years, or approximately 3 to 5 small companies each year. The future distribution of small survey companies by industry is not known, but the historical pattern of surveys suggests that companies involved in oil and gas extraction (NAICS 2111) and support activities for oil and gas (213112) will account for the majority of the survey applications by small companies.

A review of the reported annual revenues for the 34 small entities that applied for survey permits between 2006 and 2015 reveals a wide range, with the lowest revenues reported to be $0.04 million and the highest revenues reported to be $1.9 billion. Average revenues for the small entities who applied for permits were $232 million, with median revenues of $12.26 million. We note, however, that the revenues and numbers of employees reported for many of these small companies appeared to be erroneous, in multiple instances reporting annual revenues significantly less than the costs of conducting even the lowest cost surveys. As a result, these revenue estimates are likely to be inaccurate or, alternatively, permit applicants must pass survey costs on to the companies that purchase or commission the seismic data. Given that the oil and gas extraction companies are generally the entities purchasing the survey data, we expect that it is most likely that survey costs are ultimately borne by NAICS 2111 (oil and gas extraction), either as the permittees for the survey permit or because the other, smaller businesses pass these costs along in the data purchase price.

In summary, the FRFA finds the following: First, in the majority of cases (88 percent), survey permit applicants are large businesses. Second, when the permit applicants are small businesses, the majority of the time (63 percent) they are oil and gas extractors (NAICS 2111). Third, together, these permits (for large businesses and small businesses with high annual revenues for which

rule costs are a small fraction) account for 96 percent of the survey permits. Fourth, while small entities in other industries occasionally apply for permits (four percent historically), these businesses are quite small, with average annual revenues in the millions or even less. Given their size, it is unlikely that these permit applicants bear survey costs; otherwise it would be reflected in their annual revenues (*i.e.,* their revenues on average would reflect that they recover their costs). Accordingly, NMFS expects it is most likely that survey costs are passed on to oil and gas extraction companies who commission the surveys or purchase the data. And fifth, overall, up to five small businesses (NAICS 2111) per year may experience increased costs of between 0.1 and 0.7 percent of average annual revenues.

The draft version of the RIA and the Initial Regulatory Flexibility Analysis considered effects of a more stringent alternative than the proposed rule. The more stringent alternative included additional shutdown requirements and area closures for surveys, generating costs up to 20 percent greater than the proposed rule. NMFS did not elect to proceed with these elements of the more stringent alternative in the final rule, which reduces the potential for impacts to small businesses. NMFS determined that the final rule achieves the statutory objectives with a lower regulatory burden. As described above, a relatively small portion of total survey activities are undertaken by small entities and the FRFA determines that it is unlikely that small entities will bear the compliance costs described in the RIA.

This final rule revises the information collection request (ICR) requirement associated with OMB Control Number 0648–0151 to allow for the expected increase in applicants/respondents due to this final action. This revision is subject to review and approval by OMB under the Paperwork Reduction Act (PRA) and has been submitted to OMB. NMFS published a 30-day **Federal Register** notice (85 FR 60765; September 28, 2020) that provided for an additional comment period. Details on the new information collection requirements can be found in the RIA Appendix C.2. NMFS anticipates that 95 to 151 geophysical surveys will take place annually on average over the five years of the regulations in the GOM that would be subject to potential information collection requirements. Due to this final rule, NMFS estimates at least 95 new LOA applications annually. Because the existing OMB Control Number 0648–0151 expires less than a year (June 30, 2021) after this final rule publishes, there will be less than a year for respondents to carry out work under these regulations before this OMB Control Number expires. Thus, NMFS estimates no more than one-quarter of respondents (24) will complete work to the point of developing an annual report prior to when 0648–0151 must be renewed.

We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Written comments and recommendations for this information collection should be submitted at the following website: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by using the search function and entering either the title of the collection or the OMB Control Number 0648–0151.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 217

Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and recordkeeping requirements, Seafood, Transportation.

Dated: December 7, 2020.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 217 is amended as follows:

PART 217—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Add Subpart S, consisting of §§ 217.180 through 217.189, to read as follows:

Subpart S—Taking Marine Mammals Incidental to Geophysical Survey Activities in the Gulf of Mexico

Sec.

217.180 Specified activity and specified geographical region.
217.181 Effective dates.
217.182 Permissible methods of taking.
217.183 Prohibitions.
217.184 Mitigation requirements.
217.185 Requirements for monitoring and reporting.
217.186 Letters of Authorization.
217.187 Renewals and modifications of Letters of Authorization.
217.188 [Reserved]
217.189 [Reserved]

Subpart S—Taking Marine Mammals Incidental to Geophysical Survey Activities in the Gulf of Mexico

§ 217.180 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to oil and gas industry operators (LOA-holders), and those persons authorized to conduct activities on their behalf, for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to geophysical survey activities.

(b) The taking of marine mammals by oil and gas industry operators may be authorized in a Letter of Authorization (LOA) only if it occurs within U.S. waters in the Gulf of Mexico, outside the area subject to a Congressional leasing moratorium under the Gulf of Mexico Energy Security Act (GOMESA) (Pub L. 109–432, § 104) as of the effective date of these regulations.

§ 217.181 Effective dates.

Regulations in this subpart are effective from April 19, 2021 through April 19, 2026.

§ 217.182 Permissible methods of taking.

Under LOAs issued pursuant to §§ 216.106 of this chapter and 217.186, LOA-holders may incidentally, but not intentionally, take marine mammals within the area described in § 217.180(b) by Level A and Level B harassment associated with geophysical survey activities, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA.

§ 217.183 Prohibitions.

Notwithstanding takings contemplated in §§ 217.180 and 217.182, and authorized by a LOA issued under §§ 216.106 of this chapter and 217.186, no person in connection with the activities described in § 217.180 may:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under §§ 216.106 of this chapter and 217.186;

(b) Take any marine mammal not specified in such LOAs;

(c) Take any marine mammal specified in such LOAs in any manner other than as specified; or

(d) Take a marine mammal specified in such LOAs if NMFS determines such

taking results in more than a negligible impact on the species or stocks of such marine mammal.

§ 217.184 Mitigation requirements.

When conducting the activities identified in § 217.180, the mitigation measures contained in any LOA issued under §§ 216.106 of this chapter and 217.186 must be implemented. These mitigation measures shall include but are not limited to:

(a) *General conditions.* (1) A copy of any issued LOA must be in the possession of the LOA-holder, vessel operator, other relevant personnel, the lead protected species observer (PSO), and any other relevant designees operating under the authority of the LOA.

(2) The LOA-holder must instruct relevant vessel personnel with regard to the authority of the protected species monitoring team (PSO team), and must ensure that relevant vessel personnel and PSO team participate in a joint onboard briefing, led by the vessel operator and lead PSO, prior to beginning work to ensure that responsibilities, communication procedures, protected species monitoring protocols, operational procedures, and LOA requirements are clearly understood. This briefing must be repeated when relevant new personnel join the survey operations before work involving those personnel commences.

(3) The acoustic source must be deactivated when not acquiring data or preparing to acquire data, except as necessary for testing. Unnecessary use of the acoustic source must be avoided. For surveys using airgun arrays as the acoustic source, notified operational capacity (*i.e.,* total array volume) (not including redundant backup airguns) must not be exceeded during the survey, except where unavoidable for source testing and calibration purposes. All occasions where activated source volume exceeds notified operational capacity must be communicated to the PSO(s) on duty and fully documented. The lead PSO must be granted access to relevant instrumentation documenting acoustic source power and/or operational volume.

(4) PSOs must be used as specified in this paragraph (a)(4).

(i) LOA-holders must use independent, dedicated, qualified PSOs, meaning that the PSOs must be employed by a third-party observer provider, must have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements (including brief alerts regarding maritime hazards), and must be qualified pursuant to § 217.185(a) (except as specified at § 217.184(d)(2)(iii–iv)). Acoustic PSOs are required to complete specialized training for operating passive acoustic monitoring (PAM) systems and are encouraged to have familiarity with the vessel on which they will be working. PSOs may act as both acoustic and visual observers (but not simultaneously), so long as they demonstrate that their training and experience are sufficient to perform each task.

(ii) The LOA-holder must submit PSO resumes for NMFS review and approval prior to commencement of the survey (except as specified at § 217.184(d)(2)(iii)). Resumes should include dates of training and any prior NMFS approval, as well as dates and description of last experience, and must be accompanied by information documenting successful completion of an acceptable training course. NMFS is allowed one week to approve PSOs from the time that the necessary information is received by NMFS, after which PSOs meeting the minimum requirements will automatically be considered approved.

(iii) At least one visual PSO and two acoustic PSOs (when required) aboard each acoustic source vessel must have a minimum of 90 days at-sea experience working in those roles, respectively, with no more than eighteen months elapsed since the conclusion of the at-sea experience (except as specified at § 217.184(d)(2)(iii)). One visual PSO with such experience must be designated as the lead for the entire PSO team. The lead must coordinate duty schedules and roles for the PSO team and serve as the primary point of contact for the vessel operator. (Note that the responsibility of coordinating duty schedules and roles may instead be assigned to a shore-based, third-party monitoring coordinator.) To the maximum extent practicable, the lead PSO must devise the duty schedule such that experienced PSOs are on duty with those PSOs with appropriate training but who have not yet gained relevant experience.

(b) *Deep penetration surveys.* (1) Deep penetration surveys are defined as surveys using airgun arrays with total volume greater than 1,500 in^3.

(2) Visual monitoring must be conducted as specified in this paragraph (b)(2).

(i) During survey operations (*i.e.,* any day on which use of the acoustic source is planned to occur, and whenever the acoustic source is in the water, whether activated or not), a minimum of two PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset).

(ii) Visual monitoring must begin not less than 30 minutes prior to ramp-up and must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset.

(iii) Visual PSOs must coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts, and must conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner.

(iv) Visual PSOs must immediately communicate all observations of marine mammals to the on-duty acoustic PSO, including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination.

(v) Any observations of marine mammals by crew members aboard any vessel associated with the survey must be relayed to the PSO team.

(vi) During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), visual PSOs must conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the acoustic source and between acquisition periods, to the maximum extent practicable.

(vii) Visual PSOs may be on watch for a maximum of two consecutive hours followed by a break of at least one hour between watches and may conduct a maximum of 12 hours of observation per 24-hour period. NMFS may grant an exception for LOA applications that demonstrate such a ''two hours on/one hour off'' duty cycle is not practicable, in which case visual PSOs will be subject to a maximum of four consecutive hours on watch followed by a break of at least two hours between watches. Combined observational duties (visual and acoustic but not at the same time) must not exceed 12 hours per 24-hour period for any individual PSO.

(3) Acoustic monitoring must be conducted as specified in this paragraph (b)(3).

(i) All source vessels must use a towed PAM system at all times when operating in waters deeper than 100 m, which must be monitored by a minimum of one acoustic PSO beginning at least 30 minutes prior to ramp-up, at all times during use of the acoustic source, and until one hour after use of the acoustic source ceases. ''PAM system'' refers to calibrated hydrophone arrays with full system redundancy to

detect, identify, and estimate distance and bearing to vocalizing cetaceans, coupled with appropriate software to aid monitoring and listening by a PAM operator skilled in bioacoustics analysis and computer system specifications capable of running appropriate software. The PAM system must have at least one calibrated hydrophone (per each deployed hydrophone type and/or set) sufficient for determining whether background noise levels on the towed PAM system are sufficiently low to meet performance expectations. Applicants must provide a PAM plan including description of the hardware and software proposed for use prior to proceeding with any survey where PAM is required.

(ii) Acoustic PSOs must immediately communicate all detections of marine mammals to visual PSOs (when visual PSOs are on duty), including any determination by the PSO regarding species identification, distance, and bearing, and the degree of confidence in the determination.

(iii) Acoustic PSOs may be on watch for a maximum of four consecutive hours followed by a break of at least two hours between watches, and may conduct a maximum of 12 hours of observation per 24-hour period. Combined observational duties (visual and acoustic but not at the same time) must not exceed 12 hours per 24-hour period for any individual PSO.

(iv) Survey activity may continue for 30 minutes when the PAM system malfunctions or is damaged, while the PAM operator diagnoses the issue. If the diagnosis indicates that the PAM system must be repaired to solve the problem, operations may continue for an additional two hours without acoustic monitoring during daylight hours only under the following conditions:

(A) Sea state is less than or equal to BSS 4;

(B) No marine mammals (excluding delphinids) detected solely by PAM in the applicable exclusion zone in the previous two hours;

(C) NMFS is notified via email as soon as practicable with the time and location in which operations began occurring without an active PAM system; and

(D) Operations with an active acoustic source, but without an operating PAM system, do not exceed a cumulative total of four hours in any 24-hour period.

(4) PSOs must establish and monitor applicable exclusion and buffer zones. These zones must be based upon the radial distance from the edges of the airgun array (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source (*i.e.,* anytime the acoustic source is active, including ramp-up), occurrence of marine mammals within the relevant buffer zone (but outside the exclusion zone) should be communicated to the operator to prepare for the potential shutdown of the acoustic source.

(i) Two exclusion zones are defined, depending on the species and context. A standard exclusion zone encompassing the area at and below the sea surface out to a radius of 500 meters from the edges of the airgun array (0–500 m) is defined. For special circumstances (defined at § 217.184(b)(9)(v)), the exclusion zone encompasses an extended distance of 1,500 meters (0–1,500 m).

(ii) During pre-start clearance monitoring (*i.e.,* before ramp-up begins), the buffer zone acts as an extension of the exclusion zone in that observations of marine mammals within the buffer zone would also preclude airgun operations from beginning (*i.e.,* ramp-up). For all marine mammals (except where superseded by the extended 1,500-m exclusion zone), the buffer zone encompasses the area at and below the sea surface from the edge of the 0–500 meter exclusion zone out to a radius of 1,000 meters from the edges of the airgun array (500–1,000 m). The buffer zone is not applicable when the exclusion zone is greater than 500 meters, *i.e.,* the observational focal zone is not increased beyond 1,500 meters.

(5) A ramp-up procedure, involving a step-wise increase in the number of airguns firing and total active array volume until all operational airguns are activated and the full volume is achieved, is required at all times as part of the activation of the acoustic source. A 30-minute pre-start clearance observation period must occur prior to the start of ramp-up. The LOA-holder must adhere to the following pre-start clearance and ramp-up requirements:

(i) The operator must notify a designated PSO of the planned start of ramp-up as agreed upon with the lead PSO; the notification time should not be less than 60 minutes prior to the planned ramp-up.

(ii) Ramp-ups must be scheduled so as to minimize the time spent with source activated prior to reaching the designated run-in.

(iii) A designated PSO must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed.

(iv) Ramp-up must not be initiated if any marine mammal is within the applicable exclusion or buffer zone. If a marine mammal is observed within the exclusion zone or the buffer zone during the 30-minute pre-start clearance period, ramp-up must not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (15 minutes for small delphinids and 30 minutes for all other species).

(v) Ramp-up must begin by activating a single airgun of the smallest volume in the array and shall continue in stages by doubling the number of active elements at the commencement of each stage, with each stage of approximately the same duration. Total duration must not be less than 20 minutes. The operator must provide information to the PSO documenting that appropriate procedures were followed.

(vi) Ramp-up must cease and the source shut down upon observation of marine mammals within the applicable exclusion zone. Once ramp-up has begun, observations of marine mammals within the buffer zone do not require shutdown.

(vii) Ramp-up may occur at times of poor visibility, including nighttime, if appropriate acoustic monitoring has occurred with no detections of a marine mammal other than delphinids in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at night where operational planning cannot reasonably avoid such circumstances.

(viii) If the acoustic source is shut down for brief periods (*i.e.,* less than 30 minutes) for reasons other than implementation of prescribed mitigation (*e.g.,* mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant visual and/or acoustic observation and no visual or acoustic detections of any marine mammal have occurred within the applicable exclusion zone. For any longer shutdown, pre-start clearance observation and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required, but if the shutdown period was brief and constant observation maintained, pre-start clearance watch is not required.

(ix) Testing of the acoustic source involving all elements requires ramp-up. Testing limited to individual source elements or strings does not require ramp-up but does require the pre-start clearance observation period.

(6) Shutdowns must be implemented as specified in this paragraph (b)(6).

(i) Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source pursuant to the requirements of this subpart.

(ii) The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch.

(iii) When both visual and acoustic PSOs are on duty, all detections must be immediately communicated to the remainder of the on-duty PSO team for potential verification of visual observations by the acoustic PSO or of acoustic detections by visual PSOs.

(iv) When the airgun array is active (*i.e.,* anytime one or more airguns is active, including during ramp-up) and (1) a marine mammal appears within or enters the applicable exclusion zone and/or (2) a marine mammal (excluding delphinids) is detected acoustically and localized within the applicable exclusion zone, the acoustic source must be shut down. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation.

(v) The extended 1,500-m exclusion zone must be applied upon detection (visual or acoustic) of a baleen whale, sperm whale, beaked whale, or *Kogia* spp. within the zone.

(vi) Shutdown requirements are waived for dolphins of the following genera: *Tursiops, Stenella, Steno,* and *Lagenodelphis.* If a delphinid is visually detected within the exclusion zone, no shutdown is required unless the PSO confirms the individual to be of a genus other than those listed above, in which case a shutdown is required. Acoustic detection of delphinids does not require shutdown.

(vii) If there is uncertainty regarding identification or localization, PSOs may use best professional judgment in making the decision to call for a shutdown.

(viii) Upon implementation of shutdown, the source may be reactivated after the marine mammal(s) has been observed exiting the applicable exclusion zone or following a 30-minute clearance period with no further detection of the marine mammal(s).

(c) *Shallow penetration surveys.* (1) Shallow penetration surveys are defined as surveys using airgun arrays with total volume equal to or less than 1,500 in^3, single airguns, boomers, or equivalent sources.

(2) LOA-holders conducting shallow penetration surveys must follow the requirements defined for deep penetration surveys at § 217.184(b), with the following exceptions:

(i) Acoustic monitoring is not required for shallow penetration surveys.

(ii) Ramp-up for small airgun arrays must follow the procedure described above for large airgun arrays, but may occur over an abbreviated period of time. Ramp-up is not required for surveys using only a single airgun. For non-airgun sources, power should be increased as feasible to effect a ramp-up.

(iii) Two exclusion zones are defined, depending on the species and context. A standard exclusion zone encompassing the area at and below the sea surface out to a radius of 100 meters from the edges of the airgun array (if used) or from the acoustic source (0–100 m) is defined. For special circumstances (§ 217.184(b)(6)(v)), the exclusion zone encompasses an extended distance of 500 meters (0–500 m).

(iv) The buffer zone encompasses the area at and below the sea surface from the edge of the 0–100 meter exclusion zone out to a radius of 200 meters from the edges of the airgun array (if used) or from the acoustic source (100–200 meters). The buffer zone is not applicable when the exclusion zone is greater than 100 meters.

(d) *High-resolution geophysical (HRG) surveys.* (1) HRG surveys are defined as surveys using an electromechanical source that operates at frequencies less than 180 kHz, other than those defined at § 217.184(c)(1) (*e.g.,* side-scan sonar, multibeam echosounder, or chirp sub-bottom profiler).

(2) LOA-holders conducting HRG surveys must follow the requirements defined for shallow penetration surveys at § 217.184(c), with the following exceptions:

(i) No shutdowns are required for HRG surveys. Pre-start clearance watch is required as defined at § 217.184(c), *i.e.,* for a period of 30 minutes and over a 200-m radius from the acoustic source.

(ii) During survey operations (*e.g.,* any day on which use of the acoustic source is planned to occur, and whenever the acoustic source is in the water, whether activated or not), a minimum of one trained and experienced independent PSO must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) when operating in waters deeper than 100 m.

(iii) When operating in waters shallower than 100 m, LOA-holders must employ one trained visual PSO, who may be a crew member, only for purposes of conducting pre-start clearance monitoring. If PSOs are crew members, *i.e.,* are not independent PSOs, the PSOs are not subject to NMFS' approval. In these circumstances, LOA requests must describe the training that will be provided to crew members filling the role of PSO.

(iv) PSOs are not required during survey operations in which the active acoustic source(s) are deployed on an autonomous underwater vehicle.

(e) *Time-area closure.* From January 1 through May 31, no use of airguns may occur shoreward of the 20-m isobath and between 90–84° W.

(f) *Entanglement avoidance.* To avoid the risk of entanglement, LOA-holders conducting surveys using ocean-bottom nodes or similar gear must:

(1) Use negatively buoyant coated wire-core tether cable;

(2) Retrieve all lines immediately following completion of the survey; and

(3) Attach acoustic pingers directly to the coated tether cable; acoustic releases should not be used.

(g) *Vessel strike avoidance.* LOA-holders must adhere to the following requirements:

(1) Vessel operators and crews must maintain a vigilant watch for all marine mammals and must slow down, stop their vessel, or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone around the vessel, which shall be defined according to the parameters stated in this subsection. Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to distinguish marine mammals from other phenomena and broadly to identify a marine mammal as a baleen whale, sperm whale, or other marine mammal;

(2) Vessel speeds must be reduced to 10 kn or less when mother/calf pairs, pods, or large assemblages of marine mammals are observed near a vessel;

(3) All vessels must maintain a minimum separation distance of 500 m from baleen whales;

(4) All vessels must maintain a minimum separation distance of 100 m from sperm whales;

(5) All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an exception made for those animals that approach the vessel; and

(6) When marine mammals are sighted while a vessel is underway, the vessel must take action as necessary to avoid violating the relevant separation distance, *e.g.,* attempt to remain parallel

to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area. If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

(7) These requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

§ 217.185 Requirements for monitoring and reporting.

(a) *PSO qualifications.* (1) PSOs must successfully complete relevant, acceptable training, including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program.

(2) PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver must be submitted to NMFS and shall include written justification. Requests will be granted or denied (with justification) by NMFS within one week of receipt of submitted information. Alternate experience that may be considered includes, but is not limited to:

(i) Secondary education and/or experience comparable to PSO duties;

(ii) Previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; or

(iii) Previous work experience as a PSO; the PSO should demonstrate good standing and consistently good performance of PSO duties.

(b) *Equipment.* LOA-holders are required to:

(i) Provide PSOs with bigeye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality solely for PSO use. These must be pedestal-mounted on the deck at the most appropriate vantage point that provides for optimal sea surface observation, PSO safety, and safe operation of the vessel.

(ii) For each vessel required to use a PAM system, provide a PAM system that has been verified and tested by an experienced acoustic PSO who will be using it during the trip for which monitoring is required;

(iii) Work with the selected third-party observer provider to ensure PSOs have all equipment (including backup equipment) needed to adequately perform necessary tasks, including accurate determination of distance and bearing to observed marine mammals. (Equipment specified in A. through G. below may be provided by an individual PSO, the third-party observer provider, or the LOA-holder, but the LOA-holder is responsible for ensuring PSOs have the proper equipment required to perform the duties specified herein.) Such equipment, at a minimum, must include:

(A) Reticle binoculars (*e.g.,* 7 x 50) of appropriate quality (at least one per PSO, plus backups);

(B) Global Positioning Unit (GPS) (plus backup);

(C) Digital camera with a telephoto lens (the camera or lens should also have an image stabilization system) that is at least 300 mm or equivalent on a full-frame single lens reflex (SLR) (plus backup);

(D) Compass (plus backup);

(E) Radios for communication among vessel crew and PSOs (at least one per PSO, plus backups); and

(F) Any other tools necessary to adequately perform necessary PSO tasks.

(c) *Data collection.* PSOs must use standardized electronic data forms. PSOs must record detailed information about any implementation of mitigation requirements, including the distance of marine mammals to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up or activation of the acoustic source. If required mitigation was not implemented, PSOs must record a description of the circumstances. At a minimum, the following information should be recorded:

(1) Vessel names (source vessel and other vessels associated with survey), vessel size and type, maximum speed capability of vessel, port of origin, and call signs;

(2) PSO names and affiliations;

(3) Dates of departures and returns to port with port name;

(4) Dates of and participants in PSO briefings;

(5) Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;

(6) Vessel location (latitude/longitude) when survey effort began and ended and vessel location at beginning and end of visual PSO duty shifts;

(7) Vessel location at 30-second intervals (if software capability allows) or 5-minute intervals (if location must be manually recorded);

(8) Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;

(9) Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions changed significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;

(10) Vessel location when environmental conditions change significantly;

(11) Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions);

(12) Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in an array, tow depth of an acoustic source, and any other notes of significance (*i.e.,* pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.); and

(13) Upon visual observation of a marine mammal, the following information:

(i) Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);

(ii) PSO who sighted the animal and PSO location (including height above water) at time of sighting;

(iii) Time of sighting;

(iv) Vessel coordinates at time of sighting;

(v) Water depth;

(vi) Direction of vessel's travel (compass direction);

(vii) Speed of the vessel(s) from which the observation was made;

(viii) Direction of animal's travel relative to the vessel;

(ix) Pace of the animal;

(x) Estimated distance to the animal (and method of estimating distance) and its heading relative to vessel at initial sighting;

(xi) Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species;

(xii) Estimated number of animals (high/low/best);

(xiii) Estimated number of animals by cohort (adults, juveniles, group composition, etc.);

(xiv) Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);

(xv) Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior), including an assessment of behavioral responses to survey activity;

(xvi) Animal's closest point of approach (CPA) and/or closest distance from any element of the acoustic source;

(xvii) Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and

(xviii) Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up) and time and location of the action.

(12) Upon acoustic detection of a marine mammal using a PAM system, the following information:

(i) An acoustic encounter identification number, and whether the detection was linked with a visual sighting;

(ii) Date and time when first and last heard;

(iii) Types and nature of sounds heard (*e.g.,* clicks, whistles, creaks, burst pulses, continuous, sporadic, strength of signal); and

(iv) Any additional information recorded such as water depth of the hydrophone array, bearing of the animal to the vessel (if determinable), species or taxonomic group (if determinable), spectrogram screenshot, and any other notable information.

(d) *Reporting.* (1) Annual reporting must be submitted as specified in this paragraph.

(i) LOA-holders must submit a summary report to NMFS on all activities and monitoring results within 90 days of the completion of the survey or expiration of the LOA, whichever comes sooner, and must include all information described above under § 217.185(c). If an issued LOA is valid for greater than one year, the summary report must be submitted on an annual basis.

(ii) The report must describe activities conducted and sightings of marine mammals, must provide full documentation of methods, results, and interpretation pertaining to all monitoring, and must summarize the dates and locations of survey operations and all marine mammal sightings (dates, times, locations, activities, associated survey activities, and information regarding locations where the acoustic source was used). In addition to the report, all raw observational data must be made available to NMFS.

(iii) For operations requiring the use of PAM, the report must include a validation document concerning the use of PAM, which should include necessary noise validation diagrams and demonstrate whether background noise levels on the PAM deployment limited achievement of the planned detection goals. Copies of any vessel self-noise assessment reports must be included with the report.

(iv) The LOA-holder must provide geo-referenced time-stamped vessel tracklines for all time periods in which airguns (full array or single) were operating. Tracklines must include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off). GIS files must be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates must be referenced to the WGS84 geographic coordinate system.

(v) The draft report must be accompanied by a certification from the lead PSO as to the accuracy of the report, and the lead PSO may submit directly to NMFS a statement concerning implementation and effectiveness of the required mitigation and monitoring.

(vi) A final report must be submitted within 30 days following resolution of any comments on the draft report.

(2) Comprehensive reporting must be submitted as specified in this paragraph. LOA-holders must contribute to the compilation and analysis of data for inclusion in an annual synthesis report addressing all data collected and reported through annual reporting in each calendar year. The synthesis period shall include all annual reports deemed to be final by NMFS in a given one-year reporting period. The report must be submitted to NMFS within 90 days following the end of a given one-year reporting period.

(e) *Reporting of injured or dead marine mammals.* (1) In the event that personnel involved in the survey activities discover an injured or dead marine mammal, the LOA-holder must report the incident to the Office of Protected Resources (OPR), NMFS and to the Southeast Regional Stranding Network as soon as feasible. The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

(ii) Species identification (if known) or description of the animal(s) involved;

(iii) Condition of the animal(s) (including carcass condition if the animal is dead);

(iv) Observed behaviors of the animal(s), if alive;

(v) If available, photographs or video footage of the animal(s); and

(vi) General circumstances under which the animal was discovered.

(2) In the event of a ship strike of a marine mammal by any vessel involved in the survey activities, the LOA-holder must report the incident to OPR, NMFS and to the Southeast Regional Stranding Network as soon as feasible. The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the incident;

(ii) Species identification (if known) or description of the animal(s) involved;

(iii) Vessel's speed during and leading up to the incident;

(iv) Vessel's course/heading and what operations were being conducted (if applicable);

(v) Status of all sound sources in use;

(vi) Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;

(vii) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;

(viii) Estimated size and length of animal that was struck;

(ix) Description of the behavior of the marine mammal immediately preceding and following the strike;

(x) If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;

(xi) Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and

(xii) To the extent practicable, photographs or video footage of the animal(s).

(3) For deep penetration surveys, in the event of a live stranding (or near-shore atypical milling) event within 50 km of the survey operations, where the NMFS stranding network is engaged in herding or other interventions to return animals to the water, the Director of OPR, NMFS (or designee) will advise the LOA-holder of the need to

implement shutdown procedures for all active acoustic sources operating within 50 km of the stranding. Shutdown procedures for live stranding or milling marine mammals include the following:

(i) If at any time, the marine mammal(s) die or are euthanized, or if herding/intervention efforts are stopped, the Director of OPR, NMFS (or designee) will advise the LOA-holder that the shutdown around the animals' location is no longer needed.

(ii) Otherwise, shutdown procedures will remain in effect until the Director of OPR, NMFS (or designee) determines and advises the LOA-holder that all live animals involved have left the area (either of their own volition or following an intervention).

(iii) If further observations of the marine mammals indicate the potential for re-stranding, additional coordination with the LOA-holder will be required to determine what measures are necessary to minimize that likelihood (*e.g.,* extending the shutdown or moving operations farther away) and to implement those measures as appropriate.

(4) If NMFS determines that the circumstances of any marine mammal stranding found in the vicinity of the activity suggest investigation of the association with survey activities is warranted, and an investigation into the stranding is being pursued, NMFS will submit a written request to the LOA-holder indicating that the following initial available information must be provided as soon as possible, but no later than 7 business days after the request for information. In the event that the investigation is still inconclusive, the investigation of the association of the survey activities is still warranted, and the investigation is still being pursued, NMFS may provide additional information requests, in writing, regarding the nature and location of survey operations prior to the time period above.

(i) Status of all sound source use in the 48 hours preceding the estimated time of stranding and within 50 km of the discovery/notification of the stranding by NMFS; and

(ii) If available, description of the behavior of any marine mammal(s) observed preceding (*i.e.,* within 48 hours and 50 km) and immediately after the discovery of the stranding.

§ 217.186 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, prospective LOA-holders must apply for and obtain an LOA.

(b) An LOA, unless suspended or revoked, may be effective for a period not to exceed the expiration date of these regulations.

(c) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, the LOA-holder must apply for and obtain a modification of the LOA as described in § 217.187.

(d) The LOA shall set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species or stock and its habitat; and

(3) Requirements for monitoring and reporting.

(e) Issuance of the LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

(f) For LOA issuance, where either (1) the conclusions put forth in an application (*e.g.,* take estimates) are based on analytical methods that differ substantively from those used in the development of the rule, or (2) the proposed activity or anticipated impacts vary substantively in scope or nature from those analyzed for the rule, NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the differences, and solicit public comment before making a decision regarding issuance of the LOA.

(g) Notice of issuance or denial of an LOA shall be published in the **Federal Register** within thirty days of a determination.

§ 217.187 Renewals and modifications of Letters of Authorization (LOA).

(a) An LOA issued under § 216.106 of this chapter and § 217.186 for the activity identified in § 217.180 shall be modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.

(b) For LOA modification requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that result in more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under § 216.106 of this chapter and § 217.186 for the activity identified in § 217.180 may be modified by NMFS under the following circumstances:

(1) NMFS may modify (including adding or removing measures) the existing mitigation, monitoring, or reporting measures (after consulting with the LOA-holder regarding the practicability of the modifications) if doing so is practicable and creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations;

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from monitoring from previous years;

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in an LOA issued pursuant to § 216.106 of this chapter and § 217.186, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§§ 217.188–217.189 [Reserved]

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Guidance Under Section 1061; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9945]

RIN 1545–BO81

Guidance Under Section 1061

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance under section 1061 of the Internal Revenue Code (Code). Section 1061 recharacterizes certain net long-term capital gains of a partner that holds one or more applicable partnership interests as short-term capital gains. An applicable partnership interest is an interest in a partnership that is transferred to or held by a taxpayer, directly or indirectly, in connection with the performance of substantial services by the taxpayer, or any other related person, in any applicable trade or business. These final regulations also amend existing regulations on holding periods to clarify the holding period of a partner's interest in a partnership that includes in whole or in part an applicable partnership interest and/or a profits interest. These regulations affect taxpayers who directly or indirectly hold applicable partnership interests in partnerships and the passthrough entities through which the applicable partnership interest is held.

DATES:

Effective date: These regulations are effective on January 13, 2021.

Applicability date: For dates of applicability, see §§ 1.702–1(g), 1.704–3(f), 1.1061–1(b), 1.1061–2(c), 1.1061–3(f), 1.1061–4(d), 1.1061–5(g), 1.1061–6(e), and 1.1223–3(g).

FOR FURTHER INFORMATION CONTACT: Kara K. Altman or Sonia K. Kothari at (202) 317–6850 or Wendy L. Kribell at (202) 317–5279 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations under section 1061 of the Code to amend the Income Tax Regulations (26 CFR part 1). Section 1061 was added to the Code on December 22, 2017, by section 13309 of Public Law 115–97, 131 Stat. 2054 (2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA). Section 1061 applies to taxable years beginning after December 31, 2017. Section 1061 recharacterizes certain net long-term capital gain with respect to applicable partnership interests (*APIs*) as short-term capital gain.

On August 14, 2020, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–107213–18) in the **Federal Register** (85 FR 49754) containing proposed regulations under sections 702, 704, 1061, and 1223 of the Code (proposed regulations). The Treasury Department and the IRS received written and electronic comments responding to the proposed regulations. No public hearing was requested or held. All comments are available at *www.regulations.gov* or upon request. After full consideration of all comments timely received, this Treasury decision adopts the proposed regulations with modifications in response to the comments as described in the Summary of Comments and Explanation of Revisions section of this preamble.

Summary of Comments and Explanation of Revisions

Most of the comments addressing the proposed regulations are summarized in this Summary of Comments and Explanation of Revisions. However, non-substantive comments or comments merely summarizing or interpreting the proposed regulations, recommending statutory revisions, or addressing provisions outside the scope of these final regulations are not discussed in this preamble.

The final regulations retain the structure of the proposed regulations, with certain revisions. Section 1.1061–1 provides definitions of the terms used in §§ 1.1061–1 through 1.1061–6 of these final regulations (*Section 1061 Regulations* or final regulations). Section 1.1061–2 provides rules and examples regarding APIs and applicable trades or businesses (*ATBs*). Section 1.1061–3 provides guidance on the exceptions to the definition of an API, including the capital interest exception. Section 1.1061–4 provides guidance on the computation of the *Recharacterization Amount* and gives computation examples. Section 1.1061–5 provides guidance regarding the application of section 1061(d) to transfers to certain related parties. Section 1.1061–6 provides reporting rules. Because the application of section 1061 requires a clear determination of the holding period of a partnership interest that is, in whole or in part, an API, the final regulations also provide clarifying amendments to § 1.1223–3. Additional clarifying amendments to §§ 1.702–1(a)(2) and 1.704–3(e) are also provided.

Part I of this Summary of Comments and Explanation of Revisions provides an overview of the statutory provisions and defined terms used in the proposed and final regulations. Part II describes the comments received and revisions made in response to those comments with respect to the following four areas of the proposed regulations: (1) The capital interest exception; (2) the treatment of capital interests acquired with loan proceeds; (3) the *Lookthrough Rule* for certain API dispositions; and (4) transfers of APIs to *Section 1061(d) Related Persons.* Part III discusses additional comments received and revisions made in other areas of the proposed regulations. Part IV summarizes comments received on issues related to section 1061 that are beyond the scope of the regulations and are under study. Part V discusses applicability dates for the final regulations. In addition to the revisions made in response to comments, clarifying changes have been made throughout the final regulations.

I. Overview and Defined Terms

A. Section 1061(a): Recharacterization Amount, Owner Taxpayer, and Related Concepts

1. Recharacterization Amount

Section 1061(a) recharacterizes as short-term capital gain the difference between a taxpayer's net long-term capital gain with respect to one or more APIs and the taxpayer's net long-term capital gain with respect to these APIs if paragraphs (3) and (4) of section 1222, which define the terms long-term capital gain and long-term capital loss, respectively, for purposes of subtitle A of the Code, are applied using a three-year holding period instead of a one-year holding period. The regulations refer to this difference as the Recharacterization Amount. This recharacterization is made regardless of any election in effect under section 83(b).

2. Owner Taxpayers and Passthrough Entities

The regulations provide that the person who is subject to Federal income tax on the Recharacterization Amount is required to calculate such amounts and refer to this person as the *Owner Taxpayer.* Although an API can be held directly by an Owner Taxpayer, it also may be held indirectly through one or more passthrough entities (*Passthrough Entities*). A Passthrough Entity may be a partnership, trust, estate, S corporation, or a passive foreign investment company (PFIC) with respect to which the shareholder has a

qualified electing fund (QEF) election in effect. An *API Holder* is any person who holds an API. The regulations provide a framework for determining the Recharacterization Amount when an API is held through one or more tiers of Passthrough Entities (tiered structure).

3. Gains and Losses Subject to Section 1061

Section 1061(a) applies to a taxpayer's net long-term capital gain with respect to one or more APIs held during the taxable year. The regulations provide that the determination of a taxpayer's net long-term capital gain with respect to the taxpayer's APIs held during the taxable year includes the taxpayer's combined net distributive share of long-term capital gain or loss from all APIs held during the taxable year and the Owner Taxpayer's long-term capital gain and loss from the disposition of any APIs during the taxable year. The regulations generally refer to long-term capital gains and losses recognized with respect to an API as *API Gains and Losses.* However, API Gains and Losses do not include long-term capital gain determined under sections 1231 and 1256, qualified dividends described in section 1(h)(11)(B), and any other capital gain that is characterized as long-term or short-term without regard to the holding period rules in section 1222, such as capital gain characterized under the identified mixed straddle rules described in section 1092(b).

Unrealized API Gains and Losses means, with respect to a Passthrough Entity's assets, all unrealized capital gains and losses that would be realized if those assets were disposed of for fair market value in a taxable transaction and allocated to an API Holder with respect to its API, taking into account the principles of section 704(c). In a tiered structure, API Gains and Losses and Unrealized API Gains and Losses retain their character as API Gains and Losses as they are allocated through the tiers.

B. Section 1061(c)(1): Definition of an Applicable Partnership Interest

Section 1061(c)(1) provides that an API is a partnership interest held by, or transferred to, a taxpayer, directly or indirectly, in connection with the performance of substantial services by the taxpayer, or by any other related person, in any ATB. For this purpose, the regulations define a *Related Person* as a person or entity who is treated as related to another person or entity under section 707(b) or 267(b). Both section 1061(c)(1) and the regulations provide that an API does not include certain partnership interests held by employees of entities that are not engaged in an ATB.

The regulations provide that an API means any interest in a partnership which, directly or indirectly, is transferred to (or is held by) an Owner Taxpayer or Passthrough Taxpayer in connection with the performance of substantial services by the Owner Taxpayer or by a Passthrough Taxpayer, or by a Related Person, including services performed as an employee, in any ATB unless an exception applies. There may be one or more Passthrough Entities between the partnership that originally issued the API and the Passthrough Entity in which the Owner Taxpayer holds its indirect interest in the API. Each Passthrough Entity in the tiered structure is treated as holding an API under the regulations, that is, each Passthrough Entity is an API Holder as is the Owner Taxpayer. An API Holder may be an individual, partnership, trust, estate, S corporation (as defined in section 1361(a)(1)), or a PFIC with respect to which the shareholder has a QEF election in effect under section 1295.

Section 1061(c)(1), similar to section 1061(a), uses the term ''taxpayer.'' The proposed regulations provide that an Owner Taxpayer is the taxpayer for purposes of section 1061(a). The regulations further provide that the reference to ''taxpayer'' in section 1061(c)(1) also includes a *Passthrough Taxpayer.* A Passthrough Taxpayer is a Passthrough Entity that is treated as a taxpayer for the purpose of determining the existence of an API, regardless of whether such Passthrough Taxpayer itself is subject to Federal income tax. Generally, if an interest in a partnership is transferred to a Passthrough Taxpayer in connection with the performance of its own services, the services of its owners, or the services of persons related to either such Passthrough Taxpayer or its owners, the interest is an API as to the Passthrough Taxpayer. The Passthrough Taxpayer's ultimate owners will be treated as Owner Taxpayers, unless otherwise excepted.

A partnership interest is an API if it was transferred in connection with the performance of substantial services. The regulations presume that services are substantial with respect to a partnership interest transferred in connection with services. This presumption is based on the assumption, for purposes of section 1061, that the parties have economically equated the services performed or to be performed with the potential value of the partnership interest transferred. The regulations provide that, subject to certain exceptions, once a partnership interest is an API, it remains an API and never loses its API character.

C. Section 1061(c)(2): Definition of an Applicable Trade or Business

Under section 1061, for an interest in a partnership to be an API, the interest must be held or transferred in connection with the performance of substantial services in an ATB. An ATB is defined in section 1061(c)(2) as any activity conducted on a regular, continuous, and substantial basis consisting, in whole or in part, of raising or returning capital, and either (i) investing in (or disposing of) specified assets (or identifying specified assets for such investing or disposition), or (ii) developing specified assets. The regulations refer to these actions, respectively, as *Raising or Returning Capital Actions* and *Investing or Developing Actions* (collectively, *Specified Actions*). The regulations provide that an activity is conducted on a regular, continuous, and substantial basis if it meets the *ATB Activity Test.* The ATB Activity Test is met if the total level of activity (conducted in one or more entities) meets the level of activity required to establish a trade or business for purposes of section 162.

In applying the ATB Activity Test, the regulations provide that it is not necessary for both Raising or Returning Capital Actions and Investing or Developing Actions to occur in a single taxable year. In that regard, the combined Specified Actions are considered together to determine if the ATB Activity Test is met.

Section 1061(c)(3) provides that specified assets (*Specified Assets*) are securities, as defined in section 475(c)(2) (without regard to the last sentence thereof), commodities, as defined in section 475(e)(2), real estate held for rental or investment, cash or cash equivalents, options or derivative contracts with respect to any of the foregoing, and an interest in a partnership to the extent of the partnership's proportionate interest in any of the foregoing. The definition of Specified Assets in the regulations generally tracks the statutory language. It also includes an option or derivative contract on a partnership interest to the extent that the partnership interest represents an interest in other Specified Assets.

D. Section 1061(c)(4) and Other Exceptions to API Treatment

Section 1061 includes four exceptions to the treatment of a profits interest as an API and the regulations add an additional exception.

First, the statutory definition of an API in section 1061(c)(1) excludes an interest held by a person who is employed by another entity that is conducting a trade or business (other than an ATB) and provides services only to such other entity.

Second, section 1061(c)(4)(A) provides that an API does not include any interest in a partnership directly or indirectly held by a corporation. The regulations provide that the term ''corporation'' for purposes of section 1061(c)(4)(A) does not include an S corporation for which an election under section 1362(a) is in effect or a PFIC with respect to which the shareholder has a QEF election under section 1295 in effect.

Third, section 1061(c)(4)(B) provides that an API does not include a capital interest which provides a right to share in partnership capital commensurate with (i) the amount of capital contributed (determined at the time of receipt of such partnership interest), or (ii) the value of such interest subject to tax under section 83 upon the receipt or vesting of such interest (the capital interest exception). The regulations provide that long-term capital gains and losses with respect to an API Holder's capital investment in a Passthrough Entity, referred to as *Capital Interest Gains and Losses* (which can include allocations and disposition amounts meeting the requirements), are not subject to recharacterization under section 1061. As explained in more detail in Part II.A. of this Summary of Comments and Explanation of Revisions, to meet this exception to API treatment, the proposed regulations require allocations to API Holders (or Passthrough Entities that hold an API in a lower-tier Passthrough Entity) to be made in the same manner as to certain other partners. The final regulations provide a revised and simplified rule that looks to whether allocations are commensurate with capital contributed.

Fourth, section 1061(b) provides that to the extent provided by the Secretary, section 1061 will not apply to income or gain attributable to any asset not held for portfolio investment on behalf of third party investors.

Finally, the regulations provide that an interest in a partnership that was an API in the hands of the seller will not be treated as an API in the hands of the purchaser if the interest is acquired by a bona fide purchaser who (i) does not provide services in the Relevant ATB to which the acquired interest relates, (ii) is unrelated to any service provider, and (iii) acquired the interest for fair market value.

E. Section 1061(d): Transfer of API to a Section 1061(d) Related Person

Section 1061(d)(1) provides that if a taxpayer transfers an API, directly or indirectly, to a related person described in section 1061(d)(2), the taxpayer must include in gross income (as short term capital gain) the excess of so much of the taxpayer's long term capital gains with respect to such interest for the taxable year attributable to the sale or exchange of any asset held for not more than 3 years as is allocable to such interest over any amount treated as short term capital gain under section 1061(a).

A related person for purposes of section 1061(d)(2) (a *Section 1061(d) Related Person*) is defined more narrowly than a related person for purposes of section 1061(c)(1) and includes only members of the taxpayer's family within the meaning of section 318(a)(1), the taxpayer's colleagues (those who provided services in the ATB during certain time periods) and, under the regulations, a Passthrough Entity to the extent that a member of the taxpayer's family or a colleague is an owner.

F. Section 1061(e): Reporting

Section 1061(e) provides that the Secretary ''shall require such reporting (at the time and in the manner prescribed by the Secretary) as is necessary to carry out the purposes of [section 1061].'' The regulations set forth the reporting requirements and include rules for providing information required to compute the Recharacterization Amount when there is a tiered structure.

G. Regulatory Authority

Section 1061(f) provides that the Secretary ''shall issue such regulations or other guidance as is necessary or appropriate to carry out the purposes of [section 1061].'' The legislative history indicates that such guidance is to address the prevention of abuse of the purposes of the provision. *See* H.R. Conf. Rep. No. 115–466 at 422 (2017) (Conference Report); *see also* Joint Committee on Taxation, General Explanation of Public Law 115–97, JCS–1–18, at 203 (2017) (Blue Book). The Conference Report and the Blue Book also state that the guidance is to address the application of the provision to tiered structures of entities. *See id.*

II. Primary Changes to the Proposed Regulations

The majority of comments received on the proposed regulations relate to four areas: (1) The capital interest exception; (2) the treatment of capital interests acquired with loan proceeds; (3) the Lookthrough Rule for certain API dispositions; and (4) transfers of APIs to Section 1061(d) Related Persons. After considering these comments, the Treasury Department and the IRS have determined that changes in approach are required for each of these sections of the final regulations. The remainder of this section generally describes the comments received in these areas and the changes made in response. While all comments timely received were considered, comments are not described in detail to the extent that the ancillary concerns raised by the commenter were resolved by the changes made to the final regulations.

A. Capital Interest Exception

Section 1061(c)(4)(B) provides that an API does not include certain capital interests. The proposed regulations implement the capital interest exception by excepting from recharacterization long-term capital gains and losses that represent a return on an API Holder's capital invested in a Passthrough Entity. The proposed regulations refer to these amounts as Capital Interest Gains and Losses, and include in that definition *Capital Interest Allocations, Passthrough Interest Capital Allocations,* and *Capital Interest Disposition Amounts* that meet the requirements of proposed § 1.1061–3(c)(3) through (6).

The majority of comments received regarding the capital interest exception suggested that the rules in the proposed regulations are too rigid and do not reflect many common business arrangements, resulting in many capital interest holders being denied eligibility for the exception. Commenters described a variety of concerns, detailed in this Part II.A.

The final regulations provide a revised and simplified rule that looks to whether allocations are commensurate with capital contributed. An allocation will be considered a Capital Interest Allocation if the allocation to the API Holder with respect to its capital interest is determined and calculated in a similar manner to the allocations with respect to capital interests held by similarly situated *Unrelated Non-Service Partners* who have made significant aggregate capital contributions.

1. Capital Interest Allocations, in General

Proposed § 1.1061–3(c)(3) provides that for an allocation to be treated as a Capital Interest Allocation or a Passthrough Interest Capital Allocation, the allocation must be one made in the

same manner to all partners. As described further in part II.A.2. of this Summary of Comments and Explanation of Provisions, proposed § 1.1061–3(c)(4) further provides, in part, that Capital Interest Allocations are allocations of long-term capital gain or loss make to an API Holder and to Unrelated Non-Service Partners based on their respective capital account balances where the Unrelated Non-Service Partners have a significant aggregate capital account balance equal to five percent or more of the aggregate capital account balance of the partnership are the time the allocations are made. The proposed regulations also indicate that in general, an allocation will be deemed to satisfy the ''same manner'' requirement if, under the partnership agreement, the allocation is based on the relative capital accounts of the partners (or Passthrough Entity owners) who are receiving the allocation in question and the terms, priority, type and level of risk, rate of return, and rights to cash or property distributions during the partnership's operations and on liquidation are the same. Allocations to an API Holder may be subordinated to allocations to Unrelated Non-Service Partners or reduced by the cost of services provided by such API Holder or a Related Person. Under proposed § 1.1061–3(c)(3)(ii), in the case of a partnership that maintains capital accounts under § 1.704–1(b)(2)(iv), the allocation must be tested based on that partner's capital account. In the case of a Passthrough Entity that is not a partnership (or a partnership that does not maintain capital accounts under § 1.704–1(b)(2)(iv)), if the Passthrough Entity maintains and determines accounts for its owners using principles similar to those provided under § 1.704–1(b)(2)(iv), those accounts will be treated as a capital account for purposes of the proposed regulations.

Several commenters noted that requiring allocations be made in accordance with partners' overall section 704(b) capital accounts in a fund does not comport with the commercial reality of how most venture capital, private equity funds, and hedge funds make their allocations, and would preclude API Holders from ever utilizing the capital interest exception. One commenter noted that many bona fide partnerships use targeted allocations and questioned whether it is fair to exclude partnerships that do not maintain section 704(b) capital or similar accounts from the capital interest exception when those capital accounts lack economic significance in the business arrangement. The commenter asked the same question about partnerships that maintain capital accounts using generally accepted accounting principles (GAAP).

Several commenters objected to the ''same manner'' requirement on the grounds that it did not properly implement section 1061(c)(4)(B), which provides, in part, that an API ''shall not include any capital interest in the partnership which provides the taxpayer with a right to share in partnership capital commensurate with . . . the amount of capital contributed'' by such partner. Commenters explained that while fund managers may earn an economic return on both their capital investment and their APIs, they generally do not have the same economic rights with respect to their capital investment that the limited partners in the fund have with respect to their capital investment. For example, commenters indicated that an API Holder may be entitled to tax distributions, may have different allocations of expenses, may be subject to regulatory allocations (for example, minimum gain chargeback, as described in § 1.704–2), and may have different withdrawal or liquidity rights, which might be more or less favorable than those provided to Unrelated Non-Service Partners. Commenters indicated there could be varying liquidity rights between Unrelated Non-Service Partners and noted that API Holders' capital may be subject to more risk than Unrelated Non-Service Partners' capital in that API Holders may bear the first risk of loss. In the case of hedge funds, commenters noted that limited partners may invest at different times and, as such, earn a return that may not be comparable to other limited partners' returns.

In addition, several commenters explained that economic rights and allocations in private equity and venture capital funds are frequently determined and made on a deal-by-deal basis, including allocations made in a tiered structure by an API Holder that is a Passthrough Entity, and that funds may have multiple classes of interests with different rights and obligations, meaning that economic rights and allocations are rarely, if ever, aligned with respect to all partners based on the partners' section 704(b) capital accounts.

For the aforementioned reasons, several commenters recommended that the ''same manner'' requirement be eliminated and replaced with a rule that permits distributions and allocations to an API Holder, who contributes capital to a fund, to be ''commensurate'' with capital contributed by Unrelated Non-Service partners. Similarly, one commenter suggested that the only requirement be that an allocation to an API Holder be calculated and determined in a similar manner as the allocations to similarly situated Unrelated Non-Service Partners. Several commenters suggested that funds should be able to establish that they satisfied the ''commensurate'' standard using any reasonable method.

Commenters also recommended that the scope of the term ''cost of services'' as used in the proposed regulations be further explained, noting that situations where API Holders' capital investments are not subject to management fees, while other investors' interests are subject to management fees, should not prevent the API Holders' capital interests from qualifying for the capital interest exception. Commenters recommended that the final regulations clarify the meaning of the term ''cost of services'' and specify that an API Holder's capital investment that is not subject to incentive payments or to management fees may still be eligible for the capital interest exception.

Because private equity and hedge funds operate differently, commenters suggested that there should be separate rules, tailored to each structure, with respect to the capital interest exception. The commenters alluded to the notion that, although private equity and hedge funds each operate within a certain blueprint, there are many variations.

The Treasury Department and the IRS generally agree with commenters that under the test in the proposed regulations, it might be difficult for some common business arrangements to meet the capital interest exception and that a partner comparison, based on capital contributed rather than the partners' section 704(b) capital accounts, would be more accurate in determining whether an interest qualifies for the capital interest exception. Accordingly, the final regulations provide that Capital Interest Allocations must be commensurate with capital contributed in order to qualify for the capital interest exception. The final regulations replace the requirement that allocations be made to all partners in the same manner with a requirement that an allocation to an API Holder with respect to its capital interest must be determined and calculated in a similar manner as the allocations with respect to capital interests held by similarly situated Unrelated Non-Service Partners who have made significant aggregate capital contributions. In this regard, the allocations and distribution rights with respect to API Holders' capital interests and the capital interests of Unrelated Non-Service Partners who have made

significant aggregate capital contributions must be reasonably consistent. The similar manner test may be applied on an investment-by-investment basis or on the basis of allocations made to a particular class of interests. The final regulations retain the factors used in the proposed regulations to determine whether allocations and distribution rights are made in a similar manner among partners: The amount and timing of capital contributed, the rate of return on capital contributed, the terms, priority, the type and level of risk associated with capital contributed, and the rights to cash or property distributions during the partnership's operations and on liquidation. The final regulations maintain the rule that an allocation to an API Holder will not fail to qualify solely because the allocation is subordinated to allocations made to Unrelated Non-Service Partners or because an allocation to an API Holder is not reduced by the cost of services provided by the API Holder or a Related Person to the partnership. The final regulations also clarify the meaning of cost of services for this purpose. The fact that API Holders are not charged management fees on their capital or that their capital is not subject to allocations of API items will not prevent the API Holder's capital interest from being eligible for the capital interest exception. Similarly, an allocation to an API Holder will not fail if an API Holder has a right to receive tax distributions while Unrelated Non-Service Partners do not have such a right, where such distributions are treated as advances against future distributions.

The final regulations extend these concepts to allocations made through tiered structures. The final regulations remove the terms Passthrough Capital Allocation, Passthrough Interest Capital Allocation, and Passthrough Interest Direct Investment Allocation, and instead provide that an allocation made to a Passthrough Entity that holds an API in a lower-tier Passthrough Entity will be considered a Capital Interest Allocation if made in accordance with the principles applicable in determining Capital Interest Allocations. Under the final regulations, Capital Interest Allocations retain their character when allocated to an upper-tier partnership so long as they are allocated among the partners in the upper-tier partnership with respect to such partners' capital interests in a manner that is respected under section 704(b) (taking the principles of section 704(c) into account).

Because the revised rules provide sufficient flexibility for all structures, the final regulations do not adopt the suggestion to provide a separate set of rules for private equity and hedge funds. The Treasury Department and the IRS continue to study other issues raised by the commenters, including the application of the similar manner requirement to S corporations and the application of the capital interest exception to co-invest vehicles.

The Treasury Department and the IRS request any additional comments on the application of the capital interest exception in the final regulations.

2. Unrelated Non-Service Partner Requirement

As discussed in the prior section, proposed § 1.1061–3(c)(4) provides additional guidance on Capital Interest Allocations. Under the proposed regulations, Capital Interest Allocations are allocations of long-term capital gain or loss made under the partnership agreement to an API Holder and to Unrelated Non-Service Partners based on their respective capital accounts and which meet other requirements. Unrelated Non-Service Partners are defined in proposed § 1.1061–1(a) as partners who have not provided services to the Relevant ATB and who are not, and have never been, related to any API Holder in the partnership or any person who provides, or has provided, services in the Relevant ATB. Proposed § 1.1061–3(c)(4) specifies that Capital Interest Allocations must be made in the same manner to API Holders and to Unrelated Non-Service Partners with a significant aggregate capital account balance (defined as five percent or more of the aggregate capital account balance of the partnership at the time the allocations are made). Proposed § 1.1061–3(c)(4)(iii) provides that the allocations to the API Holder and the Unrelated Non-Service Partners must be clearly identified both under the partnership agreement and on the partnership's books and records as separate and apart from allocations made to the API Holder with respect to its API. The partnership agreement and the partnership books and records must also clearly demonstrate that the requirements for an allocation to be considered a Capital Interest Allocation have been met.

For allocations made on a deal-by-deal or class-by-class basis, commenters noted that it is unclear if the requirement that allocations be made in the same manner to API Holders and Unrelated Non-Service Partners with a significant aggregate capital account balance applies to each deal or class, or if it applies only to a fund generally. One commenter suggested that as an alternative to a strict percentage test, funds should also be able to satisfy the test by establishing that the return on a class of equity was determined at arm's length. Another commenter noted that a specific number or percentage of Unrelated Non-Service Partners must comprise the test group to prevent easy avoidance of the statute but questioned whether the five percent threshold for the test group is the appropriate threshold. The commenter also asked for clarification on the effect of the rule in proposed § 1.1061–3(c)(3)(ii)(C) that a capital account, for these purposes, does not include the contribution of amounts attributable to loans made by other partners or the partnership when comparing the allocations made to API Holders and Unrelated Non-Service Partners.

One commenter stated that many funds would be unable to meet the requirement that allocations to the API Holder and the Unrelated Non-Service Partners be clearly identified in the partnership agreement because their agreements use liquidating distributions to govern an API Holder's rights with respect to its API rather than allocations. The commenter recommended that the requirement be considered satisfied if the distribution provision clearly identified capital interest distributions separate and apart from distributions with respect to APIs. Several other commenters suggested that the rule requiring the allocations to be clearly identified both under the partnership agreement and on the partnership's books and records be disjunctive, that is, that the allocations be clearly demarcated in either the partnership agreement or on the partnership's books and records. Commenters noted that in order to meet the partnership agreement reporting requirement, a fund would have to update its partnership agreements, which could be done only by negotiating with the Unrelated Non-Service Partners. Initiating those negotiations could cause partners to want to negotiate other partnership items, which could take time and alter the agreements. These commenters thus suggested grandfathering existing partnership agreements or providing a transition period for funds to update their agreements to comply with this requirement.

The final regulations retain the requirement that Capital Interest Allocations to an API Holder be compared to Capital Interest Allocations made to Unrelated Non-Service Partners, as well as the requirement that Capital Interest Allocations be made to Unrelated Non-Service Partners with a significant capital account balance,

including the five percent threshold. The Treasury Department and the IRS considered a number of alternatives and determined that the five percent threshold adequately insures that there is a significant comparison to meet the statutory exception that an API does not include a capital interest which provides the API Holder with a right to share in partnership capital commensurate with the amount of capital contributed. In accordance with the provision that the similar manner test in the final regulations may be applied on an investment-by-investment or class-by-class basis, the final regulations specify that the Unrelated Non-Service Partner requirement can also be applied on an investment-by-investment basis, or on a class-by-class basis. The final regulations move the definition of Capital Interest Allocations to the definition section of the final regulations but retain the requirement that allocations with respect to, and corresponding to, contributed capital be clearly identified under both the partnership agreement and in the partnership's books and records as separate and apart from allocations made to the API Holder with respect to its API, and specify that the books and records must be contemporaneous. Documenting the allocations in the partnership agreement and in contemporaneous books and records is a necessary corollary to the rule requiring Capital Interest Allocations to be made in a similar manner between API Holders and Unrelated Non-Service Partners with a significant interest, because it shows that the partnership's Unrelated Non-Service Partners considered these allocations a valid return on their contributed capital.

The final regulations do not include a rule that would grandfather existing partnership agreements or provide a transition period for partnerships to update their agreements. Because the final regulations more closely align the capital interest exception to standard industry practice, the number of partnership agreements that will need to be amended is reduced. Allocations made to an API Holder that do not meet the requirements of these final regulations will not be considered Capital Interest Allocations. Finally, due to the revisions made to the capital interest exception in these final regulations, the Treasury and the IRS have determined that it is not necessary to clarify the effect that the rule disregarding contributions made with the proceeds of loans by other partners or by the partnership has on the comparison of the allocation made to API Holders and Unrelated Non-Service Partners.

3. Capital Interest Disposition Amounts

If an owner disposes of an interest in a Passthrough Entity that is composed of a capital interest and an API, proposed § 1.1061–3(c)(6) provides a mechanism for the owner to determine the portion of long-term capital gain or loss recognized on the disposition that is treated as a Capital Interest Disposition Amount and thus, a Capital Interest Gain or Loss.

The final regulations clarify the determination of an API Holder's Capital Interest Disposition Amount when the API Holder transfers a Passthrough Entity interest that is comprised of both an API and a capital interest at a gain and would be allocated only capital loss as a Capital Interest Allocation if all of the assets of the Passthrough Entity had been sold for their fair market value in a fully taxable transaction immediately before the interest transfer. In such an instance, the final regulations provide that all of the long-term capital gain attributable to the interest transfer is API Gain. Conversely, if such API Holder recognizes long-term capital loss on the transfer of a Passthrough Entity interest and would be allocated only capital gain as a Capital Interest Allocation if all of the assets of the Passthrough Entity had been sold for their fair market value in a fully taxable transaction immediately before the interest transfer, the final regulations provide that all of the long-term capital loss attributable to the interest transfer is API Loss. The final regulations provide additional rules where a transferred Passthrough Entity interest results in a gain and the transferor would have been allocated both Capital Interest Gain and API Gain as well as where a transferred Passthrough Entity interest results in a loss and the transferor would have been allocated both Capital Interest Loss and API Loss. In such instances, a fraction is used to determine the portion of the transferred interest gain or loss characterized as a Capital Interest Disposition Amount.

Commenters noted a concern that Example 5 in proposed regulation § 1.1061–3(c)(7)(v), did not adequately address basis proration upon a partial interest sale where a partner holds a partnership interest comprised of both an API and a capital interest. Specifically, one commenter noted that Example 5's reliance on the equitable apportionment approach of § 1.61–6(a) could lead to a situation where the characterization of the gain or loss attributable to the sale of a portion of the partner's partnership interest differs from the characterization of that partner's distributive share of asset gain or loss if all of the assets of the Passthrough Entity were sold for their fair market value in a fully taxable transaction. Another commenter suggested applying the specific identification rules in § 1.1223–3 applicable to publicly traded partnership units to transfers of private interests. These commenters noted that because the issue illustrated in Example 5 has ramifications beyond section 1061, further study should occur before proceeding with the position stated in Example 5.

The Treasury Department and the IRS continue to study the issue noted with respect to Example 5 and have removed the example in the interim as many of the concerns raised on the sale of a partial partnership interest extend beyond section 1061.

4. Unrealized API Gains and Losses

Proposed § 1.1061–1(a) defines Unrealized API Gains and Losses as all unrealized capital gains and losses, including both short-term and long-term, that would be allocated to an API Holder with respect to its API if all relevant assets were disposed of for fair market value in a taxable transaction on the relevant date. Proposed § 1.1061–2(a)(1)(ii) provides rules for the treatment of Unrealized API Gains and Losses, including the requirement to determine Unrealized API Gains and Losses in tiered structures. Proposed § 1.1061–3(c)(3)(iii) provides that Capital Interest Allocations and Passthrough Interest Capital Allocations do not include amounts treated as API Gains and Losses or Unrealized API Gains and Losses.

A commenter stated that the requirement to determine Unrealized API Gains and Losses in tiered structures is not reasonable because an upper-tier Passthrough Entity would not be able to require every uncontrolled lower-tier Passthrough Entity in the chain to revalue its assets under the principles of § 1.704–1(b)(2)(iv)(*f*). The commenter recommended that the mandatory section 1061 revaluation rules be eliminated. The commenter requested instead that the existing rules for revaluations under the section 704(b) and 704(c) regulations govern Unrealized API Gains and Losses. Alternatively, the commenter suggested that anti-abuse regulations be written to address revaluations in chains of controlled tiered partnerships.

The final regulations remove the mandatory revaluation rules and adopt the commenter's suggestion that

Unrealized API Gains and Losses be determined according to the existing rules governing unrealized gains and losses, including section 704(c) principles. Accordingly, the final regulations provide that the term Unrealized API Gains and Losses means, with respect to a Passthrough Entity's assets, all unrealized capital gains and losses that would be (i) realized if those assets were disposed of for fair market value in a taxable transaction on the relevant date, and (ii) allocated to an API Holder with respect to its API, taking into account the principles of section 704(c).

Because the proposed regulations provide that Capital Interest Allocations are made based on partners' relative section 704(b) capital accounts, several commenters questioned whether Unrealized API Gains and Losses that are reflected in an API Holder's capital account could generate Capital Interest Allocations, including book Capital Interest Allocations, before these amounts are recognized. Commenters explained that these issues are particularly relevant for hedge funds and described their operations and incentive structure. When an API Holder in a hedge fund receives incentive allocations with respect to the API, its capital account is increased by the amount of the incentive allocation, and Unrelated Non-Service Partners' capital accounts are decreased. This increase is coupled with allocations of taxable income and gain and also allocations of unrealized gain (reverse section 704(c) allocations). Commenters also requested additional guidance on the treatment of realized and unrealized gains from an API which are contributed to, or reinvested in, a partnership.

The final regulations continue to provide that Unrealized API Gains and Losses are not included in Capital Interest Gains and Losses. In response to comments, the final regulations clarify that if an API Holder is allocated API Gain by a Passthrough Entity, to the extent that an amount equal to the API Gain is reinvested in Passthrough Entity by the API Holder (either as the result of an actual distribution and recontribution of the API Gain amount or the retention of the API Gain amount by the Passthrough Entity), the amount will be treated as a contribution to the Passthrough Entity for a capital interest that may produce Capital Interest Allocations for the API Holder, provided such allocations otherwise meet the requirements to be a Capital Interest Allocation.

B. Capital Contributions Made With the Proceeds of Partnership or Partner Loans

Proposed § 1.1061–3(c)(3)(ii)(C) provides that for purposes of proposed §§ 1.1061–1 through 1.1061–6, a capital account does not include the contribution of amounts directly or indirectly attributable to any loan or other advance made or guaranteed, directly or indirectly, by any other partner, the partnership, or a Related Person with respect to any other partner or the partnership. Repayments on the loan are included in capital accounts as those amounts are paid by the partner, provided that the loan is not repaid with the proceeds of another similarly sourced loan. *Id.*

Several commenters criticized this treatment, suggesting that the exclusion of these amounts from the partner's capital account inhibits common and reasonable business practices, and creates barriers to entry for service partners, particularly those who are less represented based on age, gender, or race or do not have ready access to capital. One commenter noted that it is typical for fund managers to either extend loans to their employees, or to guarantee loans issued to such employees by third parties, so that employees may invest in the manager's own investment funds. Similarly, another commenter stated that the proposed regulations would introduce a substantial impediment to raising capital for commercial real estate investment by creating a disincentive for general partners to finance or support the financing of the participation of its employees in its commercial real estate investments. The commenter claimed that contributions made in this manner are a significant source of capital available for real estate investment and also an important factor in attracting third party capital because they create an alignment of interest between the limited partners and the general partner and its employees.

Commenters noted that neither the statute nor the legislative history indicates that the use of loan proceeds to make a capital contribution precludes the interest from being included in a partner's capital account and contended that adding such a rule is not justified by the commensurate with capital statutory language of the capital interest exception. To the contrary, commenters argued that the authors of the TCJA were familiar with prior proposals regarding profits interests that contained exceptions for loaned capital and their decision not to include such an exception in section 1061 is an indication that the choice was intentional. Instead, one commenter maintained that Congress addressed any concerns through the rule that a service provider's rights with respect to its contributed capital must match the rights of other non-service partners with respect to their shares of contributed capital.

Some commenters recognized that the exclusion from capital accounts of contributions attributable to partner or partnership loans is an attempt to control the perceived abuse of limited partners loaning the general partner of the partnership an amount of capital that entitles the general partner to a portion of the partnership's profits in order to avoid the application of section 1061 and fit within the capital interest exception. Commenters noted that section 1061(f) provides the Secretary with authority to issue guidance as is necessary or appropriate to carry out the purposes of section 1061 and that the legislative history indicates that such guidance is to address the prevention of abuse of the purposes of the provision.

Other commenters, suggesting that the policy behind the capital interest exception is to ensure a partner has capital at risk to qualify for the exception, acknowledged that there are fact patterns in which a partner might be considered less at risk. One commenter pointed to the at-risk limitation on losses under section 465, noting that a service provider would not be considered at-risk with respect to contributed capital that is financed through a loan from another partner, even if the loan were fully recourse to the service provider. By contrast, a partner is considered at-risk when an investment is funded by a third-party loan for which the partner has personal liability. Another commenter noted that the proposed regulations' treatment of a capital interest funded through a loan from the issuing partnership is consistent with the treatment of partnership loans under other areas of Subchapter K. The commenter pointed out that the contribution of a partner's own promissory note generally does not increase the partner's basis in its partnership interest under section 722. Similarly, pursuant to § 1.704–1(b)(2)(iv)(*d*)(*2*), the partner's capital account will be increased with respect to the promissory note only when there is a taxable disposition of the note by the partnership or when the partner makes principal payments on such note, provided that the note is not readily tradable on an established securities market.

Despite recognizing these concerns regarding abuse, commenters

maintained that the loan proceeds exclusion should be eliminated because general income tax principles, such as those in sections 83 and 7872, are sufficient to determine whether a loan-financed arrangement should not qualify for the capital interest exception. Other commenters suggested that if limitations must be imposed, the rule should be narrowly tailored, recommending that only loans that are nonrecourse or lack substantial security be excluded from the capital interest exception. Commenters also suggested that guarantees should not be treated in the same manner as a loan, particularly in the context of a recourse loan or a loan from a third-party bank. Another commenter suggested that if the loan or guarantee operates under normal arms-length standards, it should be eligible to support a capital contribution. Another commenter noted that the proposed regulations are silent on loans that are fully secured with partnership assets.

The Treasury Department and the IRS remain concerned that capital contributions made with the proceeds of loans made or guaranteed by another partner, the partnership, or a Related Person with respect to such partner or partnership could lead to abuse of the capital interest exception. Therefore, the final regulations do not adopt the suggestions to remove the rule. However, the Treasury Department and the IRS agree with commenters that the potential for abuse is reduced when a loan or advance is made by another partner (or Related Person with respect to such other partner, other than the partnership) to an individual service provider if the individual service provider is personally liable for the repayment of such loan or advance. Accordingly, the final regulations provide that an allocation will be treated as a Capital Interest Allocation if the allocation is attributable to a contribution made by an individual service provider that, directly or indirectly, results from, or is attributable to, a loan or advance from another partner in the partnership (or any Related Person with respect to such lending or advancing partner, other than the partnership) to such individual service provider if the individual service provider is personally liable for the repayment of such loan or advance as described in the final regulations. The final regulations apply a similar approach with respect to loans or advances made by a partner in the partnership (or a Related Person to such partner, other than the partnership) to a wholly owned entity that is disregarded as separate from an individual service provider where the individual service provider that owns such disregarded entity is personally liable for the repayment of any borrowed amounts that are not repaid by the disregarded entity. The final regulations provide that an individual service provider is personally liable for the repayment of a loan or advance made by a partner (or any Related Person, other than the partnership) if (i) the loan or advance is fully recourse to the individual service provider; (ii) the individual service provider has no right to reimbursement from any other person; and (iii) the loan or advance is not guaranteed by any other person. The Treasury Department and the IRS continue to study the treatment of guarantees generally in light of questions about who the borrower is for Federal tax purposes.

A commenter noted that the proposed regulations' treatment of loans, together with the section 704(b) capital account approach being taken with respect to the capital interest exception, could mean that a partner who borrows from a related person to make even a small portion of his or her capital contribution might be denied the capital interest exception with respect to his or her entire capital interest. A few commenters recommended that if the treatment of related party loans is retained in the final regulations, adjustments should be made to ensure that partners are able to receive appropriate credit for capital contributions they make that are not attributable to loans. Another commenter stated that the proposed regulations did not provide a tracing regime to connect loan proceeds with capital contributions. One commenter suggested that final regulations clarify how to treat a partner that fully funded a capital contribution with loan proceeds but repaid such amounts before there was a capital interest allocation, including whether a revaluation would change the answer. The commenter recommended that it would be appropriate to treat the partner's capital account as funded at the time of actual contribution. Finally, the commenter recommended that final regulations include a transition rule related to related party loans made, advanced, guaranteed, or repaid before final regulations are issued. The Treasury Department and the IRS considered these comments and believe that the concerns raised in them are resolved by the commensurate with capital approach to the capital interest exception taken in the final regulations because this approach does not rely on a comparison of allocations based on the partners' overall section 704(b) capital accounts.

C. Lookthrough Rule for Certain API Dispositions

Proposed § 1.1061–4(b)(9) provides a limited Lookthrough Rule that may apply to the sale of an API where capital gain is recognized and the holding period of the API is more than three years. In the case of a disposition of a directly held API with a holding period of more than three years, the proposed Lookthrough Rule applies if the assets of the partnership in which the API is held meet the Substantially All Test. The Substantially All Test is met if 80 percent or more of the assets of the partnership in which the API is held, based on fair market value, are assets that would produce capital gain or loss that is not described in proposed § 1.1061–4(b)(6) if disposed of by the partnership, and that have a holding period of three years or less. In the case of a tiered structure in which an API Holder holds its API through one or more Passthrough Entities, the Lookthrough Rule applies if the API Holder disposes of a Passthrough Interest held for more than three years and recognizes capital gain, and either: (i) The Passthrough Entity through which the API is directly or indirectly held has a holding period in the API that is three years or less, or (ii) the Passthrough Entity through which the API is held has a holding period in the API of more than three years and the assets of the partnership in which the API is held meet the Substantially All Test.

The Treasury Department and the IRS received several comments stating that, although the application of the Lookthrough Rule for directly-held APIs is reasonable, the application of the Lookthrough Rule for indirectly-held APIs is punitive and imposes an unreasonable and significant administrative burden. The commenters recommended that the scope of the Lookthrough Rule for indirectly-held APIs be limited, particularly in the case of indirectly-held APIs where the relevant taxpayer does not control a partnership that issued the API. Another commenter questioned the authority for the Lookthrough Rule but noted that it is consistent with partnership tax principles and that the proposed regulation would be easily manipulated without the rule.

Commenters suggested that the proposed regulations be amended in one or more of the following ways: (i) Limit the Lookthrough Rule to situations in which a Passthrough Entity controls all of the relevant lower-tier Passthrough

Entities (or only applying it to lower-tier Passthrough Entities that it controls); (ii) limit the Lookthrough Rule for indirectly held APIs to situations in which the API is held by a lower-tier Passthrough Entity for three years or less; (iii) limit the application of the Lookthrough Rule to situations in which assets that produce capital gain or loss of a type taken into account under section 1061 are a material amount (greater than 50 percent) of the value of the underlying assets of the partnership; (iv) eliminate the Substantially All Test in the context of tiered structures (that is, determine the applicability of the Substantially All Test with respect to the assets held by the partnership whose interest was sold); (v) amend the Substantially All Test so that a transferring taxpayer who has held its interest for more than three years will be required to look through to the underlying assets' character only if 80 percent or more of the assets held directly or indirectly by the Passthrough Entity have a holding period of three years or less; (vi) make information reporting related to the Lookthrough Rule mandatory for partnerships and S corporations and for required PFIC annual information statements regardless of whether a Passthrough Entity has issued or holds an API; (vii) provide a de minimis rule by which an upper-tier partnership holding a five percent or less interest in the lower-tier partnership would be allowed to use its holding period in the lower-tier partnership; and (viii) as a part of the de minimis rule, not require revaluations of lower-tier partnerships when an Owner Taxpayer disposes of an upper-tier interest that holds five percent or less of a lower-tier partnership. A commenter recommended that the Lookthrough Rule approach calculations in tiered structures from the lower-tier entities up, aligning with the approach to tiered structures elsewhere in the proposed regulations, and allowing the rule to appropriately accommodate lower-tier gains from assets whose sale proceeds are treated as capital gains without regard to section 1222(3) and (4).

After considering the comments, the Treasury Department and the IRS agree that the Lookthrough Rule as proposed could be difficult for Owner Taxpayers and Passthrough Entities to apply, particularly in the context of tiered structures. However, the Treasury Department and the IRS remain concerned that taxpayers could avoid section 1061 by transferring assets to, and issuing APIs from, existing partnerships. Accordingly, the final regulations retain the Lookthrough Rule, but instead of applying the Lookthrough Rule to the disposition of an API held for more than three years and where the Substantially All Test is met, the final regulations limit the application of the Lookthrough Rule to situations where, at the time of disposition of an API held for more than three years, (1) the API would have a holding period of three years or less if the holding period of such API were determined by not including any period prior to the date that an Unrelated Non-Service Partner is legally obligated to contribute substantial money or property directly or indirectly to the Passthrough Entity to which the API relates (this rule does not apply to the disposition of an API to the extent that the gain recognized upon the disposition of the API is attributable to any asset not held for portfolio investment on behalf of third party investors); or (2) a transaction or series of transactions has taken place with a principal purpose of avoiding potential gain recharacterization under section 1061(a). The Lookthrough Rule similarly applies with respect to a Passthrough Interest issued by an S corporation or a PFIC to the extent the Passthrough Interest is treated as an API. The final regulations also simplify the method for applying the Lookthrough Rule.

Commenters also stated that the Lookthrough Rule raises a concern that going concern value in a lower-tier entity might be subject to ordinary income rates if an upper-tier partnership interest is sold, the Lookthrough Rule applies, and the upper-tier partnership owns a lower-tier partnership interest. These commenters recommended that gain associated with goodwill or enterprise value retain the holding period of the partnership interest itself, as opposed to the underlying assets, and that the Lookthrough Rule apply only to the gain associated with the hypothetical liquidation of the underlying assets. The Treasury Department and the IRS continue to study this issue and may address it in future guidance.

One commenter requested clarification that the phrase ''total net capital gain'' in proposed § 1.1061–4(b)(9)(ii)(C)(*1*) refers to ''net long-term capital gain'' and that short- and long-term capital gains and losses cannot be netted against each other. The final regulations do not include this language. The Treasury Department and the IRS believe that the concerns raised by the commenter are alleviated by the simplified Lookthrough Rule adjustment in the final regulations.

D. Section 1.1061–5: Transfers to Related Parties

Proposed § 1.1061–5(a) provides that if an Owner Taxpayer transfers any API, or any Distributed API Property, directly or indirectly, to a Section 1061(d) Related Person, or if a Passthrough Entity in which an Owner Taxpayer holds an interest, directly or indirectly, transfers an API to a Section 1061(d) Related Person, regardless of whether gain is otherwise recognized on the transfer under the Code, the Owner Taxpayer must include in gross income as short-term capital gain, the excess of: (1) The Owner Taxpayer's net long-term capital gain with respect to such interest for such taxable year determined as provided in proposed § 1.1061–5(c), over (2) any amount treated as short-term capital gain under proposed § 1.1061–4 with respect to the transfer of such interest (that is, any amount included in the Owner Taxpayer's API One Year Disposition Gain Amount and not in the Owner Taxpayer's Three Year Disposition Gain Amount with respect to the transferred interest). Proposed § 1.1061–5(b) provides that for purposes of section 1061(d), the term transfer includes contributions, distributions, sales and exchanges, and gifts.

Several commenters addressed whether section 1061(d) should be interpreted as an acceleration provision or merely a recharacterization provision. With certain exceptions, the proposed regulations require that gain be accelerated on the transfer of an API to a Section 1061(d) Related Person, regardless of whether the transfer is otherwise a taxable transaction for Federal income taxes or whether gain is otherwise realized or recognized under the Code on the transfer. One commenter supported this treatment, noting that section 1061(d)(1) is literally worded as an income acceleration provision while acknowledging that others have viewed the language as a recharacterization provision, such as section 751(a). Another commenter noted that neither the text nor the legislative history shed any light on its purpose and stated that the provision's language is susceptible to numerous different readings. The commenter noted that section 1061(d) could be read as a narrow recharacterization lookthrough provision similar to section 751, a recharacterization and assignment of income provision that provides for nonrecognition transfers and requires the transferor rather than the transferee to include API Gain when ultimately realized, a recharacterization and acceleration provision, or a proration provision. The commenter did

not provide a recommendation, but noted that the proposed regulations create many traps for the unwary. The commenter stated that the broad definition of transfer in the proposed regulations combined with the overriding of nonrecognition treatment could lead to significant, adverse tax impacts on transferors as well as otherwise uninvolved, passive interest holders in a variety of transactions. The commenter suggested that the Treasury Department and the IRS carefully consider whether the effect of the proposed regulations is appropriate and aligns with section 1061(d)'s language, function, and origins.

Other commenters argued that applying section 1061(d) to transactions where gain is not otherwise recognized is inconsistent with the statutory language. One commenter stated that section 1061(d) itself does not refer to any nonrecognition provisions, nor does it contain any express statement of intent to override nonrecognition treatment. This commenter and others noted that section 1061(d) operates by reference to the taxpayer's long-term capital gains, which as defined in section 1223(3) include only gains that are recognized for U.S. Federal income tax purposes. Consequently, these commenters argued that the statute by its terms does not apply to situations in which the taxpayer has no actual long-term capital gain with respect to such interest. Commenters also noted that the legislative history does not provide support for treating section 1061(d) as an acceleration provision. Previous carried interest provisions included language that explicitly overrode non-recognition; section 1061 as enacted contains no such language.

One commenter stated that it is not necessary to accelerate gain on the transfer of an API to a Section 1061(d) Related Person, noting that the API in the hands of the transferee is still subject to section 1061(a) because an API includes interests held by or transferred to the taxpayer in connection with the performance of a substantial service by the taxpayer or a related person.

Commenters also raised a variety of concerns about the proposed regulation's definition of transfer. Commenters recommended that the term transfer be further defined to address potential cases involving indirect transfers of an API, such as the admission of new partners into the partnership, the withdrawal of old partners from the partnership, the transfer of an employee between teams, or an award to a high performer. One commenter explained that, in these circumstances, because there is no change in the relative economic position between fund managers and third-party investors, there should be no requirement for the fund manager or employees of the fund manager to recognize unrealized built-in gain. Commenters also recommended that the final regulations consider whether a forfeiture of an API is a transfer for purposes of section 1061(d) but stated that such an interpretation would be overbroad. One commenter noted that forfeiture and reallocations involve circumstances in which the partners' legal and economic interests in the partnership's Unrealized API Gains are contingent rather than fixed. Where a partner's interest in Unrealized API Gains is contingent, the commenter argued that it is not appropriate to tax a partner on a reduction in that interest under section 1061(d).

Another commenter asked for clarification that the distribution of an API by a direct API Holder to an Owner Taxpayer (indirect API Holder) would be exempt from the application of section 1061(d). The commenter noted that section 1061(a) would continue to apply to the distributed API and that this treatment would be consistent with the rules related to Distributed API Property in § 1.1061–4. Under those rules, a distribution of property by a Passthrough Entity to an API Holder is not subject to recharacterization under section 1061 but the Distributed API Property continues to be subject to section 1061. The commenter argued that this rule would also treat similarly situated taxpayers the same, rather than treating distributees of Distributed API Property differently from Owner Taxpayers who receive a distribution of an API from a partnership.

Another commenter asked for clarification that the definition of gift refers to transfers which are gifts for income tax purposes (rather than for gift tax purposes). The commenter noted that many common estate planning techniques involve transfers of assets to grantor trusts with the transferor as the grantor and the grantor's family members as beneficiaries of the trust, and that these types of transfers often result in a completed gift for gift tax purposes but do not constitute a transfer of ownership for income tax purposes.

Commenters also recommended that the final regulations exclude specific nonrecognition transactions, including (i) transfers resulting from the death of an Owner Taxpayer; (ii) gifts to a non-grantor trust by an Owner Taxpayer; and (iii) transfers resulting from a change in tax status of a grantor trust. One commenter noted that, in light of section 1061(d)'s specific reference to section 318(a)(1), and not to section 318(a)(2), a gift to a non-grantor trust for the benefit of a taxpayer's spouse, children, grandchildren or parents should not be considered an ''indirect transfer'' that would trigger the application of section 1061(d). The commenter noted that Congress's use of the phrase ''directly or indirectly'' does not warrant disturbing the conclusion that a transfer to a non-grantor trust does not constitute an acceleration event for purposes of section 1061(d). This commenter suggested in the alternative that if a transfer to a non-grantor trust is an acceleration event for purposes of section 1061(d), only upon a subsequent distribution of the API out of the non-grantor trust should the acceleration event occur.

After considering the comments, the Treasury Department and the IRS have determined that while section 1061(d) can reasonably be interpreted as an acceleration provision, in the absence of clear language to the contrary, it is more appropriate to apply section 1061(d) only to transfers in which long-term capital gain is recognized under chapter 1 of the Code. Interpreting section 1061(d) as only a recharacterization provision is consistent with the statutory language that looks to so much of the taxpayer's long-term capital gain with respect to such interest for such taxable year as is attributable to the sale or exchange of any asset held. This treatment also prevents the acceleration of gain in the many non-abusive nonrecognition transactions described by commenters. Furthermore, it is not necessary to accelerate gain on the transfers of an API to a Section 1061(d) Related Person in a non-taxable transaction because the API will remain an API in the hands of the transferee under § 1.1061–2(a). Accordingly, the final regulations provide that the Section 1061(d) Recharacterization Amount includes only long-term capital gain that the Owner Taxpayer recognizes under chapter 1 of the Code upon a transfer through a sale or exchange of an API to a Section 1061(d) Related Person.

Proposed § 1.1061–5(c) provides a formula for calculating the Owner Taxpayer's short-term capital gain upon a transfer of an API to a Section 1061(d) Related Person based upon a hypothetical sale of all of the partnership's property in a fully taxable transaction. A commenter noted that because the calculation is not based on the Recharacterization Amount under a hypothetical liquidation, it includes amounts excluded from the Recharacterization Amount, such as

capital interest gains and losses. The commenter recommended that the formula be amended so that it is based upon the Recharacterization Amount in a hypothetical partnership liquidation, and that the final regulations contain an exception from taxation for transactions in which the Owner Taxpayer's deemed distributions with respect to the Owner Taxpayer's API on a hypothetical liquidation basis are the same immediately before and after the transaction (not including any deemed distributions due to changes in debt allocations). Another commenter suggested that, in order to avoid double-counting in a tiered structure, there should be a cap on the amount that would be taxed equal to the gain that would be realized if the directly transferred API were sold for its fair market value by the Owner Taxpayer.

Another commenter noted that the proposed regulations provide that section 1061(d) applies to transfers of APIs by Passthrough Entities and to transfers of Distributed API Property by Owner Taxpayers, but that the rules do not provide guidance on how to calculate the amount to be included. The commenter suggested that, in the case of a transfer of an API by a Passthrough Entity, the inclusion amount should be the amount that would be allocated to each of the Passthrough Entity's direct or indirect Owner Taxpayers in a deemed taxable sale of assets by the lower-tier entity in which the Passthrough Entity holds its API, and that the amounts that such Passthrough Entity includes in the API One Year Distributive Share Amount, but not in the API Three Year Distributive Share Amount, for each Owner Taxpayer should be subtracted from the aforementioned amounts to calculate an Owner Taxpayer's recharacterization amount under section 1061(d). In the case of a transfer of Distributed API Property by an Owner Taxpayer, the commenter suggested that the inclusion amount should be the amount of long-term capital gain that the Owner Taxpayer would have recognized on a taxable sale for cash at the Distributed API Property's fair market value.

The Treasury Department and the IRS appreciate these thoughtful suggestions. The final regulations have revised and simplified the computation of the inclusion amount in § 1.1061–5(c) and have added the term Section 1061(d) Recharacterization Amount. The final regulations provide that, if section 1061(d) applies, an Owner Taxpayer's Section 1061(d) Recharacterization Amount is the Owner Taxpayer's share of the amount of net long-term capital gain from assets held for three years or less that would have been allocated to the Owner Taxpayer with respect to the transferred API if the partnership had sold all of its property in a fully taxable transaction for cash in an amount equal to the fair market value of such property immediately prior to the Owner Taxpayer's transfer of the API (or a portion of such gain if only a portion of the API is transferred).

A commenter requested clarification as to whether ''capital gain recognized'' on an otherwise taxable transfer in proposed § 1.1061–5(c)(2) means that the amount recharacterized under section 1061(d) includes only gain that would otherwise be treated as long-term gain or whether it sets the total amount of short-term gain on the transfer. The final regulations provide that the long-term gain that is recharacterized to short-term under section 1061(d) is the lesser of (i) the amount of net long-term capital gain recognized by the Owner Taxpayer upon the transfer of such interest, or (ii) the Section 1061(d) Recharacterization Amount as computed under § 1.1061–5(c). Thus, only gain that would otherwise be treated as long-term gain is recharacterized under section 1061(d).

Proposed § 1.1061–5(d) provides that the basis of a transferred API or transferred Passthrough Interest (in the case of a transferred Indirect API) is increased by the additional gain recognized. A commenter requested that the rule be revised to explicitly coordinate with section 743 so that the basis adjustments will be allocated to the assets that result in the gain recognition. The concerns raised in this comment are resolved because the final regulations limit the application of section 1061(d) to transactions in which gain is recognized.

Another commenter recommended that the final regulations explicitly exclude amounts that would be subject to the Capital Interest Exception. The final regulations do not adopt this comment because the Capital Interest Exception is an exception to the definition of an API. Therefore, such a rule is not needed. Commenters also recommended that the final regulations explicitly exclude amounts specified in proposed § 1.1061–4(b)(6) (designated as § 1.1061–4(b)(7) in the final regulations) from the calculation of the Section 1061(d) Recharacterization Amount. One commenter noted that the scope of section 1061(d)(1) is broader than the tax result that would occur if the partnership had actually sold all its property, noting that neither the statute nor the proposed regulations exclude section 1231 gains (and other excluded gains such as those under section 1256) from the Section 1061(d) Recharacterization Amount. Another commenter argued that section 1061(d) should not recharacterize section 1231 gain, stating that while the statutory language in section 1061(d) provides arguable authority for including section 1231 gains in the computation of the Section 1061(d) Recharacterization Amount, the approach is hard to justify from a policy perspective. The commenter argued that because section 1061(d) is aimed at preventing an API Holder from circumventing section 1061(a), the regulations should not impose on taxpayers a result under section 1061(d) that is worse than if section 1061(a) had applied to assets sold by the partnership. The commenter recommended that ''long-term capital gains'' should be interpreted consistently for purposes of section 1061(a) and section 1061(d), and that long-term capital gain recognized with respect to section 1231 assets should not be recharacterized under either paragraph.

The final regulations adopt these comments and provide that the Section 1061(d) Recharacterization Amount does not include amounts not taken into account for purposes of section 1061 under § 1.1061–4(b)(7).

Proposed § 1.1061–5(c)(1) provides that if an Owner Taxpayer transfers an Indirect API and is subject to section 1061(d), the computation of the Section 1061(d) Recharacterization Amount must be applied at the level of any lower-tier Passthrough Entities. One commenter recommended that this rule be aligned with the rules for tiered partnerships elsewhere in the proposed regulations, such as the Lookthrough Rule, which explicitly states that it applies only to the ''assets of the partnership in which the API is held.'' A commenter recommended that the final regulations clarify whether the transfer of a distributed asset held, or deemed to be held, by the partnership for three years or less is subject to section 1061(d). Another commenter noted that there is no principled reason for not applying section 1061(d) in tiered partnerships to transfers of Distributed API Property by Passthrough Entities to Section 1061(d) Related Persons of the ultimate Owner Taxpayer.

Under the final regulations, the Section 1061(d) Recharacterization Amount is computed by the Owner Taxpayer. The transfer of a distributed asset held, or deemed to be held, by a Passthrough Entity for three years or less is subject to section 1061(d). The final regulations clarify that for

purposes of section 1061(d), an Owner Taxpayer will be treated as transferring the Owner Taxpayer's share of any Indirect API or Distributed API Property if the Indirect API or Distributed API Property is transferred by the API Holder to a person that is a Section 1061(d) Related Person with respect to the Owner Taxpayer. The final regulations also provide that the rules for determining the Section 1061(d) Recharacterization Amount also apply to the transfer of a Passthrough Interest issued by an S corporation or PFIC to the extent the Passthrough Interest is treated as an API.

Proposed § 1.1061–5(e) defines a Section 1061(d) Related Person as: (i) A person that is a member of the taxpayer's family within the meaning of section 318(a)(1); (ii) a person that performed a service within the current calendar year or the preceding three calendar years in a Relevant ATB to the API transferred by taxpayer; or (iii) a Passthrough Entity to the extent that a person described in paragraph (e)(1)(i) or (ii) owns an interest, directly or indirectly. One commenter recommended that the definition of Section 1061(d) Related Person be amended to exclude a Passthrough Entity to the extent that a member of the taxpayer's family or colleague is an owner, noting that language is not in the statute and is not discussed in the legislative history. The final regulations do not adopt this comment. Section 1061(d)(1) provides that the inclusion required by section 1061(d) applies if a taxpayer transfers any API, directly or indirectly, to a person related to the taxpayer.

III. Additional Comments Received and Revisions Made

A. Sections 1.1061–1 and 1.1061–2: Definitions, Operational Rules, and Examples

1. Definitions, In General

A commenter expressed the view that the interrelated new terms and definitions make the proposed regulations difficult to read and comprehend in some places. The final regulations largely retain the terms and definitions provided in § 1.1061–1(a) but simplify many of the computational rules and concepts used to determine the Recharacterization Amount and the Section 1061(d) Recharacterization Amount. The terms and definitions provide a helpful roadmap to the regulations and are also needed to provide Owner Taxpayers, Passthrough Entities, and the IRS with a common vocabulary that can be used to describe the necessary computations and reporting requirements. The final regulations make clarifying changes throughout the definitions, including providing that a Passthrough Entity can also be a trust or estate. Terms have also been added and removed in accordance with the revisions discussed elsewhere in this Summary of Comments and Explanation of Revisions.

A commenter noted that the preamble to the proposed regulations provides that ''taxpayer'' means Owner Taxpayer in sections 1061(a) and (d), and both Owner Taxpayer and Passthrough Taxpayer in section 1061(c)(1). The commenter further noted that the proposed regulations use the definition of ''person'' as that term is generally used under section 7701(a)(1). The commenter requested that the final regulations provide explicit definitions of ''taxpayer'' and ''person'' in each relevant part because the terms have different meanings in different contexts.

The final regulations do not adopt this comment because defining taxpayer and person in different ways in each relevant section would introduce unnecessary complexity. However, the use of these terms has been modified in certain places in the final regulations to alleviate confusion.

2. Operational Rules

a. Definition of API; An API Remains an API

Proposed § 1.1061–1(a) provides that API means any interest in a partnership which, directly or indirectly, is transferred to (or is held by) an Owner Taxpayer or Passthrough Taxpayer in connection with the performance of substantial services by the Owner Taxpayer or by a Passthrough Taxpayer, or by any Related Person, including services performed as an employee, in any ATB unless an exception applies, and that for purposes of this definition, an interest in a partnership also includes any financial instrument or contract, the value of which is determined in whole or in part by reference to the partnership (including the amount of partnership distributions, the value of partnership assets, or the results of partnership operations.)

A commenter expressed concern that defining an interest in a partnership to include a financial instrument or contract, the value of which is determined in whole or in part by reference to the partnership, could include investment management contracts that provide for a fee based on the assets of a fund partnership and not a carried interest or other performance allocation, creating a risk that the sale of a management company or indirect sale of a management contract could be subject to section 1061. This in turn could cause the enterprise value of the management company to be taxed at ordinary income rates. The commenter recommended that the definition of API be modified to exclude financial instruments or contracts that merely reference the value of partnership assets or that provide for fee income that is subject to ordinary income tax treatment.

Because financial instruments can replicate the performance of a partnership interest, the inclusion of such items in the definition of an API is necessary for purposes of implementing section 1061. Accordingly, the final regulations do not adopt this comment. As stated in Part IV of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS continue to study the impact of section 1061 on the taxation of enterprise value related to the transfer or exchange of partnership interests and management contracts.

Proposed § 1.1061–2(a)(1)(i) provides that once a partnership interest qualifies an API, the partnership interest remains an API unless and until the requirements of one of the exceptions to qualification of a partnership interest as an API are satisfied. A commenter questioned whether this provision is valid given that it is not explicit in the statute, but reasoned that the rule is implicit in the statutory scheme and is necessary to prevent avoidance of the statute.

The Treasury Department and the IRS agree with the commenter that this rule is implicit in the statutory scheme. Neither the statute nor the legislative history provide a time limit or other means of ending API treatment beyond the exceptions to qualification as an API. Consequently, no modifications have been made to § 1.1061–2(a)(1)(i).

b. Presumption That Services are Substantial

Proposed § 1.1061–2(a)(1)(iv) provides that if a partnership interest is transferred to or held by an Owner Taxpayer, Passthrough Taxpayer, or any Related Person in connection with the performance of services, the Owner Taxpayer, the Passthrough Taxpayer, or the Related Person is presumed to have provided substantial services for purposes of section 1061. Commenters suggested that presuming all services to be substantial is overbroad and recommended that the presumption be removed. In addition, one commenter recommended the inclusion of non-exclusive safe harbors that service partners could rely on to determine that

partnership interests they hold or that have been transferred to them are not in connection with the performance of substantial services. Another commenter recommended adding a means to rebut the presumption that the services are substantial.

The final regulations retain the proposed rule's presumption that all services provided for a partnership interest are substantial services for purposes of section 1061. However, the Treasury Department and the IRS will continue to study and consider possible circumstances under which the presumption might be rebutted as well as the possibility of providing safe harbors for circumstances under which the presumption will not apply. These considerations may be addressed in future guidance.

c. Application of the ATB Activity Test

i. In General, ATB

Proposed § 1.1061–1(a) provides that applicable trade or business (ATB) means any activity for which the ATB Activity Test with respect to Specified Actions is met, and includes all Specified Actions taken by Related Persons, including combining activities occurring in separate partnership tiers or entities as one ATB. Proposed § 1.1061–1(a) defines an Owner Taxpayer as the person subject to Federal income tax on net gain with respect to an API or an Indirect API during the taxable year, including an owner of a Passthrough Taxpayer unless the owner of the Passthrough Taxpayer is a Passthrough Entity itself or is excepted under proposed § 1.1061–3(a), (b), or (d).

ii. ATB Activity Test

Proposed § 1.1061–2(b)(1) provides that the ATB Activity Test is satisfied if Specified Actions are conducted by one or more Related Persons and the total level of activity, including the combined activities of all Related Persons, satisfies the level of activity that would be required to establish a trade or business under section 162. Proposed § 1.1061–1(a) provides that Specified Actions means Raising or Returning Capital Actions and Investing or Developing Actions. Raising or Returning Capital Actions means actions involving raising or returning capital but does not include Investing or Developing Actions. Investing or Developing Actions means actions involving either (i) investing in (or disposing of) Specified Assets (or identifying Specified Assets for such investing or disposition), or (ii) developing Specified Assets.

Commenters requested clarification that joint ventures of a real estate developer involving a single stand-alone project at a single location will not satisfy the ATB Activity Test. One of these commenters recommended that the definition of Raising or Returning Capital should be refined so that it includes only raising or returning capital activities in which the business earns compensation based on either capital committed, capital contributed, or capital invested. Another commenter noted that additional guidance may be needed to make the statute more administrable because real estate held for rental or investment is a Specified Asset but holding the property may not constitute a trade or business under section 162.

The final regulations do not adopt these comments. Whether a single project or raising of capital involves the level of activity needed to constitute a trade or business under section 162 is dependent on the facts and circumstances unique to the project or raising of capital. Furthermore, guidance under section 162 is beyond the scope of these regulations.

Example 6 of proposed § 1.1061–2(b)(2)(vi) describes a situation in which A manages a hardware store that Partnership owns. A is issued a profits interest in Partnership in connection with A's services. Partnership owns the building in which the hardware store operates. The example notes that the building is held by Partnership not for rental or investment, but to conduct Partnership's hardware business and, thus, the building is not a Specified Asset. The example provides that the partnership maintains and manages a certain amount of working capital for its business, but notes that working capital is not taken into account for the purpose of determining whether the ATB Activity Test is met. A commenter suggested that another example should be added to analyze how to apply the ATB Activity Test where the facts are changed so that the business is held in a C corporation, the partnership only holds the C corporation stock, and the holding partnership is held by an investment partnership. The commenter stated that the ATB Activity Test should not be met by the holding partnership and the manager should not be an API Holder.

The final regulations do not adopt this comment. Depending on the specific facts and circumstances of the situation, the Treasury and the IRS believe that the ATB Activity Test could be met by such a holding partnership and the manager might be an API Holder.

A commenter requested clarification regarding what activities occurring in separate partnership tiers or entities will be considered combined and treated as one ATB, and recommended that the regulations be amended to include an example illustrating how the ATB and API rules work in this situation. The commenter recommended that the application of section 1061 be limited to an Owner Taxpayer solely with respect to partnership interests that serve as compensation for services relating to Specified Assets. Another commenter requested simplifying safe harbors for activities conducted in multiple entities either in the same chain or in a brother-sister chain.

The Treasury Department and the IRS continue to study these issues and may consider providing future guidance on these matters. However, the Treasury Department and the IRS note the definition of ATB includes any and all activities, no matter how minimal, conducted by entities that are Related Persons to each other, for purposes of determining whether the ATB Activity Test is met, and if that test is met, then each such participating entity is considered to be engaged in an ATB.

Another commenter requested clarification that businesses that do not both raise or return capital and engage in either investment or development activities do not satisfy the ATB Activity Test, and that the regular, continuous, and substantial standard applies independently to each prong of the ATB Activity Test. The commenter suggested that because the proposed regulations aggregate activities of one or more entities and related parties, the final regulations should not include the statement that the fact that either Raising or Returning Capital Actions or Investing or Developing Actions are only infrequently taken does not preclude the test from being satisfied if the combined Specified Actions meet the test. The commenter expressed concern that this language combined with the rule that Raising or Returning Capital Actions and Investing or Developing Actions are not required to be taken in each taxable year could cause the activities of a fund sponsor's affiliates to satisfy the raising or returning capital prong with respect to any of the sponsored funds.

The final regulations do not adopt this comment. It is necessary for both the Raising or Returning Capital Actions and Investing or Developing Actions to be present for the ATB Activity Test to be satisfied. The aggregation rule and the language regarding infrequent actions are necessary to prevent abuse of section 1061. Without these rules,

activities could be spread among multiple related entities with the intent of not satisfying the ATB Activity Test.

iii. Definition of Specified Assets

Proposed § 1.1061–1(a) defines Specified Assets as: (i) Securities, including interests in partnerships qualifying as securities (as defined in section 475(c)(2) without regard to the last sentence thereof); (ii) commodities (as defined in section 475(e)(2)); (iii) real estate held for rental or investment; (iv) cash or cash equivalents; (v) an interest in a partnership to the extent that the partnership holds Specified Assets; and, (vi) options or derivative contracts with respect to any of the foregoing.

Commenters requested additional guidance on the treatment of partnerships that engage in the production, storage, transportation, processing, or marketing of physical commodities in the ordinary course of business (including hedges with respect to the commodities). The commenters requested that such partnerships not be treated as engaged in Investing and Developing Actions as a result of such activities, and that Specified Assets only include commodities that are themselves actually actively traded on an established financial market, not merely commodities of the same type as commodities that are or can be actively traded on an established financial market.

The final regulations do not adopt this comment; however, the Treasury Department and the IRS continue to study this issue and may address it in future guidance.

Another commenter noted that it is unclear whether the rule treating a derivative contract with respect to a partnership interest as a partnership interest for purposes of applying section 1061 is needed to appropriately administer section 1061. The commenter noted that the proposed regulation's position regarding such a derivative injects unnecessary complexity into the tax system, and stated that because payments made before termination of a swap are almost always ordinary income, it may not make economic or tax sense to use such a financial instrument in lieu of a partnership interest in an attempt to avoid section 1061.

The final regulations do not adopt this comment. While the use of a derivative contract in this circumstance may be rare, the Treasury and the IRS are concerned that the potential for abuse exists. Consequently, the treatment of a derivative contract as a partnership interest for purposes of applying section 1061 is necessary to prevent the circumvention of, and compliance with, section 1061.

B. Section 1.1061–3: Exceptions to the Definition of API

1. Corporate Exception

Section 1061(c)(4)(A) provides that an API ''shall not include any interest in a partnership directly or indirectly held by a corporation.'' In implementing this exception, proposed § 1.1061–3(b)(2) provides that a corporation does not include an entity for which an election was made to treat the entity as a Passthrough Entity, and that therefore, an S corporation for which an election under 1362(a) is in effect and a PFIC with respect to which the shareholder has a QEF election under section 1295 in effect (such entity is a QEF with respect to the shareholder), are not treated as corporations for purposes of section 1061. One commenter approved of this decision, noting that section 1061(f) provides ample authority for excluding S corporations and PFICs from the term corporation. The commenter noted that allowing such structures to benefit from the corporate exception would allow section 1061 to be entirely circumvented. Another commenter, discussing PFICs subject to QEF elections, noted that the exclusion of QEFs from the definition of corporation for purposes of section 1061 is consistent with section 1(h)(9) and (h)(10).

One commenter disagreed regarding authority, noting that the ability to treat QEFs and S corporations as subject to section 1061 is subject to substantial doubt and contrary to the plain text of the statute. The commenter also noted that Notice 2018–18, 2018–2 I.R.B. 443, and the provision's legislative history offer no reason why S corporations should, or should not, qualify for the exception. Another commenter said that a legislative clarification should be sought prior to including a rule in the final regulations providing that S corporations are subject to section 1061.

The Treasury Department and the IRS agree with commenters that the exclusion of S corporations and QEFs from the corporate exception is necessary to avoid circumvention of section 1061. Accordingly, no change has been made to this section of the final regulations. As explained in the preamble to the proposed regulations, section 1061(f) provides that the Secretary has authority to issue regulations or other guidance as is necessary or appropriate to carry out the purposes of section 1061. Both the Conference Report and the Blue Book further direct the Treasury Department and the IRS to issue regulations to address the prevention of abuse of the purposes of the provision. The grant of authority in section 1061(f) is sufficient to issue regulations providing that the exception in section 1061(c)(4)(A) does not include S corporations and PFICs with respect to which shareholders have QEF elections in effect. See also section 1(h)(9) and (10).

2. Unrelated Purchaser Exception

Proposed § 1.1061–3(d) provides that if a taxpayer acquires an interest in a partnership (target partnership) by taxable purchase for fair market value that, but for the exception in § 1.1061–3(d), would be an API, the taxpayer will not be treated as acquiring an API if, immediately before the purchase (1) the taxpayer is not related within the meaning of section 267(b) or 707(b) to any person who provides services in the Relevant ATB, or any service providers who provide services to or for the benefit of the target partnership or a lower-tier partnership in which the target partnership holds a direct or indirect interest; (2) section 1061(d) does not apply to the transaction (as provided in § 1.1061–5); and (3) the taxpayer has not provided in the past, does not then provide, and does not anticipate providing services in the future to, or for the benefit of, the target partnership, directly or indirectly, or any lower-tier partnership in which the target partnership holds a direct or indirect interest.

A few commenters stated that the proposed regulations are unclear as to whether the exception applies only to an API that is directly acquired or whether it also applies to an API in which the buyer acquired an indirect interest through an upper-tier partnership. One commenter recommended that final regulations provide that the exception applies to both APIs purchased directly as well as an APIs purchased indirectly, noting that the unrelated purchaser might not be able to rely on Rev. Rul. 87–115, 1987–2 C.B. 163, to adjust the basis of the underlying fund assets to prevent the recognition of built-in gain, as fund sponsors generally do not make section 754 elections at the fund level. Further, the commenter suggested that the final regulations provide that the exception applies regardless of whether the lower-tier partnership interest is acquired after the third-party purchases the interest in the upper-tier partnership or acquires the upper-tier partnership interest by contribution. Another commenter suggested that the exception be

extended to interests in other Passthrough Entities.

The final regulations do not adopt these comments because of the complexity of administering the unrelated purchaser exception through tiers of Passthrough Entities. The final regulations make non-substantive clarifying changes to the rule.

The preamble to the proposed regulations provides that the exception does not apply to an Unrelated Non-Service Partner who becomes a partner by making a contribution to a Passthrough Entity that holds an API and in exchange receives an interest in the Passthrough Entity's API, stating that, in this case, allocations to the Unrelated Non-Service Partner with respect to the API are API Gains and Losses and retain their character as API Gains and Losses. One commenter noted that this exception to the unrelated purchaser exception is not explained in the proposed regulations' preamble and suggested that the exception to the exception is most likely intended to refer to a situation in which an investor makes a contribution in form to an upper-tier partnership, which then distributes an API with respect to a lower-tier partnership to the contributing upper-tier partner. The commenter notes that these transfers might be a purchase of the API by the investor from the upper-tier partnership. The Treasury Department and the IRS intend that the third-party purchaser exception be limited to API purchases and not apply when a third party contributes cash or property to a Passthrough Entity holding an API in a transaction qualifying for nonrecognition under section 721(a), or any similar provision, resulting in the contributor receiving allocations attributable to the transferee Passthrough Entity's API.

C. Section 1.1061–4: Computing the Recharacterization Amount

1. Computation of the Recharacterization Amount

Proposed § 1.1061–4(a)(1) provides that the Recharacterization Amount equals the Owner Taxpayer's One Year Gain Amount less the Owner Taxpayer's Three Year Gain Amount. The Owner Taxpayer's One Year Gain Amount is the sum of the Owner Taxpayer's combined net API One Year Distributive Share Amount from all APIs held during the taxable year and the Owner Taxpayer's API One Year Disposition Amount. An Owner's Taxpayer's Three Year Gain Amount is equal to the Owner Taxpayer's combined net API Three Year Distributive Share Amount from all APIs held during the taxable year and the Owner Taxpayer's API Three Year Disposition Amount. The API One Year and Three Year Distributive Share Amounts exclude Capital Interest Gains and Losses. Capital Interest Disposition Amounts are not included in the computation of the API One Year and Three Year Disposition Amounts because they relate to the disposition of a Capital Interest rather than an API.

Proposed § 1.1061–4(a)(3)(i) provides that the API One Year Distributive Share Amount equals the API Holder's distributive share of net long-term capital gain from the partnership for the taxable year, including capital gain or loss on the disposition of all or a part of an API, with respect to the partnership interest held by the API Holder calculated without the application of section 1061 less, to the extent included in the amount determined under proposed § 1.1061–4(a)(3)(i)(A), the aggregate of amounts that are excluded from section 1061 under proposed § 1.1061–4(b)(6), the *API Holder's Transition Amount* for the taxable year; and Capital Interest Gains and Losses as determined under proposed § 1.1061–3(c)(2).

One commenter stated that the definition of API One Year Distributive Share Amount does not allow for this amount to be a loss. For example, if an Owner Taxpayer holds two APIs and one partnership allocates the taxpayer a loss and the other a gain, the loss does not offset the gain because the API One Year Distributive Share Amount for the partnership that allocated the taxpayer a loss will be zero. The commenter recommended allowing the API One Year Distributive Share Amount to be less than zero. The final regulations adopt this suggestion by revising the computation for the API One Year Distributive Share Amount to include both capital gain and loss. In addition, the commenter suggested that the final regulations provide that if each of the API One Year Distributive Share Amount and the API Three Year Distributive Share Amount is greater than zero but the API One Year Distributive Share Amount is less than the API Three Year Distributive Share Amount, no portion of the API One Year Distributive Share Amount is recharacterized as short-term capital gain. The final regulations adopt this suggestion by providing that if the One Year Gain Amount and the Three Year Gain Amount are both greater than zero but the One Year Gain Amount is less than the Three Year Gain Amount, none of the One Year Gain Amount is included in the Recharacterization Amount for the taxable year. In addition to adopting this comment, the final regulations make minor clarifying changes to the computation rules.

Commenters raised several additional concerns related to the computation rules. One commenter recommended that regulations provide guidance on how losses limited by section 1211 affect the Recharacterization Amount. Another commenter noted that the proposed regulations do not address how net capital gain is computed or the order of steps in doing so under section 1(h)(1). The commenter stated that because section 1061(a) recharacterizes what would have been long-term capital gain as short-term capital gain, it is apparent that section 1061(a) must be applied somewhere in the process before the application of section 1(h). Further, the proposed regulations do not address § 1.1(h)–1, which provides a look-through rule when a partnership interest is sold, to determine what portion of the gain on sale will be treated as collectibles gain or section 1250 capital gain. The commenter also noted that, although section 1231 and section 1256 gains are excluded from section 1061 by the proposed regulations, a sale of a partnership interest holding such assets is not excluded, and all the gain is subject to section 1061(a) unless section 751(a) applies. Finally, the commenter stated that there is no provision in the proposed regulations addressing suspension of the holding period of an API when an API owner seeks to obtain a more-than-three-year holding period without undertaking additional risk—that is, the hedging of the API. The commenter recommended that an express rule be provided, such as the rule provided in § 1.1400Z2(a)–1(b) for interests in partnerships self-certified as qualified opportunity funds.

The Treasury Department and the IRS continue to study the issues raised by these comments in regard to the computation rules and may address them in future guidance.

2. Distributed API Property

Proposed § 1.1061–1(a) provides that Distributed API Property means property distributed by a Passthrough Entity to an API Holder with respect to the API if the holding period, as determined under sections 735 and 1223, in the API Holder's hands is three years or less at the time of disposition of the property by the API Holder.

A commenter questioned whether the Treasury Department and the IRS have the authority to treat Distributed API Property as subject to section 1061(a). The commenter further stated that in

order for the rule to be a valid exercise of regulatory authority, distributed property for this purpose should exclude property that, if sold by the partnership, would be excluded from section 1061, such as property that would generate 1231 and 1256 gains.

The final regulations continue to treat Distributed API Property as subject to section 1061(a) under the authority of section 1061(f). However, the Treasury Department and the IRS agree with the commenter that long-term capital gain from the disposition of Distributed API Property that, if sold by the partnership, would be excluded from section 1061, such as 1231 and 1256 gain, qualified dividends described in section 1(h)(11)(B), and any other capital gain that is characterized as long-term or short-term without regard to the holding period rules in section 1222, should not be recharacterized under section 1061(a). The final regulations clarify this point by excluding these items from the calculation of the API One Year Disposition Amount. Additionally, because a Passthrough Entity does not calculate an API One Year Disposition Amount, the final regulations clarify that for purposes of calculating the API One Year Distributive Share Amount, an API Holder's distributive share of net long-term capital gain from the partnership includes capital gain or loss on the disposition of Distributed API Property or all or part of an API by an API Holder that is a Passthrough Entity.

Another commenter suggested that the final regulations explicitly provide rules for the treatment of Distributed API Property when the Distributed API Property is distributed from one Passthrough Entity to another and the upper-tier entity disposes of the Distributed API Property. The commenter also requested confirmation in the final regulations that partnerships should subtract capital gain or loss from property that had been Distributed API Property but no longer is at the time of disposition when calculating the API One Year Distributive Share Amount because such gain is excluded from the calculation of the Recharacterization Amount.

The final regulations partially adopt this comment by revising the computation of the One Year Distributive Share Amount to explicitly include dispositions of API Distributed Property by a partnership or other Passthrough Entity. The final regulations do not adopt the suggestion to explicitly provide that partnerships should subtract capital gain or loss from property that had been Distributed API Property but no longer is at the time of disposition when calculating the API One Year Distributive Share Amount. The definition of Distributed API Property provides that it only applies to property with a holding period of three years or less on the date of disposition by an API Holder. Any property with a greater than three-year holding period is therefore not Distributed API Property. A special rule for Distributed API Property distributed to an upper-tier entity by a lower-tier entity is unnecessary because the definition of API Holder includes a Passthrough Entity.

Commenters noted that the proposed regulations are unclear as to how the Distributed API Property rules apply where an API Holder owns both a profits interest and a capital interest in a partnership, and recommended that the final regulations clarify that a distribution to a partner is not Distributed API Property to the extent that it is distributed with respect to the portion of the partner's interest qualifying for the Capital Interest Exception. One commenter suggested that such guidance should also address how to apply the recommended rule in the context of tiered structures.

The Treasury Department and the IRS continue to study this issue and may address it in future guidance.

3. Special Rules for Capital Gain Dividends From Regulated Investment Companies (RICs) and Real Estate Investment Trusts (REITs)

The preamble to the proposed regulations recognizes that long-term capital gain treatment should be available for a capital gain dividend paid by a RIC or REIT to the extent that the capital gain dividend is attributable to assets held for more than three years or is attributable to assets that are not subject to section 1061. Proposed § 1.1061–4(b)(4) facilitates this treatment by allowing a RIC or REIT to disclose two additional amounts based on modified computations of the RIC's or REIT's net capital gain. First, the RIC or REIT may disclose the amount of the capital gain dividend that is attributable to the RIC's or REIT's net capital gain excluding any amounts not taken into account for purposes of section 1061 under proposed § 1.1061–4(b)(6) from the computation. Second, the RIC or REIT may disclose the amount of the capital gain dividend that is attributable to the RIC's or REIT's net capital gain both (1) excluding any amounts not taken into account for purposes of section 1061 under proposed § 1.1061–4(b)(6) from the computation, and (2) substituting three years for one year in applying section 1222. The proposed regulations allow a RIC or REIT to disclose these two additional amounts in writing to its shareholders with its section 852(b)(3)(C)(i) capital gain dividend statement or section 857(b)(3)(B) capital gain dividend notice.

One commenter suggested that it would be extremely rare for a RIC to have shareholders for whom this provision is relevant and stated that requiring this additional reporting would be unnecessarily burdensome as it creates a third type of capital gain that RICs would need to track and report. Consequently, the commenter requested that final regulations continue to permit, but not require, RICs to report this information if they have a shareholder for whom such amounts are relevant. In addition, the commenter noted that most funds will not calculate this information at the time capital gain dividends are reported on Forms 1099–DIV. The commenter requested that final regulations allow reporting on a written statement furnished to the applicable shareholder on request, without tying the reporting of such amounts to the reporting of capital gain dividends.

Another commenter suggested that RICs and REITs should be permitted to disclose these additional amounts, upon request by a shareholder, and report the One Year Amounts Disclosure and Three Year Amounts Disclosure (as those terms are defined in proposed § 1.1061–6(c)) until the extended due date of their returns.

The final regulations retain the rules as proposed but designate them as § 1.1061–4(b)(5). As suggested by these commenters, the final regulations retain the option to disclose to shareholders the two additional amounts (that is the final regulations do not make disclosure mandatory). The final regulations do not adopt the suggestion to allow RICs and REITs to disclose these additional amounts only upon the request of a shareholder because such treatment may allow a RIC or REIT to choose to provide information only to certain shareholders but not to other shareholders. The Treasury Department and the IRS continue to study comments suggesting that the disclosure of this information be separated from the reporting of capital gain dividends and may issue guidance in the future. In the interim, the final regulations retain the rule that the disclosures are to be provided with the section 852(b)(3)(C)(i) capital gain dividend statement or section 857(b)(3)(B) capital gain dividend notice.

4. Computation of the Recharacterization Amount for Owner Taxpayers With Interests in QEFs

The proposed regulations provide special rules for Owner Taxpayers that hold their APIs indirectly through PFICs for which they have made a QEF election. Specifically, under proposed § 1.1061–4(b)(5), the API One and Three Year Distributive Share Amounts include an Owner Taxpayer's section 1293(a)(1) inclusions from QEFs, reduced by amounts that are excluded from section 1061(a) if the QEF complies with the reporting rules under § 1.1061–6(d). These reporting rules provide that QEFs may provide information to allow Owner Taxpayers to compute their Recharacterization Amount. If a QEF fails to provide such information, an Owner Taxpayer includes its entire pro rata share of the QEF's net capital gain in its API One Year Distributive Share Amount and no portion of its pro rata share of the QEF's net capital gain is ultimately included in its API Three Year Distributive Share Amount. One commenter made several suggestions regarding the computation of an Owner Taxpayer's API One Year Distributive Share Amount and API Three Year Distributive Share Amount with respect to a QEF's net capital gain. Broadly, the commenter expressed a concern that the corporate-level capital gain netting rules applicable to QEFs are not consonant with the requirement that the Recharacterization Amount be computed at the Owner Taxpayer level. A QEF determines its net capital gain at the corporate level, and may do so in one of three ways: First, the QEF may calculate and report the amount of each category of long-term capital gain described in section 1(h) of the Code; second, the QEF may report its net capital gain for the year and state that it is subject it to the highest capital gain rate of tax applicable to the shareholder; or third, the QEF may determine its current earnings and profits (E&P) and report the entire amount as ordinary earnings. Section 1.1293–1(a)(2). A QEF's net capital gain is limited to its current E&P, regardless of how it computes such amount under § 1.1293–1(a)(2) (QEF E&P limitation). Section 1293(e)(2). The commenter had several suggestions on how to clarify or improve the rules under section 1061 applicable to QEFs.

First, the commenter suggested that the three year QEF net capital gain provision was not entirely clear, particularly in regard to the API Three Year Distributive Share Amount. The commenter recommended that the final regulations clarify that an Owner Taxpayer includes in its API Three Year Distributive Share Amount the same base amount as determined for the API One Year Distributive Share Amount (as adjusted to reflect only net long-term capital gains and losses calculated by substituting a greater-than-three-year holding period for a greater-than-one-year holding period).

The Treasury Department and the IRS confirm that an Owner Taxpayer's API Three Year Distributive Share Amount is based on the amount computed for its API One Year Distributive Share Amount and adjusted to include only items that would be treated as a long-term gain or loss if three years were substituted for one year in paragraphs (3) and (4) of section 1222 if the QEF satisfies certain reporting obligations. *See* § 1.1061–6(d). However, the final regulations revise proposed § 1.1061–4(b)(5) (designated as § 1.1061–4(b)(6) in the final regulations) to more precisely identify the inputs for computing an Owner Taxpayer's API One and Three Year Distributive Share Amounts and illustrate an Owner Taxpayer's API Three Year Distributive Share Amount computation with respect to a QEF. Specifically, § 1.1061–4(b)(6)(i) provides that an Owner Taxpayer's inclusion under section 1293(a)(1)(B) that is taken into account in determining the API One Year Distributive Share Amount with respect to a QEF is limited to the QEF's E&P by section 1293(e)(2) and that the section 1293(a)(1)(B) inclusion may be reduced by the Owner Taxpayer's share of the excess (if any) of the Capital Interest Gain over Capital Interest Loss with respect to the QEF as well as amounts not taken into account for purposes of section 1061 pursuant to § 1.1061–4(b)(7). In either case, however, § 1.1061–4(b)(6)(i) permits such reductions only if a QEF has provided an Owner Taxpayer with the relevant information necessary for the Owner Taxpayer to determine those amounts.

Additionally, § 1.1061–4(b)(6)(ii) of the final regulations provides that the minuend of an Owner Taxpayer's API Three Year Distributive Share Amount computation (under § 1.1061–4(a)(3)(ii)) includes its entire amount determined under § 1.1061–4(b)(6)(i) (one year QEF net capital gain). The final regulations further provide that if the QEF does not provide the Owner Taxpayer with information necessary under § 1.1061–6(d) to determine the amount of its section 1293(a)(1)(B) inclusion (less any allowed reductions) with respect to the QEF that would be included in its API One and Three Year Distributive Share Amounts, then the entire amount of the Owner Taxpayer's one year QEF net capital gain (less any allowed reductions) is also included in the subtrahend of its API Three Year Distributive Share Amount formula (under § 1.1061–4(a)(3)(ii)(A)). This results in an Owner Taxpayer's entire section 1293(a)(1)(B) inclusion (less any allowed reductions) being treated as short-term capital gain. However, if the QEF provides the Owner Taxpayer with the additional necessary information, then the Owner Taxpayer includes only the amount of its one year QEF net capital gain amount that would not be treated as long-term capital gain substituting a greater-than-three-year holding period in applying paragraphs (3) and (4) of section 1222 in the subtrahend of this formula (under § 1.1061–4(a)(3)(ii)(A)). This can result in a portion of an Owner Taxpayer's section 1293(a)(1)(B) inclusion being characterized as long-term capital gain with the balance being treated as short-term capital gain.

To illustrate, assume an Owner Taxpayer owns an interest in a QEF that holds an API; the Owner Taxpayer owns no other API directly or indirectly. The QEF generates both long- and short-term capital gain in its taxable year, none of which are amounts described in § 1.1061–4(b)(7) or Capital Interest Gains; the Owner Taxpayer's pro rata share of the QEF's long-term capital gain is $100, $70 of which would not be long-term capital gain if a greater-than-three-year holding period were used in applying paragraphs (3) and (4) of section 1222, and its share of the QEF's short-term capital gain (determined without regard to section 1061) is $15. Before applying section 1061, under § 1.1293–1(a)(2), the Owner Taxpayer's pro rata share of the QEF's net capital gain is $100. Under § 1.1061–4(b)(6)(i), with respect to the QEF, the Owner Taxpayer's one year QEF net capital gain amount, and thus its API One Year Distributive Share Amount, is $100. In its API Three Year Distributive Share Amount computation with respect to the QEF, this $100 is the minuend (under § 1.1061–4(a)(3)(ii)). If the QEF does not provide the Owner Taxpayer with information to determine how much of its pro rata share of the QEF's net capital gain would constitute long-term capital gain if a greater-than-three-year holding period were used in applying paragraphs (3) and (4) of section 1222, the Owner Taxpayer would include all $100 under § 1.1061–4(a)(3)(ii)(A) in the subtrahend of its computation. This results in an API Three Year Distributive Share Amount of $0 with respect to the QEF (that is: $100 under § 1.1061–4(a)(3)(ii)

introductory text, minus $100 under § 1.1061–4(a)(3)(ii)(A)) and a Recharacterization Amount of $100 (that is, $100 API One Year Distributive Share Amount minus $0 API Three Year Distributive Share Amount). However, if the QEF does provide the Owner Taxpayer with this information, the Owner Taxpayer includes $70 in the subtrahend of its API Three Year Distributive Share Amount computation with respect to the QEF under § 1.1061–4(a)(3)(ii)(A). This results in an API Three Year Distributive Share Amount of $30 (that is: $100 under § 1.1061–4(a)(3)(ii) introductory text, minus $70 under § 1.1061–4(a)(3)(ii)(A)) and a $70 Recharacterization Amount (that is: $100 API One Year Distributive Share Amount minus $30 API Three Year Distributive Share Amount).

Additionally, the commenter asked that the final regulations harmonize the QEF reporting rules with the reporting rules applicable to other Passthrough Entities. Specifically, the commenter requested that if a QEF does not report relevant information, then QEF shareholders that are Owner Taxpayers should be able to substantiate amounts included in the API One Year Distributive Share Amount and Three Year Distributive Share Amount, as well as items excluded from section 1061(a), through alternative means.

The Treasury Department and the IRS have concluded that, when coupled with § 1.1061–6(d), the QEF reporting rules in § 1.1295–1(g) provide a sufficiently comprehensive framework for information reporting and no additional rule for section 1061 is necessary. Under § 1.1295–1(g)(1), for a PFIC to be treated as a QEF by its shareholders it must provide either an annual statement including the shareholder's pro rata share of the QEF's net capital gain for the year or a statement that it has granted its shareholders access to its books and records (or other documents) for the purpose of determining those amounts; under § 1.1295–1(g)(3), the same information must be reported to indirect PFIC shareholders on an intermediary statement. Under § 1.1295–1(g)(2), in ''rare and unusual circumstances,'' a PFIC can provide alternative documentation if it obtains a private letter ruling from, and enters into a closing agreement with, the IRS. In addition to these reporting requirements, § 1.1061–6(d) permits (but does not require) a QEF to provide its shareholders that are Owner Taxpayers with additional information for the purpose of determining the Owner Taxpayer's API One Year Distributive Share Amount and Three Year Distributive Share Amount.

The Treasury Department and the IRS have determined that the reporting mechanisms under §§ 1.1295–1(g) and 1.1061–6(d) provide sufficient avenues for an Owner Taxpayer to obtain information from a QEF to determine its API One Year Distributive Share Amount and Three Year Distributive Share Amount. A special rule allowing Owner Taxpayers to substantiate QEF information through alternative means for purposes of section 1061 would also run counter to § 1.1295–1(g), which generally requires a QEF, and not its shareholders, to report information for purposes of section 1293. As a result, to reconcile the optional nature of QEF reporting as compared with reporting requirements of other Passthrough Entities, the final regulations revise § 1.1061–6(b)(2)(ii) to provide that a Passthrough Entity from which information is requested must provide such information, but only to the extent the information is necessary for the requesting Passthrough Entity to meet its reporting and filing requirements under § 1.1061–6. The final regulations also revise § 1.1061–6(d) to provide that Owner Taxpayers are not permitted to separately substantiate amounts with respect to a QEF under § 1.1061–6(a)(2). Accordingly, the comments suggesting changes to the QEF reporting rules under section 1061 are not adopted.

The commenter also suggested that the final regulations should provide guidance on how to apportion the QEF E&P limitation for purposes of section 1061. Specifically, the commenter suggested that the QEF E&P limitation should be apportioned according to the shareholder's relative share of the API One Year Distributive Share Amount and the API Three Year Distributive Share Amount with respect to the QEF. The commenter also suggested that consideration be given to bypassing netting at the PFIC level, with guidance to be provided on how to allocate the QEF E&P limitation at the Owner Taxpayer level.

The QEF E&P limitation is imposed by section 1293(e)(2) and is taken into account in determining a shareholder's pro rata share of the net capital gains of a QEF that is required to be included in a shareholder's income pursuant to section 1293(a)(1). Netting of losses must therefore be carried out before determining the net capital gain of a QEF that is required to be included by a shareholder. The Treasury Department and the IRS recognize the complexity regarding apportioning the QEF E&P limitation for purposes of section 1061. This issue is particularly acute in light of the different types of capital gain and loss relevant for purposes of section 1061 that may be included in a QEF's net capital gain, including one- and three-year capital gains and losses, and amounts excluded from section 1061 under § 1.1061–4(b)(7) or under the capital interest exception. Further complication arises from the fact that a loss may arise either from a QEF's ordinary business operations, or from one or more of the four categories listed in the prior sentence.

In this regard, the Treasury Department and the IRS considered several possible ways of apportioning the QEF E&P limitation. One possibility would be to adopt an approach that apportions the QEF E&P limitation between the relevant types of capital gains for purposes of section 1061 on a pro rata basis, which the Treasury Department and the IRS determined would be appropriate in many circumstances, though not all. For example, if a loss arises from a QEF's ordinary business operations while its capital gain income is derived from an API, there may be no direct link between the ordinary loss and the API-derived capital gain. In such a case a pro rata approach may be appropriate. Alternatively, for other circumstances, the Treasury Department and the IRS considered apportioning a QEF's E&P limitation based on more specific ordering rules. For example, if a loss were related to one or more categories of capital gain, allocation first to those categories might be appropriate. Another possible approach would be to allocate the loss giving rise to the E&P limitation in the manner that most closely approximates how an Owner Taxpayer would be permitted to allocate the loss if the QEF's gains and losses were derived directly by the Owner Taxpayer and the Owner Taxpayer's income was limited to otherwise-long-term capital gain income. In light of the complexity regarding the different scenarios under which a pro rata approach or an alternative approach would be more appropriate, the Treasury Department and the IRS have determined that this issue warrants further study and welcome comments in this regard. Until the Treasury Department and the IRS issue further guidance on this issue, taxpayers may adopt any reasonable method for apportioning the QEF E&P limitation for purposes of section 1061 taking into account these considerations.

Finally, the commenter requested that the Treasury Department and the IRS provide a rule that would identify an Owner Taxpayer's distributive share of a QEF's net capital gain from a

Passthrough Entity attributable to the Owner Taxpayer's qualifying capital interest and API. The Treasury Department and the IRS continue to study this issue and may address it in future guidance.

5. Items Not Taken Into Account for Purposes of Section 1061

Proposed § 1.1061–4(b)(6) provides that certain items of long-term capital gain and loss are excluded from the calculation of the API One Year Distributive Share Amount and the API Three Year Distributive Share Amount. Specifically, long-term capital gain and long-term capital loss determined under section 1231 or 1256, qualified dividends included in net capital gain for purposes of section 1(h)(11)(B), and capital gains or losses that are characterized as long-term or short-term without regard to the holding period rules in section 1222 are excluded from these calculations.

Two commenters questioned the exclusion of long-term capital gain determined under section 1231 from recharacterization under section 1061. Those commenters discussed the discrepancies in language between section 1061(a)(1) and 1061(a)(2), noting that only section 1061(a)(2) refers to section 1222. Both commenters suggested that the treatment of section 1231 gains in the proposed regulations is contrary to the statutory text of section 1061. The first commenter stated that section 1061(a)(1) applies to net long-term capital gain and noted that other portions of section 1061 indicate that it is supposed to apply to gains that are taxed at favorable rates for disposition of investment assets. This commenter argued that the reference to section 1222 in section 1061(a)(2) can be read as excluding certain section 1222 gains from the reach of section 1061(a), rather than limiting section 1061(a) to such gains by implication. The commenter noted that if a determination is made that section 1061(a) does apply to section 1231, then regulations need to address the holding periods of section 1231 and how the netting rules of section 1231 interact with section 1061.

The second commenter suggested that, under the proposed regulations, the portion of any net section 1231 gains attributable to APIs could arguably be included in the amount described in section 1061(a)(1). The commenter stated that this would lead to nonsensical results if net section 1231 gains are included in the amount described in section 1061(a)(1) but excluded from the amount described in section 1061(a)(2). Because of the conflicting statutory language in sections 1061(a)(1) and 1061(a)(2), the commenter recommended that the treatment of section 1231 gains be reconsidered, suggesting that one approach would be to include the net 1231 gain attributable to APIs in the section 1061(a) computation after recomputing this amount by substituting 3 years for 1 year.

In contrast, several commenters supported the proposed regulation's treatment of qualified dividends and long-term capital gains determined under section 1231 and 1256 as not subject to recharacterization under section 1061 and recommended these provisions be finalized as proposed. Commenters noted that this treatment aligns with the clear language of the statute and is consistent with Congressional intent. One commenter stated that section 1256 amounts should not be subject to section 1061(a) because they are not gains that are taxed at favorable rates that arise from the disposition of assets. Another commenter noted that the statutory references to section 1223(3) and (4) raise the question of section 1061's potential effect on other Code provisions without regard to section 1222. The commenter indicated that some provisions have their own holding period, such as section 1231, while others, such as section 1256, just mandate tax treatment. The commenter stated that this results in a haphazard inclusion or exclusion of items from section 1061 and noted that because the section 1061 legislative history is devoid of guidance on this issue, the approach taken in the proposed regulations is reasonable but a technical correction from Congress would be welcome.

The final regulations do not adopt suggestions that section 1231 gain should be subject to recharacterization under section 1061(a) and maintain the rules in proposed § 1.1061–4(b)(6), which is designated as 1.1061–4(b)(7) in the final regulations. As stated in the preamble to the proposed regulations, section 1231 gains and losses are treated as long-term based on the operation of section 1231, and not by reference to paragraphs (3) and (4) of section 1222. Similarly, section 1256 provides for specific character treatment and does not calculate gain by reference to section 1222. Accordingly, the Treasury Department and the IRS have determined that it is appropriate to exclude these amounts from both the One Year and Three Year Gain Amounts. In contrast, because section 1061(d)(1) looks to the excess of long-term capital gains with respect to the transferred interest to the sale or exchange of any asset held for not more than three years as is allocable to such interest over what is otherwise short-term capital gain under section 1061(a), and does not reference section 1222, these amounts are captured in transactions to which section 1061(d) applies. The final regulations do not adopt the suggestion to provide guidance on section 1231 holding periods or netting rules because such guidance would be beyond the scope of these final regulations.

One commenter suggested that proposed § 1.1061–4(b), which excludes certain items from the calculation of the API One Year and Three Year Distributive Share Amounts, should be modified to explicitly reference both One Year Disposition Gains and One Year Distributive Share Amounts in providing for an exclusion of section 1231 property from the scope of section 1061. The commenter suggested that the Treasury Department and the IRS should also determine whether a similar modification is appropriate for the exclusion for section 1256 property.

The final regulations do not adopt this comment. The API One Year Disposition Amount includes long-term capital gains and losses recognized by an Owner Taxpayer on the disposition of all or a portion of an API. Pursuant to section 741, the sale or exchange of a partnership interest, including an API, is the sale or exchange of a capital asset. Accordingly, the character of the gain is determined with reference to section 1222. The items listed in § 1.1061–4(b)(7), including section 1231 gain, are excluded from the calculation of the API One Year and Three Year Distributive Share Amounts because they are not determined without regard to section 1222. Furthermore, asymmetrical tax treatment occasionally is a result of the difference between the sale of a partnership interest and the sale of assets by a partnership.

One commenter noted that under section 197(f), acquired goodwill is treated as depreciable property, thereby causing gain recognized on the sale of acquired goodwill to be treated as section 1231 gain. By contrast, self-created goodwill does not qualify as an amortizable intangible under section 197; therefore, any gain recognized on the sale of the self-created goodwill is not section 1231 gain. Instead, it is treated as a capital asset giving rise to capital gain upon a sale or exchange. Consequently, under the proposed regulations, gain on the sale of acquired goodwill is excluded from the Recharacterization Amount while gain on the sale of self-created goodwill is not excluded. The commenter

recommended that in addition to the exclusion for section 1231 gain, the regulations should provide that any gain recognized on the sale of goodwill held in connection with the conduct of a trade or business (whether or not determined under section 1231) is also excluded from the Recharacterization Amount because there is no evidence Congress intended to subject self-created goodwill held in connection with a trade or business to section 1061.

The final regulations do not adopt this comment. The disparate treatment of purchased and self-created goodwill is prescribed by section 197 and nothing in section 1061 changes this treatment.

6. Holding Periods

Proposed § 1.1061–4(b)(8) clarifies that the relevant holding period of either an asset or an API is determined under all provisions of the Code or regulations that are relevant to determining whether the asset or the API has been held for the long-term capital gain holding period by applying those provisions as if the holding period were three years instead of one year. For this purpose, the relevant holding period is the direct owner's holding period in the asset sold.

The final regulations maintain this rule as proposed. One commenter requested clarification that the modification of a partnership agreement does not itself create a new holding period for the API. The final regulations do not adopt this comment as section 1061 does not generally change the holding period of an asset.

7. API Holder Transition Amounts and Partnership Transition Amounts

The proposed regulations provide that a partnership that was in existence as of January 1, 2018, could irrevocably elect to treat all long-term capital gains and losses recognized from the disposition of all assets held by the partnership for more than three years as of January 1, 2018, as Partnership Transition Amounts. An amount of long-term gain or loss treated as a Partnership Transition Amount and included in the allocation of long-term capital gains and losses under sections 702 and 704 to an API Holder with respect to its interest in a Passthrough Entity was treated as an API Holder Transition Amount. API Holder Transition Amounts were not taken into account for purposes of determining the Recharacterization Amount. The preamble to the proposed regulations also requests comments on whether a transition rule is needed and whether the Partnership Transition Amount rules are useful or whether another approach would be more helpful in easing transition difficulties.

Several commenters questioned the need for an elective transition rule. One commenter noted that while they appreciated the Treasury Department and the IRS seeking to minimize the burdens associated with the change in law, they did not believe the transition rules would measurably lessen the recordkeeping burden on funds. The commenter also noted that whether and for whom the transition rules would be beneficial is unpredictable. Another commenter recommended that final regulations include an example illustrating, or otherwise better explaining, the importance of the API Holder Transition Amount rules, that is, what benefits the API Holder Transition Amount rules are intended to confer on taxpayers. No commenter provided an example of the potential applicability of the API Holder Transition Amount rules. After considering the comments, the Treasury Department and the IRS have determined that the Partnership Transition Amount rules are unnecessary. Accordingly, the final regulations do not include these rules.

D. Section 1.1061–6: Reporting Requirements

Proposed § 1.1061–6(a) provides filing and reporting requirements for Owner Taxpayers and Passthrough Entities. Proposed § 1.1061–6(a)(1) provides that an Owner Taxpayer must file such information with the IRS as the Commissioner may require in forms, instructions, or other guidance as is necessary for the Commissioner to determine that the Owner Taxpayer is in compliance with section 1061 and the regulations. Proposed § 1.1061–6(b)(1) provides that a Passthrough Entity must file such information with the IRS as the Commissioner may require in forms, instructions, or other guidance as is necessary for the Commissioner to determine that the Passthrough Entity and its partners have complied with section 1061 and the regulations and that a Passthrough Entity that has issued an API must furnish to the API Holder, including an Owner Taxpayer, such information at such time and in such manner as is necessary to determine the One Year Gain Amount and the Three Year Gain Amount with respect to the Owner Taxpayer that directly or indirectly holds the API.

Proposed § 1.1061–6(a)(2) provides that if a Passthrough Entity does not furnish the information that an Owner Taxpayer needs to determine its Recharacterization Amount and meet its reporting requirements, and the Owner Taxpayer is not able to otherwise substantiate all or a part of those amounts to the satisfaction of the Secretary, then (i) the negative adjustments under proposed § 1.1061–4(a)(3)(i)(B) necessary to calculate the API One Year Distributive Share Amount will be deemed to equal zero, and (ii) the negative adjustment to the API One Year Distributive Share Amount for purposes of determining the API Three Year Distribution Amount under proposed § 1.1061–4(a)(3)(ii)(B) will be deemed to equal zero.

Proposed § 1.1061–6(b)(2) provides that a Passthrough Entity that holds an interest in a lower-tier entity and needs information from the lower-tier entity to meet its reporting obligations under the proposed regulations must request such information from that entity by the later of the 30th day after the close of the taxable year to which the information request relates or within 14 days after the date of a request for information from an upper-tier Passthrough Entity and the lower-tier entity must respond by the due date (including extensions) of the Schedule K–1 for the taxable year. Proposed § 1.1061–6(b)(2)(vii) provides that a Passthrough Entity that fails to comply with the reporting rules in the proposed regulations or as further required in forms, instructions, or other guidance will be subject to penalties.

One commenter stated that the reporting rules are based on the assumption that there will be a limited number of individuals who are in control and who have access to all relevant factual information. Consequently, the rules are extensive and smaller partnerships and non-controlled partnerships may have difficulty complying without significant cost and expense. The commenter suggested this argued in favor of exempting small partnerships from these rules.

A few commenters stated that lower-tier passthrough entities are not required to furnish information until the due date of their returns and that this deadline does not permit upper-tier entities sufficient time to incorporate lower-tier passthrough entity information into their reporting. Further, the commenter noted that the regulations appear to prevent Owner Taxpayers from excluding anything from the API One Year Distributive Share Amount even if only part of the information cannot be substantiated. The commenter recommended that for groups of non-controlled entities, the requestor should be allowed any reasonable approach to substantiate the information and suggested that issues from non-compliant tiers should be resolved by having the IRS impose

failure to furnish penalties on those tiers. Finally, the commenter recommended guidance on how to substantiate unreported amounts.

Several commenters suggested that the information reporting requirements are onerous and that denying exclusions from recharacterization for non-compliance is too harsh a penalty for Owner Taxpayers and upper-tier partnerships who are unable to secure the necessary information from lower-tier partnerships, particularly where an Owner Taxpayer or upper-tier partnership has no control over whether the reporting requirements are met by the lower-tier partnership. One commenter argued that there is no indication in the statute or legislative history that this is what Congress intended. The commenter noted that the TCJA conference report indicates that Congress intended section 6031(b) penalties to apply to a failure to report to partners and those penalties are sufficient to deter non-compliance while not acting to change the character of distributive share items.

A few commenters noted that the reporting requirements will require significant amendments to partnership agreements and reporting systems. These commenters requested that the effective date for the reporting requirements and associated penalties be delayed until at least 12 months after the year end in which the regulations are finalized to give funds and API Holders time to amend their operations and establish proper information reporting systems, particularly in light of the increased reporting requirements resulting from partner tax capital account reporting, Forms K–2 and K–3, the section 163(j) limitation, and other recent guidance.

One commenter suggested that the regulations should provide a de minimis exception to the reporting requirements, especially in tiered partnership arrangements. The commenter suggested that if a limited partner owns less than five percent of a fund, there should be limitations on reporting requirements to those partners, arguing that information reporting is costly in a tiered fund context and the lower-tiered funds may not want to dedicate the resources to provide the proper reporting for such small fund interests.

The final regulations do not adopt these comments. The reporting rules, including the zero presumptions, are necessary to effectively administer section 1061 and the regulations. The Treasury Department and the IRS note that the amounts required to be reported under the reporting rules may be substantiated by any reasonable means if a Passthrough Entity fails to report the necessary information to the Owner Taxpayer. Similarly, a de minimis rule or an exception for small partnerships would frustrate Owner Taxpayers' ability to correctly determine the Recharacterization Amount and the IRS's ability to administer the statute. For these reasons, the Treasury Department and the IRS also decline to provide a delay in the applicability date for the reporting rules.

The final regulations retain the reporting rules as proposed with minor clarifying changes, including the changes discussed in paragraph III.C.4 of this preamble with respect to QEF reporting. In addition, the final regulations provide that if an Owner Taxpayer requires information from a Passthrough Entity to determine the Section 1061(d) Recharacterization Amount, the Owner Taxpayer should request such information from that entity. The Passthrough Entity is required to provide the information to the extent requested by an API Holder and necessary to determine the Owner Taxpayer's Section 1061(d) Recharacterization Amount. Finally, the final regulations substitute ''Commissioner'' for ''Secretary of the Treasury'' in § 1.1061–6(a)(2) to avoid any misperception that any office or bureau within the Treasury Department other than the IRS is responsible for examining taxpayers' returns.

E. Securities Partnerships

The proposed regulations include an amendment to § 1.704–3(e), which provides that a method for aggregating gains and losses by a securities partnership will not be considered reasonable unless it takes into account the application of section 1061. Specifically, the proposed regulations require partnerships that use the partial or full netting approaches described in § 1.704–3(e) to establish accounts to track API Holders' Capital Interest Gains and Losses, Unrealized API Gains and Losses, and API Gains and Losses. A commenter questioned whether these rules were necessary, given the likelihood of hedge fund managers to leave a fund before the three-year holding period expires. Another commenter noted that funds would need to implement sophisticated tracking mechanisms to distinguish between Capital Interest Gains and Losses and API Gains and Losses. The commenter thought that such tracing conflicted with the principles of aggregation provided by § 1.704–3(e).

Another commenter recommended that the final regulations confirm that partnerships can change their section 704(c) aggregation method in order to address section 1061 in a manner consistent with the regulations and that any such change would not violate the requirement to use the same aggregation approach once an approach is adopted. The commenter requested that the final regulations provide examples illustrating the intended application of the creation of separate accounts for APIs and capital interests.

The final regulations provide a simplified rule in § 1.704–3(e) that states that section 1061 must be taken into account in applying the aggregation rule for securities partnerships, but does not provide a specific method for doing so. The Treasury Department and the IRS continue to study the comments received on this issue and may provide additional guidance in the future.

IV. Additional Areas Under Study

A. Section 1061(b) Exception

Section 1061(b) provides that ''[t]o the extent provided by the Secretary, [section 1061(a)] shall not apply to income or gain attributable to any asset not held for portfolio investment on behalf of third party investors.'' The proposed regulations reserve with respect to the application of section 1061(b). The preamble to the proposed regulations states that the Treasury Department and the IRS generally believe that the section 1061(b) exception is effectively implemented in the proposed regulations with the exception to section 1061 for Passthrough Interest Direct Investment Allocations. The preamble further requested comments on the application of section 1061(b) and whether the proposed regulations' exclusion for Passthrough Interest Direct Investment Allocations properly implements the exception.

One commenter suggested that the Passthrough Interest Direct Investment Allocations would exempt certain family offices from section 1061(a) but stated that the exception is too narrow to account for all types of family offices. The commenter noted that section 1061(b) is not intended to cover family offices managed by a professional investment manager who is not a family member and who receives an API because the family members are third-party investors with respect to the professional investment manager. Several commenters suggested that additional guidance under section 1061(b) is needed for family offices, management companies, and other partnerships that do not hold assets for portfolio investment on behalf of third-party investors. One commenter argued

that the Treasury Department and the IRS should not reserve on section 1061(b) because carried interests as used in asset management businesses were the particular focus of Congress as it contemplated carried interest proposals.

One commenter noted that it had recommended prior to the issuance of the proposed regulations that the authority under section 1061(b) should be exercised to confirm that section 1061(a) does not apply to recharacterize income or gain attributable to the value of intangibles, including goodwill, created or used in an ATB. The commenter recognized that the Passthrough Interest Direct Investment Allocation rules in the proposed regulations operate in part to implement an exception for enterprise value, but recommended that final regulations should provide specifically that section 1061(a) does not apply to recharacterize income or gain attributable to enterprise value. Furthermore, the commenter argued that the enterprise value exception should apply to allocations through tiers and should not require allocations in accordance with partner capital accounts if the intangible asset it not held for portfolio investment on behalf of third-party investors.

As discussed in Part II.A. of this Summary of Comments and Explanation of Revisions, the final regulations modify the rules related to the capital interest exception, including removing the Passthrough Interest Direct Investment Allocation rules. As discussed in Part II.C. of this Summary of Comments and Explanation of Revisions, the final regulations provide that the delayed holding period prong of the Lookthrough Rule does not apply to the disposition of an API to the extent that the gain recognized upon the disposition is attributable to any asset not held for portfolio investment on behalf of third party investors. The Treasury Department and the IRS continue to study the comments regarding section 1061(b) and may address the application of the provision in future guidance, including whether section 1061(a) applies to recharacterize income or gain attributable to enterprise value. The Treasury Department and the IRS request additional comments related to section 1061(b).

B. Small Partnerships

In the preamble to the proposed regulations, the Treasury Department and the IRS requested comments and suggestions on whether a simplified method for determining and calculating the API Gain or Loss should be provided for small partnerships and if so, the criteria that should be used to determine which partnerships should be eligible to use the simplified method. One commenter stated that a small partnership exception is critically important to the integrity of the entire section 1061 regulatory regime. The commenter also noted that given the burdensome nature of the reporting requirements that could apply to small business taxpayers, a modification of these requirements for either ''small partnerships'' or ''small partners'' would appear to be justified. As discussed in the section on reporting requirements, a commenter also recommended a *de minimis* exception to the reporting requirements for passthrough entities in which a limited partner owns five percent, or less, of a fund. The Treasury Department and the IRS continue to study this issue and may address this in future guidance. The Treasury Department and the IRS request additional comments and suggestions on whether a simplified method for determining and calculating the API Gain or Loss should be provided for small partnerships and if so, the criteria that should be used to determine which partnerships should be eligible to use the simplified method.

V. Applicability Dates

The final regulations retain the applicability dates as proposed. Accordingly, the final regulations generally apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. Section 1.1061–3(b)(2)(i) applies to taxable years beginning after December 31, 2017. Section 1.1061–3(b)(2)(ii) applies to taxable years beginning after August 14, 2020. An Owner Taxpayer or Passthrough Entity may choose to apply the final regulations in their entirety to a taxable year beginning after December 31, 2017, provided that they consistently apply the final regulations in their entirety to that year and all subsequent years.

With respect to an API in a partnership with a fiscal year ending after December 31, 2017, section 706 determines the capital gains and losses the Owner Taxpayer includes in income with respect to an API after December 31, 2017. Section 706 provides that the taxable income of a partner for a taxable year includes amounts required by sections 702 and 707(c) with respect to a partnership based on the income, gain, loss, deduction, or credit of a partnership for any taxable year ending within or with the taxable year of the partner. Accordingly, if a calendar year Owner Taxpayer has an API in a fiscal year partnership whose taxable year ends after December 31, 2017, section 1061 applies to the Owner Taxpayer's distributive share of long-term capital gain or loss with respect to the API in calendar year 2018 regardless of whether the partnership disposed of the property giving rise to the gains and losses in the period prior to January 1, 2018. *See* § 1.706–1(a).

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 12866, 13563, and 13771 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

These regulations have been designated as economically significant under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations.

A. Need for Final Regulations

These final regulations provide certainty and clarity to taxpayers affected by statutory changes introduced in section 1061 by TCJA. The Treasury Department and the IRS have received questions and comments regarding the meaning of various provisions in section 1061 and issues not explicitly addressed in the statute. The Treasury Department and the IRS have determined that such comments warrant the issuance of further guidance.

B. Background

Section 1061 of the Internal Revenue Code (Code), enacted by TCJA, characterizes certain long-term capital gains recognized with respect to an API as short-term capital gains. Short-term capital gains are generally taxed at a higher rate than long-term capital gains.

Section 1061 defines an API as an interest in a partnership transferred to or held by the taxpayer in connection with the performance of substantial services by the taxpayer, or any other related person, in any ''applicable trade or business'' (ATB). Under section 1061 the term ATB encompasses a range of financial service activities. Specifically, an ATB is any activity conducted on a regular, continuous, and substantial basis which consists, in whole or in

part, of raising or returning capital, and either (i) investing in (or disposing of) ''specified assets'' (or identifying specified assets for such investing or disposition), or (ii) developing specified assets. ''Specified assets'' are certain securities, certain commodities, real estate held for rental or investment, cash or cash equivalents, options or derivative contracts with respect to any of the foregoing, and an interest in a partnership to the extent of the partnership's proportionate interest in any of the foregoing.

Prior to the TCJA, the Internal Revenue Code made no distinction between capital gains allocated to APIs versus other partnership interests and partnership assets. Generally, the required holding period to obtain the lower long-term capital gains tax rate was one year for all partnership interests and partnership capital assets. Under the new provision, the required holding period for an API must be greater than three years to obtain long-term capital gains treatment.

The Treasury Department and the IRS previously published proposed regulations under section 1061 (''proposed regulations'').

C. Overview of the Final Regulations

The final regulations provide taxpayers with definitional and computational guidance regarding the application of section 1061. In particular, the final regulations provide a number of definitions, including the term 'taxpayer' for the purpose of determining the existence of an API. Additionally, the regulations clarify the rules for certain exceptions to section 1061, including the exception for capital interests, and provide for an additional exception for bona fide purchases of APIs by an unrelated party who is not a service provider. The final regulations also provide rules for calculating the recharacterized gain amount.

D. Economic Analysis

1. Baseline

In this analysis, the Treasury Department and the IRS assess the benefits and costs of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these final regulations.

2. Summary of Economic Effects

The final regulations provide certainty and consistency in the application of section 1061 by providing definitions and clarifications regarding the statute's terms and rules. An economically efficient tax system generally aims to treat income and expense derived from similar economic decisions consistently across taxpayers and activities in order to reduce incentives for individuals and businesses to make choices based on tax rather than market incentives. In the absence of the guidance provided in these final regulations, taxpayers would bear the burden of interpreting the statute and the chances that different taxpayers might interpret the statute differently would be exacerbated. For example, two similarly situated taxpayers might interpret the statutory provisions pertaining to the definition of taxpayer or the capital interest exception differently, causing one to enter into a partnership that another comparable taxpayer might decline because of a different interpretation of how the income will be treated under section 1061. If this opportunity did not go to the more productive taxpayer, this lack of clarity results in an economically inefficient pattern of activity. An economic loss may also arise if all taxpayers have identical interpretations of the tax treatment of particular income streams under the statute but which differ slightly from the interpretation that Congress intended for these income streams. In this case, guidance provides value by bringing economic decisions closer in line with the intent and purpose of the statute.

The final regulations include multiple substantive changes compared to the proposed regulations. The Treasury Department and the IRS view these changes as favorable to taxpayers, providing more flexibility and reducing burden and complexity. In particular, the final rules governing the capital interest exception are more flexible to better accommodate common business practices, which vary considerably across industries. Compared to the proposed regulations, the final regulations considerably narrow the range of related party transactions triggering 1061 recharacterization, and the associated compliance burden. Finally, compared to the proposed regulations, the Lookthrough Rule on the sale of APIs included in the final regulations is a more narrowly targeted anti-abuse rule, only imposing a compliance burden on taxpayers that appear to have engaged in abusive practices with the primary aim of avoiding section 1061(a) recharacterization.

The proposed regulations solicited comments on the economic analysis of the proposed regulations. No such comments were received.

3. Economic Analysis of Specific Provisions

a. Provisions Not Substantially Revised From the Proposed Regulations

i. Definition of Taxpayer

The statute requires taxpayers to make a number of determinations, including the determination of the existence of an API, and the calculation of the section 1061 amount, or amount of long-term gain recharacterized under section 1061. However, the term ''taxpayer'' is not defined in either section 1061 or in the Conference Report. Comments received by the Treasury Department and IRS highlight the importance of the definition of the term taxpayer for purposes of section 1061. Without guidance, taxpayers could use different approaches to define ''taxpayer,'' leading otherwise similar taxpayers to experience different degrees of complexity, and to report different recharacterized amounts.

The final regulations include two definitions of taxpayer to address the level at which the determination of the existence of an API is made and the level at which the calculation of the section 1061 amount is made. The final regulations define the Owner Taxpayer as the person generally required to pay tax on the gain or loss with respect to the API. Under the final regulations, the section 1061 calculation is only performed by the person (the Owner Taxpayer) who must pay tax on the gains and losses recognized with respect to the API. The final regulations also introduce the term Passthrough Taxpayer. A Passthrough Taxpayer is an entity that does not itself generally pay tax on capital gains but must determine when an API exists and allocate income, gain, deduction and loss to its owners. Both the Owner Taxpayer and the Passthrough Taxpayer are treated as taxpayers for the purpose of determining whether an API exists.

The Treasury Department and the IRS considered and rejected two alternative approaches to the definition of taxpayer outlined in received comments, the ''aggregate approach'' and the ''full entity approach''. Under the aggregate approach, a partnership is not treated as a taxpayer for purposes of section 1061. Instead, section 1061 is applied solely to the partners that are ultimately subject to tax on the partnership's items of capital gain and loss. A concern with using this approach for the purpose of determining whether an API exists is that it could incentivize partners to use tiered ownership structures to avoid section 1061 recharacterization. For example, an upper tier partnership may

receive an interest in a lower-tier fund in connection with the upper-tier partnership's performance of services in an ATB. Partners of the upper-tier partnership may contend that they did not receive their interest in the upper-tier partnership in connection with the services performed by the upper-tier partnership. Stopping such avoidance strategies would require complex rules and potentially burdensome reporting requirements when tiered ownership structures are involved.

Under the ''full entity approach'', the partnership is treated as a taxpayer for purposes of both determining the existence of an API and calculating the section 1061 recharacterization amount. Treating the partnership as a taxpayer for purposes of calculating the section 1061 recharacterization amount was found to be more burdensome than the approach taken in the final regulations for three reasons. First, using the full entity approach for determining the section 1061 recharacterization amount may lead to increased recharacterization of gains under section 1061 because individuals would not be able to net gains and losses across multiple APIs. Second, the administrative burden on both the taxpayer and the IRS would be increased in cases of tiered ownership. Under the full entity approach, a separate section 1061 calculation would be required at each level at which an API is held in a tiered partnership structure. Finally, the full entity approach may add complexity and burden in cases in which an exception to section 1061 applies, such as if a corporation is a direct or indirect partner. Because corporations are excluded from section 1061, any amount recharacterized at the partnership level would need to be tracked as it is allocated to partners to ensure that corporate or other excepted partners are not subject to the three-year holding period under section 1061.

The Treasury and the IRS have concluded that the chosen alternative, incorporating the concepts of Owner Taxpayer and Passthrough Taxpayer, is less burdensome than other alternatives and provides helpful certainty to taxpayers.

ii. Clarification of the Treatment of an API Purchased by an Unrelated Party

The statute states that capital gain or loss recognized by a taxpayer on the sale of an API held for more than one year is subject to section 1061. The statute also provides guidance for ongoing treatment under section 1061 when the API is purchased by, or transferred to, a related party or another service provider. However, the statute does not provide guidance for the taxpayer who purchases an API and is neither a service provider to the relevant ATB, nor related to the seller of the API. The final regulations add an exception to section 1061 and provide that the term API does not include an interest in a partnership that would be treated as an API but is held by a bona fide purchaser of the interest who does not currently and has never provided services in the relevant ATB and who is not related to a person who provides services currently or has provided services in the past. By clarifying the treatment of an API that is sold at arm's length, the final regulations reduce uncertainty and compliance burdens for taxpayers entering into these transactions. The Treasury Department and the IRS have determined that this exception is consistent with the purpose of section 1061, which applies to service providers and persons related to service providers and which is not meant to apply to bona fide purchasers of a partnership interest who do not provide services.

The Treasury Department and the IRS considered not providing this exception. However, it was determined that failure to provide this exception would treat unrelated purchasers of an API in an inequitable fashion, and that continued treatment of the partnership interest as an API would be inconsistent with the purpose of section 1061 because unrelated purchasers did not receive their interest in connection with the performance of substantial services.

b. Provisions Substantially Revised From the Proposed Regulations

i. Capital Interest Exception

Section 1061(c)(4)(B) provides that the definition of an API does not include ''any capital interest in the partnership which provides the taxpayer with a right to share in partnership capital commensurate with—(i) the amount of capital contributed (determined at the time of receipt of such partnership interest) or (ii) the value of the interest included in income under section 83 upon the receipt or vesting of such interest.'' However, the statute does not provide guidance on what it means for a right to share in partnership capital to be ''commensurate'' with the amount of capital contributed.

The final regulations clarify that allocations are deemed commensurate with capital contributed if, under the partnership agreement, the allocation to an API Holder is calculated in a similar manner as the allocations to similarly situated Unrelated Non-Service Partners. This may be determined on an investment-by-investment or class-by-class basis. To qualify as a benchmark for comparison, the Unrelated Non-Service Partners must hold a significant investment, defined as at least five percent of the partnership. In the absence of these regulations, taxpayers might face confusion, along with substantial compliance cost, in calculating their qualifying capital interest. Further, partners with realized gains would be incentivized to engage in a series of inefficient transactions in order to minimize tax.

The Treasury Department and the IRS considered alternative interpretations of ''commensurate with capital contributed.'' In particular, the proposed regulations provide that an allocation is ''commensurate with capital'' if the allocation is based on the relative section 704(b) capital accounts of the partners under the partnership agreement. The proposed regulations then provide multiple rules for calculating an API holder's capital account, including a rule disallowing unrealized API capital gains in calculating the API holder's capital account, and a rule for determining the capital account when an API is held through another partnership. In light of numerous comments, the Treasury Department and the IRS have determined that the proposed regulations were too rigid and were not well suited to the wide variety of common business practices regarding ownership structure, accounting conventions, and compensation arrangements. Specifically, many partnerships subject to section 1061 do not maintain section 704(b) capital accounts. For many other partnerships, the capital account of one partner may relate to economic rights associated with multiple separate investments held by a partnership, while the capital account of another partner may relate to economic rights associated with a separate set of investments held by a partnership. For these reasons, the Treasury Department and the IRS have determined that the section 704(b) capital accounts of partners provide a poor means of measuring commensurate economic capital interest rights.

The proposed regulations also prohibited use of the capital interest exception if a capital contribution was funded with related party loan proceeds. Commenters noted that it is a common business practice in industries subject to Section 1061 for employees to require new partners to make substantial capital contributions, which are often acquired through a loan. This arrangement, designed not to avoid tax but to align the incentives of general

partners and limited partners, would be unduly penalized under the proposed regulations, incentivizing firms to choose a less efficient ownership and governance structure. The final regulations amend the rule to allow an individual service provider's capital contributions to be funded with loan proceeds from partners and persons related to partners if the individual service provider is personally liable for the loan, meaning the loan is fully recourse to the individual service provider, the individual service provider has no right to be reimbursed by any person, and no person has guaranteed the individual service's provider's loan. The Treasury Department and the IRS believe the final rules address abusive avoidance strategies, while imposing less burden on taxpayers engaged in standard business practices relative to not allowing any contributions from proceeds from related part loans to be eligible for the capital interest exception.

ii. Lookthrough Rule on Sale of APIs

Section 1061(a) provides that if one or more APIs are held by a taxpayer at any time during the taxable year, the excess (if any) of (1) the taxpayer's net long-term capital gain with respect to such interests for such taxable year, over (2) the taxpayer's net long-term capital gain with respect to such interests for that taxable year computed by applying paragraphs (3) and (4) of sections 1222 by substituting ''3 years'' for ''1 year,'' must be treated as short-term capital gain, notwithstanding section 83 or any election in effect under section 83(b). The House Report explains that section 1061 ''imposes a three-year holding period (not the generally applicable one-year holding period) in the case of long-term capital gain from applicable partnership interests.'' Neither section 1061 nor the Reports, however, explicitly provides what the relevant holding period is for purposes of section 1061(a) for the sale of an API with assets of different holding periods.

The final regulations include a Lookthrough Rule that is triggered if a transaction or series of transactions has taken place with a principal purpose of avoiding potential gain recharacterization under section 1061(a). Under this Lookthrough Rule, all gain not attributable to assets held for more than three years is subject to recharacterization under section 1061(a). Additionally, the Lookthrough Rule applies if the API disposition would be subject to Section 1061(a) recharacterization using a holding period not beginning until the date that Unrelated Non-Service Partners legally commit to contribute substantial capital to the applicable partnership. Without this rule, fund managers might attempt to avoid the recharacterization of gains by establishing partnerships and leaving them inactive for three years before attracting investment from limited partners, thereby circumventing Section 1061.

The Treasury Department and the IRS considered and rejected alternative approaches, including applying a simple interest approach, an alternative lookthrough rule (as provided in the proposed regulations), and an underlying assets approach. The simple interest approach looks solely to the holding period in the API, regardless of the length of time the partnership has engaged in substantive investment. This approach might allow taxpayers to avoid section 1061 characterization for long-term capital gains on assets that are not held for the more than three years by the partnership. This result would encourage distortive behavior in investment funds, which might look to create partnerships for different investors solely for tax purposes, relative to the approach adopted in the final regulations. That is, the partners of that investment partnership would not be subject to section 1061 if they had owned their APIs for more than three years, irrespective of how long the investment partnership had been active and attracting capital from outside investors.

Alternatively, the underlying asset, or full lookthrough, approach looks solely to the holding period in the underlying asset (or assets) of the partnership, regardless of whether the underlying asset is sold by the partnership or the API is sold by its owner. The underlying asset approach would be more difficult (and burdensome) for taxpayers to apply (relative to the provision provided in the final regulations) as it would require a determination of the unrealized gain for each asset held by the partnership, even in cases in which a relatively small share of assets by value have a holding period of three years or less.

The proposed regulations included an alternative lookthrough rule applied to the sale of an API if 80% or more of the value of the assets held by the partnership at the time of the API disposition were assets held for three years or less that would produce capital gain or loss subject to section 1061 if disposed of by the partnership. If the lookthrough rule in the proposed regulations applied, a portion of the capital gain on the disposition of the API attributable partnership assets held for three or fewer years would be recharacterized as short-term capital gain. This alternative was rejected in the final regulations because the calculations required by the proposed lookthrough rule would impose unnecessary compliance burden on individual taxpayers selling an API without any accompanying general economic benefit. The rules requiring partnerships to furnish taxpayers with the relevant information to perform the calculations would also impose undue additional burden on the relevant partnerships. The lookthrough rule provided in the final regulations applies in more limited circumstances, narrowly targeting taxpayers that appear to be engaged in abusive practices to avoid section 1061(a) recharacterization. Therefore, the final regulations provide helpful guidance and certainty for taxpayers, while imposing minimal compliance burden relative to the no-action baseline or alternative regulatory approaches.

iii. Treatment of API Transfers to Related Parties

Section 1061(d) recharacterizes certain long-term capital gain as short-term capital gain when a taxpayer transfers an API to a related person. While the statute provides a definition of a related person and a general description of the recharacterization amount, numerous commenters expressed uncertainty regarding the scope of transfers subject to section 1061(d), pointing out that although the statutory language of section 1061(d) refers to the transfer of an API, it refers to income inclusion associated with an API transfer that is related to the sale or exchange of partnership assets held for three years of less. Based on the statutory language, commenters expressed the view that section 1061(d) transfers should be limited to taxable transfers.

Although one read of the text of section 1061(d) suggests that the provision can be broadly applied to capture all API transfers, including gifts and other nonrecognition transfer, the Treasury Department and the IRS considered and rejected applying section 1061(d) to nontaxable transfers. Applying section 1061(d) to nontaxable transfers would impose income recognition on gifts including an API, where no income recognition is imposed on otherwise similar gifts, creating a tax disadvantage for gifts including an API. Instead, the Treasury and the IRS have determined that the section 1061(d) statute is better read as a recharacterization provision that looks to how much of the taxpayer's long-term capital gain upon the sale of an API is

attributable to the sale or exchange of any asset held for three years or less and that the provision's use of the word ''transfer'' does not supersede application of the sale or exchange requirement in the statute.

II. Paperwork Reduction Act

A. Collection of Information in § 1.1061–6(a) on the Owner Taxpayer is on Existing Forms

The collection of information in § 1.1061–6(a) requires an Owner Taxpayer to file such information with the IRS as the Commissioner may require in forms, instructions and other published guidance as is necessary for the IRS to determine that the taxpayer has properly complied with section 1061 and the Section 1061 Regulations. This information is necessary for the IRS to determine that the Owner Taxpayer has properly complied with section 1061. In general, the Owner Taxpayer is an individual and the Owner Taxpayer's Recharacterization Amount and Section 1061(d) Recharacterization Amount will be required to be reported to the IRS as short-term capital gain on Schedule D, ''Capital Gains and Losses,'' of the Form 1040, ''U.S. Individual Income Tax Return.'' Less frequently, the Owner Taxpayer is a trust and the Owner Taxpayer's Recharacterization Amount and Section 1061(d) Recharacterization Amount will be required to be reported to the IRS as short-term capital gain on Schedule D, ''Capital Gains and Losses,'' of the Form 1041, ''U.S. Income Tax Return for Estates and Trusts.''

The current status of the Paperwork Reduction Action submission related to § 1.1061–6(a) is provided in the following table. The burdens associated with the collection of information from the Owner Taxpayer to comply with section 1061 are included in the aggregate burden estimates for Form 1040 under OMB control number 1545–0074 and Form 1041 under OMB control number 1545–0092. The overall burden estimates provided in OMB Control Number 1545–0074 represents a total estimated burden time, including all other related forms and schedules for individuals, of 1.784 billion hours and total estimated monetized costs of $31.74 billion (in 2017 dollars). The overall burden estimates provided in OMB Control Number 1545–0092 represents a total estimated burden time, including all other forms and schedules for trusts and estates of 307.8 million hours and total estimated monetized costs of $9.95 billion (in 2016 dollars). These amounts are aggregate amounts that relate to all information collections associated with the applicable OMB control numbers, and will in the future include, but not isolate, the estimated burden of Owner Taxpayers as a result of the information collections in the regulations. No burden estimates specific to the final regulations are currently available. The Treasury Department and IRS have not estimated the burden, including that of any new information collections, related to the requirements under the final regulations. Those estimates would capture both changes made by the TCJA and those that arise out of discretionary authority exercised in the regulations. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the collection of information applicable to the Owner Taxpayer in these regulations. In addition, when available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

Form	Type of filer	OMB No.(s)	Status
Form 1040 (Including Schedule D).	Individual (NEW Model)	1545–0074	Published in the **Federal Register** on 9/30/19. Comment period closed on 11/29/19. 84 FR 51712. Thirty-day notice published on 12/18/19. 84 FR 69458. Approved by the Office of Information and Regulatory Affairs (OIRA) on 1/30/20.
Form 1041 (Including Schedule D).	Trusts and Estates (Legacy Model).	1545–0092	Published in the **Federal Register** on 4/4/2018. 83 FR 14552. Public comment period closed 6/4/2018. Thirty-day notice published on 9/27/18. 83 FR 48894. Approved by OIRA on 5/8/19.

B. Collection of Information on Passthrough Entities in § 1.1061–6(b) and (c) on Existing Forms

1. Passthrough Entities

The collection of information in § 1.1061–6(b) requires a Passthrough Entity that has issued an API to furnish to the API Holder, including the Owner Taxpayer, such information at such time and in such manner as the Commissioner may require in forms, instructions, and other published guidance as is necessary to determine the One Year Gain amount and the Three Year Gain Amount with respect to an Owner Taxpayer. This includes: (i) The API One Year Distributive Share Amount and the API Three Year Distributive Share Amount (as determined under § 1.1061–4); (ii) Capital gains and losses allocated to the API Holder that are excluded from section 1061 under § 1.1061–4(b)(7); (iii) Capital Interest Gains and Losses allocated to the API Holder (as determined under § 1.1061–3(c)); (iv) In the case of a disposition by the API Holder of an interest in the Passthrough Entity during the taxable year, any information required by the API Holder to properly take the disposition into account under section 1061, including information necessary to apply the Lookthrough Rule and to determine its Capital Interest Disposition Amount and any information necessary to determine an Owner Taxpayer's Section 1061(d) Recharacterization Amount. The regulations seek to minimize the information that a Passthrough Entity is required to automatically furnish annually. In some cases, an upper-tier Passthrough Entity may be an API Holder in a lower-tier Passthrough Entity, and the information furnished by the lower-tier Passthrough Entity to the upper-tier Passthrough Entity may not be sufficient for the upper-tier Passthrough Entity to meet its reporting obligations under the regulations. In this case, the regulations require the lower-tier Passthrough Entity to furnish information to the upper-tier Passthrough Entity if requested. Thus, if an upper-tier Passthrough Entity in a tiered entity structure holds an interest in a lower-tier Passthrough Entity and it needs information from the lower-tier Passthrough Entity to comply with its obligation to furnish information under the regulations, it must request information from the lower-tier entity and the lower-tier entity must furnish the requested information. This passing of information upon request between the tiers of entities is necessary to minimize the quantity of information required to be annually furnished by a Passthrough Entity and because each Passthrough Entity in a tiered entity arrangement is the only entity that has

access to the information that is required to be furnished. The collection of information in the regulations is necessary to ensure that the Owner Taxpayer receives information sufficient to correctly calculate its Recharacterization Amount under section 1061.

2. RICs and REITs

Section 1.1061–6(c) permits a RIC or a REIT that reports or designates all or a part of a dividend as a capital gain dividend, to disclose additional information to their shareholders for purposes of section 1061. The furnishing of this information may allow a Passthrough Entity to include a portion of the capital gain dividend in the API Three Year Distributive Share amount furnished to API Holders and may ultimately enable an Owner Taxpayer to reduce its Recharacterization Amount under the regulations.

3. Table for Collections of Information in § 1.1061–6(b) and (c)

The collection of information with respect to § 1.1061–6(b) and (c) is provided in the following table. In the case of a Passthrough Entity that is a partnership, the information will be required to be furnished as an attachment to the Schedule K–1, ''Partner's Share of Income, Deduction, Credit, Etc.'' of Form 1065, ''U.S. Return of Partnership Income.'' In the case of a Passthrough Entity that is an S corporation, the information will be required to be furnished as an attachment to the Schedule K–1, ''Shareholder's Share of Income, Deductions, Credit, Etc.,'' of Form 1120–S, ''U.S. Income Tax Return for an S Corporation.'' The burdens associated with the collection of information from the Passthrough Entities will be included in the aggregate burden estimates for the Form 1065 and the Form 1120S under OMB control number 1545–0123. The overall burden estimates provided in OMB Control Number 1545–0123 represents a total estimated burden time, including all others related forms and schedules, of 3.344 billion hours and total estimated monetized costs of $61.558 billion (in 2019 dollars). The burden estimates provided in OMB Control Number 1545–0123 are aggregate amounts that relate to all information collections associated with the applicable OMB control number, and will in the future include, but not isolate, the Passthrough Entities' estimated burden as a result of the information collections in the proposed regulations.

In the case of a Passthrough Entity that is a trust or estate, the information will be required to be furnished as an attachment to the Schedule K–1, ''Beneficiary's Share of Income, Deductions, Credit, Etc.,'' of Form 1041, ''U.S. Income Tax Return for Estates and Trusts.'' The burdens associated with the collection of information from a Passthrough Entity that is a trust or estate will be included in the aggregate burden estimates for the Form 1041 OMB control number 1545–0092. The overall burden estimates provided in OMB Control Number 1545–0092 represents a total estimated burden time, including all other forms and schedules for trusts and estates of 307.8 million hours and total estimated monetized costs of $9.95 billion (in 2016 dollars). The burden estimates provided in OMB Control Number 1545–0092 are aggregate amounts that relate to all information collections associated with the applicable OMB control number, and will in the future include, but not isolate, the Passthrough Entities' estimated burden as a result of the information collections in the regulations.

In the case of RICs and REITs the information will be furnished in connection with the Form 1099–DIV, ''Dividends and Distributions.'' The burden estimates associated with the collection of information from RICs and REITs will be included in the aggregate burden estimated for the Form 1099–DIV under OMB Control Number 1545–0110. The overall burden estimates provided in OMB Control Number 1545–0110 represents a total estimated burden time of 32,119,195 hours and total estimated monetized costs of $ 1.64 billion (in 2016 dollars). The burden estimates provided in OMB Control Number 1545–0110 relate to all information collections associated with the applicable OMB Control Number, and will in the future include, but not isolate, the RIC and REIT estimated burden as a result of the information collections in the regulations.

The Treasury Department and IRS have not estimated the burden, including that of any new information collections, related to the requirements under the regulations. Those estimates would capture both changes made by the TCJA and those that arise out of the discretionary authority exercised in the regulations. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the collection of information applicable to the Passthrough Entities in the regulations. In addition, when available, drafts of IRS Forms and the applicable instructions are posted for comment at *https://www.irs.gov/pub/irs-dft/.*

Form	Type of filer	OMB No.(s)	Status
Form 1041 (including Schedule K–1).	Trusts and Estates (Legacy Model).	1545–0092	Published in the **Federal Register** on 4/4/2018. 83 FR 14552. Public comment period closed 6/4/2018. Thirty-day notice published on 9/27/18. 83 FR 48894. Approved by OIRA on 5/8/19.
Form 1065 (including Schedule K–1).	Business (NEW Model)	1545–0123	Sixty-day notice published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. 84 FR 51718. Thirty-day notice published in the **Federal Register** on 12/19/19. Public Comment period closed on 1/21/20. 84 FR 69825. Approved by OIRA on 1/30/20.
Form 1120S (Including Schedule K–1).	Business (New Model)	1545–0123	Sixty-day notice published in the **Federal Register** on 9/30/19. Public Comment period closed on 11/29/19. 84 FR 51718. Thirty-day notice published in the **Federal Register** on 12/19/19. Public Comment period closed on 1/21/20. 84 FR 69825. Approved by OIRA on 1/30/20.
Form 1099–DIV	(Legacy Model)	1545–0110	Sixty-day notice published in the **Federal Register** on 9/19/19. Public comment period closed 11/18/19. 84 FR 49379. Thirty-day notice published in the **Federal Register** on 12/20/19. 84 FR 70269.

Form	Type of filer	OMB No.(s)	Status
	Link: *https://www.federal register.gov/documents/2018/05/23/2018-10981/proposed-collection-comment-request-for-form-1099-div.*		

C. Chart Showing Number of Respondents Regarding Existing Forms

The following chart shows the estimated number of returns that are expected to have attachments providing additional information with respect to section 1061. As noted previously, Owner Taxpayers will be required to provide section 1061 information on an attachment to Schedules D for Forms 1040 and 1041. Passthrough Taxpayers will be required to report section 1061 on Forms 1041, 1065, and 1120S to the IRS and to furnish information to their API Holders on attachments to the respective K–1s. RICs and REITs may voluntarily report additional information at an attachment to Form 1099–DIV.

Schedule D Form 1040	20,475
Schedule D Form 1041	2,275
Schedule K Form 1065	28,500
Schedule K–1s Form 1065 ...	57,000
Schedule K Form 1120S	1,500
Schedule K–1s Form 1120 ...	1,000
Form 1099–DIV filed by REITs	836
Form 1099–DIV filed by RICs	3,880

D. Voluntary Collection of Information in § 1.1061–6(d) on PFIC Shareholder Will Be Added to Existing OMB Control Number for PFIC Information Retention

Section 1.1061–6(d) permits a PFIC with respect to which the shareholder is an API Holder who has a QEF election is in effect for the taxable year to provide additional information to the shareholder to determine the amount of the shareholder's inclusion that would be included in the API One Year Distributive Share Amount and the API Three Year Distributive Share Amount. If the PFIC furnishes this information to the shareholder, the shareholder must retain a copy of this information along with the other information required to be retained under § 1.1295–1(f)(2)(ii). The burden associated with retaining this additional information will be included in the aggregate burden estimates for § 1.1295–1(f) under OMB Control Number 1545–1555. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books and records related to the collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act. These regulations generally only impact investment funds that have capital gains and losses that derive from the disposition of assets that have a holding period of more than one year but not more than three years. Investment funds are considered small business if they have annual average receipts of $41.5 million or less (13 CFR part 121). The rule may affect a substantial number of small entities, but data are not readily available to assess how many entities will be affected.

The Treasury Department and the IRS received no actionable comments on the impact that the proposed regulations would have on small entities. Although certain commenters requested that partnerships with an unspecified amount of limited assets be excepted from the application of the statutory rules of section 1061, these commenters did not provide any data to demonstrate that any burden would be significant. Similarly, a commenter requested an exception to the reporting requirements for passthrough entities in which a limited partner owns 5 percent or less of a fund but did not quantify the burden. In addition, the final regulations adopt other comments that limit the general burden of the regulations to all entities, including small entities.

Even if a substantial number of small entities are affected, the economic impact of these regulations on small entities is not significant. The regulations provide taxpayers with definitional and computational guidance regarding the application of section 1061. The impact of the regulations is to impose an additional reporting obligation that applies only with respect to the sale of assets held for more than one year but not more than three years. The Treasury Department and the IRS recognize that this reporting obligation may increase, at least to some extent, the tax preparation burden for affected taxpayers beyond that imposed by the statute. This reporting obligation generally will only apply to a minority of the asset dispositions by an entity. The entity will also have a reporting obligation in certain circumstances regarding the disposition of an API, but the extent of the reporting obligation depends on the number of assets disposed by the entity and their holding periods. The information reported is readily available to taxpayers and reported on forms already in use beginning with the 2019 taxable year such as Schedule D to IRS Form 1065. Finally, some taxpayers may find they need an initial investment of time to read and understand these regulations at an approximate cost of $95/hour and an estimated time of ten hours. Accordingly, the Secretary certifies that these regulations will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small businesses. No comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on

state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

VI. Congressional Review Act

The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this Treasury decision is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*). Under 5 U.S.C. 801(a)(3), a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Notwithstanding this requirement, 5 U.S.C. 808(2) allows agencies to dispense with the requirements of 5 U.S.C. 801 when the agency for good cause finds that such procedure would be impracticable, unnecessary, or contrary to the public interest and the rule shall take effect at such time as the agency promulgating the rule determines. Pursuant to 5 U.S.C. 808(2), the Treasury Department and the IRS find, for good cause, that a 60-day delay in the effective date is contrary to the public interest.

Following the enactment of section 1061 by the TCJA, the Treasury Department and the IRS published the proposed regulations to provide certainty to taxpayers. In particular, as demonstrated by the wide variety of public comments in response to the proposed regulations received, taxpayers continue to express uncertainty regarding the proper application of the statutory rules under section 1061. This is especially the case for taxpayers in the trade or business of operating investment funds, which may be unwilling to engage in certain commercial transactions without the additional clarity provided by these final regulations. Additionally, various rules contained within these regulations attempt to curb certain abusive transactions designed to avoid the application of section 1061 and an earlier effective date is necessary to address these abusive transactions. Accordingly, the Treasury Department and the IRS have determined that the rules in this Treasury decision will take effect on the date of filing for public inspection in the **Federal Register**.

Statement of Availability of IRS Documents

Notice 2018–18, 2018–2 I.R.B. 443 (in addition to any other revenue procedures or revenue rulings, etc. cited in this preamble) is published in the Internal Revenue Bulletin (or Cumulative Bulletin) and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Drafting Information

The principal authors of these regulations are Kara K. Altman, Sonia K. Kothari, and Wendy L. Kribell of the Office of Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendment to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries for §§ 1.1061–0, 1.1061–1, 1.1061–2, 1.1061–3, 1.1061–4, 1.1061–5, and 1.1061–6 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.1061–0 added under 26 U.S.C. 1061(f).

Section 1.1061–1 added under 26 U.S.C. 1061(f).

Section 1.1061–2 added under 26 U.S.C. 1061(f).

Section 1.1061–3 added under 26 U.S.C. 1(h)(9) and 1061(f).

Section 1.1061–4 added under 26 U.S.C. 1061(f).

Section 1.1061–5 added under 26 U.S.C. 1061(f).

Section 1.1061–6 added under 26 U.S.C. 1061(f).

* * * * *

■ **Par. 2.** Section 1.702–1 is amended by adding a sentence at the end of paragraph (a)(2) and adding paragraph (g) to read as follows.

§ 1.702–1 Income and credits of partner.

(a) * * *

(2) * * * Each partner subject to section 1061 must take into account gains and losses from sales of capital assets held for more than one year as provided in section 1061 and §§ 1.1061–1 through 1.1061–6.

* * * * *

(g) *Applicability date.* The last sentence of paragraph (a)(2) of this section applies for the taxable years beginning on or after January 19, 2021.

■ **Par. 3.** Section 1.704–3 is amended by:

■ 1. In paragraph (e)(3)(vi)(B), remove the word ''and'' at the end of the paragraph;

■ 2. Redesignating paragraph (e)(3)(vi)(C) as paragraph (e)(3)(vi)(D);

■ 3. Adding new paragraph (e)(3)(vi)(C); and

■ 4. Revising the heading and first sentence of paragraph (f) and adding a sentence to the end of paragraph (f).

The additions and revisions read as follows:

§ 1.704–3 Contributed property.

* * * * *

(e) * * *

(3) * * *

(vi) * * *

(C) With respect to any person who directly or indirectly holds an Applicable Partnership Interest, as defined in § 1.1061–1(a)(1), take into account the application of section 1061 with respect to such interest in an appropriate manner; and

* * * * *

(f) *Applicability dates.* With the exception of paragraphs (a)(1), (a)(8)(ii) and (iii), (a)(10) and (11), and (e)(3)(vi)(C) of this section, and of the last sentence of paragraph (d)(2) of this section, this section applies to properties contributed to a partnership and to revaluations pursuant to § 1.704–1(b)(2)(iv)(*f*) or (*s*) on or after December 21, 1993.

* * * Paragraph (e)(3)(vi)(C) of this section applies to taxable years beginning on or after January 19, 2021.

* * * * *

■ **Par. 4.** Sections 1.1061–0 through 1.1061–6 are added before the undesignated center heading ''Changes to Effectuate F.C.C. Policy'' to read as follows:

Sec.

* * * * *

1.1061–0 Table of contents.
1.1061–1 Section 1061 definitions.
1.1061–2 Applicable partnership interests and applicable trades or businesses.
1.1061–3 Exceptions to the definition of an API.
1.1061–4 Section 1061 computations.
1.1061–5 Section 1061(d) transfers to related persons.
1.1061–6 Reporting rules.

* * * * *

§ 1.1061–0 Table of contents.

This section lists the captions that appear in §§ 1.1061–1 through 1.1061–6.

§ 1.1061–1 Section 1061 definitions.
(a) Definitions.
(b) Applicability date.
§ 1.1061–2 Applicable partnership interests and applicable trades or businesses.
(a) API rules and examples.
(1) Rules.
(i) An API remains an API.
(ii) Application of section 1061 to Unrealized API Gains and Losses.
(iii) API Gains and Losses retain their character.
(iv) Substantial services by the Owner Taxpayer, Passthrough Taxpayer or any Related Person.
(v) Grantor trusts and entities disregarded as separate from their owners.
(2) Examples.
(b) Application of the ATB Activity Test.
(1) In general.
(i) Rules for applying the ATB Activity Test.
(A) Aggregate Specified Actions taken into account.
(B) Raising or Returning Capital Actions and Investing or Developing Actions are not both required to be taken in each taxable year.
(C) Combined conduct by multiple related entities taken into account.
(ii) Developing Specified Assets.
(iii) Partnerships.
(2) Examples.
(c) Applicability date.
§ 1.1061–3 Exceptions to the definition of an API.
(a) A partnership interest held by an employee of another entity not conducting an ATB.
(b) Partnership interest held by a corporation.
(1) In general.
(2) Treatment of interests held by an S corporation or a qualified electing fund.
(c) Capital Interest Gains and Losses.
(1) In general.
(2) Capital Interest Gains and Losses defined.
(3) General rules for determining Capital Interest Allocations.
(i) Commensurate with capital contributed.
(ii) In a similar manner.
(A) Relevant factors.
(B) Clear identification requirement.
(iii) Reinvestment of API Gain.
(iv) Unrelated Non-Service Partner requirement.
(v) Proceeds of certain loans not taken into account for Capital Interest Allocation purposes.
(A) General rule.
(B) Recourse liability.
(vi) Items that are not included in Capital Interest Allocations.
(4) Capital Interest Disposition Amounts.
(i) In general.
(ii) Determination of the Capital Interest Disposition Amount.
(5) Capital Interest Allocations made by a Passthrough Entity that is an API Holder.
(6) Examples.
(d) Partnership interest acquired by purchase by an unrelated person.
(1) Acquirer not a Related Person.
(2) Section 1061(d) not applicable.
(3) Acquirer not a service provider.
(e) [Reserved]
(f) Applicability date.
(1) General rule.
(2) Partnership interest held by an S corporation.
(3) Partnership interest held by a PFIC with respect to which the shareholder has a QEF election in effect.
§ 1.1061–4 Section 1061 computations.
(a) Computations.
(1) Recharacterization Amount.
(2) One Year Gain Amount and Three Year Gain Amount.
(i) One Year Gain Amount.
(ii) Three Year Gain Amount.
(3) API One Year Distributive Share Amount and API Three Year Distributive Share Amount.
(i) API One Year Distributive Share Amount.
(ii) API Three Year Distributive Share Amount.
(4) API One Year Disposition Amount and API Three Year Disposition Amount.
(i) API One Year Disposition Amount.
(ii) API Three Year Disposition Amount.
(b) Special rules for calculating the One Year Gain Amount and the Three Year Gain Amount.
(1) One Year Gain Amount equals zero or less.
(2) Three Year Gain Amount equals zero or less.
(3) One Year Gain Amount less than Three Year Gain Amount.
(4) Installment sale gain.
(5) Special rules for capital gain dividends from regulated investment companies (RICs) and real estate investment trusts (REITs).
(i) API One Year Distributive Share Amount.
(ii) API Three Year Distributive Share Amount.
(iii) Loss on sale or exchange of stock.
(6) Pro rata share of qualified electing fund (QEF) net capital gain.
(i) One year QEF net capital gain.
(ii) Three year QEF net capital gain adjustment.
(7) Items not taken into account for purposes of section 1061.
(8) Holding period determination.
(i) Determination of holding period for purposes of the Three Year Gain Amount.
(ii) Relevant holding period.
(9) Lookthrough Rule for certain API dispositions.
(i) Determination that the Lookthrough Rule applies.
(A) In general.
(B) Determination that the Lookthrough Rule applies to the disposition of a Passthrough Interest.
(ii) Application of the Lookthrough Rule.
(10) Section 83.
(c) Examples.
(1) Recharacterization rules.
(2) Special rules examples.
(d) Applicability date.
§ 1.1061–5 Section 1061(d) transfers to related persons.
(a) In general.
(b) Transfer.
(c) Section 1061(d) Recharacterization Amount.
(d) Special rules.
(e) Section 1061(d) Related Person.
(f) Examples.
(g) Applicability date.
§ 1.1061–6 Reporting rules.
(a) Owner Taxpayer filing requirements.
(1) In general.
(2) Failure to obtain information.
(b) Passthrough Entity filing requirements and reporting.
(1) Requirement to file information with the IRS and to furnish information to API Holder.
(2) Requirement to request, furnish, and file information in tiered structures.
(i) Requirement to request information.
(ii) Requirement to furnish and file information.
(iii) Timing of requesting and furnishing information.
(A) Requesting information.
(B) Furnishing information.
(iv) Manner of requesting information.
(v) Recordkeeping requirement.
(vi) Passthrough Entity is not furnished information to meet its reporting obligations under paragraph (b)(1) of this section.
(vii) Filing requirements.
(viii) Penalties.
(c) Regulated investment company (RIC) and real estate investment trust (REIT) reporting.
(1) Section 1061 disclosures.
(i) One Year Amounts Disclosure.
(ii) Three Year Amounts Disclosure.
(2) Pro rata disclosures.
(3) Report to shareholders.
(d) Qualified electing fund (QEF) reporting.
(e) Applicability date.

§ 1.1061–1 Section 1061 definitions.

(a) *Definitions.* The following definitions apply solely for purposes of this section and §§ 1.1061–2 through 1.1061–6.

API Gains and Losses are any long-term capital gains and capital losses with respect to an API and include:

(i) The *API One Year Distributive Share Amount* as defined in § 1.1061–4(a)(3)(i);

(ii) The *API Three Year Distributive Share Amount* as defined in § 1.1061–4(a)(3)(ii);

(iii) The *API One Year Disposition Amount* as defined in § 1.1061–4(a)(4)(i);

(iv) The *API Three Year Disposition Amount* as defined in § 1.1061–4(a)(4)(ii); and

(v) Capital gains or losses from the disposition of Distributed API Property.

API Holder is a person who holds an API.

Applicable Partnership Interest (API) means any interest in a partnership which, directly or indirectly, is transferred to (or is held by) an Owner Taxpayer or Passthrough Taxpayer in connection with the performance of substantial services by the Owner Taxpayer or by a Passthrough Taxpayer,

or by any Related Person, including services performed as an employee, in any ATB unless an exception in § 1.1061–3 applies. For purposes of defining an API under this section and section 1061 of the Internal Revenue Code (Code), an interest in a partnership also includes any financial instrument or contract, the value of which is determined in whole or in part by reference to the partnership (including the amount of partnership distributions, the value of partnership assets, or the results of partnership operations). An Owner Taxpayer and a Passthrough Taxpayer can hold an API directly or indirectly through one or more Passthrough Entities.

Applicable Trade or Business (ATB) means any activity for which the ATB Activity Test with respect to Specified Actions is met, and includes all Specified Actions taken by Related Persons, including combining activities occurring in separate partnership tiers or entities as one ATB.

ATB Activity Test has the meaning provided in § 1.1061–2(b)(1).

Capital account means a capital account maintained under § 1.704–1(b)(2)(iv) or similar principles.

Capital Interest Allocations means, with respect to a partnership, allocations of long-term capital gain or loss made under the partnership agreement to an API Holder and to Unrelated Non-Service Partners based on such partners' capital contributed with respect to the partnership to the extent such allocations otherwise meet the requirements of § 1.1061–3(c). With respect to other Passthrough Entities, the principles of this definition apply.

Capital Interest Disposition Amount has the meaning provided in § 1.1061–3(c)(4).

Capital Interest Gains and Losses has the meaning provided in § 1.1061–3(c)(2).

Distributed API Property means property distributed by a Passthrough Entity to an API Holder with respect to an API if the holding period, as determined under sections 735 and 1223, in the API Holder's hands is three years or less at the time of disposition of the property by the API Holder.

Indirect API means an API that is held through one or more Passthrough Entities.

Investing or Developing Actions means actions involving either—

(i) Investing in (or disposing of) Specified Assets (or identifying Specified Assets for such investing or disposition); or

(ii) Developing Specified Assets (see § 1.1061–2(b)(1)(ii)).

Lookthrough Rule means the recharacterization rule described in § 1.1061–4(b)(9).

One Year Gain Amount has the meaning provided in § 1.1061–4(a)(2)(i).

Owner Taxpayer means the person subject to Federal income tax on net gain with respect to an API or an Indirect API during the taxable year, including an owner of a Passthrough Taxpayer unless the owner of the Passthrough Taxpayer is a Passthrough Entity itself or is excepted under § 1.1061–3(a), (b), or (d).

Passthrough Entity means a partnership, trust, estate, S corporation described in § 1.1061–3(b)(2)(i), or passive foreign investment company described in § 1.1061–3(b)(2)(ii).

Passthrough Interest means an interest in a Passthrough Entity that represents in whole or in part an API.

Passthrough Taxpayer means a Passthrough Entity that is treated as a taxpayer for the purpose of determining the existence of an API.

Raising or Returning Capital Actions means actions involving raising or returning capital but does not include Investing or Developing Actions.

Recharacterization Amount has the meaning provided in § 1.1061–4(a)(1).

Related Person means a person or entity who is treated as related to another person or entity under sections 707(b) or 267(b).

Relevant ATB means the ATB in which services were provided and in connection with which an API is held or was transferred.

Section 1061(d) Recharacterization Amount has the meaning provided in § 1.1061–5(c).

Section 1061(d) Related Person has the meaning provided in § 1.1061–5(e).

Section 1061 Regulations means the provisions of this section and §§ 1.1061–2 through 1.1061–6.

Specified Actions means the combination of Raising or Returning Capital Actions and Investing or Developing Actions.

Specified Assets means—

(i) Securities, including interests in partnerships qualifying as securities (as defined in section 475(c)(2) without regard to the last sentence thereof);

(ii) Commodities (as defined in section 475(e)(2));

(iii) Real estate held for rental or investment;

(iv) Cash or cash equivalents; and

(v) An interest in a partnership to the extent that the partnership holds Specified Assets. See § 1.1061–2(b)(1)(iii).

(vi) Specified Assets include options or derivative contracts with respect to any of the items provided in paragraphs (i) through (v) of this definition.

Three Year Gain Amount has the meaning provided in § 1.1061–4(a)(2)(ii).

Unrealized API Gains and Losses means, with respect to a Passthrough Entity's assets, all unrealized capital gains and losses that would be:

(i) Realized if those assets were disposed of for fair market value in a taxable transaction on the relevant date; and

(ii) Allocated to an API Holder with respect to its API, taking into account the principles of section 704(c).

Unrelated Non-Service Partners means partners who do not (and did not) provide services in the Relevant ATB and who are not (and were not) Related Persons with respect to any API Holder in the partnership or any person who provides or has provided services in the Relevant ATB.

(b) *Applicability date.* The provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they consistently apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

§ 1.1061–2 Applicable partnership interests and applicable trades or businesses.

(a) *API rules and examples*—(1) *Rules*—(i) *An API remains an API.* Once a partnership interest qualifies as an API, the partnership interest remains an API unless and until the requirements of one of the exceptions to qualification of a partnership interest as an API, set forth in § 1.1061–3, are satisfied.

(ii) *Application of section 1061 to Unrealized API Gains and Losses.* Unrealized API Gains and Losses are API Gains and Losses subject to section 1061 when the gains and losses are realized and recognized. Unrealized API Gains and Losses do not lose their character as such until they are recognized.

(iii) *API Gains and Losses retain their character.* API Gains and Losses retain their character as API Gains and Losses as they are allocated from one Passthrough Entity to another Passthrough Entity and then to the Owner Taxpayer.

(iv) *Substantial services by an Owner Taxpayer, Passthrough Taxpayer, or any Related Person.* If an interest in a partnership is transferred to or held by an Owner Taxpayer, Passthrough Taxpayer, or any Related Person in connection with the performance of services, the Owner Taxpayer, the

Passthrough Taxpayer, or the Related Person is presumed to have provided substantial services for purposes of section 1061.

(v) *Grantor trusts and entities disregarded as separate from their owners.* A trust wholly described in subpart E, part I, subchapter J, chapter 1 of the Internal Revenue Code (that is, a grantor trust), a qualified subchapter S subsidiary described in section 1361(b)(3), and an entity with a single owner that is treated as disregarded as an entity separate from its owner under any provision of the Internal Revenue Code or any part of 26 CFR (including § 301.7701–3 of this chapter) are disregarded for purposes of the Section 1061 Regulations.

(2) *Examples.* The following examples illustrate the provisions of this paragraph (a).

(i) *Example 1: API.* (A) A is the general partner of PRS, a partnership, and provides services to PRS. A is engaged in an ATB as defined in § 1.1061–1(a). PRS transfers a PRS profits interest to A in connection with A's performance of substantial services with respect to PRS's ATB. A's interest in PRS is an API.

(B) After 6 years, A retires and is no longer engaged in an ATB and does not perform any services with respect to its ATB and with respect to PRS. However, A retains the API in PRS. PRS continues to acquire new capital assets and to allocate gain to A from the disposition of those assets. Under paragraph (a)(1)(i) of this section, A's interest in PRS remains an API after A retires.

(ii) *Example 2: Contribution of an API to a partnership.* Individuals A, B, and C each directly hold APIs in PRS, a partnership. A and B form a new partnership, GP, and contribute their APIs in PRS to GP. Following the contribution, each of A and B holds an Indirect API because each of A and B now indirectly holds an API in PRS through GP, a Passthrough Entity. Each of A's and B's interests in GP is a Passthrough Interest because each of A's and B's interest in GP represents an Indirect API.

(iii) *Example 3: Passthrough Interest, Indirect API, Passthrough Taxpayer.* Each of A, B, and C provides services to, and is an equal partner in, GP. GP is engaged in an ATB as defined in § 1.1061–1(a), is the general partner of PRS, and provides substantial management services to PRS. In connection with GP's performance of substantial services in an ATB, PRS issues a profits interest to GP. Because GP's PRS interest was received in connection with GP's providing services in an ATB, GP is a Passthrough Taxpayer and GP's interest in PRS is an API. Because A, B, and C are partners in GP, they each hold a Passthrough Interest in GP and an Indirect API in PRS. Each of A, B, and C is treated as an Owner Taxpayer because each is a partner in GP and because each holds an Indirect API in PRS in connection with the performance of its services to GP's ATB.

(iv) *Example 4: S corporation, Passthrough Interest, Indirect API, and Passthrough Taxpayer.* A owns all of the stock of S Corp, an S corporation. S Corp is engaged in an ATB, as defined in § 1.1061–1(a). S Corp is the general partner of PRS, a partnership, and provides substantial management services to PRS. A provides substantial services in S Corp's ATB. In connection with S Corp providing substantial services to PRS, PRS issues a profits interest to S Corp. S Corp's interest in PRS is its only asset. Because S Corp's profits interest in PRS was issued to S Corp in connection with substantial services in an ATB, S Corp is a Passthrough Taxpayer and its interest in PRS is an API. Because A is a shareholder in S Corp, A holds a Passthrough Interest in S Corp and an Indirect API in PRS as a result of S Corp's API in PRS. A is treated as an Owner Taxpayer because A holds an interest in S Corp, a Passthrough Taxpayer, and also indirectly holds an API in PRS in connection with A's services in S Corp's ATB.

(v) *Example 5: Indirect API, Related Person, and Passthrough Taxpayer.* Each of A, B, and C is an equal partner in partnership GP, the general partner of PRS. GP's Specified Actions do not satisfy the ATB Activity Test under § 1.1061–1(a) and as a result, GP's actions do not establish an ATB. Management Company is a Related Person with respect to GP within the meaning of sections 267(b) and 707(b), is engaged in an ATB, and provides substantial management services to PRS that are sufficient to satisfy the ATB Activity Test. Management Company's actions are attributed to GP under paragraphs (a)(1)(iv) and (b)(1)(i)(C) of this section because Management Company is a Related Person to GP. In connection with Management Company's services to PRS, PRS issues a profits interest to GP. Because its PRS profits interest is issued to GP in connection with services provided by Management Company, a Related Person, GP is a Passthrough Taxpayer and its interest in PRS is an API. Unless an exception described in § 1.1061–3 applies, because A, B, and C are partners in GP, they each hold a Passthrough Interest in GP and an Indirect API in PRS. A, B, and C are treated as Owner Taxpayers because they hold an interest in GP, a Passthrough Taxpayer.

(b) *Application of the ATB Activity Test*—(1) *In general.* The ATB Activity Test is satisfied if both Raising and Returning Actions and Investing or Developing Actions are conducted by an Owner Taxpayer, Passthrough Taxpayer, or one or more Related Persons with respect to an Owner Taxpayer or Passthrough Taxpayer, and the total level of activity, including the combined activities of all Related Persons, satisfies the level of activity that would be required to establish a trade or business under section 162.

(i) *Rules for applying the ATB Activity Test*—(A) *Aggregate Specified Actions taken into account.* The determination of whether the ATB Activity Test is satisfied is based on the combined activities conducted that qualify as either Raising or Returning Capital Actions and Investing or Developing Actions. The fact that either Raising or Returning Capital Actions or Investing or Developing Actions are only infrequently taken does not preclude the test from being satisfied if the combined Specified Actions meet the test.

(B) *Raising or Returning Capital Actions and Investing or Developing Actions are not both required to be taken in each taxable year.* Raising or Returning Capital Actions and Investing or Developing Actions are not both required to be taken in each taxable year in order to satisfy the ATB Activity Test. For example, the ATB Activity Test will be satisfied if Investing or Developing Actions are not taken in the current taxable year, but sufficient Raising or Returning Capital Actions are taken in anticipation of future Investing or Developing Actions. Additionally, the ATB Activity Test will be satisfied if no Raising or Returning Capital Actions are taken in the current taxable year, but have been taken in a prior taxable year (regardless of whether the ATB Activity Test was met in the prior year), and sufficient Investing or Developing Actions are undertaken by the taxpayer in the current taxable year.

(C) *Combined conduct by multiple related entities taken into account*—(*1*) *Related Entities.* If a Related Person(s) (within the meaning of § 1.1061–1(a)) solely or primarily performs Raising or Returning Capital Actions and one or more other Related Person(s) solely or primarily performs Investing or Developing Actions, the combination of the activities performed by these Related Persons will be taken into account in determining whether the ATB Activity Test is satisfied.

(*2*) *Actions taken by an agent or delegate.* Specified Actions taken by an agent or a delegate in its capacity as an agent or a delegate of a principal will be taken into account by the principal in determining whether the ATB Activity Test is satisfied with respect to the principal. These Specified Actions are also taken into account in determining whether the ATB Activity test is satisfied with respect to the agent or the delegate.

(ii) *Developing Specified Assets.* Developing Specified Assets takes place if it is represented to investors, lenders, regulators, or other interested parties that the value, price, or yield of a portfolio business may be enhanced or increased in connection with choices or actions of a service provider. Merely exercising voting rights with respect to shares owned or similar activities do not amount to developing Specified Assets.

(iii) *Partnerships.* Investing or Developing Actions directly conducted with respect to Specified Assets held by a partnership are counted towards the ATB Activity Test. Additionally, a portion of the Investing or Developing Actions conducted with respect to the interests in a partnership that holds Specified Assets is counted towards the ATB Activity Test. This portion is the value of the partnership's Specified Assets over the value of all of the partnership's assets. Actions taken to manage a partnership's working capital will not be taken into account in determining the portion of Investing or Developing Actions conducted with respect to the interests in the partnership.

(2) *Examples.* The following examples illustrate the application of the ATB Activity Test described in paragraph (b)(1) of this section.

(i) *Example 1: Combined activities of Raising or Returning Capital Actions and Investing or Developing Actions.* During the taxable year, B takes a small number of actions to raise capital for new investments. B takes numerous actions to develop Specified Assets. B's actions with respect to raising capital and B's actions with respect to developing Specified Assets are combined for the purpose of determining whether the ATB Activity Test is satisfied. These actions cumulatively rise to the level required to establish a trade or business under section 162. Thus, B satisfies the ATB Activity Test.

(ii) *Example 2: Combining Specified Actions in multiple entities.* GP, a partnership, conducts Raising or Returning Capital Actions. Management Company, a partnership that is a Related Person to GP, conducts Investing or Developing Actions. When GP's and Management Company's activities are combined, the ATB Activity Test is satisfied. Accordingly, both GP and Management Company are engaged in an ATB, and services performed by either GP or Management Company are performed in an ATB under paragraph (b)(1) of this section.

(iii) *Example 3: Investing or Developing Actions taken after Raising or Returning Capital Actions that do not meet the ATB Activity Test.* In year 1, PRS engaged in Raising or Returning Capital Actions to fund PRS's investment in Specified Assets. However, PRS' Specified Actions during year 1 did not satisfy the ATB Activity Test because they did not satisfy the level of activity required to establish a trade or business under section 162. Therefore, PRS was not engaged in an ATB in year 1. In year 2, PRS engaged in significant Investing or Developing Actions but did not engage in any Raising or Returning Capital Actions. In year 2, PRS's Investing or Developing Actions rise to the level required to establish a trade or business under section 162. Because PRS has cumulatively engaged in both Investing or Developing Actions and Raising or Returning Capital Actions and because the Specified Actions rise to the level of activity required to establish a trade or business under section 162, PRS is engaged in an ATB in year 2.

(iv) *Example 4: Raising or Returning Capital Actions taken in anticipation of Investing or Developing Actions.* In year 1, A only conducted Raising or Returning Capital Actions. A's Raising or Returning Capital Actions were undertaken to raise capital to invest in Specified Assets with the goal of increasing their value through Investing or Developing Actions and rise to the level of activity required to establish a trade or business under section 162. A did not take Investing or Developing Actions during the taxable year. A's Raising or Returning Capital Actions satisfy the ATB Activity Test because they were undertaken in anticipation of also engaging in Investing or Developing Actions. Therefore, the ATB Activity Test is satisfied, and A is engaged in an ATB in year 1.

(v) *Example 5: Attribution of delegate's actions.* GP is the general partner of PRS. GP is responsible for providing management services to PRS. GP contracts with Management Company to provide management services on GP's behalf to PRS. GP and Management Company are not Related Persons. The Specified Actions taken by Management Company on behalf of GP are attributed to GP for purposes of the ATB Activity Test because the Management Company is operating as a delegate of GP. Additionally, those Specified Actions are taken into account by Management Company for purposes of the ATB Activity Test and whether it is engaged in an ATB.

(vi) *Example 6: ATB Activity Test not satisfied.* A is the manager of a hardware store. Partnership owns the hardware store, including the building in which the hardware business is conducted. In connection with A's services as the manager of the hardware store, a profits interest in Partnership is transferred to A. Partnership's business involves buying hardware from wholesale suppliers and selling it to customers. The hardware is not a Specified Asset. Although real estate is a Specified Asset if it is held for rental or investment purposes, Partnership holds the building for the purpose of conducting its hardware business and not for rental or investment purposes. Therefore, the building is not a Specified Asset as to Partnership. Partnership also maintains and manages a certain amount of working capital for its business, but actions with respect to working capital are not taken into account for the purpose of determining whether the ATB Activity Test is met. Partnership is not a Related Person with respect to any person who takes Specified Actions. Partnership is not engaged in an ATB because the ATB Activity Test is not satisfied. Although Partnership raises capital, its Raising or Returning Capital Actions alone do not satisfy the ATB Activity Test. Further, Partnership takes no Investing or Developing Actions because it holds no Specified Assets other than working capital. Partnership is not in an ATB and the profits interest transferred to A is not an API.

(c) *Applicability date.* The provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

§ 1.1061–3 Exceptions to the definition of an API.

(a) *A partnership interest held by an employee of another entity not conducting an ATB.* An API does not include any interest transferred to a person in connection with the performance of substantial services by that person as an employee of another entity that is conducting a trade or business (other than an ATB) and the

person provides services only to such other entity.

(b) *Partnership interest held by a corporation*—(1) *In general.* An API does not include any interest directly or indirectly held by a corporation.

(2) *Treatment of interests held by an S corporation or a qualified electing fund.* For purposes of this section, a corporation does not include an entity for which an election was made to treat the entity as a Passthrough Entity. Thus, the following entities are not treated as corporations for purposes of section 1061—

(i) An S corporation for which an election under section 1362(a) is in effect; and

(ii) A passive foreign investment company (PFIC) with respect to which the shareholder has a qualified electing fund (QEF) election under section 1295 in effect.

(c) *Capital Interest Gains and Losses*—(1) *In general.* Capital Interest Gains and Losses are not subject to section 1061 and, therefore, are not included in calculating an Owner Taxpayer's Recharacterization Amount.

(2) *Capital Interest Gains and Losses defined.* For purposes of paragraph (c)(1) of this section, Capital Interest Gains and Losses are Capital Interest Allocations that meet the requirements of paragraph (c)(3) of this section and Capital Interest Disposition Amounts that meet the requirements of paragraph (c)(4) of this section.

(3) *General rules for determining Capital Interest Allocations*—(i) *Commensurate with capital contributed.* An allocation will be considered a Capital Interest Allocation if the allocation to the API Holder with respect to its capital interest is determined and calculated in a similar manner as the allocations with respect to capital interests held by similarly situated Unrelated Non-Service Partners who have made significant aggregate capital contributions as described in paragraph (c)(3)(iv) of this section. For purposes of this paragraph (c)(3), a capital interest is an interest that would give the holder a share of the proceeds if the partnership's assets were sold at fair market value at the time the interest was received and the proceeds were then distributed in a complete liquidation of the partnership.

(ii) *In a similar manner.* For purposes of paragraph (c)(3)(i) of this section, a Capital Interest Allocation to an API Holder will be treated as made in a similar manner if allocations and distribution rights with respect to the capital contributed by an API Holder to which the API Holder's Capital Interest Allocation relates are reasonably consistent with allocation and distribution rights with respect to capital contributed by Unrelated Non-Service Partners where the Unrelated Non-Service Partner requirement is met. For purposes of this paragraph (c)(3)(ii), allocation and distribution rights for an API Holder that are limited to a particular class of partnership capital interests or that are determined with respect to capital contributions invested in a particular partnership investment will be considered as made in a similar manner to allocations and distribution rights of Unrelated Non-Service Partners where the Unrelated Non-Service Partner requirement is met for the applicable interest class or partnership investment.

(A) *Relevant factors.* For purposes of this paragraph (c)(3)(ii), the following factors are not exclusive, but are relevant factors in determining whether allocation and distribution rights with respect to capital contributed by an API Holder are reasonably consistent with allocation and distribution rights of persons meeting the Unrelated Non-Service Partner requirement: The amount and timing of capital contributed, the rate of return on capital contributed, the terms, priority, type and level of risk associated with capital contributed, and the rights to cash or property distributions during the partnership's operations and on liquidation. Accordingly, an allocation to an API Holder will not fail to qualify solely because the allocation is subordinated to allocations made to Unrelated Non-Service Partners, because an allocation to an API Holder is not reduced by the cost of services provided by the API Holder or a Related Person to the partnership, where the cost of services provided includes management fees or API allocations, or because an API Holder has a right to receive tax distributions while Unrelated Non-Service Partners do not, where such distributions are treated as advances against future distributions.

(B) *Clear identification requirement.* For purposes of this paragraph (c)(3)(ii), allocations will be considered made in a similar manner only if the allocations to the API Holder and the Unrelated Non-Service Partners are allocations with respect to, and corresponding to, such partners' contributed capital that are separate and apart from allocations made to the API Holder with respect to its API and where both the partnership agreement and the partnership's contemporaneous books and records clearly demonstrate that the requirements of paragraph (c)(3) of this section have been met.

(iii) *Reinvestment of API Gain.* If an API Holder is allocated API Gain by a Passthrough Entity, to the extent that an amount equal to the API Gain is reinvested in the Passthrough Entity by the API Holder (either as the result of an actual distribution and recontribution of the API Gain amount or the retention of the API Gain amount by the Passthrough Entity), the amount will be treated as a contribution to the Passthrough Entity for a capital interest that may produce Capital Interest Allocations for the API Holder, provided such allocations meet the requirements of this paragraph (c)(3).

(iv) *Unrelated Non-Service Partner requirement.* For purposes of paragraph (c)(3) of this section, the Unrelated Non-Service Partner requirement means that Unrelated Non-Service Partners must have made significant aggregate capital contributions in relation to total capital contributions of all partners. Unrelated Non-Service Partners will be treated as having made significant aggregate capital contributions provided such partners possess five percent or more of the aggregate capital contributed to the partnership at the time the allocations are made. With respect to an API Holder with allocation and distribution rights that are attributable to a particular interest class or partnership investment, the Unrelated Non-Service requirement must be met with respect to that particular interest class or partnership investment.

(v) *Proceeds of certain loans not taken into account for Capital Interest Allocation purposes*—(A) *General rule.* For purposes of the Section 1061 Regulations, an allocation is not a Capital Interest Allocation to the extent the allocation is attributable to the contribution of an amount of capital to a partnership that, directly or indirectly, results from, or is attributable to, any loan or other advance made or guaranteed, directly or indirectly, by the partnership, a partner in the partnership, or any Related Person with respect to such persons, except to the extent a loan or advance is described in paragraph (c)(3)(v)(B) of this section. However, the repayments on a loan described in the preceding sentence are taken into account as capital contributed (and may therefore generate Capital Interest Allocations) as those amounts are paid by the partner, provided that the loan is not repaid with the proceeds of another loan described in the preceding sentence.

(B) *Recourse liability.* Paragraph (c)(3)(v)(A) of this section does not apply with respect to an allocation attributable to a contribution made by an individual service provider that,

directly or indirectly, results from, or is attributable to, a loan or advance from another partner in the partnership (or any Related Person with respect to such lending or advancing partner, other than the partnership) to such individual service provider if the individual service provider is personally liable for the repayment of such loan or advance. A contribution made by an individual service provider includes a contribution made by an entity that is wholly owned by, and disregarded as separate from, the individual service provider as described in § 1.1061–2(a)(1)(v), including a contribution attributable to a loan or advance made to the disregarded entity by another partner in the partnership (or any Related Person with respect to such lending or advancing partner, other that the partnership) if the individual service provider is personally liable for the repayment of any and all borrowed amounts that are not repaid by the disregarded entity. For purposes of this paragraph (c)(3)(v)(B), an individual service provider is personally liable for the repayment of a loan or advance made by a partner (or any Related Person, other than the partnership) if—

(*1*) The loan or advance is fully recourse to the individual service provider;

(*2*) The individual service provider has no right to reimbursement from any other person; and

(*3*) The loan or advance is not guaranteed by any other person.

(vi) *Items that are not included in Capital Interest Allocations.* Capital Interest Allocations do not include—

(A) Amounts that are treated as API Gains and Losses and Unrealized API Gains and Losses; or

(B) Items that are not taken into account for purposes of section 1061 under § 1.1061–4(b)(7).

(4) *Capital Interest Disposition Amounts*—(i) *In general.* The term *Capital Interest Disposition Amount* means the amount of long-term capital gain or loss recognized on the sale or disposition of all or a portion of a Passthrough Interest that is treated as Capital Interest Gain or Loss. In general, long-term capital gain or loss recognized on the sale or disposition of a Passthrough Interest is deemed to be API Gain or Loss unless it is determined under paragraph (c)(4)(ii) of this section to be a Capital Interest Disposition Amount.

(ii) *Determination of the Capital Interest Disposition Amount.* If a Passthrough Interest that includes a right to allocations of Capital Interest Gains and Losses is disposed of, the amount of long-term capital gain or loss that is treated as a Capital Interest Disposition Amount is determined under the rules provided in this paragraph (c)(4)(ii).

(A) First, determine the amount of long-term capital gain or loss that would be allocated to the Passthrough Interest (or the portion of the Passthrough Interest sold) if all the assets of the Passthrough Entity (including gain or loss with respect to assets described in § 1.1061–4(b)(7)) were sold for their fair market value in a fully taxable transaction immediately before the disposition of the Passthrough Interest (hypothetical asset sale). For purposes of this paragraph (c)(4)(ii), the assets of the Passthrough Entity include any assets held by a lower-tier Passthrough Entity in which the Passthrough Entity has a direct or indirect interest.

(B) Second, determine the amount from the hypothetical asset sale that would be allocated to the Passthrough Interest (or the portion of the Passthrough Interest sold) as Capital Interest Allocations under paragraph (c)(3) of this section.

(C) Third, if the transferor recognized long-term capital gain upon disposition of the Passthrough Interest and only net short-term capital losses, net long-term capital losses, or both, are allocated to the Passthrough Interest under paragraph (c)(4)(ii)(B) of this section from the hypothetical asset sale, all of the long-term capital gain is API Gain. If the transferor recognized long-term capital loss on the disposition of the Passthrough Interest and only net short-term capital gains, net long-term capital gains, or both, are allocated to the Passthrough Interest under paragraph (c)(4)(ii)(B) of this section, then all the long-term capital loss is API Loss.

(D) If paragraph (c)(4)(ii)(C) of this section does not apply and long-term capital gain is recognized on the disposition of the Passthrough Interest, the amount of long-term capital gain that the transferor of the Passthrough Interest recognizes that is treated as a Capital Interest Disposition Amount is determined by multiplying long-term capital gain recognized on the disposition of the Passthrough Interest by a fraction, the numerator of which is the amount of long-term capital gain determined under paragraph (c)(4)(ii)(B) of this section, and the denominator of which is the amount of long-term capital gain determined under paragraph (c)(4)(ii)(A) of this section, with the percentage represented by the fraction limited to 100 percent. Alternatively, if paragraph (c)(4)(ii)(C) of this section does not apply and long-term capital loss is recognized on the disposition of the Passthrough Interest, the amount of long-term capital loss treated as a Capital Interest Disposition Amount is determined by multiplying the transferor's capital loss by a fraction, the numerator of which is the amount of long-term capital loss determined under paragraph (c)(4)(ii)(B) of this section, and the denominator of which is the amount of long-term capital loss determined under paragraph (c)(4)(ii)(A) of this section, with the percentage represented by the fraction limited to 100 percent.

(E) In applying this paragraph (c)(4)(ii), allocations of amounts that are not included in determining the amount of long-term capital gain or loss recognized on the sale or disposition of the Passthrough Interest are not included. See, for example, section 751(a).

(5) *Capital Interest Allocations made by a Passthrough Entity that is an API Holder.* An allocation made to a Passthrough Entity that holds an API in a lower-tier Passthrough Entity will be considered a Capital Interest Allocation if it meets the principles set forth in paragraphs (c)(3) and (4) of this section (other than paragraph (c)(3)(iv) of this section). For purposes of applying the Capital Interest Allocation rules in this paragraph (c)(5) to a tiered partnership structure, to the extent that a Capital Interest Allocation that is made by a lower-tier partnership to an upper-tier partnership is properly allocated to the upper-tier partnership's partners with respect to their capital interests in the upper-tier partnership in a manner that is respected under 704(b) (taking into account the principles of section 704(c)), such allocation is a Capital Interest Allocation.

(6) *Examples.* The rules of this paragraph (c) are illustrated by the following examples.

(i) *Example 1: Capital Interest Allocations*—(A) *Facts.* Each of A, B, and C contributes $100 to GP and is an equal partner in GP, a partnership that is the general partner of PRS, a partnership. The contributions are not attributable to loans or advances described in paragraph (c)(3)(v)(A) of this section. PRS's other partners are Unrelated Non-Service Partners. Each of GP and PRS makes allocations to its partners in accordance with its partners' interests in that partnership, as described in § 1.704–1(b)(3). GP holds a 20% profits interest in PRS that is an API that GP received in exchange for providing substantial services to PRS in an ATB. GP's API is an Indirect API to each of A, B, and C. GP contributes the $300 of capital contributed by A, B and C to PRS. GP's $300 contribution equals 2% of the contributed capital made by

all of PRS's partners ($15,000). PRS's partnership agreement describes its partners' economic distribution rights with respect to its liquidating proceeds as follows: First, liquidating proceeds are proportionately distributed to each of GP and the Unrelated Non-Service Partners equal to the amount necessary to return each of those partners' unreturned capital; second, liquidating proceeds are distributed to GP with respect to its API in PRS; and, finally, any residual liquidating proceeds are distributed, proportionately, 98% to the Unrelated Non-Service Partners and 2% to GP. During its initial taxable year, PRS has $10,000 of net capital gain, causing an increase in PRS's distributable proceeds of $10,000. In accordance with the partners' economic rights as described in PRS's partnership agreement, PRS allocates $2,160 of net capital gain to GP (a $2,000 API allocation plus $160 ($8,000 ($10,000 − $2,000) × 2%), with respect to GP's contributed capital) and $7,840 of net capital gain to the Unrelated Non-Service Partners with respect to their contributed capital. GP allocates $720 ($2,160/3) of this net capital gain to each of A, B, and C in accordance with their interests in GP.

(B) *PRS's Capital Interest Allocation Analysis.* Because PRS's partnership agreement provides for no differences as to the amount and timing of capital contributed, the rate of return on capital contributed, the type and level of risk associated with capital contributed, or the rights to cash or property distributions during the PRS's operations and on liquidation, the allocations and distribution rights with respect the capital contributed by GP are reasonably consistent with the allocation and distribution rights with respect to capital contributed by Unrelated Non-Service Partners. Accordingly, GP's allocation of $160 is a Capital Interest Allocation that is treated as made in a similar manner as the allocations made to the Unrelated Non-Service Partners.

(C) *GP Capital Interest Allocation Analysis.* GP is allocated $2,160 from PRS, consisting of a $2,000 API allocation and a $160 Capital Interest Allocation. The $160 Capital Interest Allocation is allocated equally to A, B, and C based on their capital contributions to GP. Therefore, they qualify as Capital Interest Allocations by GP. See paragraph (c)(5) of this section. The $2,000 of gain allocated by PRS's to GP with respect to GP's API cannot be treated as a Capital Interest Allocation by GP and therefore is subject to section 1061. In summary, A, B, and C are each allocated $720 of capital gain from PRS ($2,160/3). Of this amount, $667 is API Gain ($2,000/3) and $53 is a Capital Interest Allocation ($160/3).

(ii) *Example 2: Sale of a Passthrough Interest*—(A) *Facts.* In Year 1, A, B, and C form GP, a partnership. Each of A, B, and C contributes $100 to GP and is an equal partner in GP. The contributions are not attributable to loans or advances described in paragraph (c)(3)(v)(A) of this section. GP invests the $300 in Asset X in Year 1. GP is also the general partner of PRS, a partnership. PRS's other partners are Unrelated Non-Service Partners. GP holds a 20% profits interest in PRS that is an API that GP received in exchange for providing substantial services to PRS in an ATB. GP's API is an Indirect API to each of A, B, and C. Each of GP and PRS makes allocations to its partners in accordance with its partners' interests in that partnership, as described in § 1.704–1(b)(3). In Year 3, A sells A's interest in GP to an unrelated third party for $800 and recognizes $700 of capital gain on the sale. If PRS had sold its assets in a hypothetical asset sale as required by paragraph (c)(4)(ii)(A) of this section and liquidated immediately before A sold its interest in GP, GP would have been allocated $1,800 of long-term capital gain with respect to GP's API in PRS, and GP would have allocated $600 of this $1,800 to A. If GP sold Asset X for its fair market value and liquidated immediately before A sold its interest in GP, A would have been allocated $100 of long-term capital gain.

(B) *Analysis.* GP does not have a capital interest in PRS. Therefore, its allocations from PRS are allocations with respect to its API which are subject to section 1061. The total gain allocable to A as a result of the hypothetical liquidations would be $700. Under paragraph (c)(4)(ii)(D) of this section, $100 of the $700 of A's interest sale gain is A's Capital Interest Disposition Amount, and is not subject to section 1061.

(iii) *Example 3: Reinvestment of Realized API Gain.* A, B, and C are partners in PRS, a partnership. At the beginning of Year 1, A is issued an API in PRS in exchange for providing substantial services to PRS in an ATB. A has no capital interest in PRS. During Year 1, PRS's assets appreciate by $100. At the end of Year 1, under the terms of its partnership agreement, if PRS were to sell all of its assets at their fair market value and distribute the proceeds in a complete liquidation, A would receive $20 with respect to its API. Thus, at the end of Year 1, A has $20 of Unrealized API Gain. In Year 2, PRS sells Asset X, an asset that PRS owned in Year 1, and allocates $8 of the long-term capital gain to A as API Gain. As a result, $8 of A's $20 of Unrealized API Gain becomes API Gain that is subject to section 1061. A reinvests A's share of the proceeds from the Asset X sale in PRS. As a result, under paragraph (c)(3)(iii) of this section, A has an $8 capital interest in PRS and, provided the requirements of paragraph (c)(3) of this section are met, A may receive future Capital Interest Allocations with respect to the capital interest.

(d) *Partnership interest acquired by purchase by an unrelated person.* If a person (acquirer) acquires an interest in a partnership (target partnership) by taxable purchase for fair market value that, but for the exception set forth in this paragraph (d), would be an API, the transferor of the interest will be treated as selling an API but the acquirer will not be treated as acquiring an API if—

(1) *Acquirer not a Related Person.* Immediately before the purchase, the acquirer is not a Related Person with respect to—

(i) Any person who provides services in the Relevant ATB; or

(ii) Any service providers who provide services to, or for the benefit of, the target partnership or a lower-tier partnership in which the target partnership holds an interest, directly or indirectly.

(2) *Section 1061(d) not applicable.* Section 1061(d) does not apply to the transaction (as provided in § 1.1061–5).

(3) *Acquirer not a service provider.* At the time of the purchase, the acquirer has not provided, does not provide, and does not anticipate providing, services in the future, to, or for the benefit of, the target partnership, directly or indirectly, or any lower-tier partnership in which the target partnership directly or indirectly holds an interest.

(e) [Reserved]

(f) *Applicability date*—(1) *General rule.* Except as provided in paragraphs (f)(2) and (3) of this section, the provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

(2) *Partnership interest held by an S corporation.* Paragraph (b)(2)(i) of this section, which provides that the exception under section 1061(c)(1) to the definition of an API does not apply to a partnership interest held by an S corporation with an election under section 1362(a) in effect, applies to

taxable years beginning after December 31, 2017.

(3) *Partnership interest held by a PFIC with respect to which the shareholder has a QEF election in effect.* Paragraph (b)(2)(ii) of this section, which provides that the exception under section 1061(c)(1) to the definition of an API does not apply to a partnership interest held by a PFIC with respect to which the shareholder has a QEF election in effect under section 1295, applies to taxable years of an Owner Taxpayer and Passthrough Entity beginning after August 14, 2020.

§ 1.1061–4 Section 1061 computations.

(a) *Computations*—(1) *Recharacterization Amount.* The Recharacterization Amount is the amount that an Owner Taxpayer must treat as short-term capital gain under section 1061(a). The Recharacterization Amount equals—

(i) The Owner Taxpayer's One Year Gain Amount; less

(ii) The Owner Taxpayer's Three Year Gain Amount.

(2) *One Year Gain Amount and Three Year Gain Amount*—(i) *One Year Gain Amount.* The Owner Taxpayer's One Year Gain Amount is the sum of—

(A) The Owner Taxpayer's combined net API One Year Distributive Share Amount from all APIs held during the taxable year; and

(B) The Owner Taxpayer's API One Year Disposition Amount.

(ii) *Three Year Gain Amount.* The Owner Taxpayer's Three Year Gain Amount is the sum of—

(A) The Owner Taxpayer's combined net API Three Year Distributive Share Amount from all APIs held during the taxable year; and

(B) The Owner Taxpayer's API Three Year Disposition Amount.

(3) *API One Year Distributive Share Amount and API Three Year Distributive Share Amount*—(i) *API One Year Distributive Share Amount.* The API One Year Distributive Share Amount equals—

(A) The API Holder's distributive share of net long-term capital gain or loss from the partnership for the taxable year (including capital gain or loss on the disposition of Distributed API Property by an API Holder that is a Passthrough Entity or the disposition of all or a part of an API by an API Holder that is a Passthrough Entity), with respect to the partnership interest held by the API Holder calculated without the application of section 1061; less

(B) To the extent included in the amount determined under paragraph (a)(3)(i)(A) of this section, the aggregate of—

(*1*) Amounts that are not taken into account for purposes of section 1061 under paragraph (b)(7) of this section; and

(*2*) Capital Interest Gains and Losses as determined under § 1.1061–3(c)(2).

(ii) *API Three Year Distributive Share Amount.* The API Three Year Distributive Share Amount equals the API One Year Distributive Share Amount, less—

(A) Items included in the API One Year Distributive Share Amount that would not be treated as a long-term gain or loss if three years is substituted for one year in paragraphs (3) and (4) of section 1222; and

(B) Any adjustments resulting from the application of the Lookthrough Rule under paragraph (b)(9)(ii) of this section when an API is disposed of by an API Holder that is a Passthrough Entity.

(4) *API One Year Disposition Amount and API Three Year Disposition Amount*—(i) *API One Year Disposition Amount.* The API One Year Disposition Amount is the combined net amount of—

(A) Long-term capital gains and losses recognized during the taxable year by an Owner Taxpayer, including long-term capital gain computed under the installment method that is taken into account for the taxable year, on the disposition of all or a portion of an API that has been held for more than one year, including a disposition to which the Lookthrough Rule applies;

(B) Long-term capital gain and loss recognized by an Owner Taxpayer due to a distribution with respect to an API during the taxable year that is treated under section 731(a) as gain or loss from the sale or exchange of a partnership interest held for more than one year; and,

(C) Long-term capital gains and losses recognized by an Owner Taxpayer on the disposition of Distributed API Property (taking into account deemed exchanges under section 751(b)) during the taxable year that has a holding period of more than one year but not more than three years to the distributee Owner Taxpayer on the date of disposition, excluding items described in paragraph (b)(7) of this section.

(ii) *API Three Year Disposition Amount.* The API Three Year Disposition Amount is the combined net amount of—

(A) Long-term capital gains and losses recognized during the taxable year by an Owner Taxpayer, including long-term capital gain computed under the installment method that is taken into account for the taxable year, on the disposition of all or a portion of an API that has been held for more than three years and to which the Lookthrough Rule does not apply;

(B) Long-term capital gains and losses recognized by an Owner Taxpayer on the disposition during the taxable year of all or a portion of an API that has been held for more than three years in a transaction to which the Lookthrough Rule in paragraph (b)(9) of this section applies, less any adjustments required under the Lookthrough Rule in paragraph (b)(9)(ii) of this section; and

(C) Long-term capital gains and losses recognized on a distribution with respect to an API during the taxable year that is treated under sections 731(a) as gain or loss from the sale or exchange of a partnership interest held for more than three years.

(b) *Special rules for calculating the One Year Gain Amount and the Three Year Gain Amount*—(1) *One Year Gain Amount equals zero or less.* If an Owner Taxpayer's One Year Gain Amount is zero or results in a loss, the Recharacterization Amount for the taxable year is zero and section 1061(a) does not apply.

(2) *Three Year Gain Amount equals zero or less.* If an Owner Taxpayer's Three Year Gain Amount is less than or equal to $0, the Three Year Gain Amount is zero for purposes of calculating the Recharacterization Amount.

(3) *One Year Gain Amount less than Three Year Gain Amount.* If the One Year Gain Amount and the Three Year Gain Amount are both greater than zero but the One Year Gain Amount is less than the Three Year Gain Amount, none of the One Year Gain Amount is included in the Recharacterization Amount for the taxable year.

(4) *Installment sale gain.* The One Year Gain Amount under paragraph (a)(2)(i) of this section and the Three Year Gain Amount, as determined under paragraph (a)(2)(ii) of this section include long-term capital gains from installment sales. This includes long-term capital gain or loss recognized with respect to an API after December 31, 2017, with respect to an installment sale that occurred on or before December 31, 2017. The holding period of the asset upon the date of disposition is used for purposes of determining whether capital gain is included in the taxpayer's One Year Gain Amount or the Three Year Gain Amount.

(5) *Special rules for capital gain dividends from regulated investment companies (RICs) and real estate investment trusts (REITs)*—(i) *API One Year Distributive Share Amount.* If a RIC or REIT reports or designates a dividend as a capital gain dividend and provides the One Year Amounts

Disclosure as defined in § 1.1061–6(c)(1)(i), the amount provided in the One Year Amounts Disclosure is included in the calculation of an API One Year Distributive Share Amount. If the RIC or REIT does not provide the One Year Amounts Disclosure, the full amount of the RIC's or REIT's capital gain dividend must be included in the calculation of an API One Year Distributive Share Amount.

(ii) *API Three Year Distributive Share Amount.* If a RIC or REIT reports or designates a dividend as a capital gain dividend and provides the Three Year Amounts Disclosure as defined in § 1.1061–6(c)(1)(ii), the amount provided in the Three Year Amounts Disclosure is used for the calculation of an API Three Year Distributive Share amount. If the RIC or REIT does not provide the Three Year Amounts Disclosure, no amount of the RIC's or REIT's capital gain dividend may be used for the calculation of an API Three Year Distributive Share Amount.

(iii) *Loss on sale or exchange of stock.* If a RIC or REIT provides the Three Year Amounts Disclosure as provided in paragraph (b)(5)(ii) of this section, any loss on the sale or exchange of shares of a RIC or REIT held for six months or less is treated as a capital loss on an asset held for more than three years, to the extent of the amount of the Three Year Amounts Disclosure from that RIC or REIT.

(6) *Pro rata share of qualified electing fund (QEF) net capital gain*—(i) *One year QEF net capital gain.* The calculation of an API One Year Distributive Share Amount includes an Owner Taxpayer's inclusion under section 1293(a)(1)(B) as limited by section 1293(e)(2) with respect to a passive foreign investment company (as defined in section 1297(a)) for which a QEF election (as described in section 1295(a)) is in effect for the taxable year. The amount of the inclusion may be reduced by the amount of long-term capital gain that is not taken into account for purposes of section 1061 as provided in paragraph (b)(7) of this section and may be reduced by the Owner Taxpayer's share of the excess, if any, of the Capital Interest Gain over Capital Interest Loss with respect to the QEF, provided in each case that the relevant information is provided by the QEF. See § 1.1061–6 for reporting rules.

(ii) *Three year QEF net capital gain adjustment.* For purposes of calculating an Owner Taxpayer's API Three Year Distributive Share Amount, the entire amount determined under paragraph (b)(6)(i) of this section, after any allowed reduction, is included as an item in paragraph (a)(3)(ii)(A) of this section unless the QEF provides information to determine the amount of the inclusion that would constitute net capital gain (as defined in § 1.1293–1(a)(2), as limited by section 1293(e)(2)) if the QEF's net capital gain for the taxable year were calculated under section 1222(11) applying paragraphs (3) and (4) of section 1222 by substituting three years for one year. If such information is provided, the amount included as an item in paragraph (a)(3)(ii)(A) of this section is the amount determined under paragraph (b)(6)(i) of this section that would not be treated as long-term gain if three years were substituted for one year in paragraphs (3) and (4) of section 1222. See § 1.1061–6 for reporting rules.

(7) *Items not taken into account for purposes of section 1061.* The following items of long-term capital gain and loss are excluded from the calculation of the API One Year Distributive Share Amount in paragraph (a)(3)(i) of this section and the API Three Year Distributive Share Amount in paragraph (a)(3)(ii) of this section—

(i) Long-term capital gain and long-term capital loss determined under section 1231;

(ii) Long-term capital gain and long-term capital loss determined under section 1256;

(iii) Qualified dividends included in net capital gain for purposes of section 1(h)(11)(B); and

(iv) Capital gains and losses that are characterized as long-term or short-term without regard to the holding period rules in section 1222, such as certain capital gains and losses characterized under the mixed straddle rules described in section 1092(b) and §§ 1.1092(b)–3T, 1.1092(b)–4T, and 1.1092(b)–6.

(8) *Holding period determination*—(i) *Determination of holding period for purposes of the Three Year Gain Amount.* For purposes of computing the Three Year Gain Amount, the relevant holding period of either an asset or an API is determined under all provisions of the Code or regulations that are relevant to determining whether the asset or the API has been held for the long-term capital gain holding period by applying those provisions as if the holding period were three years instead of one year.

(ii) *Relevant holding period.* The relevant holding period is the direct owner's holding period in the asset sold. Accordingly, for purposes of determining an API Holder's Taxpayer's API One Year Distributive Share Amount and API Three Year Distributive Share Amount for the taxable year under paragraph (a)(3) of this section, the partnership's holding period in the asset being sold or disposed of (whether a directly held asset or a partnership interest) is the relevant holding period for purposes of section 1061.

(9) *Lookthrough Rule for certain API dispositions*—(i) *Determination that the Lookthrough Rule applies*—(A) *In general.* The Lookthrough Rule will apply if, at the time of disposition of an API held for more than three years—

(*1*) The API would have a holding period of three years or less if the holding period of such API were determined by not including any period before the date that an Unrelated Non-Service Partner is legally obligated to contribute substantial money or property directly or indirectly to the Passthrough Entity to which the API relates. This paragraph (b)(9)(i)(A) does not apply to the disposition of an API to the extent that the gain recognized upon the disposition of the API is attributable to any asset not held for portfolio investment on behalf of third party investors (as defined in section 1061(c)(5)). Solely for the purpose of this paragraph (b)(9)(i)(A), a substantial legal obligation to contribute money or property is an obligation to contribute a value that is at least 5 percent of the partnership's total capital contributions as of the time of the API disposition; or

(*2*) A transaction or series of transactions has taken place with a principal purpose of avoiding potential gain recharacterization under section 1061(a).

(B) *Determination that the Lookthrough Rule applies to the disposition of a Passthrough Interest.* Paragraph (b)(9)(i)(A) of this section similarly applies with respect to a Passthrough Interest issued by an S corporation or a PFIC to the extent the Passthrough Interest is treated as an API.

(ii) *Application of the Lookthrough Rule.* If the Lookthrough Rule applies, for purposes of applying an Owner Taxpayer's Recharacterization Amount, as described in paragraph (a) of this section—

(A) The Owner Taxpayer must include the entire amount of capital gain recognized on the disposition of an API by the Owner Taxpayer in the Owner Taxpayer's API One Year Disposition Amount; and

(B) The Owner Taxpayer must include in its Three Year Disposition Amount an amount equal its One Year Disposition Amount (determined under paragraph (b)(9)(ii)(A) of this section) reduced by the Owner Taxpayer's share of the amount of any gain, directly or indirectly, from assets held for three years or less that would have been

allocated to the Owner Taxpayer (to the extent attributable to the transferred API) by the partnership if the partnership had sold all of its property in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)) immediately prior to the Owner Taxpayer's transfer of the API.

(C) In the case of an API disposition by an API Holder that is a Passthrough Entity and not an Owner Taxpayer, the principles set forth in paragraph (b)(9)(ii)(A) of this section must be applied to determine the amount to include in the Owner Taxpayer's One Year Distributive Amount and in paragraph (b)(9)(ii)(B) of this section to determine the amounts included in the Owner Taxpayer's Three Year Distributive Share Amount.

(10) *Section 83.* Except with respect to any portion of the interest that is a capital interest under § 1.1061–3(c), this section applies regardless of whether an Owner Taxpayer or Passthrough Entity has made an election under section 83(b) or included amounts in gross income under section 83.

(c) *Examples*—(1) *Recharacterization rules.* The rules of paragraph (a) of this section are illustrated by the following examples. Unless otherwise stated, all gains and losses are long-term capital gains and losses, none of the long-term capital gain or loss in this section is capital gain or loss not taken into account for purposes of section 1061 under paragraph (b)(7) of this section, and neither the Lookthrough Rule nor section 751 is applicable.

(i) *Example 1: Determination of API One Year and Three Year Distributive Share Amounts*—(A) *Facts.* A holds an API in PRS but has no capital interest in PRS and is not entitled to a Capital Interest Allocation with respect to PRS. During the taxable year, PRS allocates to A $20 of long-term capital gain from the sale of capital asset X (which had been held by PRS for two years) and $40 of long-term capital gain from the sale of capital asset Y (which had held by PRS for five years). A has no other items of long-term capital gain or loss with respect to its interest in PRS during the taxable year. A has no other long-term capital gains or losses with respect to any other API during the taxable year.

(B) *Determination of A's API One Year Distributive Share Amount.* Under paragraph (a)(3)(i) of this section, A has an API One Year Distributive Share Amount of $60. This amount is the sum of the $20 of the long-term capital gain allocated to A from PRS's sale of capital asset X and the $40 of long-term capital gain allocated to A from PRS's sale of capital asset Y.

(C) *Determination of A's API Three Year Distributive Share Amount.* (*1*) Under paragraph (a)(3)(ii) of this section, A's API Three Year Distributive Share Amount is equal to A's API One Year Distributive Amount, $60, less the sum of:

(*i*) The items included in the API One Year Distributive Share Amount that would not be treated as a long-term gain or loss if three years is substituted for one year in paragraphs (3) and (4) of section 1222, $20; and

(*ii*) Adjustments resulting from the application of the Lookthrough Rule under paragraph (b)(9)(ii) of this section, which under the facts in paragraph (c)(1)(i)(A) of this section, is inapplicable.

(*2*) Thus, A's Three Year API Distributive Share Amount is $40.

(D) *Determination of A's Recharacterization Amount.* Under paragraph (a)(2)(i) of this section, A's One Year Gain amount is equal to A's API One Year Distributive Share Amount, $60. A's Three Year Gain Amount is equal to A's API Three Year Distributive Share Amount, $40. Under paragraph (a)(1) of this section, A's Recharacterization Amount is A's One Year Gain Amount, minus A's Three Year Gain Amount, or $20.

(ii) *Example 2: API One Year and Three Year Disposition Amounts*—(A) *Facts.* During the taxable year, A disposes of an API that A has held for four years for a $100 gain. Additionally, A sells Distributed API Property for a $300 gain at a time when A has a two-year holding period in such property. A has no other items of long-term capital gain or loss with respect to any API in the year.

(B) *Determination of A's API One Year and Three Year Disposition Amounts.* Under paragraph (a)(4)(i) of this section, A's API One Year Disposition Amount is $400. This amount is the sum of A's $300 of long-term capital gain on A's disposition of the Distributed API Property and A's $100 of long-term capital gain on the disposition of the API. Under paragraph (a)(4)(ii) of this section, A's Three Year Disposition Amount is $100, which is the amount of long-term capital gain that A recognized upon disposition of the API held for more than three years. Under paragraph (a)(2) of this section, A's One Year Gain Amount is $400 and A's Three Year Gain Amount is $100.

(C) *Determination of A's Recharacterization Amount.* Under paragraph (a)(1) of this section, A's Recharacterization Amount is $300, which is the difference between A's One Year Gain Amount and Three Year Gain Amount.

(iii) *Example 3: Determination of One Year Gain Amount, Three Year Gain Amount, and Recharacterization Amount*—(A) *Facts.* A holds an API in each of PRS1 and PRS2. With respect to PRS1, A's API One Year Distributive Share Amount is $100 and A's API Three Year Distributive Share Amount is ($200). With respect to PRS2, A's API One Year Distributive Share Amount is $600 and A's API Three Year Distributive Share Amount is $300. During the taxable year, A also has an API One Year Disposition Amount of $200 of gain. A has no other items of long-term capital gain or loss with respect to an API for the taxable year.

(B) *Determination of A's One Year Gain Amount.* Under paragraph (a)(2) of this section, A's One Year Gain Amount is $900, which is an amount equal to A's $100 API One Year Distributive Share Gain from PRS1 and A's $600 API One Year Distributive Share from PRS2 (a combined net API One Year Distributive Share Amount of $700) plus A's $200 API One Year Disposition Amount.

(C) *Determination of A's Three Year Gain Amount.* Under paragraph (a)(2) of this section, A's Three Year Gain Amount is $100, which is equal to A's combined net API Three Year Distributive Share Amount for the taxable year (A's $200 API Three Year Distributive Share Amount loss from PRS1 plus A's API Three Year Distributive Share Amount Gain of $300 from PRS2). A does not have an API Three Year Disposition Amount.

(D) *Determination of A's Recharacterization Amount.* Under paragraph (a)(1) of this section, A's Recharacterization Amount is $800. (A's One Year Gain Amount of $900 less A's Three Year Gain Amount of $100.)

(2) *Special rules examples.* The principles of paragraph (b) of this section are illustrated by the following examples.

(i) *Example 1: Lookthrough Rule.* On July 1, 2021, A and B form partnership PRS. At the time of PRS's formation, A agrees to provide substantial services to PRS in exchange for a 20% profits interest in PRS, and B, a partner that is an Unrelated Non-Service Partner, contributes $1 million in exchange for an interest in PRS and PRS immediately uses the capital to purchase marketable securities. On July 1, 2023, C, another Unrelated Non-Service Partner becomes legally obligated to contribute capital to PRS ($75 million) for the purposes of investing in and developing Specified Assets and is admitted into PRS. On July 3, 2023, and after C makes a contribution of $75 million, PRS uses

this capital to acquire stock in portfolio company Z. On July 1, 2025, when Z has a value of $500 million and the value of the marketable securities is $2 million, A sells its API in PRS for $85.2 million. As a result of this sale, the Lookthrough Rule applies because B's contribution was non-substantial under paragraph (b)(9)(i)(A)(*1*) of this section. Therefore, A includes $85.2 million in its API One Year Disposition Amount and under paragraph (b)(9)(ii)(B) of this section, $200,000 (20% share of $1 million gain in marketable securities) in its API Three Year Disposition Amount. Accordingly, under paragraph (a)(1) of this section, A's Recharacterization Amount is $85 million.

(ii) *Example 2: Installment sale gain.* On December 22, 2021, A disposed of A's API in an installment sale. At the time of the disposition, A had held its API for two years. A received a payment with respect to the installment sale during A's 2022 taxable year causing A to recognize $200 of long-term capital gain. The $200 long-term capital gain recognized in 2022 is subject to section 1061 because it is recognized after December 31, 2017. Accordingly, the $200 of long-term capital gain recognized by A in 2022 is included in A's API One Year Disposition Amount. The $200 of long-term capital gain is not in A's API Three Year Disposition Amount because the API was not held for more than three years at the time of its disposition.

(iii) *Example 3: REIT capital gain dividend.* During the taxable year, A holds an API in PRS. PRS holds an interest in REIT. During the taxable year, REIT distributes a $1,000 capital gain dividend to PRS of which 50% is allocable to A's API. Part of the capital gain dividend for the year results from section 1231 gain. In accordance with § 1.1061–6(c)(1)(i), REIT discloses to PRS the One Year Amounts Disclosure of $400, which is the $1000 capital gain dividend reduced by the $600 of section 1231 capital gain dividend included in that amount. Part of the One Year Amounts Disclosure for the year results from gain from property held for three years or less. In accordance with § 1.1061–6(c)(1)(ii), REIT also discloses the Three Year Amounts Disclosure of $150, which is the $400 One Year Amounts Disclosure reduced by the $250 of gain attributable to property held for three years or less. PRS includes a $200 gain in determining A's API One Year Distributive Share Amount and a $75 gain in determining A's API Three Year Distributive Share Amount. See paragraphs (b)(5)(i) and (ii) of this section.

(d) *Applicability date.* The provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

§ 1.1061–5 Section 1061(d) transfers to related persons.

(a) *In general.* If an Owner Taxpayer transfers any API or Distributed API Property, directly or indirectly, to a Section 1061(d) Related Person (as defined in paragraph (e) of this section), the Owner Taxpayer must include in gross income as short-term capital gain, an amount equal to—

(1) The short-term capital gain recognized upon the API transfer without regard to this paragraph (a); and

(2) The lesser of—

(i) The amount of net long-term capital gain recognized by the Owner Taxpayer upon the transfer of such interest; or

(ii) The amount treated as short-term capital gain under paragraph (c) of this section (Section 1061(d) Recharacterization Amount).

(b) *Transfer.* For purposes of this section, the term *transfer* means a sale or exchange in which gain is recognized by the Owner Taxpayer under chapter 1 of the Internal Revenue Code.

(c) *Section 1061(d) Recharacterization Amount.* To the extent an Owner Taxpayer recognizes long-term capital gain upon a transfer of an API to a Section 1061(d) Related Person, the Owner Taxpayer's Section 1061(d) Recharacterization Amount is the amount of net long-term capital gain (excluding amounts not taken into account for purposes of section 1061 under § 1.1061–4(b)(7)) from assets held for three years or less that would have been allocated to the Owner Taxpayer (to the extent attributable to the transferred API) by the partnership if the partnership had sold all of its property in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)) immediately prior to the Owner Taxpayer's transfer of the API. If only a portion of an Owner Taxpayer's API is transferred, this paragraph (c) shall apply with respect to the portion of gain attributable to the transferred interest.

(d) *Special rules.* For purposes of this section, the following rules are applicable.

(1) An Owner Taxpayer will be treated as transferring the Owner Taxpayer's share of any Indirect API or Distributed API Property if the Indirect API or Distributed API Property is transferred by the API Holder to a person that is a Section 1061(d) Related Person with respect to the Owner Taxpayer.

(2) The rules set forth in paragraphs (a), (b), and (c) of this section apply upon the transfer of a Passthrough Interest issued by an S corporation or PFIC to the extent the Passthrough Interest is treated as an API.

(e) *Section 1061(d) Related Person.* For purposes of this section, the term Section 1061(d) Related Person means—

(1) A person that is a member of the taxpayer's family within the meaning of section 318(a)(1);

(2) A person that performed a service within the current calendar year or the preceding three calendar years in a Relevant ATB to the API transferred by taxpayer; or

(3) A Passthrough Entity to the extent that a person described in paragraph (e)(1) or (2) of this section owns an interest, directly or indirectly.

(f) *Examples.* The following examples illustrate the rules of this section.

(1) *Example 1: Transfer to child by gift.* A, an individual, performs services in an ATB and has held an API in connection with those services for 10 years. The API has a fair market value of $1,000 and a tax basis of $0, and no debt is associated with the API. A transfers all of the API to A's daughter as a gift. A's daughter is a section 1061(d) Related Person but A's gift is not a transfer as described in paragraph (b) of this section thus section 1061(d) does not apply to A's gift. However, the API remains an API in the hands of A's daughter under § 1.1061–2(a)(1)(i).

(2) *Example 2: Transfer of an API to a partnership owned by Section 1061(d) Related Persons*—(i) *Facts.* A, B, and C are equal partners in GP, a partnership. GP holds only one asset, an API in PRS1 which is an Indirect API as to each A, B, and C. A, B, and C each provides services in the ATB in connection with which GP was transferred its API in PRS1. A and B contribute their interests in GP to PRS2 in a Section 721(a) exchange for interests in PRS2.

(ii) *Application of section 1061(d).* Because the contribution by A and B of their interest in GP to PRS2 is an exchange in which no gain is recognized by either A or B, the contribution is not a transfer as described in paragraph (b) of this section thus section 1061(d) does not apply to A and B's contribution. However, the API remains an API in the hands of PRS2 under § 1.1061–2(a)(1)(i).

(3) *Example 3: Transfer of an API to a Section 1061(d) Related Person.* A holds an API in GP, a partnership which A has owned for four years. A transfers the API to a Section 1061(d) Related Person described in paragraph (e) of this section in exchange for $100 of cash, resulting in A recognizing long-term capital gain of $100. Because this is a transfer described in paragraph (b) of this section, section 1061(d) applies to the transfer of A's API and A must determine its Section 1061(d) Recharacterization Amount under paragraph (c) of this section. If, immediately prior to A's transfer of the API, the partnership had sold all of its assets in a fully taxable transaction for cash equal of the fair market value of the assets, A's share of the net long-term capital gain (excluding amounts not taken into account for purposes of section 1061 under § 1.1061–4(b)(7)) from assets held for three years or less would have been $120. Thus, A's Section 1061(d) Recharacterization Amount is $120. As a result, A's $100 long-term capital gain is recharacterized as short-term capital gain under paragraph (a) of this section. The API remains an API in the hands of the Section 1061(d) Related Person under § 1.1061–2(a)(1)(i).

(g) *Applicability date.* The provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

§ 1.1061–6 Reporting rules.

(a) *Owner Taxpayer filing requirements*–(1) *In general.* An Owner Taxpayer must file such information with the IRS as the Commissioner of Internal Revenue or the Commissioner's delegate (Commissioner) may require in forms, instructions, or other guidance as is necessary for the Commissioner to determine that the Owner Taxpayer has properly complied with section 1061 and the Section 1061 Regulations. If an Owner Taxpayer requires information from a Passthrough Entity to determine the Capital Interest Disposition Amount or the Section 1061(d) Recharacterization Amount, the Owner Taxpayer must request such information from that entity.

(2) *Failure to obtain information.* Paragraph (b)(1) of this section requires certain Passthrough Entities to furnish an Owner Taxpayer with certain amounts necessary to determine its Recharacterization Amount and meet its reporting requirements under paragraph (a)(1) of this section. To the extent that an Owner Taxpayer is not furnished the information required to be furnished under paragraph (b)(1) of this section in such time and in such manner as required by the Commissioner and the Owner Taxpayer is not otherwise able to substantiate all or a part of these amounts to the satisfaction of the Commissioner, then if the information with respect to the determination of the—

(i) API One Year Distributive Share Amount under § 1.1061–4(a)(3)(i) is not furnished, the API One Year Distributive Share Amount will not be reduced by—

(A) Amounts not taken into account for purposes of section 1061 under § 1.1061–4(b)(7); or

(B) Capital Interest Gains and Losses as determined under § 1.1061–3(c)(2).

(ii) API Three Year Distributive Share Amount determined under § 1.1061–4(a)(3)(ii) is not furnished, all items included in the API One Year Distributive Share Amount are treated as items that would not be treated as long-term capital gain or loss, if three years is substituted for one year in paragraphs (3) and (4) of section 1222.

(b) *Passthrough Entity filing requirements and reporting*—(1) *Requirement to file information with the IRS and to furnish information to API Holder.* A Passthrough Entity must file such information with the IRS as the Commissioner may require in forms, instructions, or other guidance as is necessary for the Commissioner to determine that it and its partners have complied with section 1061 and the Section 1061 Regulations. A Passthrough Entity that has issued an API must furnish to the API Holder, including an Owner Taxpayer, such information at such time and in such manner as the Commissioner may require in forms, instructions, or other guidance as is necessary to determine the One Year Gain Amount and the Three Year Gain Amount with respect to an Owner Taxpayer that directly or indirectly holds the API. A Passthrough Entity that has furnished information to the API Holder must file such information with the IRS, at such time and in such manner as the Commissioner may require in forms, instructions, or other guidance. This information includes:

(i) The API One Year Distributive Share Amount and the API Three Year Distributive Share Amount (as determined under § 1.1061–4);

(ii) Capital gains and losses allocated to the API Holder that are excluded from section 1061 under § 1.1061–4(b)(7);

(iii) Capital Interest Gains and Losses allocated to the API Holder (as determined under § 1.1061–3(c)); and

(iv) In the case of a disposition by an API Holder of an interest in the Passthrough Entity during the taxable year, upon the request of an API Holder, any information required by the API Holder to properly take the disposition into account under section 1061, including—

(A) Information necessary to apply the Lookthrough Rule and to determine the API Holder's Capital Interest Disposition Amount; and

(B) Information necessary to determine an Owner Taxpayer's Section 1061(d) Recharacterization Amount.

(2) *Requirement to request, furnish, and file information in tiered structures*—(i) *Requirement to request information.* If a Passthrough Entity requires information to meet its reporting and filing requirements under this section (in addition to any information required to be furnished to the Passthrough Entity under paragraph (b)(1) of this section) from a lower-tier entity in which it holds an interest, the Passthrough Entity must request such information from that entity.

(ii) *Requirement to furnish and file information.* If information is requested of a Passthrough Entity under paragraph (b)(2)(i) of this section, the Passthrough Entity must furnish the requested information to the person making the request but only to the extent the information is necessary for the requesting Passthrough Entity to meet its reporting and filing requirements under this section or is required by the Commissioner in forms, instructions, or other guidance. If the person requesting the information is an API Holder in the Passthrough Entity, the information is furnished under paragraph (b)(1) of this section. If the Passthrough Entity requesting the information is not an API Holder, the Passthrough Entity must furnish the information to the requesting Passthrough Entity as required by the Commissioner in forms, instructions, or other guidance.

(iii) *Timing of requesting and furnishing information*—(A) *Requesting information.* A Passthrough Entity described in paragraph (b)(2)(i) of this section must request information under paragraph (b)(2)(i) of this section by the later of the 30th day after the close of the taxable year to which the information request relates or 14 days after the date of a request for information from an upper-tier Passthrough Entity.

(B) *Furnishing information*—(*1*) *In general.* Except as provided in paragraph (b)(2)(iii)(B)(*2*) of this section, requested information must be furnished by the date on which the entity is required to furnish information under section 6031(b) or under section 6037(b), as applicable.

(*2*) *Late requests.* Information with respect to a taxable year that is requested by an upper-tier Passthrough Entity after the date that is 14 days prior to the due date for a lower-tier Passthrough Entity to furnish and file information under section 6031(b) or section 6037(b), as applicable, must be furnished and filed in the time and manner prescribed by forms, instructions and other guidance.

(iv) *Manner of requesting information.* Information may be requested electronically or in any manner that is agreed to by the parties.

(v) *Recordkeeping requirement.* Any Passthrough Entity receiving a request for information must retain a copy of the request and the date received in its books and records.

(vi) *Passthrough Entity is not furnished information to meet its reporting obligations under paragraph (b)(1) of this section.* If an upper-tier Passthrough Entity holds an interest in a lower-tier Passthrough Entity and it is not furnished the information described in paragraph (b)(1) of this section, or, alternatively, if it has not been furnished information after having properly requested the information under this paragraph (b)(2), the upper-tier Passthrough Entity must take actions to otherwise determine and substantiate the missing information. To the extent that the upper-tier Passthrough Entity is not able to otherwise substantiate and determine the missing information to the satisfaction of the Commissioner, the upper-tier Passthrough Entity must treat these amounts as provided under paragraph (a)(2) of this section. The upper-tier Passthrough Entity must provide notice to the API Holder and the IRS regarding the application of this paragraph (b)(2) to the information being reported as required in forms, instructions, and other guidance.

(vii) *Filing requirements.* Both the Passthrough Entity requesting the information and the Passthrough Entity furnishing the information must file all information with the IRS as the Commissioner may require in forms, instructions, or other guidance.

(viii) *Penalties.* In addition to the requirement in section 1061(e) that the Secretary shall require reporting (at the time and in the manner prescribed by the Secretary) as is necessary to carry out the purposes of this section, the information required to be furnished under this paragraph (b) is also required to be furnished under sections 6031(b) and 6037(b). Failure to report as required under this paragraph (b) will be subject to penalties under section 6722.

(c) *Regulated investment company (RIC) and real estate investment trust (REIT) reporting*—(1) *Section 1061 disclosures.* A RIC or REIT that reports or designates a dividend, or part thereof, as a capital gain dividend, may, in addition to the information otherwise required to be furnished to a shareholder, disclose two amounts for purposes of section 1061—

(i) *One Year Amounts Disclosure.* The *One Year Amounts Disclosure* of a RIC or REIT is a disclosure by the RIC or REIT of an amount that is attributable to a computation of the RIC's or REIT's net capital gain excluding capital gain and capital loss not taken into account for purposes of section 1061 under § 1.1061–4(b)(7). The aggregate amounts provided in the One Year Amounts Disclosures with respect to a taxable year of a RIC or REIT must equal the lesser of the RIC's or REIT's net capital gain, excluding any capital gains and capital losses not taken into account for purposes of section 1061 under § 1.1061–4(b)(7), for the taxable year or the RIC's or REIT's aggregate capital gain dividends for the taxable year.

(ii) *Three Year Amounts Disclosure.* The *Three Year Amounts Disclosure* of a RIC or REIT is a disclosure by the RIC or REIT of an amount that is attributable to a computation of the RIC's or REIT's One Year Amounts Disclosure substituting ''three years'' for ''one year'' in applying section 1222. The aggregate amounts provided in the Three Year Amounts Disclosures with respect to a taxable year of a RIC or REIT must equal the lesser of the aggregate amounts provided in the RIC's or REIT's One Year Amounts Disclosures substituting ''three years'' for ''one year'' in applying section 1222 for the taxable year or the RIC's or REIT's aggregate capital gain dividends for the taxable year.

(2) *Pro rata disclosures.* The One Year Amounts Disclosure and Three Year Amounts Disclosure made to each shareholder of a RIC or REIT must be proportionate to the share of capital gain dividends reported or designated to that shareholder for the taxable year.

(3) *Report to shareholders.* A RIC or REIT that provides the section 1061 disclosures described in paragraphs (c)(1)(i) and (ii) of this section must provide those section 1061 disclosures in writing to its shareholders with the statement described in section 852(b)(3)(C)(i) or the notice described in section 857(b)(3)(B) in which the capital gain dividend is reported or designated.

(d) *Qualified electing fund (QEF) reporting.* A passive foreign investment company with respect to which the shareholder has a QEF election (as described in section 1295(a)) in effect for the taxable year that determines net capital gain as provided in § 1.1293–1(a)(2)(i)(A), as limited by section 1293(e)(2), may provide some or all of the information listed in paragraph (b)(1) of this section (and any other relevant information) to its shareholders to enable API Holders to determine the amount of their inclusion under section 1293(a)(1) that would be included in the API One Year Distributive Share Amounts and API Three Year Distributive Share Amounts. To the extent that such information is not provided, paragraph (a)(2) of this section will apply except that Owner Taxpayers are not permitted to separately substantiate the information. An API Holder who receives the additional information described in this paragraph (d) must retain such information as required by § 1.1295–1(f)(2)(ii).

(e) *Applicability date.* The provisions of this section apply to taxable years of Owner Taxpayers and Passthrough Entities beginning on or after January 19, 2021. An Owner Taxpayer or Passthrough Entity may choose to apply this section to a taxable year beginning after December 31, 2017, provided that they apply the Section 1061 Regulations in their entirety to that year and all subsequent years.

■ **Par. 5.** Section 1.1223–3 is amended by:

■ 1. Redesignating paragraph (b)(5) as paragraph (b)(6);

■ 2. Adding a new paragraph (b)(5);

■ 3. Designating *Examples 1* through *8* of paragraph (f) as paragraphs (f)(1) through (8);

■ 4. Adding paragraphs (f)(9) and (10); and

■ 5. Revising the heading and adding a sentence at the end of paragraph (g).

The additions and revision read as follows:

§ 1.1223–3 Rules relating to the holding periods of partnership interests.

* * * * *

(b) * * *

(5) *Divided holding period if partnership interest comprises in whole or in part one or more profits interests*—(i) *In general.* If a partnership interest is comprised in whole or in part of one or more profits interests (as defined in paragraph (b)(5)(ii) of this section), then, for purposes of applying paragraph

(b)(1) of this section, the portion of the holding period to which a profits interest relates is determined based on the fair market value of the profits interest upon the disposition of all, or part, of the interest (and not at the time that the profits interest is acquired). Paragraph (b)(1) of this section continues to apply to the extent that a partner acquires portions of a partnership interest that are not comprised of a profits interest and the value of the profits interest is not included for purposes of determining the value of the entire partnership interest under paragraph (b)(1).

(ii) *Definition of capital interest and profits interest.* For purposes of this paragraph (b)(5), a profits interest is a partnership interest other than a capital interest. A capital interest is an interest that would give the holder a share of the proceeds if the partnership's assets were sold at fair market value at the time the interest was received and then the proceeds were distributed in a complete liquidation of the partnership. A profits interest, for purposes of this paragraph (b)(5), is received in connection with the performance of services to or for the benefit of a partnership in a partner capacity or in anticipation of being a partner, and the receipt of the interest is not treated as a taxable event for the partner or the partnership under applicable Federal income tax guidance.

* * * * *

(f) * * *

(9) *Example 9.* On June 1, 2020, GP contributes $10,000 to PRS for a partnership interest in PRS. On June 30, 2023, GP receives a 20% interest in the profits of PRS that is an Applicable Partnership Interest (API) as defined in § 1.1061–1(a). On June 30, 2025, GP sells its interest in PRS for $30,000. At the time of GP's sale of its interest, the API has a fair market value of $15,000. GP has a divided holding period in its interest in PRS; 50% of the partnership interest has a holding period beginning on June 1, 2020, and 50% has a holding period that begins on June 30, 2023.

(10) *Example 10.* Assume the same facts as in paragraph (f)(9) of this section (*Example 9*), except that on June 30, 2024, GP contributes an additional $5,000 cash to GP prior to GP's sale of its interest in 2025. Immediately after the contribution of the $5,000 on June 30, 2024, GP's interest in PRS has a value of $15,000, not taking into account the value of GP's profits interest in PRS. GP calculates its holding period in the portions not comprised by the profits interest and two-thirds of its holding period runs from June 30, 2020, and one-third runs from June 30, 2024. On June 30, 2025, GP sells its interest for $30,000 and the API has a fair market value of $15,000. Accordingly, on the date of disposition, one-third of GP's interest has a five year holding period from its interest received in 2020 for its $10,000 contribution, one-half of GP's interest has a two year holding period from the profits interest issued on June 30, 2023, and one-sixth of GP's interest has a one year holding period from the contribution of the $5,000.

(g) *Applicability dates.* * * * Paragraphs (b)(5) and (f)(9) and (10) of this section apply to taxable years beginning on or after January 19, 2021.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: January 5, 2021.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Additional Guidance Regarding Limitation on Deduction for Business Interest Expense; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9943]

RIN 1545–BP73

Additional Guidance Regarding Limitation on Deduction for Business Interest Expense

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide additional guidance regarding the limitation on the deduction for business interest expense under section 163(j) of the Internal Revenue Code (Code) to reflect amendments made by the Tax Cuts and Jobs Act and the Coronavirus Aid, Relief, and Economic Security Act. Specifically, the regulations address the application of the limitation in contexts involving passthrough entities, regulated investment companies (RICs), and controlled foreign corporations. The regulations also provide guidance regarding the definitions of real property development, real property redevelopment, and syndicate. The regulations affect taxpayers that have business interest expense, particularly passthrough entities, their partners and shareholders, as well as foreign corporations and their United States shareholders. The regulations also affect RICs that have business interest income, RIC shareholders that have business interest expense, and corporations that are members of a consolidated group.

DATES:

Effective date: The regulations are effective on January 13, 2021.

Applicability dates: For dates of applicability, see §§ 1.163–15(b), 1.163(j)–1(c)(4), 1.163(j)–2(k), 1.163(j)–6, 1.163(j)–7(m), 1.163(j)–10(f), 1.469–11(a)(1) and (4), and 1.1256(e)–2(d).

FOR FURTHER INFORMATION CONTACT: Concerning § 1.163–15, or 1.163(j)–2(d)(3), Nathaniel Kupferman, (202) 317–4855, or James Williford, (202) 317–3225; concerning § 1.163(j)–1(b)(1)(iv), § 1.163(j)–2(b)(3)(iii) or (iv) or § 1.163(j)–10, John B. Lovelace, (202) 317–5357; concerning § 1.163(j)–1(b)(22) or (b)(35), Steven Harrison, (202) 317–6842, or Michael Chin, (202) 317–6842; concerning § 1.163(j)–6, § 1.469–4 or § 1.469–9, Vishal Amin, Brian Choi, or Jacob Moore, (202) 317–5279; concerning § 1.163(j)–7, Azeka J. Abramoff, (202) 317–3800, or Raphael J. Cohen, (202) 317–6938; concerning § 1.1256(e)–2, Pamela Lew, (202) 317–7053 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Statutory Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 163 (in particular, section 163(j)), 469, and 1256(e) of the Code. Section 163(j) was amended by Public Law 115–97, 131 Stat. 2054 (December 22, 2017), commonly referred to as the Tax Cuts and Jobs Act (TCJA), and the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281 (March 27, 2020) (CARES Act). Section 13301(a) of the TCJA amended section 163(j) by removing prior section 163(j)(1) through (9) and adding section 163(j)(1) through (10). The provisions of section 163(j) as amended by section 13301 of the TCJA are effective for taxable years beginning after December 31, 2017. The CARES Act further amended section 163(j) by redesignating section 163(j)(10), as amended by the TCJA, as new section 163(j)(11), and adding a new section 163(j)(10) providing special rules for applying section 163(j) to taxable years beginning in 2019 or 2020.

Section 163(j) generally limits the amount of business interest expense (BIE) that can be deducted in the current taxable year (sometimes referred to in this preamble as the current year). Under section 163(j)(1), the amount allowed as a deduction for BIE is limited to the sum of (1) the taxpayer's business interest income (BII) for the taxable year; (2) 30 percent of the taxpayer's adjusted taxable income (ATI) for the taxable year (30 percent ATI limitation); and (3) the taxpayer's floor plan financing interest expense for the taxable year (in sum, the section 163(j) limitation). As further described later in this Background section, section 163(j)(10), as amended by the CARES Act, provides special rules relating to the 30 percent ATI limitation for taxable years beginning in 2019 or 2020. Under section 163(j)(2), the amount of any BIE that is not allowed as a deduction in a taxable year due to the section 163(j) limitation is treated as business interest paid in the succeeding taxable year.

The section 163(j) limitation applies to all taxpayers, except for certain small businesses that meet the gross receipts test in section 448(c) of the Code and certain trades or businesses listed in section 163(j)(7) (excepted trades or businesses). More specifically, section 163(j)(3) provides that the section 163(j) limitation does not apply to any taxpayer that meets the gross receipts test under section 448(c), other than a tax shelter prohibited from using the cash receipts and disbursements method of accounting under section 448(a)(3). Under section 163(j)(7), the excepted trades or businesses are the trade or business of providing services as an employee, electing real property businesses, electing farming businesses, and certain regulated utility businesses.

Section 163(j)(4) provides special rules for applying section 163(j) in the case of passthrough entities. Section 163(j)(4)(A) requires that the section 163(j) limitation be applied at the partnership level, and that a partner's ATI be increased by the partner's share of excess taxable income, as defined in section 163(j)(4)(C), but not by the partner's distributive share of income, gain, deduction, or loss. Section 163(j)(4)(B) provides that the amount of partnership BIE exceeding the section 163(j)(1) limitation is carried forward at the partner level as excess business interest expense (EBIE). Section 163(j)(4)(B)(ii) provides that EBIE allocated to a partner and carried forward is available to be deducted in a subsequent year only to the extent that the partnership allocates excess taxable income to the partner. As further described later in this Background section, section 163(j)(10), as amended by the CARES Act, provides a special rule for EBIE allocated to a partner in a taxable year beginning in 2019. Section 163(j)(4)(B)(iii) provides rules for the adjusted basis in a partnership of a partner that is allocated EBIE. Section 163(j)(4)(D) provides that rules similar to the rules of section 163(j)(4)(A) and (C) apply to S corporations and S corporation shareholders.

Section 163(j)(5) and (6) define ''business interest'' and ''business interest income,'' respectively, for purposes of section 163(j). Generally, these terms include interest expense and interest includible in gross income that is properly allocable to a trade or business (as defined in section 163(j)(7)) and do not include investment income or investment expense within the meaning of section 163(d). The legislative history states that ''a corporation has neither investment interest nor investment income within the meaning of section 163(d). Thus, interest income and interest expense of a corporation is properly allocable to a trade or business, unless such trade or business is otherwise explicitly excluded from the application of the provision.'' H. Rept. 115–466, at 386, fn. 688 (2017).

Section 163(j)(8) defines ATI as the taxable income of the taxpayer (1) computed without regard to items not

properly allocable to a trade or business; BIE and BII; net operating loss (NOL) deductions; deductions for qualified business income under section 199A; and deductions for depreciation, amortization, and depletion with respect to taxable years beginning before January 1, 2022, and (2) computed with such other adjustments as provided by the Secretary of the Treasury or his delegate (Secretary).

As noted previously, section 163(j)(1) includes floor plan financing interest in computing the amount of deductible business interest. Section 163(j)(9) defines ''floor plan financing interest'' and ''floor plan financing indebtedness.'' These provisions allow taxpayers incurring interest expense for the purpose of securing an inventory of motor vehicles held for sale or lease to deduct the full expense without regard to the section 163(j) limitation.

Under section 163(j)(10)(A)(i), the amount of BIE that is deductible under section 163(j)(1) for taxable years beginning in 2019 or 2020 is computed using 50 percent, rather than 30 percent, of the taxpayer's ATI for the taxable year (50 percent ATI limitation). A taxpayer may elect not to apply the 50 percent ATI limitation to any taxable year beginning in 2019 or 2020, and instead apply the 30 percent ATI limitation. This election must be made separately for each taxable year. Once the taxpayer makes the election, the election may not be revoked without the consent of the Secretary. See section 163(j)(10)(A)(iii).

Sections 163(j)(10)(A)(ii)(I) and 163(j)(10)(A)(iii) provide that, in the case of a partnership, the 50 percent ATI limitation does not apply to partnerships for taxable years beginning in 2019, and the election to not apply the 50 percent ATI limitation may be made only for taxable years beginning in 2020, and may be made only by the partnership. Under section 163(j)(10)(A)(ii)(II), however, a partner treats 50 percent of its allocable share of a partnership's EBIE for 2019 as BIE in the partner's first taxable year beginning in 2020 that is not subject to the section 163(j) limitation (50 percent EBIE rule). The remaining 50 percent of the partner's allocable share of the partnership's EBIE remains subject to the section 163(j) limitation applicable to EBIE carried forward at the partner level. A partner may elect out of the 50 percent EBIE rule.

Section 163(j)(10)(B)(i) allows a taxpayer to elect to substitute its ATI for the last taxable year beginning in 2019 (2019 ATI) for the taxpayer's ATI for a taxable year beginning in 2020 (2020 ATI) in determining the taxpayer's section 163(j) limitation for the taxable year beginning in 2020.

Section 163(j)(11) provides cross-references to provisions requiring that electing farming businesses and electing real property businesses excepted from the section 163(j) limitation use the alternative depreciation system (ADS), rather than the general depreciation system, for certain types of property. The required use of ADS results in the inability of these electing trades or businesses to use the additional first-year depreciation deduction under section 168(k) for those types of property.

II. Published Guidance

On April 16, 2018, the Department of the Treasury (Treasury Department) and the IRS published Notice 2018–28, 2018–16 I.R.B. 492, which described regulations intended to be issued under section 163(j). On December 28, 2018, the Treasury Department and the IRS (1) published proposed regulations under section 163(j), as amended by the TCJA, in a notice of proposed rulemaking (REG–106089–18) (2018 Proposed Regulations) in the **Federal Register** (83 FR 67490), and (2) withdrew the notice of proposed rulemaking (1991–2 C.B. 1040) published in the **Federal Register** on June 18, 1991 (56 FR 27907 as corrected by 56 FR 40285 (August 14, 1991)) to implement rules under section 163(j) before its amendment by the TCJA. On September 14, 2020, the Treasury Department and the IRS published final regulations under section 163(j) and other sections in the **Federal Register** (85 FR 56686) (T.D. 9905) to finalize most sections of the 2018 Proposed Regulations.

Concurrently with the publication of T.D. 9905, the Treasury Department and the IRS published additional proposed regulations under section 163(j) in a notice of proposed rulemaking (REG–107911–18) in the **Federal Register** (85 FR 56846) (2020 Proposed Regulations) to provide additional guidance regarding the section 163(j) limitation in response to certain comments received in response to the 2018 Proposed Regulations and to reflect the amendments made by the CARES Act. The 2020 Proposed Regulations provided proposed rules: For allocating interest expense associated with debt proceeds of a partnership or S corporation to supplement the rules in § 1.163–8T regarding the allocation of interest expense for purposes of section 163(d) and (h) and section 469 (proposed §§ 1.163–14 and 1.163–15); amending the definition of ATI and permitting certain RICs to pay section 163(j) interest dividends (proposed § 1.163(j)–1); amending the rules for applying section 163(j)(4) to partnerships and S corporations (proposed § 1.163(j)–6); re-proposing the proposed rules for applying the section 163(j) limitation to foreign corporations and United States shareholders (proposed § 1.163(j)–7) and to foreign persons with effectively connected income (proposed § 1.163(j)–8); amending the definition of real property trade or business (proposed § 1.469–9); amending the rules for determining tax shelter status and providing guidance on the election to use 2019 ATI to determine 2020 section 163(j) limitation (proposed §§ 1.163(j)–2 and 1.1256(e)–2); and amending the corporate look-through rules as applicable to tiered structures (proposed § 1.163(j)–10).

All written comments received in response to the 2020 Proposed Regulations are available at *www.regulations.gov* or upon request. After consideration of the comments received, this Treasury decision adopts most of the 2020 Proposed Regulations as revised in response to the comments, which are described in the Summary of Comments and Explanation of Revisions section. The Treasury Department and the IRS plan to finalize other portions of the 2020 Proposed Regulations separately, to allow additional time to consider the comments received.

On April 27, 2020, the Treasury Department and the IRS published Revenue Procedure 2020–22, 2020–18 I.R.B. 745, to provide the time and manner of making a late election, or withdrawing an election, under section 163(j)(7)(B) to be an electing real property trade or business or under section 163(j)(7)(C) to be an electing farming business for taxable years beginning in 2018, 2019, or 2020. Revenue Procedure 2020–22 also provides the time and manner of making or revoking elections provided by the CARES Act under section 163(j)(10) for taxable years beginning in 2019 or 2020. These elections are: (1) To not apply the 50 percent ATI limitation under section 163(j)(10)(A)(iii); (2) to use the taxpayer's 2019 ATI to calculate the taxpayer's section 163(j) limitation for any taxable year beginning in 2020 under section 163(j)(10)(B); and (3) for a partner to elect out of the 50 percent EBIE rule under section 163(j)(10)(A)(ii)(II).

Summary of Comments and Explanation of Revisions

I. Overview

The Treasury Department and the IRS received approximately 20 written comments in response to the 2020

Proposed Regulations. Most of the comments addressing the 2020 Proposed Regulations are summarized in this Summary of Comments and Explanation of Revisions section. However, comments merely summarizing or interpreting the 2020 Proposed Regulations generally are not discussed in this preamble. Additionally, comments outside the scope of this rulemaking are generally not addressed in this Summary of Comments and Explanation of Revisions section.

The Treasury Department and the IRS continue to study comments on certain issues related to section 163(j), including issues that are beyond the scope of the final regulations, and may discuss those comments if future guidance on those issues is published.

The final regulations retain the same basic structure as the 2020 Proposed Regulations, with the revisions described in this Summary of Comments and Explanation of Revisions section.

II. Notice 89–35 and Comments on and Changes to Proposed § 1.163–15: Debt Proceeds Distributed From Any Taxpayer Account or From Cash

Section 1.163–15 of the 2020 Proposed Regulations supplemented the rules in § 1.163–8T, temporary regulations issued prior to TCJA, regarding debt proceeds distributed from any taxpayer account or from cash proceeds. Consistent with section VI of Notice 89–35, 1989–1 C.B. 675, proposed § 1.163–15 provided that taxpayers may treat any expenditure made from an account of the taxpayer, or from cash, within 30 days before or after debt proceeds are deposited in any account of the taxpayer, or received in cash, as made from such proceeds. Section 1.163–14 of the 2020 Proposed Regulations related to sections I–V of Notice 89–35. The Treasury Department and the IRS received no comments with respect to proposed § 1.163–15. Accordingly, the final regulations adopt this section unchanged. Additional consideration is being given to § 1.163–14, which is not being finalized in these final regulations; thus Notice 89–35 remains in effect.

III. Comments on and Changes to § 1.163–1: Definitions

A. Adjustments to Tentative Taxable Income

Part III.A.1.a of this Summary of Comments and Explanation of Revisions section provides an overview of the negative adjustments to tentative taxable income in § 1.163(j)–1(b)(1)(ii)(C) through (E) and the alternative computations for those negative adjustments in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). Part III.A.1.b of this Summary of Comments and Explanation of Revisions section provides an overview of the special rules in § 1.163(j)–1(b)(1)(iv)(A), (C), and (D) for the application of § 1.163(j)–1(b)(1)(ii)(C) through (E). Part III.A.2 of this Summary of Comments and Explanation of Revisions section summarizes the comments received on § 1.163(j)–1(b)(1)(ii)(C) through (E) and the alternative computations in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). Part III.A.3 of this Summary of Comments and Explanation of Revisions section summarizes the comments received on the special rules in § 1.163(j)–1(b)(1)(iv)(A), (C), and (D).

In response to comments received, the final regulations provide a number of clarifications to the ATI computation and provide new examples demonstrating their application.

1. Overview

a. Section 1.163(j)–1(b)(1)(ii)(C) Through (E) and Proposed § 1.163(j)–1(b)(1)(iv)(B) and (E)

Section 1.163(j)–1(b)(43) provides that tentative taxable income is the amount to which adjustments are made in computing ATI. Section 1.163(j)–1(b)(1)(i) provides for certain additions to tentative taxable income in computing ATI. For example, § 1.163(j)–1(b)(1)(i)(D) provides that, subject to the rule in § 1.163(j)–1(b)(1)(iii), any depreciation under section 167, section 168, or former section 168 for taxable years beginning before January 1, 2022, is added back to tentative taxable income to compute ATI. Section 1.163(j)–1(b)(1)(i)(E) and (F) provide similar rules for amortization and depletion, respectively.

Section 1.163(j)–1(b)(1)(ii) provides for certain subtractions from (or negative adjustments to) tentative taxable income in computing ATI. For example, § 1.163(j)–1(b)(1)(ii)(C) provides that, if property is sold or otherwise disposed of, the greater of the allowed or allowable depreciation, amortization, or depletion of the property for the taxpayer (or, if the taxpayer is a member of a consolidated group, the consolidated group) for taxable years beginning after December 31, 2017, and before January 1, 2022 (such years, the EBITDA period), with respect to such property is subtracted from tentative taxable income. Section 1.163(j)–1(b)(1)(ii)(D) provides that, with respect to the sale or other disposition of stock of a member of a consolidated group by another member, the investment adjustments under § 1.1502–32 with respect to such stock that are attributable to deductions described in § 1.163(j)–1(b)(1)(ii)(C) are subtracted from tentative taxable income. Section 1.163(j)–1(b)(1)(ii)(E) provides that, with respect to the sale or other disposition of an interest in a partnership, the taxpayer's distributive share of deductions described in § 1.163(j)–1(b)(1)(ii)(C) with respect to property held by the partnership at the time of such sale or other disposition is subtracted from tentative taxable income to the extent such deductions were allowable under section 704(d). See the preamble to T.D. 9905 for a discussion of the rationale for these adjustments.

The preamble to T.D. 9905 noted that, in the 2018 Proposed Regulations, § 1.163(j)–1(b)(1)(ii)(C) incorporated a ''lesser of'' standard. In other words, the lesser of (i) the amount of gain on the sale or other disposition of property, or (ii) the amount of depreciation deductions with respect to such property for the EBITDA period, was required to be subtracted from tentative taxable income to determine ATI. As explained in the preamble to T.D. 9905, commenters raised several questions and concerns regarding this ''lesser of'' standard. T.D. 9905 removed the ''lesser of'' approach due in part to concerns that this approach would be more difficult to administer than the approach reflected in T.D. 9905.

However, the Treasury Department and the IRS recognize that, in certain cases, the ''lesser of'' approach might not create administrative difficulties for taxpayers. Thus, the 2020 Proposed Regulations permitted taxpayers to choose whether to compute the amount of their adjustment upon the disposition of property, member stock, or partnership interests using a ''lesser of'' standard. See proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). The Treasury Department and the IRS requested comments on the ''lesser of'' approach, including how such an approach should apply to dispositions of member stock and partnership interests. The comments received on the ''lesser of'' approach are summarized in part III.A.2 of this Summary of Comments and Explanation of Revisions section.

b. Section 1.163(j)–1(b)(1)(iv)(A) Through (D)

Section 1.163(j)–1(b)(1)(iv) provides special rules for the application of § 1.163(j)–1(b)(1)(ii)(C) through (E). Section 1.163(b)(1)(iv)(A)(*1*) provides that, for purposes of § 1.163(j)–1(b)(1)(ii)(C) through (E), the term ''sale

or other disposition'' does not include a transfer of an asset to an acquiring corporation in a transaction to which section 381(a) of the Code applies, except as otherwise provided in § 1.163(j)–1(b)(1)(iv)(A). Section 1.163(j)–1(b)(1)(iv)(A)(*2*) provides that, for purposes of § 1.163(j)–1(b)(1)(ii)(C) and (D), the term ''sale or other disposition'' excludes all intercompany transactions, within the meaning of § 1.1502–13(b)(1)(i). This provision reflects the general treatment of a consolidated group as a single entity for purposes of section 163(j). Section 1.163(j)–1(b)(1)(iv)(A)(*3*) provides that, notwithstanding any other rule in § 1.163(j)–1(b)(1)(iv)(A) (including the rule regarding section 381(a) transactions), any transaction in which a member leaves a consolidated group is treated as a ''sale or other disposition'' for purposes of § 1.163(j)–1(b)(1)(ii)(C) and (D), unless the transaction is an acquisition described in § 1.1502–13(j)(5)(i)(A).

Section 1.163(j)–1(b)(1)(iv)(B) provides that, for purposes of § 1.163(j)–1(b)(1)(ii)(C) through (E), the amount of a consolidated group's adjustment under § 1.163(j)–1(b)(1)(ii)(C) is computed by reference to the depreciation, amortization, or depletion deductions of the group. The 2020 Proposed Regulations added § 1.163(j)–1(b)(1)(iv)(B)(*2*) to clarify the computation under proposed § 1.163(j)–1(b)(iv)(E)(*1*) for consolidated groups.

Section 1.163(j)–1(b)(1)(iv)(C) provides successor asset rules for certain intercompany transactions. More specifically, if deductions described in § 1.163(j)–1(b)(1)(ii)(C) are allowed or allowable to a consolidated group member (S), the depreciable property or S's stock is transferred to another member (S1), and the transferor's basis in the S1 stock received in the intercompany transaction is determined, in whole or in part, by reference to its basis in the transferred property or S stock, then the S1 stock is treated as a successor asset for purposes of the negative adjustments to tentative taxable income upon the disposition of member stock.

Section 1.163(j)–1(b)(1)(iv)(D) contains anti-duplication rules. For example, § 1.163(j)–1(b)(1)(iv)(D)(*2*) provides that depreciation, amortization, or depletion deductions allowed or allowable for a corporation for a consolidated return year of a group are disregarded in applying § 1.163(j)–1(b)(1)(iv)(D) to a separate return year of that corporation. Section 1.163(j)–1(b)(1)(iv)(D)(*2*) also provides an example in which S deconsolidates from a consolidated group (Group 1) (thereby triggering an adjustment under §§ 1.163(j)–1(b)(1)(ii)(D) and 1.163(j)–1(b)(1)(iv)(A)(*3*)) and then sells the depreciable property. The example states that no further adjustment is required under § 1.163(j)–1(b)(1)(ii)(C) upon the asset disposition with regard to the amounts included in Group 1.

2. Comments on § 1.163(j)–1(b)(1)(ii)(C) through (E) and Proposed § 1.163(j)–1(b)(1)(iv)(B) and (E)

a. Adoption of a ''Lesser of'' Standard

Several commenters contended that the final regulations should continue to allow taxpayers to choose whether to compute the amount of their adjustment upon the disposition of property, member stock, or partnership interests using a ''lesser of'' standard, as in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). Commenters asserted that such an approach would ameliorate the adverse impact of the subtractions from tentative taxable income in § 1.163(j)–1(b)(1)(ii)(C) through (E). One commenter further asserted that a ''lesser of'' option is preferable to the approach in T.D. 9905 because the latter could create an incentive for taxpayers to retain assets solely because the adverse tax consequences of disposing of the assets outweigh the cost of keeping the assets.

The Treasury Department and the IRS agree with these comments, and the final regulations retain a ''lesser of'' option for purposes of the negative adjustments to tentative taxable income in § 1.163(j)–1(b)(1)(ii)(C) through (E). The final regulations also update the special rules in § 1.163(j)–1(b)(1)(iv)(A), (C), and (D) to add cross–references to the ''lesser of'' computations in § 1.163(j)–1(b)(1)(iv)(B) and (E).

b. Modification of the ''Lesser of'' Standard

Several commenters also recommended modifications to the ''lesser of'' rules in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). For example, one commenter stated that the proposed ''lesser of'' approach is likely to be less accurate for dispositions of member stock or partnership interests than for asset dispositions because the gain prong of the ''lesser of'' computation in either case is based on the gain in the member stock or partnership interests, respectively, rather than on the gain that would be recognized on the sale of the underlying assets.

The Treasury Department and the IRS received recommendations regarding several alternative approaches. Under one alternative, the negative adjustment under the gain prong of the ''lesser of'' computation for dispositions of member stock or partnership interests would equal the amount of the negative adjustment if the assets of the subsidiary or partnership were sold. However, the commenter acknowledged that this ''deemed asset sale'' approach could create unnecessary administrative difficulties and lead to valuation disputes by requiring asset valuations upon dispositions of member stock or partnership interests.

Among other alternative approaches, a commenter recommended that the gain prong of the ''lesser of'' computation for dispositions of member stock should be based on the excess of tax depreciation over economic depreciation with respect to the underlying assets. The commenter based this approach on the theory that only stock gain that reflects non-economic depreciation should give rise to a negative basis adjustment. The commenter who recommended this approach suggested several different computational methods for this alternative approach, but acknowledged that this approach likely would not be appropriate for certain types of assets (for example, real estate or purchased goodwill) because metrics that might be used under this approach, such as earnings and profits basis or book value, would not be a good proxy for fair market value for such assets. Another commenter recommended revising the proposed ''lesser of'' computation for dispositions of partnership interests such that certain negative adjustments would be made at the partnership level and others would be made at the partner level.

After considering these comments, the Treasury Department and the IRS have determined that the proposed ''lesser of'' computations strike a proper balance between accuracy and administrability. In particular, as one commenter noted, there would be unnecessary administrative complexity under the first suggested alternative approach. This complexity includes the need for separate asset valuations that would be costly and may be subject to dispute, resulting in additional controversy between taxpayers and the IRS. The second proposed approach would require an accurate determination of economic depreciation. However, as the commenter acknowledged, there is no single, simple method for accurately determining economic depreciation. Additionally, with regard to economic depreciation, different types of assets depreciate at different rates, and some assets, such as land or certain improvements to land, may not

depreciate at all. As a result, basing the gain prong of the ''lesser of'' computation on non-economic depreciation would create less certainty, and would not clearly be a more accurate approach, than the proposed ''lesser of'' standard. Requiring certain adjustments at the partner level and other adjustments at the partnership level also would add further complexity to the ''lesser of'' computations.

Thus, the final regulations adopt the approach in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). However, the Treasury Department and the IRS acknowledge that gain on upper-tier member stock generally becomes further removed from asset gain at each additional tier within a consolidated group. Therefore, for purposes of the ''lesser of'' computation in § 1.163(j)–1(b)(1)(iv)(E)(*2*), the final regulations provide that the only stock gain that is relevant is the gain that is deemed recognized on the stock of the member holding the item of property (or the stock of a successor).

The Treasury Department and the IRS appreciate the comments received on the proposed ''lesser of'' rules and will continue to consider these comments for purposes of potential future guidance.

c. Limitation of Negative Adjustments to Tax Benefit From Adding Back Depreciation, Amortization, and Depletion Deductions to Tentative Taxable Income

The additions to tentative taxable income for depreciation, amortization, and depletion deductions during the EBITDA period (see § 1.163(j)–1(b)(1)(i)(D) through (F), respectively) do not necessarily increase a taxpayer's ability to deduct BIE. For example, the taxpayer's section 163(j) limitation already may be sufficiently high to permit a deduction of all of the taxpayer's BIE even without such additions to tentative taxable income.

Commenters have stated that, in such a situation, the adjustments in § 1.163(j)–1(b)(1)(ii)(C) through (E) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) could inappropriately decrease the amount of the taxpayer's BIE deduction in the year the property, member stock, or partnership interest is sold because the taxpayer derived no benefit from the adjustment under § 1.163(j)–1(b)(1)(i)(D) through (F) in a prior taxable year. The commenters asserted that this detrimental outcome is inconsistent with both congressional intent and the statement in the preamble to T.D. 9905 that § 1.163(j)–1(b)(1)(ii)(C) through (E) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) are intended to ensure that the positive adjustment to tentative taxable income for depreciation deductions results in a timing benefit. See part II.A.5 of the Summary of Comments and Explanation of Revisions in the preamble to T.D. 9905. Moreover, if a taxpayer that did not benefit from a positive adjustment under § 1.163(j)–1(b)(1)(i)(D) through (F) were required to reduce its tentative taxable income in the year of disposition, the negative adjustment could put the taxpayer in a worse position than if the depreciation, amortization, or depletion deductions were not added back to tentative taxable income in the first place. The commenters thus recommended providing that a negative adjustment under § 1.163(j)–1(b)(1)(ii)(C) through (E) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) is required only to the extent the prior-year addback under § 1.163(j)–1(b)(1)(i)(D) through (F) resulted in an increase in deductible BIE.

The Treasury Department and the IRS agree with this recommendation. Thus, the final regulations provide that a negative adjustment to tentative taxable income under § 1.163(j)–1(b)(1)(ii)(C) through (E) or § 1.163(j)–1(b)(1)(iv)(B) or (E) is reduced to the extent the taxpayer establishes that the additions to tentative taxable income under § 1.163(j)–1(b)(1)(i)(D) through (F) in a prior taxable year did not result in an increase in the amount allowed as a deduction for BIE for such year. The final regulations also provide examples illustrating the application of this rule.

d. Capitalized Depreciation

T.D. 9905 provides that, for the additions to tentative taxable income in § 1.163(j)–1(b)(1)(i), amounts of depreciation, amortization, or depletion that are capitalized under section 263A of the Code (collectively, capitalized depreciation) during the taxable year are deemed to be included in the computation of the taxpayer's tentative taxable income for such year, regardless of when the capitalized amount is recovered. See § 1.163(j)–1(b)(1)(iii). Thus, a taxpayer makes a positive adjustment to tentative taxable income under § 1.163(j)–1(b)(1)(i)(D) through (F) when the taxpayer capitalizes the depreciation, amortization, or depletion, rather than later when the capitalized amount is recovered (for example, through cost of goods sold).

Commenters requested clarification regarding the application of §§ 1.163(j)–1(b)(1)(ii)(C) through (E) and 1.163(j)–1(b)(1)(iv) to capitalized depreciation. For example, commenters asked whether the adjustments in § 1.163(j)–1(b)(1)(ii)(C) and proposed § 1.163(j)–1(b)(iv)(B) and (E) occur upon the disposition of the depreciated property or upon the disposition of the property into which the depreciation was capitalized. A commenter asked the same question regarding the application of the successor asset rules in § 1.163(j)–1(b)(1)(iv)(C). A commenter also requested clarification as to how the negative adjustments in § 1.163(j)–1(b)(1)(ii)(D) and proposed § 1.163(j)–1(b)(1)(iv)(E)(*2*) apply to capitalized depreciation because there are no basis adjustments under § 1.1502–32 when depreciation is capitalized.

The Treasury Department and the IRS have determined that a negative adjustment under § 1.163(j)–1(b)(1)(ii)(C) or proposed § 1.163(j)–1(b)(1)(iv)(B) or (E) would be required upon the sale or other disposition of property with respect to which depreciation, amortization, or depletion was allowed or allowable during the EBITDA period, because it is the allowed or allowable depreciation, amortization, or depletion of that property that is added back to tentative taxable income. The final regulations have been modified accordingly. For the same reason, the final regulations also clarify that the successor asset rules in § 1.163(j)–1(b)(1)(iv)(C) would apply if such property subsequently were transferred to another member (S1) in an intercompany transaction in which the transferor receives S1 stock. The Treasury Department and the IRS are continuing to consider how the negative adjustments in § 1.163(j)–1(b)(1)(ii)(D) and proposed § 1.163(j)–1(b)(1)(iv)(E)(*2*) apply to capitalized depreciation.

A commenter also expressed concern that, if a taxpayer does not elect to apply T.D. 9905 retroactively, then capitalized depreciation arising in taxable years beginning before November 13, 2020, would not be added back to tentative taxable income, but negative adjustments under § 1.163(j)–1(b)(1)(ii)(C) through (E) still would be required for any ''allowable'' depreciation, including capitalized depreciation, if the relevant property, member stock, or partnership interest were disposed of in a year to which T.D. 9905 applies. The commenter thus recommended that negative adjustments under § 1.163(j)–1(b)(1)(ii)(C) through (E) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) not apply to capitalized depreciation amounts that were incurred in a taxable year that began before November 13, 2020, unless the taxpayer included a positive adjustment reflecting such amounts in calculating its tentative taxable income.

As discussed in part III.A.2.c of this Summary of Comments and Explanation of Revisions section, the final

regulations adopt the recommendation that a negative adjustment to tentative taxable income under § 1.163(j)–1(b)(1)(ii)(C) through (E) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) be reduced to the extent the taxpayer establishes that the additions to tentative taxable income under § 1.163(j)–1(b)(1)(i)(D) through (F) in a prior taxable year resulted in no increase in deductible BIE in that year. If a taxpayer does not elect to apply T.D. 9905 retroactively, the taxpayer will have no additions to tentative taxable income under § 1.163(j)–1(b)(1)(i)(D) through (F) in a prior taxable year (and, thus, no increase in deductible BIE in that year) with respect to capitalized depreciation. Because the final regulations already address the commenter's concern, the Treasury Department and the IRS have not incorporated the commenter's specific recommendation.

e. Dispositions by Consolidated Groups

The final regulations also revise §§ 1.163(j)–1(b)(1)(iv)(A)(*2*), 1.163(j)–1(b)(1)(iv)(B)(*2*), and 1.163(j)–1(b)(1)(iv)(E) to clarify that the amount of gain taken into account by a consolidated group upon a ''sale or other disposition'' includes the net gain the group would take into account, including as a result of intercompany transactions. One commenter contended that this clarification is needed to ensure that the amount of gain taken into account by a consolidated group for purposes of the negative adjustments in proposed §§ 1.163(j)–1(b)(1)(iv)(B)(*2*) and 1.163(j)–1(b)(1)(iv)(E) is the same regardless of whether the property, member stock, or partnership interest is sold in an intercompany transaction before leaving the group (that is, to achieve single-entity treatment of the group). For example, assume that S would recognize $100 of gain upon the sale of property to a nonmember. However, rather than sell the property directly to a nonmember, S first might sell the property to member B and recognize $60 of gain, and B then could sell the property to the nonmember and recognize an additional $40 of gain. In either case, the group would recognize a net gain of $100 in relation to the property, and that same $100 should be relevant in determining the amount of any negative adjustment to ATI.

3. Comments on § 1.163(j)–1(b)(1)(iv)(A), (C), and (D)

a. Section 1.163(j)–1(b)(1)(iv)(A)

Commenters questioned why, under the rules for deconsolidating transactions in § 1.163(j)–1(b)(1)(iv)(A)(*3*), the exception to ''sale or other disposition'' treatment is limited to whole-group acquisitions described in § 1.1502–13(j)(5)(i)(A) and does not also include whole-group acquisitions that take the form of reverse acquisitions, as described in § 1.1502–13(j)(5)(i)(B). The Treasury Department and the IRS did not intend this exception to exclude transactions described in § 1.1502–13(j)(5)(i)(B), and the final regulations revise § 1.163(j)–1(b)(1)(iv)(A)(*3*) to correct this typographical error.

The Treasury Department and the IRS received another comment regarding the exceptions to ''sale or other disposition'' treatment for whole-group acquisitions in § 1.163(j)–1(b)(1)(iv)(A)(*3*) and for section 381 transactions in § 1.163(j)–1(b)(1)(iv)(A)(*1*) (see the summary in part III.A.1.b of this Summary of Comments and Explanation of Revisions section). The commenter noted that the tax law generally treats the successor in a section 381 transaction (and the acquiring group in a whole-group acquisition) as stepping into the shoes of the acquired entity (or group). However, the commenter also noted that § 1.163(j)–1(b)(1)(iv)(A) does not expressly provide that the acquiring entity (or group) steps into the shoes of the acquired entity (or group) for purposes of the negative adjustments in §§ 1.163(j)–1(b)(1)(ii)(C) through (E) and 1.163(j)–1(b)(1)(iv)(B) and (E). The commenter recommended clarifying this point.

The Treasury Department and the IRS agree with the commenter. Thus, the final regulations clarify this point by expressly stating that the acquiring corporation in a section 381 transaction and the surviving group in a transaction described in § 1.1502–13(j)(5)(i) is treated as a successor to the distributor or transferor corporation or the terminating group, respectively, for purposes of §§ 1.163(j)–1(b)(1)(ii)(C) through (E) and 1.163(j)–1(b)(1)(iv)(B) and (E) of this section.

A commenter also noted that the ''lesser of'' computation for dispositions of member stock in proposed § 1.163(j)–1(b)(1)(iv)(E)(*2*) could be misconstrued as overriding the rules for negative adjustments to a group's tentative taxable income in the case of deconsolidating transactions subject to § 1.163(j)–1(b)(1)(iv)(A)(*3*). Under this erroneous interpretation, if a sale or other disposition resulted in a deconsolidation, the ''lesser of'' computation would apply solely with respect to the member stock that was sold, even though the deconsolidation rules in § 1.163(j)–1(b)(1)(iv)(A)(*3*) would treat the transaction as a disposition of all of the departing member's stock. Thus, the ''lesser of'' computation would not reflect the full amount of gain recognized upon the complete disposition of the departing member's stock.

The Treasury Department and the IRS did not intend the ''lesser of'' rule in proposed § 1.163(j)–1(b)(1)(iv)(E)(*2*) to override the rules for deconsolidating transactions. The regulations under section 163(j) generally treat a consolidated group as a single entity; thus, the rules for deconsolidations in § 1.163(j)–1(b)(1)(iv)(A)(*3*) treat the date of a member's deconsolidation as the appropriate time to make adjustments to tentative taxable income with regard to all of that member's stock. Thus, the final regulations clarify § 1.163(j)–1(b)(1)(iv)(A)(*3*) to provide that any transaction in which a member leaves a consolidated group is treated as a taxable disposition of all stock of the departing member held by any member of the consolidated group for purposes of § 1.163(j)–1(b)(1)(ii)(C) and (D) and § 1.163(j)–1(b)(1)(iv)(B), (E)(*1*), and (E)(*2*), unless the transaction is described in § 1.1502–13(j)(5)(i).

A commenter also suggested that nonrecognition transactions in which a member leaves a consolidated group should not be treated as a ''sale or other disposition'' for purposes of the negative adjustments in § 1.163(j)–1(b)(1)(ii)(C) and (D) and proposed § 1.163(j)–1(b)(1)(iv)(B) and (E). The final regulations do not accept this comment because, under the single–entity theory of consolidated groups in the section 163(j) regulations, such negative adjustments should be made when a member deconsolidates, regardless of the form of the deconsolidation transaction, other than in a whole-group acquisition described in § 1.1502–13(j)(5)(i). In other words, because the section 163(j) regulations generally treat a consolidated group as a unified taxpayer, any adjustments to ATI related to property should occur when the item of property leaves the group. This result should be consistent whether the property is disposed of directly by a group member or whether the property leaves the group upon the deconsolidation of a member.

The Treasury Department and the IRS also received a comment that the gain prong of the proposed ''lesser of'' computation could yield unintended results for certain nonrecognition transactions. Under T.D. 9905, dispositions are treated as ''sales or other dispositions'' for purposes of the negative adjustments under § 1.163(j)–1(b)(1)(ii)(C) through (E) unless an express exception applies. As

previously discussed in this part III.A.3.a of this Summary of Comments and Explanation of Revisions section, T.D. 9905 provides exceptions for section 381 transactions and whole-group acquisitions. However, T.D. 9905 does not provide an exception to ''sale or other disposition'' treatment for other nonrecognition transactions, such as transactions to which section 351 or section 721 applies.

The commenter noted that the ''lesser of'' computations in proposed § 1.163(j)–1(b)(1)(iv)(B) and (E) could be construed to suggest that a taxpayer would have no negative adjustment under these provisions if the taxpayer transferred an asset in a transaction to which section 351 or section 721 applies. The Treasury Department and the IRS did not intend the proposed ''lesser of'' computations to create additional exceptions to ''sale or other disposition'' treatment for purposes of the negative adjustments required under § 1.163(j)–1(b)(1)(ii)(C) through (E). Thus, the final regulations clarify that the disposition of property, member stock, or partnership interests in a transaction other than a deconsolidation (the treatment of which is addressed in § 1.163(j)–1(b)(1)(iv)(A)(*3*)) that is a nonrecognition transaction other than a section 381 transaction is treated as a taxable disposition for purposes of the gain prong of the ''lesser of'' computation.

b. Section 1.163(j)–1(b)(1)(iv)(C)

As noted in part III.A.1.b of this Summary of Comments and Explanation of Revisions section, the successor asset rules in § 1.163(j)–1(b)(1)(iv)(C) apply to certain intercompany transactions. For example, assume that S (a member of the P group) acquires a depreciable asset and fully depreciates the asset under section 168(k). P then contributes its S stock to S1 (another member of the P group) in exchange for S1 stock in a transaction to which section 351 applies. In this case, the S1 stock is a successor asset to the S stock. Moreover, if P sells its S1 stock to a third party in a transaction that causes both S1 and S to deconsolidate, the transaction is treated as a taxable disposition of both the S1 stock and the S stock for purposes of §§ 1.163(j)–1(b)(1)(ii)(C) and (D) and 1.163(j)–1(b)(1)(iv)(B) and (E). See § 1.163(j)–1(b)(1)(iv)(A)(*3*). In that case, both the actual sale of the S1 stock and the disposition of the S stock on its deconsolidation pursuant to § 1.163(j)–1(b)(1)(iv)(A)(*3*) could produce negative adjustments to ATI. Application of the anti-duplication rule in § 1.163(j)–1(b)(1)(iv)(D) effectively would mean that the total subtraction from ATI would equal the greater of the two stock gains (if any).

One commenter agreed with this reading of the regulations but suggested that an example would be helpful to clarify the interaction of these multiple rules. The Treasury Department and the IRS agree with this suggestion, and the final regulations include an example illustrating the operation of these rules.

c. Section 1.163(j)–1(b)(1)(iv)(D)

Commenters have stated that the anti-duplication rule in § 1.163(j)–1(b)(1)(iv)(D)(*2*) is unclear, does not properly support the example in that paragraph, and does not take into account the exception to the deconsolidation rule in § 1.163(j)–1(b)(1)(iv)(A)(*3*). For example, a commenter stated that it is unclear whether the operative rule, which does not reference § 1.163(j)–1(b)(1)(ii)(C), actually supports the conclusion in the example, which references § 1.163(j)–1(b)(1)(ii)(C). Another commenter requested clarification that the anti-duplication rule in § 1.163(j)–1(b)(1)(iv)(D)(*2*) does not apply to a whole-group acquisition, which is not treated as a ''sale or other disposition'' for purposes of § 1.163(j)–1(b)(1)(ii)(C) through (E). See § 1.163(j)–1(b)(1)(iv)(A)(*3*).

The Treasury Department and the IRS agree with these comments and have revised § 1.163(j)–1(b)(1)(iv)(D)(*2*) to clarify the application of this provision. The Treasury Department and the IRS also have clarified the application of § 1.163(j)–1(b)(1)(iv)(D)(*1*), including by clarifying that the paragraph contains two separate rules, rather than one rule and one example.

A commenter also requested examples illustrating the application of the anti-duplication rule in § 1.163(j)–1(b)(1)(iv)(D) when the taxpayer's negative adjustment under the ''lesser of'' computation is based on gain recognized rather than on depreciation deductions taken during the EBITDA period. The final regulations add an example to § 1.163(j)–1(b)(1)(viii) to illustrate the application of this rule.

B. Dividends From Regulated Investment Company (RIC) Shares

If a RIC has certain items of income or gain, part 1 of subchapter M and other Code provisions provide rules under which a RIC may pay dividends that a shareholder in the RIC may treat in the same manner (or a similar manner) as the shareholder would treat the underlying item of income or gain if the shareholder realized it directly. Like the preamble to the 2020 Proposed Regulations, this preamble refers to this treatment as ''conduit treatment.'' The 2020 Proposed Regulations provide rules under which a RIC that earns BII may pay section 163(j) interest dividends. The total amount of a RIC's section 163(j) interest dividends for a taxable year is limited to the excess of the RIC's BII for the taxable year over the sum of the RIC's BIE for the taxable year and the RIC's other deductions for the taxable year that are properly allocable to the RIC's BII. The 2020 Proposed Regulations provide that a RIC shareholder that receives a section 163(j) interest dividend may treat the dividend as interest income for purposes of section 163(j), subject to holding period requirements and other limitations. The Treasury Department and the IRS received one comment requesting that the proposed rules providing this treatment be finalized. These final regulations adopt those proposed rules.

A few commenters requested that conduit treatment be extended to funds other than RICs, such as foreign regulated investment funds and foreign money market funds, so that investors in those funds may treat earnings from those funds as interest income to the extent the earnings can be traced to interest income of the funds. These final regulations do not adopt these recommendations. The Treasury Department and the IRS received similar recommendations in response to the 2018 Proposed Regulations, and they were not adopted in T.D. 9905. As explained in the preamble to T.D. 9905, there are significant differences between the rules governing income inclusions in respect of passive foreign investment companies (PFICs), such as foreign money market funds, and RICs. These significant differences would require a different mechanical approach if conduit treatment were extended to PFICs and present additional policy considerations. The Treasury Department and the IRS continue to study this comment and these issues.

Another commenter requested that conduit treatment be extended to allow shareholders in real estate investment trusts (REITs) to treat REIT dividends as interest income, to the extent that the income earned by the REIT is interest income. The Treasury Department and the IRS continue to consider this comment.

IV. Comments on and Changes to Proposed § 1.163(j)–6: Application of the Business Interest Expense Deduction Limitations to Partnerships and Subchapter S Corporations

A. Overview

Section 1.163(j)–6 provides rules for applying section 163(j) to partnerships, S corporations and their owners. As described in this part IV of the Summary of Explanation of Revisions section, the Treasury Department and the IRS continue to study aspects of proposed § 1.163(j)–6. Accordingly, the final regulations reserve on §§ 1.163(j)–6(e)(6) (partnership deductions capitalized by a partner), (h)(4) (partner basis adjustments upon liquidating distributions), (h)(5) (partnership basis adjustments upon partner dispositions), (j) (tiered partnerships), and (l)(4)(iv) (S corporation deductions capitalized by an S corporation shareholder). These paragraphs of the 2020 Proposed Regulations are retained in proposed form and may be relied on to the extent provided in the Applicability Dates section of this preamble.

B. Trading Partnerships

The 2020 Proposed Regulations addressed the application of section 163(j) to partnerships engaged in a trade or business activity of trading personal property (including marketable securities) for the account of owners of interests in the activity, as described in § 1.469–1T(e)(6) (trading partnership). Specifically, the 2020 Proposed Regulations included a rule requiring a partnership engaged in a trading activity (*i.e.,* trade or business activities described in section 163(d)(5)(A)(ii) and illustrated in Revenue Ruling 2008–12, 2008–1 C.B. 520 (March 10, 2008)) to bifurcate its interest expense from the trading activity between partners that are passive investors (taxpayers that do not materially participate in the activity within the meaning of section 469) in the trading activity and all other partners, and subject only the portion of the interest expense that is allocable to the non-passive investors to limitation under section 163(j) at the partnership level. The portion of interest expense from the trading activity allocable to passive investors is subject to limitation under section 163(d) at the partner level, as provided in section 163(d)(5)(A)(ii). Accordingly, proposed § 1.163(j)–1(c)(1) and (2) include rules applicable to trading partnerships that modify the definitions of BII and BIE to effectuate this bifurcation.

In addition, proposed § 1.163(j)–6(d)(4) requires that a trading partnership bifurcate all of its other items of income, gain, loss and deduction from its trading activity between partners that are passive investors and all other partners. The portion of the partnership's other items of income, gain, loss or deduction from its trading activity properly allocable to the passive investors in the partnership will not be taken into account at the partnership level as items from a trade or business for purposes of applying section 163(j) at the partnership level. Instead, all such partnership items properly allocable to passive investors will be treated as items from an investment activity of the partnership, for purposes of sections 163(j) and 163(d).

As stated in the preamble to 2020 Proposed Regulations, this approach, in order to be effective, presumes that a trading partnership generally will possess knowledge regarding whether its individual partners are passive investors in its trading activity. Because no rules currently exist requiring a partner to inform the partnership whether the partner has grouped activities of the trading partnership with other activities of the partner outside of the partnership, the 2020 Proposed Regulations include a revision to the section 469 activity grouping rules to provide that any activity described in section 163(d)(5)(A)(ii) may not be grouped with any other activity of the partner, including any other activity described in section 163(d)(5)(A)(ii).

In response to the decision to bifurcate interest expenses from a trading activity, one commenter stated that the bifurcation approach was inconsistent with section 163(j)(5). According to the comment, the statute does not support the partnership having BIE for some partners and investment interest expense for others. Rather, once a partnership determines that it is investment interest expense that same interest expense cannot also be BIE of the partnership. The commenter read section 163(j) to mean that if a partnership is engaged in a trade or business that is not a passive activity and with respect to which certain owners do not materially participate, then the interest expense allocable to the partnership's trade or business is investment interest and section 163(j) does not apply to any of the interest expense.

Alternatively, the commenter recommended that, to the extent the Treasury Department and the IRS determine that materially participating partners should be subject to limitation under either section 163(d) or section 163(j), a rule similar to that for corporate partners should be adopted. Under such a rule, a trading partnership would treat all of its interest expense as investment interest expense at the partnership level with respect to all of its partners, and the interest expense allocable to a non-passive investor would be recharacterized as BIE by such non-passive investor. This approach, according to the commenter, would achieve a similar result as the proposed bifurcation approach while eliminating the administrative complexities associated with a partnership having to determine whether each of its partners is materially participating.

As stated in the preamble to the 2020 Proposed Regulations, the Treasury Department and the IRS considered treating all interest expense of a trading partnership as investment interest expense but concluded that it was inconsistent with the intent of section 163(j) to limit BIE of a partnership. The commenter's alternative approach also is inconsistent with the statute because it ignores the fact that the trading partnership is engaged in trade or business and, therefore, any BIE should be subject to section 163(j). Such an approach would further diverge from the application of section 163(j), particularly with respect to business interest carryforwards. Partnership BIE that is limited under section 163(j)(4) is carried forward by the partner as EBIE and is not treated as paid or accrued in succeeding taxable years until the partner receives ETI from the same partnership. Under the commenter's approach, the partner, if subject to section 163(j), would treat the interest expense as paid or accrued in the succeeding tax year under section 163(j)(2) without requiring an allocation of ETI or excess BII (EBII) from the partnership. The bifurcation approach in the 2020 Proposed Regulations, and in these final regulations, preserves the partnership-level application of section 163(j) for those partners who are non-passive investors in the trade or business of the partnership as well as the carryover rules applicable at the partner-level.

Another commenter suggested an alternative under which section 163(j) would be applied at the partnership level and any EBIE would be allocated to the partners. Any direct or indirect partner that is a non-passive investor in the partnership's trading activity would continue to apply the rules of section 163(j) to the EBIE received from the partnership. For partners who did not materially participate in the partnership's trading activity, any allocated EBIE from the partnership would be fully deductible subject to any partner-level section 163(d) limitation.

Under this approach, any EBIE received by a passive investor would be treated as paid or accrued in the current year and not subject to the carryover rules under section 163(j)(4)(B). The Treasury Department and the IRS do not adopt this comment as the approach is inconsistent with the statutory language and intent of section 163(j)(5) because the second sentence of section 163(j)(5) specifically states that BIE shall not include investment interest expense.

Several commenters opposed the revision of the grouping rule under section 469 to prohibit the grouping of trading activities. Proposed § 1.469–4(d)(6) provides that a trading activity described in section 163(d)(5)(A)(ii) may not be grouped with any other activity of the taxpayer, including another trading activity. One commenter observed that such a rule would discourage trading funds from using multiple partnerships because it may result in partners never being able to demonstrate material participation in the trading activity under the 500 hour test or any other material participation test (*i.e.,* § 1.469–5T(a)) for any one partnership, even though the partner would materially participate in a properly grouped activity. Another acknowledged the administrative burden associated with partnerships evaluating the activities of their passive partners but highlighted that partnerships were already required to collect details about partner's tax status in similar situations. A third suggested that the grouping rule could be modified to permit a partner to group activities provided the partner provides sufficient information to the partnership to enable it to identify the taxpayer as a materially participating partner.

The Treasury Department and the IRS do not adopt these recommendations because the rules under section 469 adequately address these concerns. Activity under section 469 is broadly defined to be a trade or business under section 162 and the rules further provide for grouping by a partnership or S corporation. As addressed previously, for the bifurcation method to be effective, modification of the section 469 grouping rules is necessary to avoid potential abuse and to allow the trading partnership to presume that an individual partner is a passive investor in the trading activity based solely on the partnership's understanding as to the lack of work performed in the trading activity. Additionally, if grouping were allowed, then passive partners could group their other trade or business activities, in which they materially participate, with their trading activity in order to become a material participant as to the trading activity, thus, avoiding the section 163(d) limit at the partner level. The final regulations clarify that this grouping rule applies only to individuals, estates, trusts, closely held C corporations, and personal service corporations that may directly or indirectly own interests in trading activities described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(ii).

One commenter observed that the proposed regulations do not discuss a tiered partnership structure with respect to the material participation rules. The Treasury Department and the IRS determined that such a rule is not needed. The bifurcation approach in proposed § 1.163(j)–1(c)(1) and (2) applies where interest income or expense is allocable to one or more partners that do not materially participate (within the meaning of section 469), as described in section 163(d)(5)(A)(ii). Thus, in a tiered structure where interest is not allocable to one or more partners that do not materially participate, the rules in § 1.163(j)–6(c)(1) and (2) do not apply and the interest expense is subject to the rules under section 163(j)(4).

The same commenter recommended the final regulations provide that if a partner that has EBIE ceases to materially participate in a later taxable year, the EBIE would be allowed in a later year subject to any section 163(d) limitation; and conversely, if a passive investor partner has a section 163(d) investment carryover and then materially participates in a later taxable year, the 163(d) carryover would be allowed subject to any partner-level section 163(j) limitation. In light of concerns with partners shifting between participating and not participating in the trading activity in order to unsuspend EBIE, the Treasury Department and the IRS determined that such a rule is not warranted.

One commenter requested transition relief for trading partnerships that may have relied on the statement contained in the preamble to the 2018 Proposed Regulations that the BIE of the partnership allocable to trading activity will be subject to section 163(j) at the entity level, even if the interest expense is later subject to limitation under section 163(d) at the individual partner level. Partnerships that relied on the 2018 Proposed Regulations may have allocated EBIE to partners who do not materially participate in the trading activity of the partnership. Under the final regulations, partnerships carrying on trading activities do not allocate ETI or EBII from trading activities to their partners who do not materially participate in those activities. Rather, any interest expense and all other items from such activities allocable to these partners will be treated as items derived from an investment activity of the partnership. As a result, passive investors that were previously allocated EBIE from the trading partnership generally will not be allocated any ETI or EBII from that partnership in future years against which they can offset the EBIE.

The Treasury Department and the IRS agree that relief should be accorded to partners of trading partnerships that do not materially participate in the trading activity and that relied on the statement in the preamble to the 2018 Proposed Regulations. Accordingly, a transition rule is provided in the final regulations to permit passive investors in a partnership engaged in a trading activity to deduct EBIE allocated to them from the partnership in any taxable year ending prior to the effective date of the final regulations without regard to the amount of ETI or EBII that may be allocated by the partnership to the partner in the first taxable year ending on or after the effective date of these final regulations.

For purposes of this transition rule, any EBIE that is no longer subject to disallowance under section 163(j) solely as a result of this transition rule will not be subject to limitation or disallowance under section 163(d). In such case, the partnership treated the interest expense as business interest expense for purposes of calculating its limitation under section 163(j). The treatment of interest expense by the partnership as BIE in prior years is not affected by this transition rule. Accordingly, the rule in section 163(j)(5) that interest expense cannot be treated as both BIE and investment interest expense would still apply, and the BIE of the partnership cannot be treated as investment interest expense of the partner in future years.

The commenter also observed that a corporate partner is never subject to section 163(d) regardless of material participation and requested clarification whether section 163(j) applies to a trading partnership's corporate partner at the partner or partnership level. The Treasury Department and the IRS have determined that the regulations as proposed adequately addressed this situation. Generally, a corporate partner is not a passive investor subject to section 163(d)(5)(A)(ii); therefore, the rules under proposed § 1.163(j)–6(c) would not apply.

In the 2020 Proposed Regulations, the Treasury Department and the IRS requested comments regarding whether similar rules should be adopted with

respect to S corporations that also may be involved in trading activities, and whether such rules would be compatible with subchapter S. One commenter recommended that the final regulations provide that an S corporation engaged in a trading activity be required to bifurcate its interest expense between shareholders who materially participate in the trading activity and shareholders who do not materially participate and apply section 163(j) to the former and section 163(d) to the latter at the S corporation level.

The Treasury Department and the IRS appreciate this recommendation but, as acknowledged by the commenter, the implementation of such a rule would require different allocations of S corporation income and other items among shareholders of the S corporation. Unlike partnerships, S corporations must allocate items pro rata to the shareholders, in accordance with their respective percentages of stock ownership in the corporation. See generally section 1377(a)(1). Therefore, with regard to S corporations, the Treasury Department and the IRS have determined that (i) section 163(d) should continue to be applied at the shareholder level, and (ii) as provided by section 163(j)(4)(A) and (D), section 163(j) should continue to be applied at the S corporation level. Consequently, the final regulations do not incorporate the commenter's recommendation.

C. Treatment of Business Interest Income and Business Interest Expense With Respect to Lending Transactions Between a Partnership and a Partner (Self-Charged Lending Transactions)

The 2020 Proposed Regulations provide that, in the case of a self-charged lending transaction between a lending partner and a borrowing partnership in which the lending partner owns a direct interest, any BIE of the borrowing partnership attributable to a self-charged lending transaction is BIE of the borrowing partnership for purposes of proposed § 1.163(j)–6(n). However, to the extent the lending partner receives interest income attributable to the self-charged lending transaction and also is allocated EBIE from the borrowing partnership in the same taxable year, the lending partner may treat such interest income as an allocation of EBII from the borrowing partnership in that taxable year, but only to the extent of the lending partner's allocation of EBIE from the borrowing partnership in the same taxable year. To prevent the potential double counting of BII, the lending partner includes interest income re-characterized as EBII only once when calculating the lending partner's own section 163(j) limitation. In cases where the lending partner is not a C corporation, to the extent that any interest income exceeds the lending partner's allocation of EBIE from the borrowing partnership for the taxable year, and such interest income otherwise would be properly treated as investment income of the lending partner for purposes of section 163(d) for that year, such excess amount of interest income will continue to be treated as investment income of the lending partner for that year for purposes of section 163(d).

One commenter generally supported the approach for self-charged lending transactions provided in the 2020 Proposed Regulations and expected that many taxpayers may benefit from this rule. However, the commenter noted that the rule applies only to self-charged lending transactions where the lending partners directly own interests in the borrowing partnerships and stated that this rule is too narrow. The commenter recommended that the rule be broadened to include loans to a partnership by other members in the same consolidated group as a corporate partner. In addition, the commenter recommended that the rule for self-charged lending transactions should be expanded to include lending partners in upper-tier partnerships who make loans to lower-tier partnerships. The commenter stated that in both cases, the interest expense would ultimately flow up to the same taxpayer that recognizes the interest income.

The Treasury Department and the IRS have determined that the rule for self-charged lending transactions should be adopted in the final regulations without change. With respect to the recommendation that the self-charged lending rule should apply to indirect lenders in tiered-partnership situations, the Treasury Department and the IRS concluded that adopting a rule to allow interest income of a partner in an upper-tier partnership that lent money to a lower-tier partnership to offset EBIE that may be suspended in a lower-tier partnership would add undue complexity to these rules, and such rules would likely become more difficult to administer, particularly with respect to large and complex multi-tiered entity structures. With respect to the recommendation to extend the rule to apply to corporate partners where the lender is a member of the same consolidated group of corporations, the Treasury Department and the IRS continue to consider whether this would be appropriate for inclusion in future guidance. The Treasury Department and the IRS are also considering additional guidance that would limit the application of the self-charged interest rule to a lender that is subject to tax under section 511, due to the special rules that apply to the calculation of unrelated business taxable income under section 512. See § 1.512(a)–6.

The Treasury Department and the IRS solicited comments in the 2020 Proposed Regulations regarding whether the rule for self-charged lending transactions between partnerships and lending partners (or a similar rule) should apply to, lending transactions between S corporations and lending shareholders. No comments were received in response to this solicitation. The pro rata allocation requirements applicable to S corporations make adopting rules similar to those provided for partnership self-charged lending transactions difficult to apply and could potentially impact the eligibility requirements under subchapter S. Accordingly, the final regulations do not provide such a rule.

D. CARES Act Partnership Rules

The 2020 Proposed Regulations provide special rules for partners and partnerships for taxable years beginning in 2019 or 2020 under section 163(j)(10) as enacted by the CARES Act. Proposed § 1.163(j)–6(g)(4) provides that 50 percent of any EBIE allocated to a partner for any taxable year beginning in 2019 is treated as BIE paid or accrued by the partner in the partner's first taxable year beginning in 2020 (referred to in the 2020 Proposed Regulations as § 1.163(j)–6(g)(4) business interest expense). The amount that is treated as BIE paid or accrued by the partner in the partner's 2020 taxable year is not subject to a section 163(j) limitation at the partner level. The 2020 Proposed Regulations further provide that if a partner disposes of its interest in the partnership in the partnership's 2019 or 2020 taxable year, the amount treated as BIE paid or accrued by the partner under proposed § 1.163(j)–6(g)(4) is deductible by the partner and thus does not result in a basis increase under § 1.163(j)–6(h)(3). The 2020 Proposed Regulations state that a taxpayer may elect to not have § 1.163(j)–6(g)(4) apply, and provide two examples illustrating these rules in §§ 1.163(j)–6(o)(35) and (o)(36). The Treasury Department and the IRS specifically requested comments on these proposed rules and on whether further guidance was necessary.

One commenter agreed with the approach taken in the 2020 Proposed Regulations, but requested that the final regulations clarify that an election out of

the 50 percent EBIE rule is made by a partner with respect to each partnership in which the partner holds an interest. The commenter stated that partners may have different reasons to elect out of the 50 percent EBIE rule and that by allowing partners to make the election out with respect to each partnership, partners will have greater flexibility in managing their tax consequences.

The Treasury Department and the IRS agree with this comment. Thus, the final regulations clarify that partners may elect out of the 50 percent EBIE rule on a partnership by partnership basis.

Another commenter requested confirmation with respect to an aspect of the example in § 1.163(j)–6(o)(36). In the example, the partner is allocated EBIE in 2018 and 2019 and sells its partnership interest in 2019. The commenter requested confirmation that the partner would not deduct 50 percent of the EBIE since the sale of the partnership interest occurred in 2019, resulting in a gain/loss recognition event during the 2019 taxable year, and there would be no basis in the partnership for the partner to deduct 50 percent of the 2019 EBIE.

The Treasury Department and the IRS believe that the example, as drafted in the proposed regulations, represents a correct interpretation of the regulations and are therefore finalizing the example without change. However, these final regulations clarify that § 1.163(j)–6(g)(4) business interest expense can be deducted by the disposing partner except to the extent that the business interest expense is negative section 163(j) expense as defined in § 1.163(j)–6(h)(1) immediately before the disposition. Under the example in § 1.163(j)–6(o)(36), the partner treats 50 percent of 2019 EBIE ($10 x 50%) as § 1.163(j)–6(g)(4) business interest expense. Section 1.163(j)–6(g)(4) provides that if a partner disposes of a partnership interest in the partnership's 2019 or 2020 taxable year, the partner can deduct the § 1.163(j)–6(g)(4) business interest expense and there is no basis increase under § 1.163(j)–6(h)(3) for this amount. Thus, unless the partner elects out of the 50 percent EBIE rule, the partner would have a $25 loss (instead of a $30 loss) from the sale of its partnership interest in 2019 and $5 of deductible BIE that is not subject to a section 163(j) limitation at the partner level.

The Treasury Department and the IRS received one comment on proposed § 1.163(j)–6(d)(5). This commenter stated that the proposed regulations disregard the ''11–step approach'' in § 1.163(j)–6(f)(2), and instead point to different mechanics of a tiered partnership allocation rule under proposed § 1.163(j)–6(j)(9). The commenter recommended additional guidance and examples on the application of the proposed regulations to non-tiered partnerships and partnerships that historically allocate all items pro rata.

In light of this comment, and in light of the fact that the tiered partnership rules in the proposed regulations are not being finalized at this time, the Treasury Department and the IRS believe that a simpler method for a partnership to take into account 2019 ATI in 2020 is warranted. Therefore, these final regulations prescribe a simplified method that applies when a partnership uses its 2019 section 704 income, gain, loss, and deduction amounts in determining its 2020 allocable ATI and include an illustrative example.

V. Comments on and Changes to Proposed § 1.163(j)–7: Application of the Section 163(j) Limitation to Foreign Corporations and United States Shareholders

A. Overview

Section 1.163(j)–7 provides rules for applying section 163(j) to relevant foreign corporations and their United States shareholders (U.S. shareholders).

As described in this part V of the Summary of Comments and Explanation of Revisions section, the Treasury Department and the IRS continue to study aspects of proposed § 1.163(j)–7. Accordingly, the final regulations reserve on § 1.163(j)–7(c)(2)(iii) (treating a CFC group as single C corporation for purposes of allocations to an excepted trade or business) and (iv) (treating a CFC group as single taxpayer for purposes of treating amounts as interest), (f)(2) (ordering rule when a CFC group member has ECI), and (j) (computation of ATI of certain United States shareholders of applicable CFCs), and related definitions in § 1.163(j)–7(k). These paragraphs of the 2020 Proposed Regulations are retained in proposed form and may be relied on to the extent provided in the Applicability Dates section.

B. Negative Adjusted Taxable Income of CFC Group Members

Proposed § 1.163(j)–7(c) provided rules for applying section 163(j) to CFC group members. Proposed § 1.163(j)–7(c)(2)(i) provided that a single section 163(j) limitation is computed for a specified period of a CFC group based on the sum of the current–year business interest expense, disallowed BIE carryforwards, BII, floor plan financing interest expense, and ATI of each CFC group member. For this purpose, the ATI and other items of a CFC group member were generally computed on a separate–entity basis. Proposed § 1.163(j)–7(c)(2)(i).

Under the general rule of § 1.163(j)–1(b)(1)(vii), ATI of a taxpayer cannot be less than zero (no-negative ATI rule). Two comments were received regarding the application of the no-negative ATI rule with respect to CFC groups and CFC group members. One of the comments stated that it is unclear how the rule applies to CFC group members. Both comments asserted that the no-negative ATI rule should apply with respect to the CFC group, rather than each separate CFC group member. As a result, the ATI of a CFC group would generally be reduced by the negative ATI of CFC group members, if any. One comment noted that consolidated groups have a single ATI amount, which takes into account losses of consolidated group members. Another comment noted that, if negative ATI of CFC group members is not taken into account, CFC group members could be required to deduct BIE in a taxable year in which the sum of the CFC group members' tested losses exceed the sum of their tested income; the comment questioned whether this result is appropriate, noting that it would often be more beneficial to carry forward the disallowed BIE to the subsequent taxable year in light of the fact that tested losses cannot be carried forward to subsequent taxable years.

The Treasury Department and the IRS agree that the ATI of CFC group members should take into account amounts less than zero for purposes of determining the ATI of a CFC group. Accordingly, the final regulations provide that the no-negative ATI rule applies with respect to the ATI of a CFC group, rather than a CFC group member.

C. Transactions Between CFC Group Members

In general, intragroup transactions are taken into account for purposes of computing a CFC group's section 163(j) limitation. However, proposed § 1.163(j)–7(c)(2)(ii) provided an anti-abuse rule that disregarded an intragroup transaction between CFC group members if a principal purpose of entering into the transaction was to affect the CFC group's or a CFC group member's section 163(j) limitation by increasing or decreasing the CFC group or a CFC group member's ATI. Some comments requested a broader rule that would permit taxpayers to elect annually to disregard BII and BIE between CFC group members for purposes of applying section 163(j). The

comments asserted that this election would reduce the compliance burden on taxpayers.

The final regulations do not provide an election to disregard intragroup BII and BIE. The effect of the requested election would be to allow a deduction for all intragroup BIE and to cause the section 163(j) limitation applicable to other BIE (that is, BIE with respect to debt that is not between members of a CFC group) to be determined without regard to intragroup BII. Although the requested election would not affect the total amount of deductible BIE within the CFC group, it would change the location of the deduction within the CFC group (that is, the CFC group member for which a deduction is allowed). Moving a BIE deduction from one CFC group member to another may have significant Federal income tax consequences. For example, the location of a CFC group's interest deduction can affect the amount of a CFC group member's subpart F income and tested income (or tested loss) and, therefore, the amount of a U.S. shareholder's income inclusion under section 951(a) or 951A(a), respectively. Thus, the requested election could be used to inappropriately manipulate the impact of BIE deductions within a CFC group.

However, the final regulations expand the anti-abuse rule so that it may apply not only to certain intragroup transactions that affect ATI but also to intragroup transactions entered into with a principal purpose of affecting a CFC group or a CFC group member's section 163(j) limitation by increasing the CFC group or a CFC group member's BII. This rule is intended to prevent taxpayers from artificially increasing the total amount of BII and BIE within a CFC group for a specified period in order to shift disallowed BIE from one CFC group member to another or change the timing of deductions of BIE. For example, a payment of BIE by a payor CFC group member to a payee CFC group member will generally result in an equal increase in the CFC group's section 163(j) limitation (and therefore the amount of deductible BIE) as a result of the increase in the CFC group's BII. However, the increase in the CFC group's section 163(j) limitation is not necessarily allocated to the payor. Instead, under the ordering rules of § 1.163(j)–7(c)(3), the additional section 163(j) limitation would be allocated first to the payee to the extent it has BIE, and then may be allocated to other CFC group members. This type of transaction would be subject to the anti-abuse rule if it was entered into with a principal purpose of increasing the amount of BIE deductible by other CFC group members.

D. High-Tax Exceptions

1. Application of Section 163(j) to Controlled Foreign Corporations With High-Taxed Income

One comment suggested that the Treasury Department and the IRS consider a special rule for the application of section 163(j) to CFC group members that are subject to the subpart F high-tax exception under § 1.954–1(d) or the GILTI high-tax exclusion under § 1.951A–2(c)(7) (together, high-tax exceptions). For example, the comment suggested a multi-step approach under which section 163(j) would first be applied to CFC group members on a separate-entity basis for the purpose of applying the high-tax exceptions, and then ATI and BIE of CFC group members subject to the high-tax exceptions could be excluded in computing the CFC group's section 163(j) limitation.

The Treasury Department and the IRS have determined that applying section 163(j) first to each CFC group member on a separate-entity basis, then applying the high-tax exceptions, and then reapplying section 163(j) to a CFC group by excluding income eligible for the high-tax exceptions, would significantly increase the administrative and compliance burdens of section 163(j) and therefore reduce the benefits of making a CFC group election. Furthermore, such an approach would be inconsistent with the general concept and purpose of a consolidated approach to the CFC group election; for example, it would increase the relevance of the location of intragroup debt and ATI within a CFC group and could inappropriately enhance the effective foreign tax rate of such income. Accordingly, the final regulations do not adopt this recommendation.

2. Disallowed Business Interest Expense Carryforwards and the High-Tax Exceptions

Section 163(j) and the section 163(j) regulations generally apply to determine the deductibility of BIE of a relevant foreign corporation (which includes an applicable CFC) in the same manner as those provisions apply to determine the deductibility of BIE of a domestic C corporation. Section 1.163(j)–7(b). One comment requested that the Treasury Department and the IRS confirm that a CFC to which the high-tax exceptions apply can still have a disallowed BIE carryforward.

The high-tax exception does not modify the rules for determining the section 163(j) limitation or the amount of an applicable CFC's disallowed BIE carryforward. See part V.D.1 of this Summary of Comments and Explanation of Revisions section. Accordingly, an applicable CFC may have disallowed BIE carryforwards if the applicable CFC is subject to a high-tax exception in the taxable year(s) in which the disallowed BIE carryforwards arose.

E. Allocation of CFC Group Items to an Excepted Trade or Business

Proposed § 1.163(j)–7(c)(2)(iii) provided that, for purposes of allocating items to an excepted trade or business under § 1.163(j)–10, all CFC group members are treated as a single C corporation. Similarly, proposed § 1.163(j)–7(c)(2)(iv) provided that, for purposes of determining whether certain amounts are treated as interest within the meaning of § 1.163(j)–1(b)(22), all CFC group members are treated as a single taxpayer. Several comments addressed the method of allocating items of a CFC group member to an excepted trade or business under § 1.163(j)–10. The Treasury Department and the IRS continue to study the proper method for allocating CFC group members' items to an excepted trade or business and when it is appropriate to treat a CFC group as a single entity. The Treasury Department and the IRS may address these issues in future guidance and will consider the comments at that time. Accordingly, the final regulations reserve on § 1.163(j)–7(c)(2)(iii) and (iv).

F. Limitation on Pre-Group Disallowed Business Interest Expense Carryforwards

1. Pre-Group Disallowed Business Interest Expense Carryforwards Attributable to Specified Group Members

The 2020 Proposed Regulations provided special rules relating to disallowed BIE carryforwards of a CFC group member that arose in a taxable year before it joined the CFC group (pre-group disallowed BIE carryforwards). Under proposed § 1.163(j)–7(c)(3)(iv)(A)(*1*), a CFC group member cannot deduct pre-group disallowed BIE carryforwards in excess of the cumulative section 163(j) pre-group carryforward limitation. This limitation is determined in a manner similar to the limitation on the use of carryovers of a member of a consolidated group arising in a separate return limitation year (SRLY). See § 1.1502–21(c).

One comment requested that the limitation on pre-group disallowed BIE carryforwards be removed, because it increases the compliance burden on taxpayers and any potential for loss

trafficking could adequately be addressed by an anti-abuse rule. Alternatively, if this request is not adopted, the comment requested that the limitation on pre-group disallowed BIE carryforwards not apply to disallowed BIE carryforwards that arose in a taxable year in which a CFC group election was available but prior to the first taxable year for which the CFC group election was in effect. The comment asserted that applying the limitation to such carryforwards is inappropriate because there is no loss trafficking concern unless a CFC is acquired from outside the group.

The Treasury Department and the IRS have determined that it would be inappropriate for the limitation on deduction of pre-group disallowed BIE carryforwards to be replaced with an anti-abuse rule focused on loss trafficking. Loss trafficking concerns may arise anytime the ATI or BII of one CFC group member is used to allow a deduction for BIE of another CFC group member attributable to a taxable year before the other CFC group member joined the CFC group. As a result, the final regulations retain the limitation on the deduction of pre-group disallowed BIE carryforwards.

2. Application of Section 382 to CFCs Joining or Leaving a CFC Group

As a general matter, the SRLY limitations described in §§ 1.1502–21(c) and 1.163(j)–5(d) do not apply to a member of a consolidated group if their application would result in an overlap with the application of section 382 (SRLY overlap rule). See §§ 1.1502–21(g)(1) and 1.163(j)–5(f). One comment requested clarification as to whether section 382 applies to a CFC that does not have ECI. The comment generally supported the limitation on pre-group disallowed BIE carryforwards but suggested that, if section 382 applies to CFCs, a rule similar to the SRLY overlap rule should be adopted to prevent the limitation on pre-group disallowed BIE carryforwards from applying to a CFC group member if its application would result in an overlap with the application of section 382.

Section 382, by its terms, applies to the disallowed BIE carryforwards of foreign corporations regardless of whether they have ECI. However, the Treasury Department and the IRS continue to study certain aspects of the application of sections 163(j) and 382 to foreign corporations, including the possible application of a SRLY overlap rule to applicable CFCs joining or leaving a CFC group, as well as the computation of any relevant section 382(a) limitation. The Treasury Department and the IRS may address these issues in future guidance and will consider the comments at that time.

G. Specified Groups and Specified Group Members

1. The 80-Percent Ownership Threshold

Proposed § 1.163(j)–7(d) provided rules for determining a specified group and specified group members. A specified group includes one or more chains of applicable CFCs connected through stock ownership with a specified group parent, but only if the specified group parent owns stock meeting the requirements of section 1504(a)(2)(B) (which requires 80 percent ownership by value) in at least one applicable CFC, and stock meeting the requirements of section 1504(a)(2)(B) in each of the applicable CFCs (except the specified group parent) is owned by one or more of the other applicable CFCs or the specified group parent. Indirect ownership through a partnership or through a foreign estate or trust is taken into account for this purpose.

Some comments requested that the ownership threshold for applying this rule be reduced to 50 percent, or ''more than 50 percent,'' in order to make the rule consistent with the ownership rules in sections 957 and 954(d)(3). The comments asserted that a lower threshold would reduce the compliance burden of applying section 163(j) to CFCs on a separate-entity basis, would allow joint ventures to be included in the CFC group, and could prevent taxpayers from manipulating their ownership interests in order to break affiliation and exclude entities from the CFC group. One comment noted that local regulatory restrictions may prevent a U.S. shareholder from owning 80 percent of the stock in a CFC.

Another comment requested that the ownership threshold be reduced to 50 percent with respect to a CFC that has only one U.S. shareholder. The comment asserted that, if a CFC has only one U.S. shareholder, there is no concern of potentially inconsistent treatment by different shareholders and there would be no need for additional procedural requirements (for example, a requirement to provide notice to other shareholders). Alternatively, the comment suggested that a specified group parent that is a qualified U.S. person be permitted to elect to treat a CFC as a CFC group member if it meets the 50 percent (but not the 80 percent) ownership threshold, even if the specified group parent is not the sole U.S. shareholder.

The Treasury Department and the IRS have determined that it would be inappropriate to reduce the specified group ownership threshold below 80 percent. The application of section 163(j) to a CFC group is modeled on the rules for applying section 163(j) to a U.S. consolidated group under § 1.163(j)–5. Accordingly, the definition of a specified group is generally consistent with the definition of an affiliated group under section 1504. In certain respects, the rules of § 1.163(j)–7(c) have the effect of treating a CFC group as a single entity for purposes of section 163(j). Such treatment is not appropriate for CFCs that do not share at least 80 percent common ownership, that is, CFCs that are not highly related. Moreover, because one CFC group member's ATI and BII can be used by other CFC group members to deduct BIE, reducing the specified ownership threshold would increase the potential for one CFC group member to disproportionately benefit, or suffer a detriment, from the attributes of another CFC group member even though those CFCs are not highly related.

As an alternative, one comment requested that a U.S. shareholder be permitted to take into account its pro rata share of CFC attributes in computing the CFC group section 163(j) limitation without regard to the percentage of the U.S. shareholder's ownership interest. This approach is not adopted in the final regulations because it would require different U.S. shareholders to calculate the section 163(j) limitation differently and separately track disallowed BIE carryforwards with respect to the same CFC.

2. Clarifications to Rules for Determining a Specified Group and Specified Group Members

The final regulations make several clarifying changes to the rules for determining a specified group and specified group members. First, the definition of specified group in § 1.163(j)–7(d)(2)(i) is modified to clarify that a specified group may exist when a qualified U.S. person directly owns all of its applicable CFCs rather than owning one or more chains of applicable CFCs.

Second, the definition of specified group member in § 1.163(j)–7(d)(3) is modified to clarify that there must be at least two applicable CFCs in a specified group in order for any applicable CFC to be a specified group member and for a CFC group election to be available.

Finally, the rule in § 1.163(j)–7(d)(2)(vii) (concerning when a specified group ceases to exist) is modified to clarify that references to the common parent in § 1.1502–75(d)(1),

(d)(2)(i) through (d)(2)(ii), and (d)(3)(i) through (d)(3)(iv) are treated as references to the specified group parent. This is the case even if the specified group parent is a qualified U.S. person and therefore not included in the specified group.

H. CFC Group Election

1. Timing and Revocation of the CFC Group Election

Proposed § 1.163(j)–7(e) provided rules and procedures for treating specified group members as CFC group members and for determining a CFC group. Proposed § 1.163(j)–7(e)(5) provided rules for making and revoking a CFC group election. Under the 2020 Proposed Regulations, a CFC group election could not be revoked with respect to any specified period of the specified group that begins during the 60-month period following the last day of the first specified period for which the election was made. Similarly, once revoked, a CFC group election could not be made again with respect to any specified period of the specified group that begins during the 60-month period following the last day of the first specified period for which the election was revoked. The preamble to the proposed regulations requested comments as to whether a specified group that does not make a CFC group election when it first comes into existence (or for the first specified period following 60 days after the date of publication of the Treasury decision adopting the 2020 Proposed Regulations as final in the **Federal Register**) should be precluded from making the CFC group election for the following 60-month period.

Some comments requested that taxpayers be permitted to make or revoke the CFC group election on an annual basis, due to the difficulty of predicting the effect of the election five years in advance (including the potential for changes in fact or law that could interact adversely with the CFC group election). The comments noted that, although the election is favorable in most cases, it could have unfavorable consequences in some circumstances.

Some comments recommended against imposing a 60-month waiting period on specified groups for which a CFC group election is not made for the first specified period in which a specified group exists (or the specified period beginning 60 days after the regulations are finalized), because taxpayers may lack the resources or information to determine whether to make the election for the first taxable year in which it is available. Furthermore, some comments asked for clarification concerning when the 60-month period begins if a CFC group election is made or revoked with respect to a prior specified period. Finally, one comment recommended that the Treasury Department and the IRS consider providing an exception to the 60-month rule that would allow a CFC group election to be revoked when there is a ''change in control.'' The comment did not suggest a definition of change in control.

The Treasury Department and the IRS have determined that taxpayers should not be permitted to revoke the CFC group election for a specified period beginning within 60 months after the specified period for which it is made or to make the CFC group election for a specified period beginning within 60 months after the specified period for which it is revoked. The CFC group rules are based in part on the consolidated return rules, which do not allow affiliated groups that have elected to file a consolidated return to discontinue the filing of a consolidated return without the consent of the Commissioner (which generally requires a showing of good cause). See § 1.1502–75(c). In addition, if a corporation ceases to be a member of a consolidated group, that corporation generally is not permitted to rejoin the consolidated group before the 61st month beginning after its first taxable year in which it ceased to be a member of the group. Section 1504(a)(3)(A).

Moreover, an annual election would enable taxpayers to use section 163(j) to inappropriately control the timing of BIE deductions. In general, the CFC group election is intended, in large part, to reduce taxpayer burden, including compliance costs and costs that might otherwise be incurred to restructure the location of debt within a CFC group solely for purposes of section 163(j), and to permit allocation of a CFC group's section 163(j) limitation to CFC group members with BIE. The CFC group election is not intended to allow taxpayers to select the most favorable result in every taxable year.

The Treasury Department and the IRS agree that it is not necessary to impose the 60-month waiting period on specified groups that have neither made nor revoked a CFC group election. Accordingly, the final regulations do not impose a 60-month waiting period on a specified group for which a CFC group election is not made for the first specified period in which a specified group exists (or the specified period beginning 60 days after the regulations are finalized). The final regulations provide, consistent with the 2020 Proposed Regulations, that the 60-month period begins after the last day of the specified period for which the election was made or revoked. See § 1.163(j)–7(e)(5). Therefore, if an election is made or revoked with respect to a specified period, the 60-month period begins to run on the day after the end of that specified period. Finally, the Treasury Department and the IRS continue to study whether an exemption to the 60-month rule for revoking a CFC group election is appropriate when the ownership of the CFC group changes but the specified group continues and, therefore, the CFC group would also otherwise continue absent an exemption.

2. Disclosure Required for Taxable Years in Which a CFC Group Election is in Effect

Under the 2020 Proposed Regulations, a designated U.S. person makes a CFC group election by attaching a statement to its relevant Federal income tax or information return. Proposed § 1.163(j)–7(e)(5)(iv). However, the 2020 Proposed Regulations did not require a statement to be filed for taxable years following the taxable year for which an election is made. In order to facilitate ongoing disclosure of the computation of the CFC group 163(j) limitation in subsequent taxable years, the final regulations provide that (in accordance with publications, forms, instructions, or other guidance) each designated U.S. person must attach a statement to its relevant Federal income tax or information return for each of its taxable years that includes the last day of a specified period of a specified group for which a CFC group election is in effect. See § 1.163(j)–7(e)(6). The CFC group election remains in effect even if the required statement is not filed.

I. CFC Group Members With Effectively Connected Income

Proposed § 1.163(j)–7(f) provided that if a CFC group member has income that is effectively connected with the conduct of a U.S. trade or business (ECI), then ECI items and related attributes of the CFC group member are not included in the calculation of the section 163(j) limitation of the CFC group or in the allocation of the limitation among CFC group members, but are treated as items of a separate CFC (ECI deemed corporation) that is not treated as a CFC group member. A comment requested clarification concerning the proper method for allocating assets between the CFC group member and the ECI deemed corporation, which is relevant to the

allocation of BII and BIE to an excepted trade or business under § 1.163(j)–10.

As discussed in part VI of this Summary of Comments and Explanation of Revisions section, the Treasury Department and the IRS continue to study the application of section 163(j) to foreign corporations with ECI. The Treasury Department and the IRS may address these issues in future guidance and will consider the comment at that time. Before the issuance of such guidance, taxpayers should use a reasonable method for allocating assets between the CFC group member and the ECI deemed corporation. The method must be consistently applied to all CFC group members and each specified period of the CFC group after the first specified period in which it is applied.

In addition, because the Treasury Department and the IRS continue to study the application of section 163(j) to foreign corporations with ECI, the final regulations reserve on § 1.163(j)–7(f)(2) (ordering rule with § 1.163(j)–8 when a CFC group member has ECI).

J. ATI Computation of an Applicable CFC

1. Foreign Income Taxes

The 2020 Proposed Regulations provided that, for purposes of computing the ATI of a relevant foreign corporation for a taxable year, tentative taxable income takes into account a deduction for foreign income taxes. Proposed § 1.163(j)–7(g)(3). The preamble to the 2020 Proposed Regulations requested comments on whether, and the extent to which, the ATI of a relevant foreign corporation should be determined without regard to a deduction for foreign income taxes. Some comments asserted that all foreign income taxes, or foreign income taxes imposed by the country in which a CFC is organized or a tax resident, should not be taken into account as a deduction for purposes of computing a CFC's ATI. The comments asserted that not taking into account a deduction for such foreign income taxes would provide parity between CFCs and domestic corporations, which do not deduct Federal income taxes (but may deduct state and foreign taxes) in determining their ATI.

Other comments noted that, if a domestic corporation elects to claim a foreign tax credit, the deduction for foreign income taxes is disallowed under section 275(a)(4) and is not taken into account in determining the domestic corporation's ATI. Therefore, disregarding a CFC's deduction for foreign income taxes would conform the ATI of a CFC with that of a domestic corporation doing business through a foreign branch that elects to credit foreign income taxes. Another comment asserted that foreign income taxes should not be deducted to the extent a CFC's U.S. shareholders elect to credit foreign income taxes. Finally, several comments suggested that the proposed rule penalizes CFCs operating in high-tax jurisdictions.

The Treasury Department and the IRS agree that it is appropriate to determine the ATI of a relevant foreign corporation without regard to a deduction for foreign income taxes that are eligible to be claimed as a foreign tax credit. Accordingly, the final regulations provide that no deduction for foreign income taxes (within the meaning of § 1.960–1(b)) is taken into account for purposes of determining the ATI of a relevant foreign corporation. Thus, regardless of whether an election is made to claim a credit for these foreign income taxes, the foreign income taxes do not reduce ATI.

2. Anti-Abuse Rule

Proposed § 1.163(j)–7(g)(4) provided that, if certain conditions are met, when one specified group member or applicable partnership (specified borrower) pays interest to another specified group member or applicable partnership (specified lender), and the payment is BIE to the specified borrower and income to the specified lender, then the ATI of the specified borrower is increased by the amount necessary for the BIE of the specified borrower not to be limited under section 163(j). A partnership is an applicable partnership if at least 80 percent of the interests in capital or profits is owned, in the aggregate, directly or indirectly through one or more other partnerships, by specified group members of the same specified group.

The final regulations provide that, for purposes of determining whether a partnership is an applicable partnership, a partner's interests in the profits and capital of the partnership are determined in accordance with the rules and principles of § 1.706–1(b)(4)(ii) through (iii).

K. Safe Harbor

Proposed § 1.163(j)–7(h) provided a safe-harbor election for stand-alone applicable CFCs and CFC groups. If the safe-harbor election is in effect for a taxable year of a stand-alone applicable CFC or specified taxable year of a CFC group member, no portion of the BIE of the stand-alone applicable CFC or of each CFC group member, as applicable, is disallowed under section 163(j). The safe-harbor election is intended to reduce the compliance burden with respect to applicable CFCs that would not have disallowed BIE if they applied section 163(j) by allowing taxpayers in general to use subpart F income and GILTI items in lieu of ATI. In general, the safe-harbor election measures whether BIE is less than or equal to the sum of 30 percent of the applicable CFC's subpart F income and GILTI (not to exceed the applicable CFC's taxable income), taking into account only amounts attributable to a non-excepted trade or business.

The preamble to the 2020 Proposed Regulations requested comments on appropriate modifications, if any, to the safe-harbor election that would further the goal of reducing the compliance burden on stand-alone applicable CFCs and CFC groups that would not have disallowed BIE if they applied the section 163(j) limitation. In this regard, comments requested that the safe harbor be expanded to cover applicable CFCs and CFC groups that have BII that is greater than or equal to BIE. The comments noted that an application of section 163(j) would not disallow any BIE of an applicable CFC or CFC group that has net BII.

The Treasury Department and the IRS agree that it is appropriate for the safe-harbor to be expanded as requested because an application of section 163(j) in this case would not disallow any BIE. Accordingly, the final regulations provide that a safe-harbor election may be made with respect to a stand-alone applicable CFC or CFC group if its BIE does not exceed either (i) its BII, or (ii) 30 percent of the lesser of its eligible amount (in general, the sum of the applicable CFC's subpart F income and GILTI, taking into account only items properly allocable to a non-excepted trade or business) or its qualified tentative taxable income (that is, the applicable CFC's tentative taxable income determined by taking into account only items properly allocable to a non-excepted trade or business). Thus, under the final regulations, if either a stand-alone applicable CFC or a CFC group has BII that is greater than or equal to its BIE, it is not necessary to determine its qualified tentative taxable income or eligible amount in order to make the safe-harbor election. However, consistent with the 2020 Proposed Regulations, the election may not be made for a CFC group that has pre-group disallowed BIE carryforwards.

In addition, consistent with the changes described in part V.B of the Summary of Comments and Explanation of Revisions section (providing that negative ATI of a CFC group member is taken into account for purposes of

computing the CFC group's section 163(j) limitation), the determination of the eligible amount of a stand–alone applicable CFC or a CFC group has been modified to account for tested losses, if any, of an applicable CFC. See § 1.163(j)–7(h)(3). Rather than providing a formula for calculating each component of the eligible amount, the final regulations rely on existing rules under sections 951, 951A, 245A (to the extent provided in section 964(e)(4)), and 250 to determine the taxable income a domestic corporation would have had if it wholly owned the stand–alone applicable CFC or CFC group members and had no other assets or income. See § 1.163(j)–7(h)(3).

L. Increase in Adjusted Taxable Income of United States Shareholders

Proposed § 1.163(j)–7(j) provided rules that increase a U.S. shareholder's ATI by a portion of its specified deemed inclusions (as defined in § 1.163(j)–1(b)(1)(ii)(G)). Several comments were received on these rules. The Treasury Department and the IRS continue to study the method for determining the portion of the specified deemed inclusions of a U.S. shareholder that should increase its ATI. The Treasury Department and the IRS may address this issue in future guidance and will consider the comments at that time. Accordingly, the final regulations reserve on § 1.163(j)–7(j).

VI. Comments on and Changes to Proposed § 1.163(j)–8: Application of the Business Interest Deduction Limitation to Foreign Persons With Effectively Connected Income

Proposed § 1.163(j)–8 provides rules for applying section 163(j) to a nonresident alien individual or foreign corporation with ECI. The Treasury Department and the IRS continue to study methods of determining the amount of deductible BIE and disallowed business interest expense carryforwards that are allocable to ECI, such as the ATI ratio defined in proposed § 1.163(j)–8(c)(1)(ii) and the interaction of proposed § 1.163(j)–8 with the tiered partnership rules in proposed § 1.163(j)–6(j). The Treasury Department and the IRS anticipate addressing these issues in future guidance and will consider the comments at that time. Accordingly, the final regulations continue to reserve on § 1.163(j)–8.

VII. Comments on and Changes to Proposed § 1.469–9: Definition of Real Property Trade or Business

Section 469(c)(7)(C) defines real property trade or business by reference to eleven types of trades or businesses that are not defined in the statute. The 2020 Proposed Regulations, in response to questions about the application of section 469(c)(7)(C) to timberlands, provided definitions for two terms—real property development and real property redevelopment—to further clarify what constitutes a real property trade or business.

One commenter questioned why the preamble to the 2020 Proposed Regulations references the definition of ''farming'' in section 464(e), when the term ''farming business'' in section 163(j)(7)(C) is defined by reference to section 263A(e)(4) rather than to section 464(e). The commenter further noted that a section 263A(e)(4) ''farming business'' excludes not only timber but also any evergreen tree which is more than 6 years old at the time severed from the roots. The commenter posited that there is no reason why such trees should be treated differently from timber for section 163(j) purposes.

The Treasury Department and the IRS have concluded that no change is required to the definition of real property trade or business and that the definitions of ''real property development'' and ''real property redevelopment'' in proposed § 1.469–9(b)(2)(ii)(C) and (D) should be adopted in the final regulations without change. However, it should be noted that § 1.469–9(b)(2)(i)(B) references section 464(e) to exclude farming activities from the definition of real property trade or business for purposes of section 469(c)(7)(C). In promulgating § 1.469–9(b)(2)(i)(B), the Treasury Department and the IRS determined that the term ''farming'' as provided in section 464(e) is the most appropriate definition for purposes of section 469(c)(7). Section 464(e) generally excludes the cultivation and harvesting of trees (except those bearing fruit or nuts) from the definition of ''farming.'' Accordingly, the Treasury Department and the IRS note that the term ''timberland'' as used in § 1.469–9(b)(2)(ii)(C) and (D) includes evergreen trees (including those described in section 263A(e)(4)). Therefore, to the extent the evergreen trees may be located on parcels of land covered by forest, the Treasury Department and the IRS have concluded that the business activities of cultivating and harvesting such evergreen trees may be properly considered as a component of a ''real property development'' or ''real property redevelopment'' trade or business under the final regulations, and no additional clarification is needed in this regard. To the extent that any business activities of cultivating or harvesting evergreen trees do not explicitly fall within these two definitions, then such business activities may otherwise qualify under one or more of the other terms provided in section 469(c)(7)(C). Providing a definition for any of the remaining undefined terms in section 469(c)(7)(C) is beyond the scope of the final regulations.

VIII. Comments on and Changes to Proposed § 1.163(j)–10

A. Proposed Limitation on Corporate Look-Through Rules

For purposes of determining the extent to which a shareholder's basis in the stock of a domestic non-consolidated C corporation or CFC is allocable to an excepted or non-excepted trade or business under § 1.163(j)–10, § 1.163(j)–10(c)(5)(ii)(B) provides several look-through rules whereby the shareholder ''looks through'' to the corporation's basis in its assets.

The application of these look-through rules may produce distortive results in certain situations. For example, assume Corporation X's basis in its assets is split equally between X's excepted and non-excepted trades or businesses, and that (as a result) X has a 50 percent exempt percentage applied to its interest expense. However, rather than operate its excepted trade or business directly, X operates its excepted trade or business through a wholly owned, non-consolidated subsidiary (Corporation Y), and each of X and Y borrows funds from external lenders. Assuming for purposes of this example that neither the anti-avoidance rule in § 1.163(j)–2(h) nor the anti-abuse rule in § 1.163(j)–10(c)(8) applies, Y's interest expense would not be subject to the section 163(j) limitation because Y is engaged solely in an excepted trade or business. Moreover, a portion of X's interest expense also would be allocable to an excepted trade or business by virtue of the application of the look-through rule in § 1.163(j)–10(c)(5)(ii)(B)(2) to X's basis in Y's stock.

The anti-avoidance rule in § 1.163(j)–2(h) and the anti-abuse rule in § 1.163(j)–10(c)(8) would preclude the foregoing result in certain circumstances. However, proposed § 1.163(j)–10(c)(5)(ii)(D)(*2*) would modify the look-through rule for domestic non-consolidated C corporations and CFCs to limit the potentially distortive effect of this look-through rule on tiered structures in situations to which the anti-avoidance and anti-abuse rules do not apply. More specifically, proposed § 1.163(j)–10(c)(5)(ii)(D)(*2*) would modify the look-through rule for non-consolidated C

corporations to provide that, for purposes of determining a taxpayer's basis in its assets used in excepted and non-excepted trades or businesses, any such corporation whose stock is being looked through may not itself apply the look-through rule (Limited Look-Through Rule).

For example, P wholly and directly owns S1, which wholly and directly owns S2. Each of these entities is a non-consolidated C corporation to which the small business exemption does not apply. In determining the extent to which its interest expense is subject to the section 163(j) limitation, S1 may look through the stock of S2 for purposes of allocating S1's basis in its S2 stock between excepted and non-excepted trades or businesses. However, in determining the extent to which P's interest expense is subject to the section 163(j) limitation, S1 may not look through the stock of S2 for purposes of allocating P's basis in its S1 stock between excepted and non-excepted trades or businesses.

Several commenters objected to the Limited Look-Through Rule. One commenter stated that the Limited Look-Through Rule should not be finalized because it would penalize taxpayers that incur debt at the holding company level but hold excepted trade or business assets through tiers of non-consolidated subsidiaries (such as CFCs) for non-tax reasons. The commenter contended that this result is especially distortive in regulated industries, such as utilities, in which debt financing at the operating-entity level may be limited or prohibited by regulators. Another commenter noted that the Limited Look-Through Rule potentially conflicts with the single C corporation approach for CFCs under proposed § 1.163(j)–7(c)(2)(iii).

The Treasury Department and the IRS remain concerned that application of the look-through rules in § 1.163(j)–10 to non-consolidated C corporations may produce distortive results in certain situations. However, as stated in the preamble to the 2020 Proposed Regulations, the Treasury Department and the IRS are aware that taxpayers are organized into multi-tiered structures for legitimate, non-tax reasons and that it may be commercially difficult or impossible for taxpayers to limit or reduce the number of tiers in many cases. The Treasury Department and the IRS have therefore determined that such multi-tiered structures should be able to apply the look through rules in § 1.163(j)–10. However, the Treasury Department and the IRS have also determined that the application of the look through rules in § 1.163(j)–10 is inappropriate in cases where a principal purpose of a multi-tiered structure is to benefit from distortion under those rules.

Thus, the final regulations replace the Limited Look-Through Rule with an anti-abuse rule providing that, for purposes of applying the look-through rules in § 1.163(j)–10(c)(5)(ii)(B) and (C) to a non-consolidated C corporation (upper-tier entity), that upper-tier entity may not apply those look-through rules to a lower-tier non-consolidated C corporation if a principal purpose for borrowing funds at the upper-tier entity level or adding an upper-tier or lower-tier entity to the ownership structure is increasing the amount of the taxpayer's basis allocable to excepted trades or businesses.

For example, P wholly and directly owns S1 (the upper-tier entity), which wholly and directly owns S2. Each of S1 and S2 is a non-consolidated C corporation to which the small business exemption does not apply, and S2 is engaged in an excepted trade or business. With a principal purpose of increasing the amount of its basis allocable to excepted trades or businesses, P has S1 (rather than S2) borrow funds from a third party. S1 may not look through the stock of S2 (and may not apply the asset basis look-through rule described in § 1.163(j)–10(c)(5)(ii)(B)(*2*)(*iv*)) for purposes of P's allocation of its basis in its S1 stock between excepted and non-excepted trades or businesses; instead, S1 must treat its stock in S2 as an asset used in a non-excepted trade or business for that purpose. However, S1 may look through the stock of S2 for purposes of S1's allocation of its basis in its S2 stock between excepted and non-excepted trades or businesses.

B. 80-Percent Ownership Threshold in § 1.163(j)–10(c)(7)(i)

A commenter recommended eliminating the 80-percent ownership threshold in § 1.163(j)–10(c)(7)(i) for applying the look-through rules in § 1.163(j)–10(c)(5)(ii) to non-consolidated C corporations. More specifically, the commenter recommended providing that interest expense allocable to an equity interest in an entity engaged in an electing real property trade or business (RPTOB) be treated as allocated to an electing RPTOB to the extent the assets of that entity are attributable to an electing RPTOB, regardless of the level of the equity interest. The commenter stated that, because a less-than-80-percent interest in a subsidiary corporation is treated as allocable to a ''trade or business'' for purposes of the section 163(j) limitation, it is appropriate to treat the stock of that corporation as allocable to an electing RPTOB if the subsidiary corporation is an electing RPTOB, without regard to an ownership threshold.

As stated in the preamble to the 2018 Proposed Regulations, the Treasury Department and the IRS have determined that non-consolidated entities generally should not be aggregated for purposes of applying the section 163(j) limitation. Moreover, as stated in the preamble to T.D. 9905, the Treasury Department and the IRS have determined that an 80-percent ownership threshold is appropriate for domestic non-consolidated C corporations because, unlike a partnership, a corporation generally is respected as an entity separate from its owner(s) for tax purposes and, unlike a partnership or an S corporation, a C corporation is not taxed as a flow-through entity. Thus, the final regulations do not accept the commenter's recommendation.

C. Application of Look-Through Rules to Small Businesses

Section 1.163(j)–10(c)(5)(ii)(D) provides that a taxpayer may not apply the look-through rules in § 1.163(j)–10(c)(5)(ii) to a partnership, S corporation, or non-consolidated C corporation that is eligible for the small business exemption under section 163(j)(3) and § 1.163(j)–2(d)(1), unless that entity elects under § 1.163(j)–9 for a trade or business to be an electing RPTOB or an electing farming business. Under § 1.163(j)–9(b)(2)(i), an exempt small business entity that conducts a RPTOB may make a ''protective election'' for its RPTOB to be an excepted trade or business.

A commenter noted that, if a taxpayer indirectly holds an interest in an electing RPTOB through an exempt upper-tier partnership that does not conduct an excepted trade or business, the taxpayer would be ineligible to allocate the taxpayer's interest expense to the electing RPTOB under T.D. 9905. To ensure that the owners of an exempt small business entity are treated consistently regardless of the entity's overall capital structure, the commenter recommended either (i) allowing the owners of an exempt small business entity to apply the look-through rules without the need for a ''protective election'' to be an excepted trade or business, or (ii) allowing the small business entity to elect to opt into the look-through rules.

The Treasury Department and the IRS appreciate the comments received on the application of the look-through rules

to small businesses. These comments concern provisions in T.D. 9905 that were not revised in the 2020 Proposed Regulations, and the Treasury Department and the IRS have determined that addressing these comments would exceed the scope of the final regulations. However, the Treasury Department and the IRS will continue to consider these comments for purposes of potential future guidance.

D. Alternative to Asset Basis Allocation

A commenter recommended amending § 1.163(j)–10 to permit taxpayers to use a fair market value allocation method when determining allocations of BIE for purposes of section 163(j). To discourage taxpayers from shifting allocation methods, the commenter recommended that a fair market value allocation election be irrevocable absent consent from the IRS.

As explained in the preamble to T.D. 9905, disputes between taxpayers and the IRS over the fair market value of an asset are a common and costly occurrence. Moreover, in the TCJA, Congress repealed the use of fair market value in the apportionment of interest expense under section 864 of the Code (see section 14502(a) of the TCJA). As noted in the preamble to T.D. 9905, Congress stated that the ability to elect to allocate interest expense under section 864 on the basis of fair market value of assets has led to inappropriate results and needless complexity. For these and other reasons, the Treasury Department and the IRS continue to believe that allocating interest expense based on relative amounts of asset basis is more appropriate than a regime based on the relative fair market value of assets. Thus, the final regulations do not accept this comment.

Applicability Dates

These final regulations apply to taxable years beginning on or after March 22, 2021. See additional discussion in part VI of the Special Analyses addressing the Congressional Review Act.

Some provisions regarding the choice to apply the final regulations to taxable years beginning before the applicability date have changed from the 2020 Proposed Regulations. Commenters noted that these provisions in the 2020 Proposed Regulations were complicated. More specifically, in the 2020 Proposed Regulations, retroactive application of certain provisions requires application of all of the section 163(j) regulations contained in T.D. 9905, some or all of the provisions in these final regulations, and other specified provisions. Additionally, most provisions had to be applied to subsequent taxable years once applied for a taxable year (subsequent year application). As provided in this section, to simplify the applicability date provisions and provide certainty to taxpayers, these final regulations, except as otherwise described later in this Applicability Dates section, require taxpayers choosing to apply the final regulations to a taxable year beginning before the applicability date to apply the section 163(j) regulations contained in T.D. 9905 as modified by these final regulations, along with other specified provisions, and require subsequent year application.

Except for §§ 1.163–15 and 1.1256(e)–2, pursuant to section 7805(b)(7), taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules of these final regulations to a taxable year beginning after December 31, 2017,[1] and before March 22, 2021, provided that they consistently apply the section 163(j) regulations contained in T.D. 9905 as modified by these final regulations and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.382–7, 1.383–0, 1.383–1,1.469–9, 1,469–11, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–36, 1.1502–79, 1.1502–90, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905 as modified by these final regulations to that taxable year and each subsequent taxable year.

Pursuant to section 7805(b)(7), taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may apply the provisions of § 1.163–15 or 1.1256(e)–2 of the final regulations for a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that they consistently apply the rules in § 1.163–15 or 1.1256(e)–2, as applicable, to that taxable year and each subsequent taxable year.

Alternatively, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may rely on the rules in the 2020 Proposed Regulations to the extent provided in the 2020 Proposed Regulations.

To the extent that a rule in the 2020 Proposed Regulations is not finalized in these final regulations, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may rely on that rule for a taxable year beginning on or after March 22, 2021, provided that they consistently follow all of the rules in the 2020 Proposed Regulations that are not being finalized to that taxable year and each subsequent taxable year beginning on or before the date the Treasury decision adopting that rule as final is applicable or other guidance regarding continued reliance is issued.

Statement of Availability of IRS Documents

The IRS Notices, Revenue Rulings, and Revenue Procedures cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 13771, 13563, and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. For purposes of E.O. 13771 this rule is regulatory.

These final regulations have been designated by the Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. OIRA has designated these

[1] Under the 2020 Proposed Regulations, for purposes of determining applicability dates, the term ''related party'' has the meaning provided in sections 267(b) and 707(b)(1). Section 267(c)(3) broadens the scope of related parties under section 267(b) by potentially treating individual partners in a partnership as related to a corporation owned by the partnership, even if the individual partners own only a small interest in the partnership. The Treasury Department and the IRS have determined that this broad scope is unnecessary in this context and may impede the ability of certain taxpayers to choose to apply the regulations to pre-applicability taxable years. Accordingly, under these final regulations, for purposes of determining applicability dates, the term ''related party'' is determined without regard to section 267(c)(3).

regulations as economically significant under section 1(c) of the MOA. Accordingly, the OMB has reviewed these regulations.

A. Need for the Final Regulations

The Tax Cuts and Jobs Act (TCJA) substantially modified the statutory rules of section 163(j) to limit the amount of net business interest expense that can be deducted in the current taxable year. Because this limitation on deduction for business interest expense is relatively new, taxpayers would benefit from regulations that explain key terms and calculations. The Treasury Department and the IRS published proposed regulations in December 2018 (2018 Proposed Regulations) and published final regulations in September 2020 (T.D. 9905) to finalize most sections of the 2018 Proposed Regulations. Concurrently with the publication of T.D. 9905, the Treasury Department and the IRS published proposed regulations (2020 Proposed Regulations) to provide additional section 163(j) limitation guidance to T.D. 9905 in response to certain comments to the 2018 Proposed Regulations. The final regulations are needed to bring clarity to instances where the meaning of the statute was unclear and to respond to comments received on the 2020 Proposed Regulations.

B. Background and Overview

Section 163(j), substantially revised by the TCJA, provides a set of statutory rules that impose a limitation on the amount of business interest expense that a taxpayer may deduct for Federal tax purposes. This limitation does not apply to businesses with gross receipts of $25 million or less (inflation adjusted). This provision has the general effect of putting debt-financed investment by businesses on a more equal footing with equity-financed investment, a treatment that Congress believed would lead to a more efficient capital structure for firms. See Senate Budget Explanation of the Bill as Passed by SFC (2017–11–20) at pp. 163–4. Subsequently, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amended section 163(j) to provide special rules relating to the ATI limitation for taxable years beginning in 2019 or 2020.

C. Economic Analysis

1. Baseline

In this analysis, the Treasury Department and the IRS assess the economic effects of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of the final regulations.

2. Summary of Economic Effects

The final regulations provide certainty and clarity to taxpayers regarding terms and calculations that are contained in section 163(j), which was substantially modified by TCJA. In the absence of this clarity, the likelihood that different taxpayers would interpret the rules regarding the deductibility of business interest expense (BIE) differently would be exacerbated. In general, overall economic performance is enhanced when businesses face more uniform signals about tax treatment. Certainty and clarity over tax treatment also reduce compliance costs for taxpayers.

For those situations where taxpayers would generally adopt similar interpretations of the statute even in the absence of guidance, the final regulations provide value by helping to ensure that those interpretations are consistent with the purpose of the statute. For example, the final regulations may specify a tax treatment that few or no taxpayers would adopt in the absence of specific guidance.

The Treasury Department and the IRS project that the final regulations will have an annual economic effect greater than $100 million ($2020) relative to the no-action baseline. This determination is based on the substantial volume of business interest payments in the economy [2] and the general responsiveness of business investment to effective tax rates,[3] one component of which is the deductibility of interest expense. Based on these two factors, even modest changes in the deductibility of interest payments (and in the certainty of that deductibility) provided by the final regulations, relative to the no-action baseline, can be expected to have annual effects greater than $100 million. This claim is particularly likely to hold for the first set of general section 163(j) guidance that is promulgated following major legislation, such as TCJA, and for other major guidance, which the Treasury Department and the IRS have determined includes the final regulations.

Regarding the nature of the economic effects, the Treasury Department and the IRS project that the final regulations will increase investment in the United States and increase the proportion that is debt-financed, relative to the no-action baseline. They have further determined that these effects are consistent with the intent and purpose of the statute. Because the final regulations are projected to lead to a decrease in Federal tax revenue relative to the no-action baseline, there may be an increase in the Federal deficit relative to the no-action baseline. This may lead to a decrease in investment by taxpayers not directly affected by these final regulations, relative to the no-action baseline. This effect should be weighed against the enhanced efficiency arising from the clarity and enhanced consistency with the intent and purpose of the statute provided by these regulations. The Treasury Department and the IRS have determined that the final regulations provide a net benefit to the U.S. economy relative to the no-action baseline.

The Treasury Department and the IRS have not undertaken more precise quantitative estimates of these effects because many of the definitions and calculations under section 163(j) are new and many of the economic decisions that are implicated by these final regulations involve highly specific taxpayer circumstances. The Treasury Department and the IRS do not have readily available data or models to estimate with reasonable precision the types and volume of different financing arrangements that taxpayers might undertake under the final regulations versus the no-action baseline.

In the absence of such quantitative estimates, the Treasury Department and the IRS have undertaken a qualitative analysis of the economic effects of the final regulations relative to the no-action baseline and relative to alternative regulatory approaches. This analysis is presented in Part I.C.3 of this Special Analyses.

No comments on the economic analysis of the 2020 Proposed Regulations were received.

3. Economic Effects of Specific Provisions

a. Definition of Interest

T.D. 9905 set forth several categories of amounts and transactions that generate interest for purposes of section 163(j). The final regulations provide further guidance on the definition of interest relevant to the calculation of interest expense and interest income. In particular, the final regulations provide rules under which the dividends paid by a regulated investment company (RIC) that earns net business interest income (BII) (referred to as section

[2] Interest deductions in tax year 2013 for corporations, partnerships, and sole proprietorships were approximately $800 billion.

[3] See E. Zwick and J. Mahon, ''Tax Policy and Heterogeneous Investment Behavior,'' at *American Economic Review* 2017, 107(1): 217–48 and articles cited therein.

163(j) interest dividends) are to be treated as interest income by the RIC's shareholders. That is, under the final regulations, certain interest income earned by the RIC and paid to a shareholder as a dividend is treated as if the shareholder earned the interest income directly for purposes of section 163(j).

These final regulations clarify that reported dividends paid by RICs can include designations of BII for the purposes of the section 163(j) limitation. This clarification makes clear that investment through RICs is treated, for purposes of the section 163(j) limitation, similarly to investment through other possible debt instruments. To the extent that taxpayers believed, in the absence of the final regulations, that dividends paid by RICs are not treated as BII for the purposes of the section 163(j) limitation, then taxpayers may respond to the final regulations by increasing investment in RICs. The Treasury Department and the IRS have determined that this treatment is consistent with the intent and purpose of the statute.

Affected Taxpayers. The Treasury Department and the IRS have determined that the rules regarding section 163(j) interest dividends will potentially affect approximately 10,000 RICs. The Treasury Department and the IRS do not have readily available data on the number of RIC shareholders that would receive section 163(j) interest dividends that the shareholder could treat as BII for purposes of the shareholder's section 163(j) limitation. They further do not have data on the volume of dividends that would be eligible for this treatment.

b. Provisions Related to Partnerships

i. Trading Partnerships

Section 163(j) limits the deductibility of interest expense at the partnership level. The final regulations address commenter concerns about the interaction between this section 163(j) limitation and the section 163(d) partner level limitation on interest expense that existed prior to TJCA. Under logic described in the preamble to the 2018 Proposed Regulations, section 163(j) limitations would apply at the partnership level while section 163(d) limitations would apply at the partner level and these tests would be applied independently. Commenters suggested and the Treasury Department and the IRS have agreed that the correct interpretation of the statute is to exempt interest expense that is limited at the partner level by section 163(d) from the partnership-level section 163(j) limitation in accordance with the language of section 163(j)(5).

The final regulations provide that interest expense at the partnership level that is allocated to non-materially participating partners subject to section 163(d) is not included in the section 163(j) limitation calculation of the partnership. Generally, the section 163(d) limitation is more generous than the section 163(j) limitation. Relative to the 2018 Proposed Regulations, this change may encourage these partners to incur additional interest expense because they will be less likely to be limited in their ability to use it to offset other income. Commenters argued that exempting from section 163(j) any interest expense allocated to non-materially participating partners subject to section 163(d) will treat this interest expense in the same way as the interest expense generated through separately managed accounts, which are not subject to section 163(j) limitations.

The Treasury Department and the IRS project that the final regulations will result in additional investment in trading partnerships and generally higher levels of debt in any given trading partnership relative to the 2018 Proposed Regulations. Because investments in trading partnerships may be viewed as economically similar to investments in separately managed accounts arrangements, they further project that the final regulations, by making the tax treatments of these two arrangements generally similar, will improve U.S. economic performance relative to the no-action baseline.

Number of Affected Taxpayers. The Treasury Department and the IRS have determined that the rules regarding trading partnerships will potentially affect approximately 275,000 partnerships, not including their partners. This number was reached by determining, using data for the 2017 taxable year, the number of Form 1065 and Form 1065–B filers that (1) completed Schedule B to Form 1065 and marked box b, c, or d in question 1 to denote limited partnership, limited liability company, or limited liability partnership status; and (2) have a North American Industry Classification System (NAICS) code starting with 5231 (securities and commodity contracts intermediation and brokerage), 5232 (securities and commodity exchanges), 5239 (other financial investment activities), or 5259 (other investment pools and funds). Additionally, the Treasury Department and the IRS have determined that the rules regarding publicly traded partnerships will potentially affect approximately 80 partnerships, not including their partners. This number was reached by determining, using data for the 2017 taxable year, the number of Form 1065 and 1065–B filers with gross receipts exceeding $25 million that answered ''yes'' to question 5 on Schedule B to Form 1065 denoting that the entity is a publicly traded partnership. The Treasury Department and the IRS do not have readily available data on the number of filers that are tax shelters that are potentially affected by these provisions.

ii. Self-Charged Lending

The 2018 Proposed Regulations requested comments on the treatment of lending transactions between a partnership and a partner (self-charged lending transactions). Suppose that a partnership receives a loan from a partner and allocates the resulting interest expense to that partner. Prior to TCJA, the interest income and interest expense from this loan would net precisely to zero on the lending partner's tax return. Under section 163(j) as revised by TCJA, however, the partnership's interest expense deduction may now be limited. Therefore, in absence of specific regulatory guidance, the lending partner may receive interest income from the partnership accompanied by less-than-fully-offsetting interest expense. Instead, the lending partner would receive excess business interest expense (EBIE), which would not be available to offset his personal interest income. This outcome has the effect of increasing the cost of lending transactions between partners and their partnerships relative to otherwise similar financing arrangements.

To avoid this outcome, the final regulations treat the lending partner's interest income from the loan as excess business interest income (EBII) from the partnership, but only to the extent of the partner's share of any EBIE from the partnership for the taxable year. This allows the interest income from the loan to be offset by the EBIE. The business interest expense (that is, BIE) of the partnership attributable to the lending transaction will thus be treated as BIE of the partnership for purposes of applying section 163(j) to the partnership.

The Treasury Department and the IRS expect that the final regulations will lead a higher proportion of self-charged lending transactions in partnership financing, relative to the no-action baseline. In a self-charged lending transaction, the lending partner is on both sides of the transaction. It is the lender and, through the partnership, the borrower. Because of this, debt from

self-charged lending transactions is generally viewed as less risky than traditional debt, as both the lender and the borrower are incentivized to repay the loan without default. Therefore, the Treasury Department and the IRS believe that the better policy choice is to not subject self-charged lending transactions to section 163(j). The Treasury Department and the IRS further project that the final regulations will increase the proportion of partnership financing that is debt-financed relative to the no-action baseline. The Treasury Department and the IRS have determined that these effects are consistent with the intent and purpose of the statute.

Number of Affected Taxpayers. The Treasury Department and the IRS do not have readily available data to determine the number of taxpayers affected by rules regarding self-charged interest because no reporting modules currently connect these payments by and from partnerships.

c. Provisions Related to Controlled Foreign Corporations (CFCs)

i. How To Apply Section 163(j) When CFCs Have Shared Ownership

T.D. 9905 clarified that section 163(j) and the section 163(j) regulations generally apply to determine the deductibility of a CFC's BIE for tax purposes in the same manner as these provisions apply to a domestic corporation. The final regulations provide additional rules and guidance as to how section 163(j) applies to CFCs, including when CFCs have shared ownership and are eligible to be members of CFC groups.

The Treasury Department and the IRS considered three options with respect to the application of section 163(j) to CFC groups. The first option was to apply the 163(j) limitation to CFCs on a stand-alone basis, regardless of whether CFCs have shared ownership. However, if section 163(j) were applied on a stand-alone basis, business interest deductions of individual CFCs might be limited by section 163(j) even when, if calculated on a group basis, business interest deductions would not be limited.

Taxpayers could restructure or ''self-help'' to mitigate the effects of the section 163(j) limitation. Such an option would lead to restructuring costs for the taxpayer (relative to the third option, described later) with no corresponding economically productive activity.

The second option, which was proposed in the 2018 Proposed Regulations, was to allow an election to treat related CFCs in a similar manner as partnerships with respect to their U.S. shareholders. Under this option, while the section 163(j) rules would still be computed at the individual CFC level, the business interest expense of each CFC group member that was subject to section 163(j) was limited to its share of the net business interest expense of the CFC group, and the ''excess taxable income'' of a CFC could be passed up from lower-tier CFCs to upper-tier CFCs and U.S. shareholders in the same group. Excess taxable income is the amount of income by which a CFC's ATI exceeds the threshold amount of ATI below which there would be disallowed BIE.

Comments to the 2018 Proposed Regulations suggested that computing a section 163(j) limitation for each CFC and rolling up CFC excess taxable income would be burdensome for taxpayers, especially since some multinational organizations have hundreds of CFCs. In addition, comments noted that the ability to pass up excess taxable income would encourage multinational organizations to restructure such that CFCs with low interest payments and high ATI are lower down the ownership chain and CFCs with high interest payments and low ATI are higher up in the chain of ownership. Similar to the first option, this restructuring would impose costs on taxpayers without any corresponding productive economic activity.

The third option, which is adopted by the Treasury Department and the IRS in the final regulations, was to allow taxpayers to elect to apply the section 163(j) rules to CFC groups on an aggregate basis, similar to the rules applicable to U.S. consolidated groups. This option was suggested by many comments and is the approach taken in the final regulations. Under this option, a single section 163(j) limitation is computed for a CFC group by summing the items necessary for this computation (for example, current-year BIE and ATI) across all CFC group members. The CFC group's limitation is then allocated to each CFC member using allocation rules similar to those that apply to U.S. consolidated groups.

The choice to use the consolidated approach versus the stand-alone entity approach may affect the amount of interest that can be deducted. The amount of interest that can be deducted may affect the amount of subpart F income and tested income for purposes of determining the amount of inclusions under sections 951 and 951A. However, the consolidated approach applies only for purposes of computing the section 163(j) limitation and not for purposes of applying any other Code provision, such as section 951 or 951A.

This option reduces the compliance burden on taxpayers in comparison to applying the section 163(j) rules on an individual CFC basis and calculating the excess taxable income to be passed up from lower-tier CFCs to higher-tier CFCs. In comparison to the first and second options, this option also removes the incentive for taxpayers to undertake costly restructuring, since the location of interest payments and ATI among CFC group members will not affect the interest disallowance for the group. The Treasury Department and the IRS have not estimated this difference in compliance costs because they do not have readily available data or models to do so.

The final regulations also set out a number of rules to govern membership in a CFC group. These rules specify which CFCs can be members of the same CFC group, how CFCs with U.S. effectively connected income (ECI) should be treated, and the timing for making or revoking a CFC group election. These rules provide clarity and certainty to taxpayers regarding the CFC group election for section 163(j). In the absence of these regulations, taxpayers may make financing decisions or undertake restructuring based on differential interpretations of the appropriate tax treatment, an outcome that is generally inefficient relative to decisions based on the more uniform interpretation provided by the final regulations.

Number of Affected Taxpayers. The set of taxpayers affected by this rule includes any taxpayer with ownership in a CFC that is a member of a CFC group that has average gross receipts over a three-year period in excess of $25 million. The Treasury Department and the IRS estimate that there are approximately 7,500 taxpayers with two or more CFCs based on counts of e-filed tax returns for tax years 2015–2017. This estimate includes C corporations, S corporations, partnerships, and individuals with CFC ownership.

ii. Foreign Income Taxes and ATI of a CFC

The 2020 Proposed Regulations provided that the ATI of a CFC is determined by taking into account a deduction for foreign income taxes. The preamble to the 2020 Proposed Regulations requested comments on whether, and the extent to which, the ATI of a CFC should be determined without regard to a deduction for foreign income taxes. The final regulations provide that the ATI of a CFC is determined without regard to a deduction for foreign income taxes that are eligible to be claimed as a foreign tax

credit. Thus, regardless of whether an election is made to claim a credit for these foreign income taxes, the foreign income taxes do not reduce ATI.

The Treasury Department and the IRS considered three options, based on comments received, in determining the extent to which foreign income taxes paid by a CFC should be taken into account in determining its ATI. The first option would not take into account a deduction for foreign income taxes imposed by the national government of the country in which a CFC is organized or a tax resident, but would take into account a deduction for taxes imposed by sub-national levels of government. This would result in treating a CFC in an analogous manner to a domestic corporation, which does not deduct Federal income taxes (but may deduct state and foreign taxes) in determining its ATI. However, this option would result in the ATI of a CFC being determined in a different manner than the ATI of a domestic corporation doing business through a foreign branch that elects to credit foreign income taxes (as discussed in the next option). Furthermore, this option would increase (relative to the next option) the administrative and compliance burdens of taxpayers required to determine which foreign income taxes paid by a CFC are imposed by a national government and which are imposed by sub-national levels of government.

The second option considered would not take into account foreign income taxes for which an election is made to claim a foreign tax credit. This option would conform the ATI of a CFC with that of a domestic corporation doing business through a foreign branch. If a domestic corporation doing business through a foreign branch elects to claim a foreign tax credit, the deduction for foreign income taxes is disallowed under section 275(a)(4) and is not taken into account in determining the domestic corporation's ATI. However, unlike a foreign branch that has a single owner, a CFC may have multiple shareholders. Because the election to credit foreign income taxes is made at the shareholder-level, this option would require a CFC to determine which of its shareholders elects to credit foreign income taxes, thereby increasing the administrative and compliance burdens. Furthermore, some shareholders of a CFC may elect to credit foreign income taxes, while other shareholders of the CFC may not elect or may not be eligible to elect a credit (for example, because the shareholder is a foreign corporation). Since the section 163(j) limitation is determined at the CFC-level, rather than on a shareholder-by-shareholder basis, this option could result in one shareholder being affected by the election of an unrelated shareholder of the same CFC, an outcome that would generally lead to economically inefficient decision-making.

The third option, which is adopted by the Treasury Department and the IRS in the final regulations, does not take into account a deduction for foreign income taxes that are eligible to be claimed as a foreign tax credit for purposes of calculating a CFC's ATI, regardless of whether the CFC's U.S. shareholders have made an election to claim a foreign tax credit. Relative to the first and second options, this option minimizes the administrative and compliance burden of determining ATI of a CFC, and also results in the greatest amount of ATI and section 163(j) limitation. In addition, this option does not treat CFCs located in high-tax countries differently than CFCs located in low-tax countries. Otherwise similar CFCs will have similar ATIs regardless of their foreign income taxes. In this way, the rule does not penalize U.S. shareholders of CFCs with high foreign taxes.

Number of Affected Taxpayers. The population of affected taxpayers includes any taxpayer that is a U.S. shareholder of a CFC. The Treasury Department and the IRS estimate that there are approximately 10,000 to 11,000 affected taxpayers based on a count of e-filed tax returns for tax years 2015–2017. These counts include C corporations, S corporations, partnerships, and individuals with CFC ownership that meet a $25 million three-year average gross receipts threshold. The Treasury Department and the IRS do not have readily available data on the number of filers that are tax shelters that are potentially affected by these provisions.

d. Election To Use 2019 ATI To Determine 2020 Section 163(j) Limitation for Consolidated Groups

The final regulations provide that if a taxpayer filing as a consolidated group elects to substitute its 2019 ATI for its 2020 ATI, that group can use the consolidated group ATI for the 2019 taxable year, even if membership of the consolidated group changed in the 2020 taxable year. For example, suppose consolidated group C has three members in the 2019 taxable year, P, the common parent of the consolidated group, and S1 and S2, which are both wholly owned by P. In the 2019 taxable year, each member of consolidated group C had $100 of ATI on a stand-alone basis, and that consolidated group C had $300 of ATI. In the 2020 taxable year, consolidated group C sells all of the stock of S2 and acquires all of the stock of a new member, S3. In the 2019 taxable year, S3 had $50 in ATI on a stand-alone basis. Under the final regulations, consolidated group C may elect to use $300 in ATI from 2019 as a substitute for its ATI in the 2020 taxable year.

The Treasury Department and the IRS considered as an alternative basing the 2019 ATI on the membership of the consolidated group in the 2020 taxable year. In the example in the previous paragraph, this approach would subtract out the $100 in ATI from S2 and add the $50 in ATI from S3, for a total of $250 in 2019 ATI that could potentially be substituted for 2020 ATI for consolidated group C. This approach would add burden to taxpayers relative to the final regulations by requiring additional calculations and tracking of ATI on a member-by-member basis to determine the amount of 2019 ATI that can be used in the 2020 taxable year without providing any general economic benefit.

In addition, the 2019 tax year will have closed for most taxpayers by the time the final regulations will be published. This implies that a final rule based on the consolidated group composition in the 2019 taxable year to calculate the amount of 2019 ATI that can be used in the 2020 taxable year will, relative to the alternative approach of using the composition in the 2020 taxable year, reduce the incentive for taxpayers to engage in costly mergers, acquisitions, or divestures to achieve a favorable tax result for those taxpayers for whom the 2020 taxable year has not closed by the time the final regulations are published.

Number of Affected Taxpayers. The Treasury Department and the IRS estimate that approximately 34,000 corporate taxpayers filed a consolidated group tax return for tax year 2017. This represents an upper-bound of the number of taxpayers affected by the final rule as not all consolidated groups would need to calculate the amount of section 163(j) interest limitation in tax years 2019 and 2020.

II. Paperwork Reduction Act

The collection of information in the final regulations has been submitted to the OMB for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) (PRA). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

Books or records relating to a collection of information must be

retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by section 6103 of the Code.

iv. Collections of Information

The collections of information subject to the PRA in the final regulations are in §§ 1.163(j)–6(d)(5), 1.163(j)–6(g)(4), 1.163(j)–7(e)(5)(iv), 1.163(j)–7(e)(6), and 1.163(j)–7(h)(5).

The collections of information in §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4) are required to make two elections relating to changes made to section 163(j) by the CARES Act. The election under § 1.163(j)–6(d)(5) is for a passthrough taxpayer to use the taxpayer's ATI for the last taxable year beginning in 2019 as its ATI for any taxable year beginning in 2020, in accordance with section 163(j)(10)(B). The election under § 1.163(j)–6(g)(4) relates to EBIE of a partnership for any taxable year beginning in 2019 that is allocated to a partner. Section 163(j)(10)(A)(ii)(II) provides that, unless the partner elects out, in 2020, the partner treats 50 percent of the EBIE as not subject to the section 163(j) limitation. If the partner elects out, the partner treats all EBIE as subject to the same limitations as other EBIE allocated to the partner.

Revenue Procedure 2020–22 describes the time and manner for making these elections. For both elections, taxpayers make the election by timely filing a Federal income tax return or Form 1065, including extensions, an amended Federal income tax return, amended Form 1065, or administrative adjustment request, as applicable. More specifically, taxpayers complete the Form 8990, ''Limitation on Business Interest Expense under Section 163(j),'' using the taxpayer's 2019 ATI and/or not applying the rule in section 163(j)(10)(ii)(II), as applicable. No formal statements are required to make these elections. Accordingly, the reporting burden associated with the collections of information in §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4) will be reflected in the IRS Form 8990 PRA Submissions (OMB control number 1545–0123).

The collections of information in § 1.163(j)–7 are required for taxpayers (1) to make or revoke an election under § 1.163(j)–7(e)(5)(iv) to apply section 163(j) to a CFC group (CFC group election) and to file an annual information statement to demonstrate how the CFC group calculated its section 163(j) limitation under § 1.163(j)–7(e)(6) (annual information statement), or (2) to make an annual election to exempt a CFC or CFC group from the section 163(j) limitation under § 1.163(j)–7(h)(5) (safe-harbor election). The CFC group election or revocation of the CFC group election are made by attaching a statement to the US shareholder's annual return. Similarly, the annual information statement must be attached to the US shareholder's annual return. The CFC group election remains in place until revoked and may not be revoked for any period beginning before 60 months following the period for which it is initially made. The safe-harbor election is made on an annual basis.

Under § 1.964–1(c)(3)(i), to make an election on behalf of a foreign corporation, the controlling domestic shareholder provides a statement with its return and notice of the election to the minority shareholders under § 1.964–1(c)(3)(ii) and (iii). See also § 1.952–2(b)–(c). These collections are necessary to ensure that the election is properly effectuated, and that taxpayers properly report the amount of interest that is potentially subject to the limitation.

B. Future Modifications to Forms To Collect Information

At this time, the Treasury Department and the IRS are considering modifications to the Form 8990, ''Limitation on Business Interest Expense IRC 163(j),'' with regard to the elections under section 163(j)(10) regarding the election under §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4), the CFC group election, annual information statement, and safe-harbor election. Any modifications to Form 8990 would not be effective until the form cycle for the 2021 taxable year. For the PRA, the reporting burden of Form 8990 is associated with OMB control number 1545–0123. In the 2018 Proposed Regulations, Form 8990 was estimated to be required by fewer than 92,500 taxpayers.

If an additional information collection requirement is imposed through these regulations in the future, for purposes of the PRA, any reporting burden associated with these regulations will be reflected in the aggregated burden estimates and the OMB control numbers for general income tax forms or the Form 8990, ''Limitation on Business Interest Expense Under Section 163(j)''.

The forms are available on the IRS website at:

Form	OMB No.	IRS website link	Status
Form 1040	1545–0074	*https://www.irs.gov/pub/irs-pdf/f1040.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i1040gi.pdf*).	Published in the **Federal Register** on 10/30/2020. Public comment period ends 12/29/2020.
	Link: *https://www.federalregister.gov/documents/2020/10/30/2020-24139/proposed-extension-of-information-collection-request-submitted-for-public-comment-comment-request.*		
Form 1120	1545–0123	*https://www.irs.gov/pub/irs-pdf/f1120.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i1120.pdf.*).	Published in the **Federal Register** on 11/3/2020. Public comment period ends January 4, 2021.
Form 1120S	.....	*https://www.irs.gov/pub/irs-pdf/f1120s.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i1120s.pdf.*).	
Form 1065	.....	*https://www.irs.gov/pub/irs-pdf/f1065.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i1065.pdf.*).	
Form 1120–REIT.	.....	*https://www.irs.gov/pub/irs-pdf/f1120rei—2018.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i1120rei.pdf.*).	
Form 8990	.....	*https://www.irs.gov/pub/irs-pdf/f8990_accessible.pdf* (Instructions: *https://www.irs.gov/pub/irs-pdf/i8990.pdf.*).	

Form	OMB No.	IRS website link	Status
	Link: *https://www.federalregister.org/documents/2020/11/03/2020-24251/proposed-collection-comment-request-for-forms-1065-1066-1120-1120-c-1120-f-1120-h-1120-nd-1120-s.*		

In addition, when available, drafts of IRS forms are posted for comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.htm.* IRS forms are available at *https://www.irs.gov/forms-instructions.* Forms will not be finalized until after they have been approved by OMB under the PRA.

C. Burden Estimates

The following estimates for the collections of information in the final regulations are based on the most recently available Statistics of Income (SOI) tax data.

For the collection of income in § 1.163(j)–6(d)(5), where a passthrough taxpayer elects to use the taxpayer's ATI for the last taxable beginning in 2019 as the taxpayer's ATI for any taxable year beginning in 2020, the most recently available 2017 SOI tax data indicates that, on the high end, the estimated number of respondents is 49,202. This number was determined by examining, for the 2017 tax year, Form 1065 and Form 1120–S filers with greater than $26 million in gross receipts that have reported interest expense, and do not have an NAICS code that is associated with a trade or business that normally would be excepted from the section 163(j) limitation.

For the collection of information under § 1.163(j)–6(g)(4), in which a partner elects out of treating 50 percent of any EBIE allocated to the partner in 2019 as not subject to a limitation in 2020, the Treasury Department and the IRS estimate that only taxpayers that actively want to reduce their deductions will make this election. The application of the base erosion minimum tax under section 59A depends, in part, on the amount of a taxpayer's deductions. Accordingly, the Treasury Department and the IRS estimate that taxpayers that are subject to both the base erosion minimum tax under section 59A and section 163(j) are the potential filers of this election. Using the 2017 SOI tax data, the Treasury Department estimates that 1,182 firms will make the election. This estimate was determined by examining three criteria: First, the number of taxpayers subject to section 59A, namely, C corporations with at least $500,000,000 in gross receipts, second, the portion of those taxpayers that do not have an NAICS code associated with a trade or business that is generally not subject to the section 163(j) limitation (2211 (electric power generation, transmission and distribution), 2212 (natural gas distribution), 2213 (water, sewage and other systems), 111 or 112 (farming), 531 (real property)), and, third, the portion of taxpayers satisfying the first two criteria that received a Form K–1, ''Partner's Share of Income, Deductions, Credits, etc.''

The reporting burdens associated with the information collections in §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4) are included in the aggregated burden estimates for OMB control numbers 1545–0074 in the case of individual filers and 1545–0123 in the case of business filers. The overall burden estimates associated with those OMB control numbers are aggregate amounts that relate to the entire package of forms associated with the applicable OMB control number and will in the future include, but not isolate, the estimated burden of the tax forms that will be created or revised as a result of the information collections in these regulations. No burden estimates specific to §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4) of the final regulations are currently available.

The Treasury Department and the IRS request comments on all aspects of the forms that reflect the information collection burdens related to the final regulations, including estimates for how much time it would take to comply with the paperwork burdens related to the forms described and ways for the IRS to minimize the paperwork burden.

For the collections of information in § 1.163(j)–7, namely the CFC group election and annual statement, and the safe-harbor election, and the corresponding notice under § 1.964–1(c)(3)(iii), the most recently available 2017 SOI tax data indicates that, on the high end, the estimated number of respondents is 4,980 firms. This number was determined by examining, for the 2017 tax year, Form 1040, Form 1120, Form 1120–S, and Form 1065 filers with greater than $26 million in gross receipts that filed a Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, where an interest expense amount was reported on Schedule C of the Form 5471.

The estimated number of respondents that could be subject to the collection of information for the CFC group or safe-harbor election is 4,980. The estimated annual burden per respondent/recordkeeper varies from 0 to 30 minutes, depending on individual circumstances, with an estimated average of 15 minutes. The estimated total annual reporting and/or recordkeeping burden is 1,245 hours (4,980 respondents * 15 minutes). The estimated annual cost burden to respondents is $95 per hour. Accordingly, we expect the total annual cost burden for the CFC group election and safe-harbor election statements to be $118,275 (4,980 * .25 * $95).

III. Regulatory Flexibility Act

It is hereby certified that the final regulations will not have a significant economic impact on a substantial number of small entities.

This certification can be made because the Treasury Department and the IRS have determined that the number of small entities that are affected as a result of the regulations is not significant. These rules do not disincentivize taxpayers from their operations, and any burden imposed is not significant because the cost of implementing the rules, if any, is low.

As discussed in the 2018 Proposed Regulations, section 163(j) provides exceptions for which many small entities will qualify. First, under section 163(j)(3), the limitation does not apply to any taxpayer, other than a tax shelter under section 448(a)(3), which meets the gross receipts test under section 448(c) for any taxable year. A taxpayer meets the gross receipts test under section 448(c) if the taxpayer has average annual gross receipts for the 3-taxable year period ending with the taxable year that precedes the current taxable year that do not exceed $26,000,000. The gross receipts threshold is indexed annually for inflation. Because of this threshold, the Treasury Department and the IRS project that entities with 3-year average gross receipts below $26 million will not be affected by these regulations except in rare cases.

Section 163(j) provides that certain trades or businesses are not subject to the limitation, including the trade or business of performing services as an employee, electing real property trades or businesses, electing farming businesses, and certain utilities as defined in section 163(j)(7)(A)(iv). Under the 2018 Proposed Regulations, taxpayers that otherwise qualified as

real property trades or businesses or farming businesses that satisfied the small business exemption in section 448(c) were not eligible to make an election to be an electing real property trade or business or electing farming business. Under T.D. 9905, however, those taxpayers are eligible to make an election to be an electing real property trade or business or electing farming business. Additionally, T.D. 9905 provides that certain utilities not otherwise excepted from the limitation can elect for a portion of their non-excepted utility trade or business to be excepted from the limitation. Any economic impact on any small entities as a result of the requirements in the final regulations, not just the requirements that impose a PRA burden, is not expected to be significant because the cost of implementing the rules, if any, is low.

The Treasury Department and the IRS do not have readily available data on the number of filers that are tax shelters, as defined in section 448(a)(3), that are potentially affected by these provisions. As described in more detail earlier in this preamble, the final regulations cover several topics, including, but not limited to, self-charged interest, the treatment of section 163(j) in relation to trader funds, the impact of section 163(j) on publicly traded partnerships, and the application of section 163(j) to United States shareholders of controlled foreign corporations.

The Treasury Department and the IRS do not have readily available data to determine the number of taxpayers affected by rules regarding self-charged interest because no reporting modules currently connect these payments by and from partnerships. Additionally, the Treasury Department and the IRS do not have readily available data to determine the number of taxpayers affected by rules regarding debt proceeds distributed from a taxpayer account or from cash. However, the rules do not impose a significant paperwork or implementation cost burden on taxpayers. Under Notice 89–35, taxpayers have been required to maintain books and records to properly report the tax treatment of interest. The rules in § 1.163–15 are a finalization of the rules in section VI of Notice 89–35, which extends the period in § 1.163–8T(c)(4)(iii)(B) from 15 to 30 days to determine whether debt proceeds have been distributed from a particular account.

As shown in the following table, the Treasury Department and the IRS estimate that approximately 276 trading partnerships will be affected by these rules. The table was calculated using data for the 2018 taxable year, the number of Form 1065 and Form 1065–B filers, with more than $26 million in gross receipts but less than the amount considered to be a small entity for purposes of this Regulatory Flexibility Act analysis, that (1) completed Schedule B to Form 1065 and marked box b, c, or d in question 1 to denote limited partnership, limited liability company or limited liability partnership status; and (2) have a North American Industry Classification System (NAICS) code starting with 5231 (securities and commodity contracts intermediation and brokerage), 5232 (securities and commodity exchanges), 5239 (other financial investment activities) or 5259 (other investment pools and funds).

FORM 1065 AND 1065–B FILERS + NAICS CODES + GROSS RECEIPTS RANGE + SCHEDULE B, QUESTION 1 BOX b, c, OR d MARKED

NAICS code (description)	Gross receipts range	Schedule B, question 1 box b, c or d
5231 (securities and commodity contracts intermediation and brokerage)	>$26M but not more than $41.5M	22
5232 (securities and commodity exchanges)	>$26M but not more than $41.5M	0
6239 (other financial investment activities)	>$26M but not more than $41.5M	242
5259 (other investment pools and funds)	>$26M but not more than $35M	12
Total		276

Additionally, the Treasury Department and the IRS have determined that the rules regarding publicly traded partnerships might affect approximately 71 taxpayers. This number was reached by determining, using data for the 2018 taxable year, the number of Form 1065 and 1065–B filers with gross receipts exceeding $25 million that answered ''yes'' to question 5 on Schedule B to Form 1065 denoting that the entity is a publicly traded partnership.

As noted earlier, the final regulations do not impose any new collection of information on these entities. These final regulations actually assist small entities in meeting their filing obligations by providing definitive advice on which they can rely.

For the section 163(j)(10) elections for passthrough taxpayers under final §§ 1.163(j)–6(d)(5) and 1.163(j)–6(g)(4), most small taxpayers do not need to make the elections because, as discussed above, they are not subject to the section 163(j) limitation. For small taxpayers that are subject to the limitation, the cost to implement the election is low. Pursuant to Revenue Procedure 2020–22, these passthrough taxpayers simply complete the Form 8990 as if the election has been made. Accordingly, the burden of complying with the elections, if needed, is no different than for taxpayers who do not make the elections.

The persons potentially subject to final § 1.163(j)–7 are U.S. shareholders of one or more CFCs for which BIE is reported, and that (1) have average annual gross receipts for the 3-taxable year period ending with the taxable year that precedes the current taxable year exceeding $26,000,000, and (2) want to make the CFC group election or safe-harbor election. Section 1.163(j)–7 of the final regulations requires such taxpayers to attach a statement to their return providing basic information regarding the CFC group or standalone CFC.

As discussed in the PRA section of this preamble, the reporting burden for both statements is estimated at 0 to 30 minutes, depending on individual circumstances, with an estimated average of 15 minutes for all affected entities, regardless of size. The estimated monetized burden for compliance is $95 per hour.

Accordingly, the Secretary certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding this final rule was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business. No comments on the notice

were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. These final regulations do not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. These final regulations do not have federalism implications and do not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

VI. Congressional Review Act

The Administrator of OIRA has determined that this is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (CRA). Under section 801(3) of the CRA, a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Notwithstanding this requirement, section 808(2) of the CRA allows agencies to dispense with the requirements of section 801 when the agency for good cause finds that such procedure would be impracticable, unnecessary, or contrary to the public interest and the rule shall take effect at such time as the agency promulgating the rule determines. Pursuant to section 808(2) of the CRA, the Treasury Department and the IRS find, for good cause, that a 60-day delay in the effective date is unnecessary and contrary to the public interest.

These final regulations resolve ambiguity with respect to the statute and certain aspects of the 2020 Proposed Regulations, prevent abuse through the application of several anti-abuse rules, and grant taxpayer relief that would not be available based solely on the statute. Following the amendments to section 163(j) by the TCJA, the Treasury Department and the IRS published the proposed regulations to provide certainty to taxpayers. In particular, as demonstrated by the wide variety of public comments in response to the proposed regulations received after the publication of the final regulations, taxpayers continue to express uncertainty regarding the proper application of the statutory rules and the final regulations under section 163(j). This uncertainty extends to the application of a number of important temporary provisions in section 163(j) enacted as part of the CARES Act that were intended to provide relief for taxpayers impacted by COVID–19. The final regulations provide rules that are relevant to the application of these taxpayer-favorable provisions. Certainty with respect to these temporary provisions is essential so that taxpayers can accurately model the impact of these provisions on their liquidity in order to make timely informed business decisions during the limited periods in which these provisions are in place. Furthermore, in order to make informed business decisions, taxpayers will need to consider the potentially complex interaction of these temporary provisions, and section 163(j) more generally, with other Code provisions (for example, sections 59A, 172, and 250), which further heightens the need for prompt guidance. Consistent with Executive Order 13924 (May 19, 2020), the Treasury Department and the IRS have therefore determined that an expedited effective date of the final regulations would ''give businesses . . . the confidence they need to re-open by providing guidance on what the law requires.'' 85 FR 31353–4. Accordingly, the Treasury Department and the IRS have determined that the rules in this Treasury decision will take effect on the date it is filed with the Office of the Federal Register for public inspection.

Drafting Information

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Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.163–15 is added to read as follows:

§ 1.163 –15 Debt Proceeds Distributed from Any Taxpayer Account or from Cash.

(a) *In general.* Regardless of paragraphs (c)(4) and (5) of § 1.163–8T, in the case of debt proceeds deposited in an account, a taxpayer that is applying § 1.163–8T or § 1.163–14 may treat any expenditure made from any account of the taxpayer, or from cash, within 30 days before or 30 days after debt proceeds are deposited in any account of the taxpayer as made from such proceeds to the extent thereof. Similarly, in the case of debt proceeds received in cash, a taxpayer that is applying § 1.163–8T or § 1.163–14 may treat any expenditure made from any account of the taxpayer, or from cash, within 30 days before or 30 days after debt proceeds are received in cash as made from such proceeds to the extent thereof. For purposes of this section, terms used have the same meaning as in § 1.163–8T(c)(4) and (5).

(b) *Applicability date.* This section applies to taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in this section to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of

the rules in this section to that taxable year and each subsequent taxable year.

■ **Par. 3.** Section 1.163(j)–0 is amended by:

■ 1. Adding entries for §§ 1.163(j)–1(b)(1)(iv)(A)(*4*) and 1.163(j)–1(b)(1)(iv)(B)(*1*) and (*2*).

■ 2. Revising the entry for § 1.163(j)–1(b)(1)(iv)(C).

■ 3. Adding entries for § 1.163(j)–1(b)(1)(iv)(E) through (G).

■ 4. Revising the entries for § 1.163(j)–1(b)(22)(iii)(F) and (b)(35).

■ 5. Adding entries for §§ 1.163(j)–1(c)(4), 1.163(j)–2(b)(3)(i) through (iv), and 1.163(j)–2(d)(3).

■ 6. Revising the entries for §§ 1.163(j)–2(k) and 1.163(j)–6(c)(1) through (3).

■ 7. Adding entries for §§ 1.163(j)–6(c)(4), 1.163(j)–6(d)(3) through (5), 1.163(j)–6(e)(5) and (6), 1.163(j)–6(f)(1)(iii), 1.163(j)–6(g)(4), and 1.163(j)–6(l)(4)(iv).

■ 8. Revising the entries for §§ 1.163(j)–6(n) and (p), 1.163(j)–7(c) through (f) and (h) through (m).

■ 9. Adding entries for § 1.163(j)–7(g)(3) and (4).

■ 10. Revising the entries for §§ 1.163(j)–10(c)(5)(ii)(D) and 1.163(j)–10(f).

The revisions and additions read as follows:

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* * * * *

■ **Par. 4.** Section 1.163(j)–1 is amended by:
■ 1. In paragraph (b)(1)(iv)(A)(*1*), adding the text ''and paragraphs (b)(1)(iv)(B) and (E)'' after the text ''paragraphs (b)(1)(ii)(C), (D), and (E)''.
■ 2. Revising paragraphs (b)(1)(iv)(A)(*2*) and (*3*).
■ 3. Adding paragraph (b)(1)(iv)(A)(*4*).
■ 4. Revising paragraphs (b)(1)(iv)(B), (C), and (D).
■ 5. Adding paragraphs (b)(1)(iv)(E), (F), and (G).
■ 6. Revising paragraphs (b)(1)(viii)(A) through (D).
■ 7. Adding paragraph (b)(1)(viii)(E).
■ 8. Adding paragraphs (b)(22)(iii)(F) and (b)(35).
■ 9. In paragraph (c)(1), removing ''paragraphs (c)(2) and (3)'' from the first sentence and adding ''paragraphs (c)(2), (3), and (4)'' in its place.
■ 10. Adding paragraph (c)(4).

The revisions and additions read as follows:

§ 1.163(j)–1 Definitions.

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(b) * * *
(1) * * *
(iv) * * *
(A) * * *
(*2*) *Intercompany transactions.* For purposes of paragraphs (b)(1)(ii)(C) and (D) and paragraphs (b)(1)(iv)(B) and (b)(1)(iv)(E)(*1*) and (*2*) of this section, the term *sale or other disposition* excludes all intercompany transactions, within the meaning of § 1.1502–13(b)(1)(i), to the extent necessary to achieve single-entity taxation of the consolidated group.
(*3*) *Deconsolidations.* Notwithstanding any other rule in this paragraph (b)(1)(iv)(A), any transaction in which a member (S) leaves a consolidated group (selling group), including a section 381(a) transaction described in paragraph (b)(1)(iv)(A)(*1*) of this section, is treated as a taxable disposition of all S stock held by any member of the selling group for purposes of paragraphs (b)(1)(ii)(C) and (D) and paragraphs (b)(1)(iv)(B) and (b)(1)(iv)(E)(*1*) and (*2*) of this section, unless the transaction is described in § 1.1502–13(j)(5)(i). Following S's deconsolidation, any subsequent sales or dispositions of S stock by the selling group do not trigger further adjustments under paragraphs (b)(1)(ii)(C) and (D) and paragraphs (b)(1)(iv)(B) and (b)(1)(iv)(E)(*1*) and (*2*) of this section. If a transaction is described in § 1.1502–13(j)(5)(i), the transaction is not treated as a sale or other disposition for purposes of paragraphs (b)(1)(ii)(C) and (D) and paragraphs (b)(1)(iv)(B) and (b)(1)(iv)(E)(*1*) and (*2*) of this section. See also the successor rules in paragraph (b)(1)(iv)(C) of this section.
(*4*) *Nonrecognition transactions.* The disposition of property, member stock (other than in a deconsolidation described in paragraph (b)(1)(iv)(A)(*3*) of this section), or partnership interests in a nonrecognition transaction, other than a section 381(a) transaction described in paragraph (b)(1)(iv)(A)(*1*) of this section, is treated as a taxable disposition of the property, member stock, or partnership interest disposed of for purposes of paragraph (b)(1)(iv)(E)(*1*)(*i*), (b)(1)(iv)(E)(*2*)(*i*), and (b)(1)(iv)(E)(*3*)(*i*) of this section, respectively. For example, if a taxpayer transfers property to a wholly owned, non-consolidated subsidiary, the transfer of the property is treated as a taxable disposition for purposes of paragraph (b)(1)(iv)(E)(*1*)(*i*) of this section notwithstanding the application of section 351.
(B) *Deductions by members of a consolidated group*—(*1*) *In general.* If paragraph (b)(1)(ii)(C), (D), or (E) of this section applies to adjust the tentative taxable income of a consolidated group, and if the consolidated group does not use the alternative computation method

in paragraph (b)(1)(iv)(E) of this section, the amount of the adjustment under paragraph (b)(1)(ii)(C) of this section equals the greater of the allowed or allowable depreciation, amortization, or depletion of the property, as provided under section 1016(a)(2), for the consolidated group for the taxable years beginning after December 31, 2017, and before January 1, 2022, with respect to such property.

(*2*) *Application of the alternative computation method.* If paragraph (b)(1)(ii)(C), paragraph (b)(1)(ii)(D), or paragraph (b)(1)(ii)(E) of this section applies to adjust the tentative taxable income of a consolidated group, and if the consolidated group uses the alternative computation method in paragraph (b)(1)(iv)(E) of this section, the amount of the adjustment computed under paragraph (b)(1)(iv)(E)(*1*)(*i*), paragraph (b)(1)(iv)(E)(*2*)(*i*), or paragraph (b)(1)(iv)(E)(*3*)(*i*) of this section must take into account the net gain that would be taken into account by the consolidated group, including from intercompany transactions, determined by treating the sale or other disposition as a taxable transaction (see paragraphs (b)(1)(iv)(A)(*3*) and (*4*) of this section regarding deconsolidations and certain nonrecognition transactions, respectively).

(C) *Successor rules*—(*1*) *Successor assets.* This paragraph (b)(1)(iv)(C)(*1*) applies if deductions described in paragraph (b)(1)(ii)(C) of this section are allowed or allowable to a consolidated group member (S) and either the depreciable property or S's stock is subsequently transferred to another member (S1) in an intercompany transaction in which the transferor receives S1 stock. If this paragraph (b)(1)(iv)(C)(*1*) applies, and if the transferor's basis in the S1 stock received in the intercompany transaction is determined, in whole or in part, by reference to its basis in the depreciable property or the S stock, the S1 stock received in the intercompany transaction is treated as a successor asset for purposes of paragraph (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section. Thus, except as otherwise provided in paragraph (b)(1)(iv)(D) of this section, the subsequent disposition of either the S1 stock or the S stock (or both) may require the application of the adjustment rules of paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section.

(*2*) *Successor entities.* The acquiring corporation in a section 381(a) transaction to which the exception in paragraph (b)(1)(iv)(A)(*1*) of this section applies is treated as a successor to the distributor or transferor corporation for purposes of paragraphs (b)(1)(ii)(C) through (E) and (b)(1)(iv)(B) and (E) of this section. Therefore, for example, in applying paragraphs (b)(1)(ii)(C) through (E) and (b)(1)(iv)(B) and (E) of this section, the acquiring corporation is treated as succeeding to the allowed or allowable items of the distributor or transferor corporation. Similarly, the surviving group in a transaction described in § 1.1502–13(j)(5)(i) to which the exception in paragraph (b)(1)(iv)(A)(*3*) of this section applies is treated as a successor to the terminating group for purposes of paragraphs (b)(1)(ii)(C) through (E) and (b)(1)(iv)(B) and (E) of this section.

(D) *Anti-duplication rule*—(*1*) *In general.* The aggregate of the subtractions from tentative taxable income of a consolidated group under paragraphs (b)(1)(ii)(C) through (E) or paragraphs (b)(1)(iv)(E)(*1*) through (*3*) of this section with respect to an item of property (including with regard to dispositions of successor assets described in paragraph (b)(1)(iv)(C)(*1*) of this section) cannot exceed the aggregate amount of the consolidated group members' deductions described in paragraph (b)(1)(ii)(C) of this section with respect to such item of property. In addition, once an item of property is no longer held by any member of a consolidated group (whether or not an adjustment to the tentative taxable income of the group is made under paragraph (b)(1)(ii)(C) of this section with respect to the direct or indirect disposition of that property), no further adjustment to the group's tentative taxable income is made under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section in relation to the same property with respect to any subsequent stock disposition.

(2) *Adjustments following deconsolidation.* If a corporation (S) leaves a consolidated group (Group 1) in a transaction that requires an adjustment under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section, no further adjustment is required under paragraph (b)(1)(ii)(C) or (E) or paragraph (b)(1)(iv)(E) of this section in a separate return year (as defined in § 1.1502–1(e)) of S with respect to depreciation, amortization, or depletion deductions allowed or allowable to Group 1. See paragraph (b)(1)(iv)(A) of this section for special rules regarding the meaning of the term ''sale or other disposition'' for purposes of the adjustments required under paragraphs (b)(1)(ii)(C) through (E) and paragraphs (b)(1)(iv)(B) and (E) of this section. For example, assume that S deconsolidates from Group 1 in a transaction not described in § 1.1502–13(j)(5)(i) after holding property for which depreciation, amortization, or depletion deductions were allowed or allowable in Group 1. On the deconsolidation, S and Group 1 would adjust tentative taxable income with regard to that property. See paragraphs (b)(1)(iv)(A)(*3*), (b)(1)(ii)(D), and (b)(1)(iv)(E)(*2*) of this section. If, following the deconsolidation, S sells the property referred to in the previous sentence, no subtraction from tentative taxable income is made under paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section during S's separate return year with regard to the amounts included in Group 1. See paragraphs (b)(1)(iv)(A)(*3*), (b)(1)(ii)(D), and (b)(1)(iv)(E)(*2*) of this section.

(E) *Alternative computation method.* If paragraph (b)(1)(ii)(C), (D), or (E) of this section applies to adjust the tentative taxable income of a taxpayer, the taxpayer may compute the amount of the adjustments required by such paragraph using the formulas in paragraph (b)(1)(iv)(E)(*1*), (*2*), and (*3*) of this section, respectively, provided that the taxpayer applies such formulas to all dispositions for which an adjustment is required under paragraph (b)(1)(ii)(C), (D), or (E) of this section. For special rules regarding the treatment of deconsolidating transactions and nonrecognition transactions, see paragraph (b)(1)(iv)(A)(*3*) and (*4*) of this section, respectively. For special rules regarding the application of the formulas in paragraph (b)(1)(iv)(E)(*1*), (*2*), and (*3*) of this section by consolidated groups, see paragraph (b)(1)(iv)(B)(*2*) of this section.

(*1*) *Alternative computation method for property dispositions.* With respect to the sale or other disposition of property, the lesser of:

(*i*) Any gain recognized on the sale or other disposition of such property by the taxpayer (or, if the taxpayer is a member of a consolidated group, the consolidated group); and

(*ii*) The greater of the allowed or allowable depreciation, amortization, or depletion of the property, as provided under section 1016(a)(2), for the taxpayer (or, if the taxpayer is a member of a consolidated group, the consolidated group) for the taxable years beginning after December 31, 2017, and before January 1, 2022, with respect to such property.

(*2*) *Alternative computation method for dispositions of member stock.* With respect to the sale or other disposition by a member of a consolidated group of stock of another member for whom depreciation, amortization, or depletion was allowed or allowable with regard to

an item of property (or stock of any successor to that member), the lesser of:

(*i*) Any gain recognized on the sale or other disposition of such stock; and

(*ii*) The investment adjustments under § 1.1502–32 with respect to such stock that are attributable to deductions described in paragraph (b)(1)(ii)(C) of this section. The investment adjustments referred to in this paragraph (b)(1)(iv)(E)(*2*)(*ii*) include investment adjustments replicated in stock of members that are successor entities.

(*3*) *Alternative computation method for dispositions of partnership interests.* With respect to the sale or other disposition of an interest in a partnership, the lesser of:

(*i*) Any gain recognized on the sale or other disposition of such interest; and

(*ii*) The taxpayer's (or, if the taxpayer is a consolidated group, the consolidated group's) distributive share of deductions described in paragraph (b)(1)(ii)(C) of this section with respect to property held by the partnership at the time of such sale or other disposition to the extent such deductions were allowable under section 704(d).

(F) *Cap on negative adjustments*—(*1*) *In general.* A subtraction from (or negative adjustment to) tentative taxable income that is required under paragraph (b)(1)(ii)(C), (D), or (E) or paragraph (b)(1)(iv)(B) or (E) of this section is reduced to the extent the taxpayer establishes that the positive adjustments to tentative taxable income under paragraphs (b)(1)(i)(D) through (F) of this section in a prior taxable year did not result in an increase in the amount allowed as a deduction for business interest expense for such year. The extent to which the positive adjustments under paragraphs (b)(1)(i)(D) through (F) of this section resulted in an increase in the amount allowed as a deduction for business interest expense in a prior taxable year (such amount of positive adjustments, the *negative adjustment cap*) is determined after taking into account all other adjustments to tentative taxable income under paragraph (b)(1)(i) and (ii) of this section for that year, as established through books and records. The amount of the negative adjustment cap for a prior taxable year is reduced in future taxable years to the extent of negative adjustments under paragraphs (b)(1)(ii)(C) through (E) and paragraphs (b)(1)(iv)(B) and (E) of this section with respect to the prior taxable year.

(*2*) *Example.* A is a calendar-year individual taxpayer engaged in a trade or business that is neither an excepted trade or business nor eligible for the small business exemption. A has no disallowed business interest expense carryforwards. In 2021, A has $100x of business interest expense, no business interest income or floor plan financing interest expense, and $400x of tentative taxable income. After taking into account the adjustments to tentative taxable income under paragraph (b)(1)(i) and (ii) of this section other than positive adjustments under paragraphs (b)(1)(i)(D) through (F) of this section, A has tentative taxable income of $450x. A increases its tentative taxable income by $30x (from $450x to $480x) under paragraph (b)(1)(i)(D) of this section to reflect $30x of depreciation deductions with respect to Asset Y in 2021. Thus, for 2021, A would have a section 163(j) limitation of $135x ($450x × 30 percent) without regard to adjustments under paragraphs (b)(1)(i)(D) through (F) of this section. After the application of paragraph (b)(1)(i)(D) of this section, A has a section 163(j) limitation of $144x ($480x × 30 percent). In 2022, A sells Asset Y at a gain of $50x. Under paragraph (b)(1)(iv)(F)(*1*) of this section, A is not required to reduce its tentative taxable income in 2022 under paragraph (b)(1)(ii)(C) through (E) or paragraph (b)(1)(iv)(E) of this section. As established by A, the $30x addition to tentative taxable income under paragraph (b)(1)(i)(D) of this section resulted in no increase in the amount allowed as a deduction for business interest expense in 2021.

(G) *Treatment of depreciation, amortization, or depletion capitalized under section 263A.* Paragraphs (b)(1)(ii)(C) through (E) of this section and this paragraph (b)(1)(iv) apply with respect to the sale or other disposition of property to which paragraph (b)(1)(iii) of this section applies. For example, if a taxpayer with depreciable machinery capitalizes the depreciation into inventory under section 263A, paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E) of this section (and, if the taxpayer is a consolidated group, paragraph (b)(1)(iv)(B) of this section) applies upon the disposition of the machinery, subject to the cap in paragraph (b)(1)(iv)(F) of this section. Similarly, the successor asset rules in paragraph (b)(1)(iv)(C)(*1*) of this section would apply if the depreciable machinery subsequently were transferred to another member (S1) in an intercompany transaction in which the transferor received S1 stock.

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(viii) * * *

(A) *Example 1*—(*1*) *Facts.* In 2021, A purchases a depreciable asset (Asset X) for $30x and fully depreciates Asset X under section 168(k). For the 2021 taxable year, A establishes that its ATI before adding back depreciation deductions with respect to Asset X under paragraph (b)(1)(i)(D) of this section is $130x, and that its ATI after adding back depreciation deductions with respect to Asset X under paragraph (b)(1)(i)(D) of this section is $160x. A incurs $45x of business interest expense in 2021. In 2024, A sells Asset X to an unrelated third party for $25x.

(*2*) *Analysis.* A's section 163(j) limitation for 2021 is $48x ($160x × 30 percent). Thus, all $45x of A's business interest expense incurred in 2021 is deductible in that year. Under paragraph (b)(1)(ii)(C) of this section, A must subtract $30x from its tentative taxable income in computing its ATI for its 2024 taxable year. Alternatively, under paragraph (b)(1)(iv)(E)(*1*) of this section, A must subtract $25x (the lesser of $30x or $25x ($25x − $0x)) from its tentative taxable income in computing its ATI for its 2024 taxable year. However, the negative adjustments under paragraphs (b)(1)(ii)(C) and (b)(1)(iv)(E)(*1*) of this section are both subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Under that paragraph, A's negative adjustment under either paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section is capped at $20x, or $150x (the amount of ATI that A needed in order to deduct all $45x of business interest expense in 2021) minus $130x (the amount of A's tentative taxable income in 2021 before adding back any amounts under paragraph (b)(1)(i)(D) through (F) of this section). As established by A, the additional $10x ($30x − $20x) of depreciation deductions that were added back to tentative taxable income in 2021 under paragraph (b)(1)(i)(D) of this section did not increase A's business interest expense deduction for that year.

(*3*) *Transfer of assets in a nonrecognition transaction to which section 381 applies.* The facts are the same as in paragraph (b)(1)(viii)(A)(*1*) of this section, except that, rather than sell Asset X to an unrelated third party in 2024, A merges with and into an unrelated third party in 2024 in a transaction described in section 368(a)(1)(A) in which no gain is recognized. As provided in paragraph (b)(1)(iv)(A)(*1*) of this section, the merger transaction is not treated as a ''sale or other disposition'' for purposes of paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section. Thus, no adjustment to tentative taxable income is required in 2024 under paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section.

(*4*) *Transfer of assets in a nonrecognition transaction to which section 351 applies.* The facts are the same as in paragraph (b)(1)(viii)(A)(*1*) of this section, except that, rather than sell Asset X to an unrelated third party in 2024, A transfers Asset X to B (A's wholly owned subsidiary) in 2024 in a transaction to which section 351 applies. The section 351 transaction is treated as a ''sale or other disposition'' for purposes of paragraphs (b)(1)(ii)(C) and (b)(1)(iv)(E)(*1*) of this section, and it is treated as a taxable disposition for purposes of paragraph (b)(1)(iv)(E)(*1*) of this section. See paragraph (b)(1)(iv)(A)(*1*) and (*4*) of this section. However, the negative adjustments under paragraphs (b)(1)(ii)(C) and (b)(1)(iv)(E)(*1*) of this section are both subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Thus, A must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year.

(B) *Example 2*—(*1*) *Facts.* In 2021, S purchases a depreciable asset (Asset Y) for $30x and fully depreciates Asset Y under section 168(k). P reduces its basis in its S stock by $30x under § 1.1502–32 to reflect S's depreciation deductions with respect to Asset Y. For the 2021 taxable year, the P group establishes that its ATI before adding back S's depreciation deductions with respect to Asset Y under paragraph (b)(1)(i)(D) of this section is $130x, and that its ATI after adding back S's depreciation deductions with respect to Asset Y under paragraph (b)(1)(i)(D) of this section is $160x. The P group incurs $45x of business interest expense in 2021. In 2024, P sells all of its S stock to an unrelated third party at a gain of $25x.

(*2*) *Analysis.* The P group's section 163(j) limitation for 2021 is $48x ($160x × 30 percent). Thus, all $45x of the P group's business interest expense incurred in 2021 is deductible in that year. Under paragraph (b)(1)(ii)(D) of this section, the P group must subtract $30x from its tentative taxable income in computing its ATI for its 2024 taxable year. Alternatively, under paragraph (b)(1)(iv)(E)(*2*) of this section, the P group must subtract $25x (the lesser of $30x or $25x) from its tentative taxable income in computing its ATI for its 2024 taxable year. However, the negative adjustments under paragraphs (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section are both subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Under that paragraph, the P group's negative adjustment under either paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section is capped at $20x, or $150x (the amount of ATI the P group needed in order to deduct all $45x of business interest expense in 2021) minus $130x (the amount of the P group's tentative taxable income in 2021 before adding back any amounts under paragraph (b)(1)(i)(D) through (F) of this section). As established by the P group, the additional $10x ($30x − $20x) of depreciation deductions that were added back to tentative taxable income in 2021 under paragraph (b)(1)(i)(D) of this section did not increase the P group's business interest expense deduction for that year.

(*3*) *Disposition of less than all member stock.* The facts are the same as in paragraph (b)(1)(viii)(B)(*1*) of this section, except that, in 2024, P sells half of its S stock to an unrelated third party. The results are the same as in paragraph (b)(1)(viii)(B)(*2*) of this section. See paragraph (b)(1)(iv)(A)(*3*) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year. No further adjustment under paragraphs (b)(1)(ii)(C) and (D) or paragraphs (b)(1)(iv)(E)(*1*) and (*2*) of this section is required if P subsequently sells its remaining S stock or if S subsequently disposes of Asset Y. See paragraphs (b)(1)(iv)(A)(*3*) and (b)(1)(iv)(D) of this section.

(*4*) *Intercompany transfer; disposition of successor assets*—(*i*) *Adjustments in 2024.* The facts are the same as in paragraph (b)(1)(viii)(B)(*1*) of this section, except that, rather than sell all of its S stock to an unrelated third party in 2024, P transfers all of its S stock to T in 2024 in a transaction to which section 351 applies and, in 2025, P sells all of its T stock to an unrelated third party at a gain of $40x. As provided in paragraph (b)(1)(iv)(A)(*2*) of this section, P's intercompany transfer of its S stock to T is not a ''sale or other disposition'' for purposes of paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section. Thus, no adjustment to tentative taxable income is required in 2024 under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section.

(*ii*) *Adjustments in 2025.* Pursuant to paragraph (b)(1)(iv)(C)(*1*) of this section, P's stock in T is treated as a successor asset for purposes of paragraph (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section. Moreover, P's sale of its T stock causes both T and S to deconsolidate. Thus, under paragraph (b)(1)(iv)(A)(*3*) of this section, the transaction is treated as a taxable disposition of all of the T stock and all of the S stock held by all members of the P group. Under the anti-duplication rule in paragraph (b)(1)(iv)(D) of this section, the total amount of gain recognized for purposes of paragraph (b)(1)(iv)(E)(*2*)(*i*) of this section is $40x, the greater of the gain on the disposition of the T stock ($40x) or on the disposition of the S stock ($25x). However, the negative adjustments under paragraph (b)(1)(iv)(E)(*2*) of this section are subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2025 taxable year.

(*5*) *Alternative computation and non-deconsolidating disposition of member stock.* The facts are the same as in paragraph (b)(1)(viii)(B)(*1*) of this section, except that, in 2024, P sells just ten percent of its S stock to an unrelated third party at a gain of $2.5x. Under paragraph (b)(1)(iv)(E)(*2*) of this section, the lesser of P's gain recognized on the sale of the S stock ($2.5x) and the investment adjustments under § 1.1502–32 with respect to the S stock P sold ($3x) is $2.5x, an amount less than the $20x limitation under paragraph (b)(1)(iv)(F) of this section. Thus, the P group must subtract $2.5x from its tentative taxable income in computing its ATI for its 2024 taxable year.

(*6*) *Non-deconsolidating disposition of member stock followed by asset disposition.* The facts are the same as in paragraph (b)(1)(viii)(B)(*5*) of this section, except that, in 2025, S sells Asset Y to an unrelated third party for a gain of $20x. Under paragraph (b)(1)(iv)(E)(*1*) of this section, the amount of the adjustment in 2025 is the lesser of two amounts. The first amount is the amount of S's gain recognized on the sale of Asset Y ($20x). See paragraph (b)(1)(iv)(E)(*1*)(*i*) of this section. The second amount is the amount of depreciation with respect to Asset Y (see paragraph (b)(1)(iv)(E)(*1*)(*ii*) of this section), reduced by the amount of depreciation previously taken into account in the computation under paragraph (b)(1)(iv)(E)(*2*)(*ii*) of this section ($30x − $3x, or $27x). See paragraph (b)(1)(iv)(D)(*1*) of this section. Thus, the amount of the adjustment under paragraphs (b)(1)(iv)(D) and (b)(1)(iv)(E)(*1*) of this section is $20x. In turn, this amount is subject to the negative adjustment cap under paragraph (b)(1)(iv)(F), which, after accounting for the negative adjustment on the earlier sale of S stock in 2024, is $17.5x ($20x − $2.5x). Accordingly, the P group must subtract $17.5x from its tentative taxable income in computing its ATI for its 2025 taxable year.

(C) *Example 3*—(*1*) *Facts.* The facts are the same as in paragraph (b)(1)(viii)(B)(*1*) of this section, except that, in 2024, S sells Asset Y to an

unrelated third party for $25x and, in 2025, P sells all of its S stock to an unrelated third party at a gain of $25x.

(2) *Analysis.* The results are the same as in paragraph (b)(1)(viii)(B)(*2*) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year. P's sale of all of its S stock in 2025 is a ''sale or other disposition'' for purposes of paragraph (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section. However, pursuant to paragraph (b)(1)(iv)(D)(*1*) of this section, no further adjustment to the P group's tentative taxable income is required in 2025 under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section.

(*3*) *Disposition of S stock prior to S's asset disposition.* The facts are the same as in paragraph (b)(1)(viii)(C)(*1*) of this section, except that, in 2024, P sells all of its S stock to an unrelated third party at a gain of $25x and, in 2025, S sells Asset Y to an unrelated third party for $25x. The results are the same as in paragraph (b)(1)(viii)(B)(*2*) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year. Pursuant to paragraph (b)(1)(iv)(D)(*2*) of this section, no adjustment to the acquiring group's tentative taxable income is required in 2025 under paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section.

(*4*) *Deconsolidation of S in nonrecognition transaction.* The facts are the same as in paragraph (b)(1)(viii)(C)(*3*) of this section, except that, rather than sell all of its S stock to an unrelated third party, P causes S to merge with and into an unrelated third party in a transaction described in section 368(a)(1)(A). As provided in paragraph (b)(1)(iv)(A)(*3*) of this section, the merger transaction is treated as a taxable disposition of all of P's stock in S for purposes of paragraphs (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section because S leaves the P group. Thus, the results are the same as in paragraph (b)(1)(viii)(C)(*3*) of this section.

(D) *Example 4*—(*1*) *Facts.* P wholly owns T, which wholly owns S. In 2021, S purchases a depreciable asset (Asset Z) for $30x and fully depreciates Asset Z under section 168(k). T reduces its basis in its S stock, and P reduces its basis in its T stock, by $30x under § 1.1502–32 to reflect S's depreciation deductions with respect to Asset Z. For the 2021 taxable year, the P group establishes that its ATI before adding back S's depreciation deductions with respect to Asset Z under paragraph (b)(1)(i)(D) of this section is $130x, and that its ATI after adding back S's depreciation deductions with respect to Asset Z under paragraph (b)(1)(i)(D) of this section is $160x. The P group incurs $45x of business interest expense in 2021. In 2024, T sells all of its S stock to an unrelated third party at a gain of $25x. In 2025, P sells all of its T stock to an unrelated third party at a gain of $40x.

(*2*) *Analysis.* The results are the same as in paragraph (b)(1)(viii)(B)(*2*) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year. Pursuant to paragraph (b)(1)(iv)(D)(*1*) of this section, no negative adjustment to the P group's tentative taxable income is required in 2025 under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section.

(*3*) *Disposition of T stock in 2024.* The facts are the same as in paragraph (b)(1)(viii)(D)(*1*) of this section, except that, in 2024, P sells all of its T stock to another consolidated group at a gain of $40x and, in 2025, T sells all of its S stock to an unrelated party at a gain of $25x. Whereas the transaction described in paragraph (b)(1)(viii)(B)(*4*) of this section is treated as a taxable disposition of both the T stock and the S stock, only the actual disposition of the T stock in the transaction described in this paragraph (b)(1)(viii)(D)(*3*) is treated as a taxable disposition for purposes of paragraphs (b)(1)(ii)(D) and (b)(1)(iv)(E)(*2*) of this section. See paragraph (b)(1)(iv)(A)(*3*) of this section. However, the results are the same as in paragraph (b)(1)(viii)(B)(*2*) and (b)(1)(viii)(B)(*4*) of this section because of the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Thus, the P group must subtract $20x from its tentative taxable income in computing its ATI for its 2024 taxable year. Pursuant to paragraph (b)(1)(iv)(D) of this section, no negative adjustment to the acquiring group's tentative taxable income is required in 2025 under paragraph (b)(1)(ii)(D) or paragraph (b)(1)(iv)(E)(*2*) of this section.

(E) *Example 5*—(*1*) *Facts.* In 2021, A purchases Assets X and Y for $30x and $80x, respectively, and fully depreciates each asset under section 168(k). For the 2021 taxable year, A establishes that its ATI before adding back depreciation deductions with respect to Assets X and Y under paragraph (b)(1)(i)(D) of this section is $150x, and that its ATI after adding back depreciation deductions with respect to Assets X and Y under paragraph (b)(1)(i)(D) of this section is $260x. A incurs $75x of business interest expense in 2021. In 2024, A sells Assets X and Y to an unrelated third party for $40x and $90x, respectively.

(*2*) *Analysis.* A's section 163(j) limitation for 2021 is $78x ($260x × 30 percent). Thus, all $75x of A's business interest expense incurred in 2021 is deductible in that year. Under paragraph (b)(1)(ii)(C) of this section, A must subtract $110x ($30x + $80x) from its tentative taxable income in computing its ATI for its 2024 taxable year. Alternatively, under paragraph (b)(1)(iv)(E)(*1*) of this section, A must subtract $30x with respect to Asset X (the lesser of $30x or $40x ($40x − $0x)), and $80x with respect to Asset Y (the lesser of $80x or $90x ($90x − $0x)), from its tentative taxable income in computing its ATI for its 2024 taxable year. However, the negative adjustments under paragraphs (b)(1)(ii)(C) and (b)(1)(iv)(E)(*1*) of this section are both subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Under that paragraph, A's negative adjustment in 2024 under either paragraph (b)(1)(ii)(C) ($110x) or paragraph (b)(1)(iv)(E)(*1*) (also $110x) of this section is limited to $100x. This amount equals $250x (the amount of ATI that A needed in order to deduct all $75x of business interest expense in 2021) minus $150x (the amount of A's tentative taxable income in 2021 before adding back any amounts under paragraph (b)(1)(i)(D) through (F) of this section). As established by A, the additional $10x ($110x − $100x) of depreciation deductions that were added back to tentative taxable income in 2021 under paragraph (b)(1)(i)(D) of this section did not increase A's business interest expense deduction for that year.

(*3*) *Sale of assets in different taxable years.* The facts are the same as in paragraph (b)(1)(viii)(E)(*1*) of this section, except that A sells Asset Y to an unrelated third party for $90x in 2025. Under paragraph (b)(1)(ii)(C) of this section, A must subtract $30x from its tentative taxable income in computing its ATI for its 2024 taxable year. Alternatively, under paragraph (b)(1)(iv)(E)(*1*) of this section, A must subtract $30x (the lesser of $30x or $40x ($40x − $0x)) from its tentative taxable income in computing its ATI for its 2024 taxable year. Because A's negative adjustment cap for its 2021 taxable year is $100x (see paragraph (b)(1)(viii)(E)(*2*) of this section), A's negative adjustment in 2024 of $30x is not reduced under paragraph (b)(1)(iv)(F) of this section. In 2025, A must subtract $80x from its tentative taxable income under paragraph (b)(1)(ii)(C) of this section in computing its ATI. Alternatively, under paragraph (b)(1)(iv)(E)(*1*) of this section, A must subtract $80x (the lesser of $80x

or $90x ($90x − $0x)) from its tentative taxable income in computing its ATI for its 2025 taxable year. However, the negative adjustments under paragraphs (b)(1)(ii)(C) and (b)(1)(iv)(E)(*1*) of this section are both subject to the negative adjustment cap in paragraph (b)(1)(iv)(F) of this section. Moreover, A's negative adjustment cap for its 2021 taxable year is reduced from $100x to $70x to reflect A's $30x negative adjustment in 2024. See paragraph (b)(1)(iv)(F) of this section. Thus, A's negative adjustment for 2025 under either paragraph (b)(1)(ii)(C) or paragraph (b)(1)(iv)(E)(*1*) of this section is reduced from $80x to $70x. As established by A, the additional $10x ($110x − $100x) of depreciation deductions that were added back to tentative taxable income in 2021 under paragraph (b)(1)(i)(D) of this section did not increase A's business interest expense deduction for that year.

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(22) * * *

(iii) * * *

(F) *Section 163(j) interest dividends*—(*1*) *In general.* Except as otherwise provided in this paragraph (b)(22)(iii)(F), a section 163(j) interest dividend is treated as interest income.

(*2*) *Limitation on amount treated as interest income.* A shareholder may not treat any part of a section 163(j) interest dividend as interest income to the extent the amount of the section 163(j) interest dividend exceeds the excess of the amount of the entire dividend that includes the section 163(j) interest dividend over the sum of the conduit amounts other than interest-related dividends under section 871(k)(1)(C) and section 163(j) interest dividends that affect the shareholder's treatment of that dividend.

(*3*) *Conduit amounts.* For purposes of paragraph (b)(22)(iii)(F)(*2*) of this section, the term *conduit amounts* means, with respect to any category of income (including tax-exempt interest) earned by a RIC for a taxable year, the amounts identified by the RIC (generally in a designation or written report) in connection with dividends of the RIC for that taxable year that are subject to a limit determined by reference to that category of income. For example, a RIC's conduit amount with respect to its net capital gain is the amount of the RIC's capital gain dividends under section 852(b)(3)(C).

(*4*) *Holding period.* Except as provided in paragraph (b)(22)(iii)(F)(*5*) of this section, no dividend is treated as interest income under paragraph (b)(22)(iii)(F)(*1*) of this section if the dividend is received with respect to a share of RIC stock—

(*i*) That is held by the shareholder for 180 days or less (taking into account the principles of section 246(c)(3) and (4)) during the 361-day period beginning on the date which is 180 days before the date on which the share becomes ex-dividend with respect to such dividend; or

(*ii*) To the extent that the shareholder is under an obligation (whether pursuant to a short sale or otherwise) to make related payments with respect to positions in substantially similar or related property.

(*5*) *Exception to holding period requirement for money market funds and certain regularly declared dividends.* Paragraph (b)(22)(iii)(F)(*4*)(*i*) of this section does not apply to dividends distributed by any RIC regulated as a money market fund under 17 CFR 270.2a–7 (Rule 2a–7 under the 1940 Act) or to regular dividends paid by a RIC that declares section 163(j) interest dividends on a daily basis in an amount equal to at least 90 percent of its excess section 163(j) interest income, as defined in paragraph (b)(35)(iv)(E) of this section, and distributes such dividends on a monthly or more frequent basis.

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(35) *Section 163(j) interest dividend.* The term *section 163(j) interest dividend* means a dividend paid by a RIC for a taxable year for which section 852(b) applies to the RIC, to the extent described in paragraph (b)(35)(i) or (ii) of this section, as applicable.

(i) *In general.* Except as provided in paragraph (b)(35)(ii) of this section, a section 163(j) interest dividend is any dividend, or part of a dividend, that is reported by the RIC as a section 163(j) interest dividend in written statements furnished to its shareholders.

(ii) *Reduction in the case of excess reported amounts.* If the aggregate reported amount with respect to the RIC for the taxable year exceeds the excess section 163(j) interest income of the RIC for such taxable year, the section 163(j) interest dividend is—

(A) The reported section 163(j) interest dividend amount; reduced by

(B) The excess reported amount that is allocable to that reported section 163(j) interest dividend amount.

(iii) *Allocation of excess reported amount*—(A) *In general.* Except as provided in paragraph (b)(35)(iii)(B) of this section, the excess reported amount, if any, that is allocable to the reported section 163(j) interest dividend amount is that portion of the excess reported amount that bears the same ratio to the excess reported amount as the reported section 163(j) interest dividend amount bears to the aggregate reported amount.

(B) *Special rule for noncalendar year RICs.* In the case of any taxable year that does not begin and end in the same calendar year, if the post-December reported amount equals or exceeds the excess reported amount for that taxable year, paragraph (b)(35)(iii)(A) of this section is applied by substituting ''post-December reported amount'' for ''aggregate reported amount,'' and no excess reported amount is allocated to any dividend paid on or before December 31 of such taxable year.

(iv) *Definitions.* The following definitions apply for purposes of this paragraph (b)(35):

(A) *Reported section 163(j) interest dividend amount.* The term *reported section 163(j) interest dividend amount* means the amount of a dividend distribution reported to the RIC's shareholders under paragraph (b)(35)(i) of this section as a section 163(j) interest dividend.

(B) *Excess reported amount.* The term *excess reported amount* means the excess of the aggregate reported amount over the RIC's excess section 163(j) interest income for the taxable year.

(C) *Aggregate reported amount.* The term *aggregate reported amount* means the aggregate amount of dividends reported by the RIC under paragraph (b)(35)(i) of this section as section 163(j) interest dividends for the taxable year (including section 163(j) interest dividends paid after the close of the taxable year described in section 855).

(D) *Post-December reported amount.* The term *post-December reported amount* means the aggregate reported amount determined by taking into account only dividends paid after December 31 of the taxable year.

(E) *Excess section 163(j) interest income.* The term *excess section 163(j) interest income* means, with respect to a taxable year of a RIC, the excess of the RIC's business interest income for the taxable year over the sum of the RIC's business interest expense for the taxable year and the RIC's other deductions for the taxable year that are properly allocable to the RIC's business interest income.

(v) *Example*—(A) *Facts.* X is a domestic C corporation that has elected to be a RIC. For its taxable year ending December 31, 2021, X has $100x of business interest income (all of which is qualified interest income for purposes of section 871(k)(1)(E)) and $10x of dividend income (all of which is qualified dividend income within the meaning of section 1(h)(11) and would be eligible for the dividends received deduction under section 243,

determined as described in section 854(b)(3)). X has $10x of business interest expense and $20x of other deductions. X has no other items for the taxable year. On December 31, 2021, X pays a dividend of $80x to its shareholders, and reports, in written statements to its shareholders, $71.82x as a section 163(j) interest dividend; $10x as dividends that may be treated as qualified dividend income or as dividends eligible for the dividends received deduction; and $72.73x as interest-related dividends under section 871(k)(1)(C). Shareholder A, a domestic C corporation, meets the holding period requirements in paragraph (b)(22)(iii)(F)(*4*) of this section with respect to the stock of X, and receives a dividend of $8x from X on December 31, 2021.

(B) *Analysis.* X determines that $18.18x of other deductions are properly allocable to X's business interest income. X's excess section 163(j) interest income under paragraph (b)(35)(iv)(E) of this section is $71.82x ($100x business interest income—($10x business interest expense + $18.18x other deductions allocated) = $71.82x). Thus, X may report up to $71.82x of its dividends paid on December 31, 2021, as section 163(j) interest dividends to its shareholders. X may also report up to $10x of its dividends paid on December 31, 2021, as dividends that may be treated as qualified dividend income or as dividends that are eligible for the dividends received deduction. X determines that $9.09x of interest expense and $18.18x of other deductions are properly allocable to X's qualified interest income. Therefore, X may report up to $72.73x of its dividends paid on December 31, 2021, as interest-related dividends under section 871(k)(1)(C) ($100x qualified interest income—$27.27x deductions allocated = $72.73x). A treats $1x of its $8x dividend as a dividend eligible for the dividends received deduction and no part of the dividend as an interest-related dividend under section 871(k)(1)(C). Therefore, under paragraph (b)(22)(iii)(F)(*2*) of this section, A may treat $7x of the section 163(j) interest dividend as interest income for purposes of section 163(j) ($8x dividend—$1x conduit amount = $7x limitation).

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(c) * * *

(4) *Paragraphs (b)(1)(iv)(A)(2) through (4), (B) through (G), (b)(22)(iii)(F), and (b)(35).* Paragraphs (b)(1)(iv)(A)(*2*) through (*4*), (b)(1)(iv)(B) through (G), (b)(22)(iii)(F), and (b)(35) of this section apply to taxable years beginning on or after March 22, 2021. Taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in paragraphs (b)(1)(iv)(A)(*2*) through (*4*), (b)(1)(iv) (B) through (G), (b)(22)(iii)(F), and (b)(35) of this section to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules in the section 163(j) regulations contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.382–7, 1.383–0, 1.383–1, 1.469–9, 1.469–11, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–36, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905, as modified by T.D. 9943, to that taxable year and all subsequent taxable years.

■ **Par. 5.** Section 1.163(j)–2 is amended by:

■ 1. Adding paragraphs (b)(3)(iii) and (iv) and (d)(3).

■ 2. Redesignating paragraph (k) as paragraph (k)(1).

■ 3. Adding a new subject heading for paragraph (k).

■ 4. Revising the subject heading of newly redesignated paragraph (k)(1).

■ 5. Adding paragraph (k)(2).

The revisions and additions read as follows:

§ 1.163 (j)–2 Deduction for business interest expense limited.

* * * * *

(b) * * *

(3) * * *

(iii) *Transactions to which section 381 applies.* For purposes of the election described in paragraph (b)(3)(i) of this section, and subject to the limitation in paragraph (b)(3)(ii) of this section, the 2019 ATI of the acquiring corporation in a transaction to which section 381 applies equals the amount of the acquiring corporation's ATI for its last taxable year beginning in 2019.

(iv) *Consolidated groups.* For purposes of the election described in paragraph (b)(3)(i) of this section, and subject to the limitation in paragraph (b)(3)(ii) of this section, the 2019 ATI of a consolidated group equals the amount of the consolidated group's ATI for its last taxable year beginning in 2019.

* * * * *

(d) * * *

(3) *Determining a syndicate's loss amount.* For purposes of section 163(j), losses allocated under section 1256(e)(3)(B) and § 1.448–1T(b)(3) are determined without regard to section 163(j). See also § 1.1256(e)–2(b).

* * * * *

(k) *Applicability dates.*

(1) *In general.* * * *

(2) *Paragraphs (b)(3)(iii), (b)(3)(iv), and (d)(3).* Paragraphs (b)(3)(iii) and (iv) and (d)(3) of this section apply to taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in paragraphs (b)(3)(iii), (b)(3)(iv), and (d)(3) of this section to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules in paragraphs (b)(3)(iii) and (iv) of this section and the rules in the section 163(j) regulations contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.382–7, 1.383–0, 1.383–1, 1.469–9, 1.469–11, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–36, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905 as modified by T.D. 9943, for that taxable year and for each subsequent taxable year.

■ **Par. 6.** Section 1.163(j)–6 is amended by:

■ 1. Adding paragraphs (c)(1) and (2).

■ 2. Redesignating paragraph (c)(3) as paragraph (c)(4).

■ 3. Adding new paragraph (c)(3) and paragraphs (d)(3) through (5) and (e)(5).

■ 4. Adding paragraphs (f)(1)(iii) and (g)(4).

■ 5. Adding paragraph (n).

■ 6. Adding paragraphs (o)(24) through (26), reserved paragraphs (o)(27). through (33), and paragraphs (o)(34) through (36).

■ 7. Redesignating paragraph (p) as paragraph (p)(1), revising the subject heading of paragraph (p), and adding a subject heading for newly designated paragraph (p)(1).

■ 8. Adding paragraph (p)(2).

The revisions and additions read as follows:

§ 1.163 (j)–6 Application of the section 163(j) limitation to partnerships and subchapter S corporations.

* * * * *

(c) * * *

(1) *Modification of business interest income for partnerships.* The business interest income of a partnership generally is determined in accordance with § 1.163(j)–1(b)(4). However, to the extent that interest income of a partnership that is properly allocable to trades or businesses that are per se non-passive activities is allocated to partners that do not materially participate (within the meaning of section 469), as described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii), such interest income shall not be considered business interest income for purposes of determining the section 163(j) limitation of a partnership pursuant to § 1.163(j)–2(b). A per se non-passive activity is an activity that is not treated as a passive activity for purposes of section 469 regardless of whether the owners of the activity materially participate in the activity.

(2) *Modification of business interest expense for partnerships.* The business interest expense of a partnership generally is determined in accordance with § 1.163(j)–1(b)(3). However, to the extent that interest expense of a partnership that is properly allocable to trades or businesses that are per se non-passive activities is allocated to partners that do not materially participate (within the meaning of section 469), as described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii), such interest expense shall not be considered business interest expense for purposes of determining the section 163(j) limitation of a partnership pursuant to § 1.163(j)–2(b).

(3) *Transition rule.* With respect to a partner in a partnership engaged in a trade or business described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii), if such partner had been allocated EBIE from the partnership with respect to the trade or business described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii) in any prior taxable year in which the partner did not materially participate, such partner may treat such excess business interest expense not previously treated as paid or accrued under § 1.163(j)–6(g)(2) as paid or accrued by the partner in the first taxable year ending on or after the effective date of the final regulations and not subject to further limitation under section 163(j) or 163(d).

* * * * *

(d) * * *

(3) *Section 743(b) adjustments and publicly traded partnerships.* Solely for purposes of § 1.163(j)–6, a publicly traded partnership, as defined in § 1.7704–1, shall treat the amount of any section 743(b) adjustment of a purchaser of a partnership unit that relates to a remedial item that the purchaser inherits from the seller as an offset to the related section 704(c) remedial item. For this purpose, § 1.163(j)–6(e)(2)(ii) applies. See *Example 25* in paragraph (o)(25) of this section.

(4) *Modification of adjusted taxable income for partnerships.* The adjusted taxable income of a partnership generally is determined in accordance with § 1.163(j)–1(b)(1). However, to the extent that the items comprising the adjusted taxable income of a partnership that are properly allocable to trades or businesses that are per se non-passive activities are allocated to partners that do not materially participate (within the meaning of section 469), as described in section 163(d)(5)(A)(ii), such partnership items shall not be considered adjusted taxable income for purposes of determining the section 163(j) limitation of a partnership pursuant to § 1.163(j)–2(b).

(5) *Election to use 2019 adjusted taxable income for taxable years beginning in 2020.* In the case of any taxable year beginning in 2020, a partnership may elect to apply this section by substituting its adjusted taxable income for the last taxable year beginning in 2019 for the adjusted taxable income for such taxable year (post-election ATI or 2019 ATI). See § 1.163(j)–2(b)(4) for the time and manner of making or revoking this election. An electing partnership determines each partner's allocable ATI (as defined in paragraph (f)(2)(ii) of this section) by using the partnership's 2019 section 704 income, gain, loss, and deduction as though such amounts were recognized by the partnership in 2020. See *Example 34* in paragraph (o)(34) of this section.

(e) * * *

(5) *Partner basis items, remedial items, and publicly traded partnerships.* Solely for purposes of § 1.163(j)–6, a publicly traded partnership, as defined in § 1.7704–1, shall either allocate gain that would otherwise be allocated under section 704(c) based on a partner's section 704(b) sharing ratios, or, for purposes of allocating cost recovery deductions under section 704(c), determine a partner's remedial items, as defined in § 1.163(j)–6(b)(3), based on an allocation of the partnership's asset basis (inside basis) items among its partners in proportion to their share of corresponding section 704(b) items (rather than applying the traditional method, described in § 1.704–3(b)). See *Example 24* in paragraph (o)(24) of this section.

(f) * * *

(1) * * *

(iii) *Exception applicable to publicly traded partnerships.* Publicly traded partnerships, as defined in § 1.7704–1, do not apply the rules in paragraph (f)(2) of this section to determine a partner's share of section 163(j) excess items. Rather, publicly traded partnerships determine a partner's share of section 163(j) excess items by applying the same percentage used to determine the partner's share of the corresponding section 704(b) items that comprise ATI.

* * * * *

(g) * * *

(4) *Special rule for taxable years beginning in 2019 and 2020.* In the case of any excess business interest expense of a partnership for any taxable year beginning in 2019 that is allocated to a partner under paragraph (f)(2) of this section, 50 percent of such excess business interest expense (§ 1.163(j)–6(g)(4) business interest expense) is treated as business interest expense that, notwithstanding paragraph (g)(2) of this section, is paid or accrued by the partner in the partner's first taxable year beginning in 2020. Additionally, § 1.163(j)–6(g)(4) business interest expense is not subject to the section 163(j) limitation at the level of the partner. For purposes of paragraph (h)(1) of this section, any § 1.163(j)–6(g)(4) business interest expense is, similar to deductible business interest expense, taken into account before any excess business interest expense. This paragraph applies after paragraph (n) of this section. If a partner disposes of a partnership interest in the partnership's 2019 or 2020 taxable year, § 1.163(j)–6(g)(4) business interest expense is deductible by the partner (except to the extent that the business interest expense is negative section 163(j) expense as defined in § 1.163(j)–6(h)(1) immediately prior to the disposition) and thus does not result in a basis increase under paragraph (h)(3) of this section. See *Example 35* and *Example 36* in paragraphs (o)(35) and (o)(36), respectively, of this section. A partner may elect to not have this provision apply with respect to each partnership interest held by the partner on an interest by interest basis. The rules and procedures regarding the time and manner of making, or revoking, such an election are provided in Revenue Procedure 2020–22, 2020–18 I.R.B. 745, and may be further modified through

other guidance (see §§ 601.601(d) and 601.602 of this chapter).

* * * * *

(n) *Treatment of self-charged lending transactions between partnerships and partners.* In the case of a lending transaction between a partner (lending partner) and partnership (borrowing partnership) in which the lending partner owns a direct interest (self-charged lending transaction), any business interest expense of the borrowing partnership attributable to the self-charged lending transaction is business interest expense of the borrowing partnership for purposes of this section. If in a given taxable year the lending partner is allocated excess business interest expense from the borrowing partnership and has interest income attributable to the self-charged lending transaction (interest income), the lending partner is deemed to receive an allocation of excess business interest income from the borrowing partnership in such taxable year. The amount of the lending partner's deemed allocation of excess business interest income is the lesser of such lending partner's allocation of excess business interest expense from the borrowing partnership in such taxable year or the interest income attributable to the self-charged lending transaction in such taxable year. To prevent the double counting of business interest income, the lending partner includes interest income that was treated as excess business interest income pursuant to this paragraph (n) only once when calculating its own section 163(j) limitation. To the extent an amount of interest income received by a lending partner is attributable to a self-charged lending transaction, and is deemed to be an allocation of excess business interest income from the borrowing partnership pursuant to this paragraph (n), such an amount of interest income will not be treated as investment income for purposes of section 163(d). In cases where the lending partner is not a C corporation, to the extent that any interest income exceeds the lending partner's allocation of excess business interest expense from the borrowing partnership for the taxable year, and such interest income otherwise would be properly treated as investment income of the lending partner for purposes of section 163(d) for that year, such excess amount of interest income will continue to be treated as investment income of the lending partner for that year for purposes of section 163(d). See *Example 26* in paragraph (o)(26) of this section.

(o) * * *

(24) *Example 24*—(i) *Facts.* On January 1, 2020, L and M form LM, a publicly traded partnership (as defined in § 1.7704–1), and agree that each will be allocated a 50 percent share of all LM items. The partnership agreement provides that LM will make allocations under section 704(c) using the remedial allocation method under § 1.704–3(d). L contributes depreciable property with an adjusted tax basis of $4,000 and a fair market value of $10,000. The property is depreciated using the straight-line method with a 10-year recovery period and has 4 years remaining on its recovery period. M contributes $10,000 in cash, which LM uses to purchase land. Except for the depreciation deductions, LM's expenses equal its income in each year of the 10 years commencing with the year LM is formed. LM has a valid section 754 election in effect.

(ii) *Section 163(j) remedial items and partner basis items.* LM sells the asset contributed by L in a fully taxable transaction at a time when the adjusted basis of the property is $4,000. Under § 1.163(j)–6(e)(2)(ii), solely for purposes of § 1.163(j)–6, the tax gain of $6,000 is allocated equally between L and M ($3,000 each). To avoid shifting built-in gain to the non-contributing partner (M) in a manner consistent with the rule in section 704(c), a remedial deduction of $3,000 is allocated to M (leaving M with no net tax gain), and remedial income of $3,000 is allocated to L (leaving L with total tax gain of $6,000).

(25) *Example 25*—(i) *Facts.* The facts are the same as *Example 24* in paragraph (o)(24) of this section except the property contributed by L had an adjusted tax basis of zero. For each of the 10 years following the contribution, there would be $500 of section 704(c) remedial income allocated to L and $500 of remedial deductions allocated to M with respect to the contributed asset. A buyer of M's units would step into M's shoes with respect to the $500 of annual remedial deductions. A buyer of L's units would step into L's shoes with respect to the $500 of annual remedial income and would have an annual section 743(b) deduction of $1,000 (net $500 of deductions).

(ii) *Analysis.* Pursuant to § 1.163(j)–6(d)(2)(ii), solely for purposes of § 1.163(j)–6, a buyer of L's units immediately after formation of LM would offset its $500 annual section 704(c) remedial income allocation with $500 of annual section 743(b) adjustment (leaving the buyer with net $500 of section 743(b) deduction). As a result, such buyer would be in the same position as a buyer of M's units. Each buyer would have net deductions of $500 per year, which would not affect ATI before 2022.

(26) *Example 26*—(i) *Facts.* X and Y are partners in partnership PRS. In Year 1, PRS had $200 of excess business interest expense. Pursuant to § 1.163(j)–6(f)(2), PRS allocated $100 of such excess business interest expense to each of its partners. In Year 2, X lends $10,000 to PRS and receives $1,000 of interest income for the taxable year (self-charged lending transaction). X is not in the trade or business of lending money. The $1,000 of interest expense resulting from this loan is allocable to PRS's trade or business assets. As a result, such $1,000 of interest expense is business interest expense of PRS. X and Y are each allocated $500 of such business interest expense as their distributive share of PRS's business interest expense for the taxable year. Additionally, in Year 2, PRS has $3,000 of ATI. PRS allocates the items comprising its $3,000 of ATI $0 to X and $3,000 to Y.

(ii) *Partnership-level.* In Year 2, PRS's section 163(j) limit is 30 percent of its ATI plus its business interest income, or $900 ($3,000 × 30 percent). Thus, PRS has $900 of deductible business interest expense, $100 of excess business interest expense, $0 of excess taxable income, and $0 of excess business interest income. Pursuant to § 1.163(j)–6(f)(2), $400 of X's allocation of business interest expense is treated as deductible business interest expense, $100 of X's allocation of business interest expense is treated as excess business interest expense, and $500 of Y's allocation of business interest expense is treated as deductible business interest expense.

(iii) *Lending partner.* Pursuant to § 1.163(j)–6(n), X treats $100 of its $1,000 of interest income as excess business interest income allocated from PRS in Year 2. Because X is deemed to have been allocated $100 of excess business interest income from PRS, and excess business interest expense from a partnership is treated as paid or accrued by a partner to the extent excess business interest income is allocated from such partnership to a partner, X treats its $100 allocation of excess business interest expense from PRS in Year 2 as business interest expense paid or accrued in Year 2. X, in computing its limit under section 163(j), has $100 of business interest income ($100 deemed allocation of excess business interest income from PRS in Year 2) and $100 of business interest expense ($100 allocation of excess business interest expense treated as paid or accrued in Year 2). Thus, X's $100 of business interest expense is deductible business interest expense. At the end of Year 2,

X has $100 of excess business interest expense from PRS ($100 from Year 1). X treats $900 of its $1,000 of interest income as investment income for purposes of section 163(d).

(27)–(33) [Reserved]

(34) *Example 34*—(i) *Facts.* X and Y are equal partners in partnership PRS. Further, X and Y share the profits of PRS equally. In 2019, PRS had ATI of $100. Additionally, in 2019, PRS had $100 of section 704(b) income which was allocated $50 to X and $50 to Y (PRS did not have any section 704(c) income in 2019). In 2020, PRS's only items of income, gain, loss or deduction was $1 of trade or business income, which it allocated to X pursuant to section 704(c).

(ii) *Partnership-level.* In 2020, PRS makes the election described in § 1.163(j)–6(d)(5) to use its 2019 ATI in 2020. As a result, PRS has $100 of ATI in 2020. PRS does not have any business interest expense. Therefore, PRS has $100 of excess taxable income in 2020.

(iii) *Partner-level allocations.* PRS allocates its $100 of excess taxable income to X and Y pursuant to § 1.163(j)–6(f)(2). To determine each partner's share of the $100 of excess taxable income, PRS must determine each partner's allocable ATI (as defined in § 1.163(j)–6(f)(2)(ii)). Because PRS made the election described in § 1.163(j)–6(d)(5), PRS must determine the allocable ATI of each of its partners pursuant to paragraph (d)(5). Specifically, PRS determines each partner's share of allocable ATI based on PRS's 2019 section 704 income, gain, loss, and deduction. PRS had $100 of section 704(b) income in 2019 which was allocated $50 to X and $50 to Y. Therefore, in 2020, X and Y are both allocated $50 of excess taxable income (50% × $100).

(35) *Example 35*—(i) *Facts.* X, a partner in partnership PRS, was allocated $20 of excess business interest expense from PRS in 2018 and $10 of excess business interest expense from PRS in 2019. In 2020, PRS allocated $16 of excess taxable income to X.

(ii) *Analysis.* X treats 50 percent of its $10 of excess business interest expense allocated from PRS in 2019 as § 1.163(j)–6(g)(4) business interest expense. Thus, $5 of § 1.163(j)–6(g)(4) business interest expense is treated as paid or accrued by X in 2020 and is not subject to the section 163(j) limitation at X's level. Because X was allocated $16 of excess taxable income from PRS in 2020, X treats $16 of its $25 of excess business interest expense as business interest expense paid or accrued pursuant to § 1.163(j)–6(g)(2). X, in computing its limit under section 163(j) in 2020, has $16 of ATI (as a result of its allocation of $16 of excess taxable income from PRS), $0 of business interest income, and $16 of business interest expense ($16 of excess business interest expense treated as paid or accrued in 2020). Pursuant to § 1.163(j)–2(b)(2)(i), X's section 163(j) limit in 2020 is $8 ($16 × 50 percent). Thus, X has $8 of business interest expense that is deductible under section 163(j). The $8 of X's business interest expense not allowed as a deduction ($16 business interest expense subject to section 163(j), less $8 section 163(j) limit) is treated as business interest expense paid or accrued by X in 2021. At the end of 2020, X has $9 of excess business interest expense from PRS ($20 from 2018, plus $10 from 2019, less $5 treated as paid or accrued pursuant to § 1.163(j)–6(g)(4), less $16 treated as paid or accrued pursuant to § 1.163(j)–6(g)(2)).

(36) *Example 36*—(i) *Facts.* X is a partner in partnership PRS. At the beginning of 2018, X's outside basis in PRS was $100. X was allocated $20 of excess business interest expense from PRS in 2018 and $10 of excess business interest expense from PRS in 2019. X sold its PRS interest in 2019 for $70.

(ii) *Analysis.* X treats 50 percent of its $10 of excess business interest expense allocated from PRS in 2019 as § 1.163(j)–6(g)(4) business interest expense. Thus, $5 of § 1.163(j)–6(g)(4) business interest expense is treated as paid or accrued by X in 2020 and is not subject to the section 163(j) limitation at X's level. Pursuant to paragraph (h)(3) of this section, immediately before the disposition, X increases the basis of its PRS interest from $70 to $95 (add back of $20 of EBIE from 2018 and $5 of remaining EBIE from 2019). Thus, X has a $25 section 741 loss recognized on the sale ($70 − $95).

(p) *Applicability dates.*

(1) *In general.** * *

(2) *Paragraphs (c)(1) and (2), (d)(3) through (5), (e)(5), (f)(1)(iii), (g)(4), (n), and (o)(24) through (29), and (34) through (36).* Paragraphs (c)(1) and (2), (d)(3) through (5), (e)(5), (f)(1)(iii), (g)(4), (n), and (o)(24) through (29), and (34) through (36) of this section apply to taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in paragraphs (c)(1) and (2), (d)(3) through (5), (e)(5), (f)(1)(iii), (g)(4), (n), and (o)(24) through (29), and (34) through (36) to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.382–7, 1.383–0, 1.383–1, 1.469–9, 1.469–11, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–36, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905 as modified by T.D. 9943, for that taxable year and for each subsequent taxable year.

■ **Par. 7.** Section 1.163(j)–7 is amended by revising paragraph (a), adding paragraphs (c) through (f), (g)(3) and (4), (h), (k), and (l), and revising paragraph (m) to read as follows:

§ 1.163 (j)–7 Application of the section 163(j) limitation to foreign corporations and United States shareholders.

(a) *Overview.* This section provides rules for the application of section 163(j) to relevant foreign corporations and United States shareholders of relevant foreign corporations. Paragraph (b) of this section provides the general rule regarding the application of section 163(j) to a relevant foreign corporation. Paragraph (c) of this section provides rules for applying section 163(j) to CFC group members of a CFC group. Paragraph (d) of this section provides rules for determining a specified group and specified group members. Paragraph (e) of this section provides rules and procedures for treating a specified group member as a CFC group member and for determining a CFC group. Paragraph (f) of this section provides rules regarding the treatment of a CFC group member that has ECI. Paragraph (g) of this section provides rules concerning the computation of ATI of an applicable CFC. Paragraph (h) of this section provides a safe harbor that exempts certain stand-alone applicable CFCs and CFC groups from the application of section 163(j) for a taxable year. Paragraphs (i) and (j) of this section are reserved. Paragraph (k) of this section provides definitions that apply for purposes of this section (see also § 1.163(j)–1 for additional definitions). Paragraph (l) of this section provides examples illustrating the application of this section.

* * * * *

(c) *Application of section 163(j) to CFC group members of a CFC group*—(1) *Scope.* This paragraph (c) provides rules for applying section 163(j) to a

CFC group and a CFC group member. Paragraph (c)(2) of this section provides rules for computing a single section 163(j) limitation for a specified period of a CFC group. Paragraph (c)(3) of this section provides rules for allocating a CFC group's section 163(j) limitation to CFC group members for specified taxable years. Paragraph (c)(4) of this section provides currency translation rules. Paragraph (c)(5) of this section provides special rules for specified periods beginning in 2019 or 2020.

(2) *Calculation of section 163(j) limitation for a CFC group for a specified period*—(i) *In general.* A single section 163(j) limitation is computed for a specified period of a CFC group. For purposes of applying section 163(j) and the section 163(j) regulations, the current-year business interest expense, disallowed business interest expense carryforwards, business interest income, floor plan financing interest expense, and ATI of a CFC group for a specified period equal the sums of each CFC group member's respective amounts for its specified taxable year with respect to the specified period. A CFC group member's current-year business interest expense, business interest income, floor plan financing interest expense, and ATI for a specified taxable year are generally determined on a separate-company basis. For purposes of determining the ATI of a CFC group, § 1.163(j)–1(b)(1)(vii) (providing that ATI cannot be less than zero) applies with respect to the ATI of the CFC group but not the ATI of any CFC group member.

(ii) *Certain transactions between CFC group members disregarded.* Any transaction between CFC group members of a CFC group that is entered into with a principal purpose of affecting a CFC group or a CFC group member's section 163(j) limitation by increasing or decreasing a CFC group or a CFC group member's ATI or business interest income for a specified taxable year is disregarded for purposes of applying section 163(j) and the section 163(j) regulations.

(3) *Deduction of business interest expense*—(i) *CFC group business interest expense*—(A) *In general.* The extent to which a CFC group member's current-year business interest expense and disallowed business interest expense carryforwards for a specified taxable year that ends with or within a specified period may be deducted under section 163(j) is determined under the rules and principles of § 1.163(j)–5(a)(2) and (b)(3)(ii), subject to the modifications described in paragraph (c)(3)(i)(B) of this section.

(B) *Modifications to relevant terms.* For purposes of paragraph (c)(3)(i)(A) of this section, the rules and principles of § 1.163(j)–5(b)(3)(ii) are applied by—

(*1*) Replacing ''§ 1.163(j)–4(d)(2)'' in § 1.163(j)–5(a)(2)(ii) with ''§ 1.163(j)–7(c)(2)(i)'';

(*2*) Replacing the term ''allocable share of the consolidated group's remaining section 163(j) limitation'' with ''allocable share of the CFC group's remaining section 163(j) limitation'';

(*3*) Replacing the terms ''consolidated group'' and ''group'' with ''CFC group'';

(*4*) Replacing the term ''consolidated group's remaining section 163(j) limitation'' with ''CFC group's remaining section 163(j) limitation'';

(*5*) Replacing the term ''consolidated return year'' with ''specified period'';

(*6*) Replacing the term ''current year'' or ''current-year'' with ''current specified period'' or ''specified taxable year with respect to the current specified period,'' as the context requires;

(*7*) Replacing the term ''member'' with ''CFC group member''; and

(*8*) Replacing the term ''taxable year'' with ''specified taxable year with respect to a specified period.''

(ii) *Carryforwards treated as attributable to the same taxable year.* For purposes of applying the principles of § 1.163(j)–5(b)(3)(ii), as required under paragraph (c)(3)(i) of this section, CFC group members' disallowed business interest expense carryforwards that arose in specified taxable years with respect to the same specified period are treated as disallowed business interest expense carryforwards from taxable years ending on the same date and are deducted on a pro rata basis, under the principles of § 1.163(j)–5(b)(3)(ii)(C)(*3*), pursuant to paragraph (c)(3)(i) of this section.

(iii) *Multiple specified taxable years of a CFC group member with respect to a specified period.* If a CFC group member has more than one specified taxable year (each year, an *applicable specified taxable year*) with respect to a single specified period of a CFC group, then all the applicable specified taxable years are taken into account for purposes of applying the principles of § 1.163(j)–5(b)(3)(ii), as required under paragraph (c)(3)(i) of this section, with respect to the specified period. The portion of the section 163(j) limitation allocable to disallowed business interest expense carryforwards of the CFC group member that arose in taxable years before the first applicable specified taxable year is prorated among the applicable specified taxable years in proportion to the number of days in each applicable specified taxable year.

(iv) *Limitation on pre-group disallowed business interest expense carryforward*—(A) *General rule*—(*1*) *CFC group member pre-group disallowed business interest expense carryforward.* This paragraph (c)(3)(iv) applies to pre-group disallowed business interest expense carryforwards of a CFC group member. The amount of the pre-group disallowed business interest expense carryforwards described in the preceding sentence that may be included in any CFC group member's business interest expense deduction for any specified taxable year under this paragraph (c)(3) may not exceed the aggregate section 163(j) limitation for all specified periods of the CFC group, determined by reference only to the CFC group member's items of income, gain, deduction, and loss, and reduced (including below zero) by the CFC group member's business interest expense (including disallowed business interest expense carryforwards) taken into account as a deduction by the CFC group member in all specified taxable years in which the CFC group member has continuously been a CFC group member of the CFC group (*cumulative section 163(j) pre-group carryforward limitation*).

(*2*) *Subgrouping.* In the case of a pre-group disallowed business interest expense carryforward, a pre-group subgroup is composed of the CFC group member with the pre-group disallowed business interest expense carryforward (the *loss member*) and each other CFC group member of the loss member's CFC group (the *current group*) that was a member of the CFC group in which the pre-group disallowed business interest expense carryforward arose and joined the specified group of the current group at the same time as the loss member. A CFC group member that is a member of a pre-group subgroup remains a member of the pre-group subgroup until its first taxable year during which it ceases to be a member of the same specified group as the loss member. For purposes of this paragraph (c), the rules and principles of § 1.163(j)–5(d)(1)(B) apply to a pre-group subgroup as if the pre-group subgroup were a SRLY subgroup.

(*3*) *Transition rule.* Solely for purposes of paragraph (c)(3)(iv)(A)(*2*) of this section, a CFC group includes a group of applicable CFCs for which a CFC group election was made under guidance under section 163(j) published on December 28, 2018. Therefore, if the requirements of paragraph (c)(3)(iv)(A)(*2*) of this section are satisfied, a group of applicable CFCs described in the preceding sentence may be treated as a pre-group subgroup.

(B) *Deduction of pre-group disallowed business interest expense carryforwards.* Notwithstanding paragraph (c)(3)(iv)(A)(*1*) of this section, pre-group disallowed business interest expense carryforwards are available for deduction by a CFC group member in its specified taxable year only to the extent the CFC group has remaining section 163(j) limitation for the specified period after the deduction of current-year business interest expense and disallowed business interest expense carryforwards from earlier taxable years that are permitted to be deducted in specified taxable years of CFC group members with respect to the specified period. See paragraph (c)(3)(i) of this section and § 1.163(j)–5(b)(3)(ii)(A). Pre-group disallowed business interest expense carryforwards are deducted on a pro rata basis (under the principles of paragraph (c)(3)(i) of this section and § 1.163(j)–5(b)(3)(ii)(C)(*4*)) with other disallowed business interest expense carryforwards from taxable years ending on the same date.

(4) *Currency translation.* For purposes of applying this paragraph (c), items of a CFC group member are translated into a single currency for the CFC group and back to the functional currency of the CFC group member using the average exchange rate for the CFC group member's specified taxable year. The single currency for the CFC group may be the U.S. dollar or the functional currency of a plurality of the CFC group members.

(5) *Special rule for specified periods beginning in 2019 or 2020*—(i) *50 percent ATI limitation applies to a specified period of a CFC group.* In the case of a CFC group, § 1.163(j)–2(b)(2) (including the election under § 1.163(j)–2(b)(2)(ii)) applies to a specified period of the CFC group beginning in 2019 or 2020, rather than to a specified taxable year of a CFC group member. An election under § 1.163(j)–2(b)(2)(ii) for a specified period of a CFC group is not effective unless made by each designated U.S. person. Except as otherwise provided in this paragraph (c)(5)(i), the election is made in accordance with Revenue Procedure 2020–22, 2020–18 I.R.B. 745. For purposes of applying § 1.964–1(c), the election is treated as if made for each CFC group member.

(ii) *Election to use 2019 ATI applies to a specified period of a CFC group*—(A) *In general.* In the case of a CFC group, for purposes of applying paragraph (c)(2) of this section, an election under § 1.163(j)–2(b)(3)(i) is made for a specified period of a CFC group beginning in 2020 and applies to the specified taxable years of each CFC group member with respect to such specified period, taking into account the application of paragraph (c)(5)(ii)(B) of this section. The election under § 1.163(j)–2(b)(3)(i) does not apply to any specified taxable year of a CFC group member other than those described in the preceding sentence. An election under § 1.163(j)–2(b)(3)(i) for a specified period of a CFC group is not effective unless made by each designated U.S. person. Except as otherwise provided in this paragraph (c)(5)(ii)(A), the election is made in accordance with Revenue Procedure 2020–22, 2020–18 I.R.B. 745. For purposes of applying § 1.964–1(c), the election is treated as if made for each CFC group member.

(B) *Specified taxable years that do not begin in 2020.* If a specified taxable year of a CFC group member with respect to the specified period described in paragraph (c)(5)(ii)(A) of this section begins in 2019, then, for purposes of applying paragraph (c)(2) of this section, § 1.163(j)–2(b)(3) is applied to such specified taxable year by substituting ''2018'' for ''2019'' and ''2019'' for ''2020.'' If a specified taxable year of a CFC group member with respect to the specified period described in paragraph (c)(5)(ii)(A) of this section begins in 2021, then, for purposes of applying paragraph (c)(2) of this section, § 1.163(j)–2(b)(3) is applied to such specified taxable year by substituting ''2020'' for ''2019'' and ''2021'' for ''2020.''

(d) *Determination of a specified group and specified group members*—(1) *Scope.* This paragraph (d) provides rules for determining a specified group and specified group members. Paragraph (d)(2) of this section provides rules for determining a specified group. Paragraph (d)(3) of this section provides rules for determining specified group members.

(2) *Rules for determining a specified group*—(i) *Definition of a specified group.* Subject to paragraph (d)(2)(ii) of this section, the term *specified group* means one or more applicable CFCs or chains of applicable CFCs connected through stock ownership with a specified group parent (which is included in the specified group only if it is an applicable CFC), but only if—

(A) The specified group parent owns directly or indirectly stock meeting the requirements of section 1504(a)(2)(B) in at least one applicable CFC; and

(B) Stock meeting the requirements of section 1504(a)(2)(B) in each of the applicable CFCs (except the specified group parent) is owned directly or indirectly by one or more of the other applicable CFCs or the specified group parent.

(ii) *Indirect ownership.* For purposes of applying paragraph (d)(2)(i) of this section, stock is owned indirectly only if it is owned under section 318(a)(2)(A) through a partnership or under section 318(a)(2)(A) or (B) through an estate or trust not described in section 7701(a)(30).

(iii) *Specified group parent.* The term *specified group parent* means a qualified U.S. person or an applicable CFC.

(iv) *Qualified U.S. person.* The term *qualified U.S. person* means a United States person described in section 7701(a)(30)(A) or (C). For purposes of this paragraph (d), members of a consolidated group that file (or that are required to file) a consolidated U.S. Federal income tax return are treated as a single qualified U.S person and individuals described in section 7701(a)(30)(A) whose filing status is married filing jointly are treated as a single qualified U.S. person.

(v) *Stock.* For purposes of this paragraph (d)(2), the term *stock* has the same meaning as ''stock'' in section 1504 (without regard to § 1.1504–4, except as provided in paragraph (d)(2)(vi) of this section) and all shares of stock within a single class are considered to have the same value. Thus, control premiums and minority and blockage discounts within a single class are not taken into account.

(vi) *Options treated as exercised.* For purposes of this paragraph (d)(2), options that are reasonably certain to be exercised, as determined under § 1.1504–4(g), are treated as exercised. For purposes of this paragraph (d)(2)(vi), options include call options, warrants, convertible obligations, put options, and any other instrument treated as an option under § 1.1504–4(d), determined by replacing the term ''a principal purpose of avoiding the application of section 1504 and this section'' with ''a principal purpose of avoiding the application of section 163(j).''

(vii) *When a specified group ceases to exist.* The principles of § 1.1502–75(d)(1), (d)(2)(i) and (ii), and (d)(3)(i) through (iv) apply for purposes of determining when a specified group ceases to exist. Solely for purposes of applying these principles, references to the common parent are treated as references to the specified group parent and each applicable CFC that is treated as a specified group member for a taxable year with respect to a specified period is treated as affiliated with the specified group parent from the beginning to the end of the specified

period, without regard to the beginning or end of its taxable year.

(3) *Rules for determining a specified group member.* If two or more applicable CFCs are included in a specified group on the last day of a taxable year of each applicable CFC that ends with or within a specified period, then each applicable CFC is a *specified group member* with respect to the specified period for its entire taxable year ending with or within the specified period. If only one applicable CFC is included in a specified group on the last day of its taxable year that ends with or within the specified period, it is not a specified group member. If an applicable CFC has multiple taxable years that end with or within a specified period, this paragraph (d)(3) is applied separately to each taxable year to determine if the applicable CFC is a specified group member for such taxable year.

(e) *Rules and procedures for treating a specified group as a CFC group*—(1) *Scope.* This paragraph (e) provides rules and procedures for treating a specified group member as a CFC group member and for determining a CFC group for purposes of applying section 163(j) and the section 163(j) regulations.

(2) *CFC group and CFC group member*—(i) *CFC group.* The term *CFC group* means, with respect to a specified period, all CFC group members for their specified taxable years.

(ii) *CFC group member.* The term *CFC group member* means, with respect to a specified taxable year and a specified period, a specified group member of a specified group for which a CFC group election is in effect. However, notwithstanding the prior sentence, a specified group member is not treated as a CFC group member for a taxable year of the specified group member beginning before January 1, 2018.

(3) *Duration of a CFC group.* A CFC group continues until the CFC group election is revoked, or there is no longer a specified period with respect to the specified group. A failure to provide the information described in paragraph (e)(6) of this section does not terminate a CFC group election.

(4) *Joining or leaving a CFC group.* If an applicable CFC becomes a specified group member for a specified taxable year with respect to a specified period of a specified group for which a CFC group election is in effect, the CFC group election applies to the applicable CFC and the applicable CFC becomes a CFC group member. If an applicable CFC ceases to be a specified group member for a specified taxable year with respect to a specified period of a specified group for which a CFC group election is in effect, the CFC group election terminates solely with respect to the applicable CFC.

(5) *Manner of making or revoking a CFC group election*—(i) *In general.* An election is made or revoked under this paragraph (e)(5) (*CFC group election*) with respect to a specified period of a specified group. A CFC group election remains in effect for each specified period of the specified group until revoked. A CFC group election that is in effect with respect to a specified period of a specified group applies to each specified group member for its specified taxable year that ends with or within the specified period. The making or revoking of a CFC group election is not effective unless made or revoked by each designated U.S. person.

(ii) *Revocation by election.* A CFC group election cannot be revoked with respect to any specified period beginning before 60 months following the last day of the specified period for which the election was made. Once a CFC group election has been revoked, a new CFC group election cannot be made with respect to any specified period beginning before 60 months following the last day of the specified period for which the election was revoked.

(iii) *Timing.* A CFC group election must be made or revoked with respect to a specified period of a specified group no later than the due date (taking into account extensions, if any) of the original Federal income tax return for the taxable year of each designated U.S. person in which or with which the specified period ends.

(iv) *Election statement.* To make or revoke a CFC group election for a specified period of a specified group, each designated U.S. person must attach a statement to its relevant Federal income tax or information return in accordance with publications, forms, instructions, or other guidance. The statement must include the name and taxpayer identification number of all designated U.S. persons, a statement that the CFC group election is being made or revoked, as applicable, the specified period for which the CFC group election is being made or revoked, and the name of each CFC group member and its specified taxable year with respect to the specified period. The statement must be filed in the manner prescribed in publications, forms, instructions, or other guidance.

(v) *Effect of prior CFC group election.* A CFC group election is made solely pursuant to the provisions of this paragraph (e)(5), without regard to whether a CFC group election described in guidance under section 163(j) published on December 28, 2018, was in effect.

(6) *Annual information reporting.* Each designated U.S. person must attach a statement to its relevant Federal income tax or information return for each taxable year in which a CFC group election is in effect that contains information concerning the computation of the CFC group's section 163(j) limitation and the application of paragraph (c)(3) of this section to the CFC group in accordance with publications, forms, instructions, or other guidance.

(f) *Treatment of a CFC group member that has ECI*—(1) *In general.* If a CFC group member has ECI in its specified taxable year, then for purposes of section 163(j) and the section 163(j) regulations—

(i) The items, disallowed business interest expense carryforwards, and other attributes of the CFC group member that are ECI are treated as items, disallowed business interest expense carryforwards, and attributes of a separate applicable CFC (such deemed corporation, an *ECI deemed corporation*) that has the same taxable year and shareholders as the applicable CFC; and

(ii) The ECI deemed corporation is not treated as a specified group member for the specified taxable year.

(2) [Reserved].

(g) * * *

(3) *Treatment of certain foreign income taxes.* For purposes of computing the ATI of a relevant foreign corporation for a taxable year, no deduction is taken into account for any foreign income tax (as defined in § 1.960–1(b), but substituting the phrase ''relevant foreign corporation'' for the phrase ''controlled foreign corporation'').

(4) *Anti-abuse rule*—(i) *In general.* If a specified group member of a specified group or an applicable partnership (*specified lender*) includes an amount (*payment amount*) in income and such amount is attributable to business interest expense incurred by another specified group member or an applicable partnership of the specified group (*specified borrower*) during its taxable year, then the ATI of the specified borrower for the taxable year is increased by the ATI adjustment amount if—

(A) The business interest expense is incurred with a principal purpose of reducing the Federal income tax liability of any United States shareholder of a specified group member (including over other taxable years);

(B) Absent the application of this paragraph (g)(4), the effect of the specified borrower treating all or part of the payment amount as disallowed business interest expense would be to reduce the Federal income tax liability of any United States shareholder of a specified group member; and

(C) Either no CFC group election is in effect with respect to the specified group or the specified borrower is an applicable partnership.

(ii) *ATI adjustment amount*—(A) *In general.* For purposes of this paragraph (g)(4), the term *ATI adjustment amount* means, with respect to a specified borrower and a taxable year, the product of 3⅓ and the lesser of the payment amount or the disallowed business interest expense, computed without regard to this paragraph (g)(4).

(B) *Special rule for taxable years or specified periods beginning in 2019 or 2020.* For any taxable year of an applicable CFC or specified taxable year of a CFC group member with respect to a specified period for which the section 163(j) limitation is determined based, in part, on 50 percent of ATI, in accordance with § 1.163(j)–2(b)(2), paragraph (g)(4)(ii)(A) of this section is applied by substituting ''2'' for ''3⅓.''

(iii) *Applicable partnership.* For purposes of this paragraph (g)(4), the term *applicable partnership* means, with respect to a specified group, a partnership in which at least 80 percent of the interests in profits or capital is owned, directly or indirectly through one or more other partnerships, by specified group members of the specified group. For purposes of this paragraph (g)(4)(iii), a partner's interest in the profits of a partnership is determined in accordance with the rules and principles of § 1.706–1(b)(4)(ii) and a partner's interest in the capital of a partnership is determined in accordance with the rules and principles of § 1.706–1(b)(4)(iii).

(h) *Election to apply safe-harbor*—(1) *In general.* If an election to apply this paragraph (h)(1) (*safe-harbor election*) is in effect with respect to a taxable year of a stand-alone applicable CFC or a specified taxable year of a CFC group member, as applicable, then, for such year, no portion of the applicable CFC's business interest expense is disallowed under the section 163(j) limitation. This paragraph (h) does not apply to excess business interest expense, as described in § 1.163(j)–6(f)(2), until the taxable year in which it is treated as paid or accrued by an applicable CFC under § 1.163(j)–6(g)(2)(i). Furthermore, excess business interest expense is not taken into account for purposes of determining whether the safe-harbor election is available for a stand-alone applicable CFC or a CFC group until the taxable year in which it is treated as paid or accrued by an applicable CFC under § 1.163(j)–6(g)(2)(i).

(2) *Eligibility for safe-harbor election*—(i) *Stand-alone applicable CFC.* The safe-harbor election may be made for the taxable year of a stand-alone applicable CFC only if, for the taxable year, the business interest expense of the applicable CFC is less than or equal to either—

(A) The business interest income of the applicable CFC; or

(B) 30 percent of the lesser of the eligible amount or the qualified tentative taxable income of the applicable CFC.

(ii) *CFC group.* The safe-harbor election may be made for the specified period of a CFC group only if, for the specified period, no CFC group member has any pre-group disallowed business interest expense carryforward and the business interest expense of the CFC group for the specified period is less than or equal to either—

(A) The business interest income of the CFC group; or

(B) 30 percent of the lesser of the eligible amount or the qualified tentative taxable income of the CFC group.

(iii) *Currency translation.* For purposes of applying this paragraph (h), BII, BIE, and qualified tentative taxable income of a stand-alone applicable CFC or a CFC group must be determined using the U.S. dollar. If BII, BIE, or any items of income, gain, deduction, or loss that are taken into account in computing qualified tentative taxable income are maintained in a currency other than the U.S. dollar, then those items must be translated into the U.S. dollar using the average exchange rate for the taxable year or the specified taxable year, as applicable.

(3) *Eligible amount*—(i) *Stand-alone applicable CFC.* The *eligible amount* of a stand-alone applicable CFC for a taxable year is the sum of the amounts a domestic corporation would include in gross income under sections 951(a)(1)(A) and 951A(a), reduced by any deductions that would be allowed under section 245A (by reason of section 964(e)(4)) or section 250(a)(1)(B)(i), determined as if the domestic corporation has a taxable year that ends on the last date of the taxable year of the stand-alone applicable CFC, it wholly owns the stand-alone applicable CFC throughout the CFC's taxable year, it does not own any assets other than stock in the stand-alone applicable CFC, and it has no other items of income, gain, deduction, or loss.

(ii) *CFC group.* The *eligible amount* of a CFC group for a specified period is the sum of the amounts a domestic corporation would include in gross income under sections 951(a)(1)(A) and 951A(a), reduced by any deductions that would be allowed under section 245A (by reason of section 964(e)(4)) or section 250(a)(1)(B)(i), determined as if the domestic corporation has a taxable year that is the specified period, it wholly owns each CFC group member throughout the CFC group member's specified taxable year, it does not own any assets other than stock in the CFC group members, and it has no other items of income, gain, deduction, or loss.

(iii) *Additional rules for determining an eligible amount.* For purposes of paragraphs (h)(3)(i) and (ii) of this section, the amounts that would be included in gross income of a United States shareholder under sections 951(a)(1)(A) and 951A(a), and any corresponding deductions that would be allowed under section 245A (by reason of section 964(e)(4)) or section 250(a)(1)(B)(i), are determined by taking into account any elections that are made with respect to the applicable CFC(s), including under § 1.954–1(d)(5) (relating to the subpart F high-tax exception) and § 1.951A–2(c)(7)(viii) (relating to the GILTI high-tax exclusion). These amounts are also determined without regard to any section 163(j) limitation on business interest expense and without regard to any disallowed business interest expense carryovers. In addition, those amounts are determined by only taking in account items of the applicable CFC(s) that are properly allocable to a non-excepted trade or business under § 1.163(j)–10.

(4) *Qualified tentative taxable income.* The term *qualified tentative taxable income* means, with respect to a taxable year of a stand-alone applicable CFC, the applicable CFC's tentative taxable income, and with respect to a specified period of a CFC group, the sum of each CFC group member's tentative taxable income for the specified taxable year; provided that for purposes of this paragraph (h)(4), tentative taxable income is determined by taking into account only items properly allocable to a non-excepted trade or business under § 1.163(j)–10.

(5) *Manner of making a safe-harbor election*—(i) *In general.* A safe-harbor election is an annual election made under this paragraph (h)(5) with respect to a taxable year of a stand-alone applicable CFC or with respect to a specified period of a CFC group. A safe-

harbor election that is made with respect to a specified period of a CFC group is effective with respect to each CFC group member for its specified taxable year. A safe-harbor election is only effective if made by each designated U.S. person with respect to a stand-alone applicable CFC or a CFC group. A safe-harbor election is made with respect to a taxable year of a stand-alone applicable CFC, or a specified period of a CFC group, no later than the due date (taking into account extensions, if any) of the original Federal income tax return for the taxable year of each designated U.S. person, respectively, in which or with which the taxable year of the stand-alone applicable CFC ends or the specified period of the CFC group ends.

(ii) *Election statement.* To make a safe-harbor election, each designated U.S. person must attach to its relevant Federal income tax return or information return a statement that includes the name and taxpayer identification number of all designated U.S. persons, a statement that a safe-harbor election is being made pursuant to § 1.163(j)–7(h) and a calculation that substantiates that the requirements for making the election are satisfied, and the taxable year of the stand-alone applicable CFC or the specified period of the CFC group, as applicable, for which the safe-harbor election is being made in accordance with publications, forms, instructions, or other guidance. In the case of a CFC group, the statement must also include the name of each CFC group member and its specified taxable year that ends with or within the specified period for which the safe-harbor election is being made. The statement must be filed in the manner prescribed in publications, forms, instructions, or other guidance.

(6) *Special rule for taxable years or specified periods beginning in 2019 or 2020.* In the case of a stand-alone applicable CFC, for any taxable year beginning in 2019 or 2020, paragraph (h)(2)(i) of this section is applied by substituting ''50 percent'' for ''30 percent.'' In the case of a CFC group, for any specified period beginning in 2019 or 2020, paragraph (h)(2)(ii)(A) of this section is applied by substituting ''50 percent'' for ''30 percent.''

* * * * *

(k) *Definitions.* The following definitions apply for purposes of this section.

(1) *Applicable partnership.* The term *applicable partnership* has the meaning provided in paragraph (g)(4)(iii) of this section.

(2) *Applicable specified taxable year.* The term *applicable specified taxable year* has the meaning provided in paragraph (c)(3)(iii) of this section.

(3) *ATI adjustment amount.* The term *ATI adjustment amount* has the meaning provided in paragraph (g)(4)(ii) of this section.

(4)–(5) [Reserved].

(6) *CFC group.* The term *CFC group* has the meaning provided in paragraph (e)(2)(i) of this section.

(7) *CFC group election.* The term *CFC group election* means the election described in paragraph (e)(5) of this section.

(8) *CFC group member.* The term *CFC group member* has the meaning provided in paragraph (e)(2)(ii) of this section.

(9) [Reserved].

(10) *Cumulative section 163(j) pre-group carryforward limitation.* The term *cumulative section 163(j) pre-group carryforward limitation* has the meaning provided in paragraph (c)(3)(iv)(A)(*1*) of this section.

(11) *Current group.* The term *current group* has the meaning provided in paragraph (c)(3)(iv)(A)(*2*) of this section.

(12) *Designated U.S. person.* The term *designated U.S. person* means—

(i) With respect to a stand-alone applicable CFC, each controlling domestic shareholder, as defined in § 1.964–1(c)(5)(i) of the applicable CFC; or

(ii) With respect to a specified group, the specified group parent, if the specified group parent is a qualified U.S. person, or each controlling domestic shareholder, as defined in § 1.964–1(c)(5)(i), of the specified group parent, if the specified group parent is an applicable CFC.

(13) *ECI deemed corporation.* The term *ECI deemed corporation* has the meaning provided in paragraph (f)(1)(i) of this section.

(14) *Effectively connected income.* The term *effectively connected income* (or *ECI*) means income or gain that is ECI, as defined in § 1.884–1(d)(1)(iii), and deduction or loss that is allocable to, ECI, as defined in § 1.884–1(d)(1)(iii).

(15) *Eligible amount.* The term *eligible amount* has the meaning provided in paragraph (h)(3)(i) of this section.

(16) *Former group.* The term *former group* has the meaning provided in paragraph (c)(3)(iv)(A)(*2*) of this section.

(17) *Loss member.* The term *loss member* has the meaning provided in paragraph (c)(3)(iv)(A)(*2*) of this section.

(18) *Payment amount.* The term *payment amount* has the meaning provided in paragraph (g)(4)(i) of this section.

(19) *Pre-group disallowed business interest expense carryforward.* The term *pre-group disallowed business interest expense carryforward* means, with respect to a CFC group member and a specified taxable year, any disallowed business interest expense carryforward of the CFC group member that arose in a taxable year during which the CFC group member (or its predecessor) was not a CFC group member of the CFC group.

(20) *Qualified tentative taxable income.* The term *qualified tentative taxable income* has the meaning provided in paragraph (h)(4) of this section.

(21) *Qualified U.S. person.* The term *qualified U.S. person* has the meaning provided in paragraph (d)(2)(iv) of this section.

(22) *Relevant period.* The term *relevant period* has the meaning provided in paragraph (c)(3)(iv)(A)(*2*) of this section.

(23) *Safe-harbor election.* The term *safe-harbor election* has the meaning provided in paragraph (h)(1) of this section.

(24) *Specified borrower.* The term *specified borrower* has the meaning provided in paragraph (g)(4)(i) of this section.

(25) *Specified group.* The term *specified group* has the meaning provided in paragraph (d)(2)(i) of this section.

(26) *Specified group member.* The term *specified group member* has the meaning provided in paragraph (d)(3) of this section.

(27) *Specified group parent.* The term *specified group parent* has the meaning provided in paragraph (d)(2)(iii) of this section.

(28) *Specified lender.* The term *specified lender* has the meaning provided in paragraph (g)(4)(i) of this section.

(29) *Specified period*—(i) *In general.* Except as otherwise provided in paragraph (k)(29)(ii) of this section, the term *specified period* means, with respect to a specified group—

(A) If the specified group parent is a qualified U.S. person, the period ending on the last day of the taxable year of the specified group parent and beginning on the first day after the last day of the specified group's immediately preceding specified period; or

(B) If the specified group parent is an applicable CFC, the period ending on the last day of the specified group parent's required year described in section 898(c)(1), without regard to section 898(c)(2), and beginning on the first day after the last day of the specified group's immediately preceding specified period.

(ii) *Short specified period.* A specified period begins no earlier than the first

date on which a specified group exists. A specified period ends on the date a specified group ceases to exist under paragraph (d)(2)(vii) of this section. If the last day of a specified period, as determined under paragraph (k)(29)(i) of this section, changes, and, but for this paragraph (k)(29)(ii), the change in the last day of the specified period would result in the specified period being longer than 12 months, the specified period ends on the date on which the specified period would have ended had the change not occurred.

(30) *Specified taxable year.* The term *specified taxable year* means, with respect to an applicable CFC that is a specified group member of a specified group and a specified period, a taxable year of the applicable CFC that ends with or within the specified period.

(31) *Stand-alone applicable CFC.* The term *stand-alone applicable CFC* means any applicable CFC that is not a specified group member.

(32) *Stock.* The term *stock* has the meaning provided in paragraph (d)(2)(v) of this section.

(l) *Examples.* The following examples illustrate the application of this section. For each example, unless otherwise stated, no exemptions from the application of section 163(j) are available, no foreign corporation has ECI, and all relevant taxable years and specified periods begin after December 31, 2020.

(1) *Example 1. Specified taxable years included in specified period of a specified group*—(i) *Facts.* As of June 30, Year 1, USP, a domestic corporation, owns 60 percent of the common stock of FP, which owns all of the stock of FC1, FC2, and FC3. The remaining 40 percent of the common stock of FP is owned by an unrelated foreign corporation. FP has a single class of stock. FP acquired the stock of FC3 from an unrelated person on March 22, Year 1. The acquisition did not result in a change in FC3's taxable year or a close of its taxable year. USP's interest in FP and FP's interest in FC1 and FC2 has been the same for several years. USP has a taxable year ending June 30, Year 1, which is not a short taxable year. Each of FP, FC1, FC2, and FC3 are applicable CFCs. Pursuant to section 898(c)(2), FP and FC1 have taxable years ending May 31, Year 1. Pursuant to section 898(c)(1), FC2 and FC3 have taxable years ending June 30, Year 1.

(ii) *Analysis*—(A) *Determining a specified group and specified period of the specified group.* Pursuant to paragraph (d) of this section, FP, FC1, FC2, and FC3 are members of a specified group, and FP is the specified group parent. Because the specified group parent, FP, is an applicable CFC, the specified period of the specified group is the period ending on June 30, Year 1, which is the last day of FP's required year described in section 898(c)(1), without regard to section 898(c)(2), and beginning on July 1, Year 0, which is the first day following the last day of the specified group's immediately preceding specified period (June 30, Year 0). See paragraph (k)(29)(i)(B) of this section.

(B) *Determining the specified taxable years with respect to the specified period.* Pursuant to paragraph (d)(3) of this section, because each of FP and FC1 are included in the specified group on the last day of their taxable years ending May 31, Year 1, and such taxable years end with or within the specified period ending June 30, Year 1, FP and FC1 are specified group members with respect to the specified period ending June 30, Year 1, for their entire taxable years ending May 31, Year 1, and those taxable years are specified taxable years. Similarly, because each of FC2 and FC3 are included in the specified group on the last day of their taxable years ending June 30, Year 1, and such taxable years end with or within the specified period ending June 30, Year 1, FC2 and FC3 are specified group members with respect to the specified period ending June 30, Year 1, for their entire taxable years ending June 30, Year 1, and those taxable years are specified taxable years. The fact that FC3 was acquired on March 22, Year 1, does not prevent FC3 from being a specified group member with respect to the specified period for the portion of its specified taxable year before March 22, Year 1.

(2) *Example 2. CFC groups*—(i) *Facts.* The facts are the same as in *Example 1* in paragraph (l)(1)(i) of this section except that, in addition, a CFC group election is in place with respect to the specified period ending June 30, Year 1.

(ii) *Analysis.* Because a CFC group election is in place for the specified period ending June 30, Year 1, pursuant to paragraph (e)(2)(ii) of this section, each specified group member is a CFC group member with respect to its specified taxable year ending with or within the specified period. Accordingly, FP, FC1, FC2, and FC3 are CFC group members with respect to the specified period ending June 30, Year 1, for their specified taxable years ending May 31, Year 1, and June 30, Year 1, respectively. Pursuant to paragraph (e)(2)(i) of this section, the CFC group for the specified period ending June 30, Year 1, consists of FP, FC1, FC2, and FC3 for their specified taxable years ending May 31, Year 1, and June 30, Year 1, respectively. Pursuant to paragraph (c)(2) of this section, a single section 163(j) limitation is computed for the specified period ending June 30, Year 1. That section 163(j) calculation will include FP and FC1's specified taxable years ending May 31, Year 1, and FC2 and FC3's specified taxable years ending June 30, Year 1.

(3) *Example 3. Application of anti-abuse rule*—(i) *Facts.* USP, a domestic corporation, owns all of the stock of CFC1 and CFC2. Thus, USP is the specified group parent of a specified group, the specified group members of which are CFC1 and CFC2. USP has a calendar year taxable year. All specified group members also have a calendar year taxable year and a functional currency of the U.S. dollar. CFC1 is organized in, and a tax resident of, a jurisdiction that imposes no tax on certain types of income, including interest income. With respect to Year 1, USP expects to pay no residual U.S. tax on its income inclusion under section 951A(a) (GILTI inclusion amount) and expects to have unused foreign tax credits in the category described in section 904(d)(1)(A). A CFC group election is not in effect for Year 1. With a principal purpose of reducing USP's Federal income tax liability in subsequent taxable years, on January 1, Year 1, CFC1 loans $100x to CFC2. On December 31, Year 1, CFC2 pays interest of $10x to CFC1 and repays the principal of $100x. Absent the application of paragraph (g)(4)(i) of this section, all $10x of CFC2's interest expense would be disallowed business interest expense and, therefore, CFC2 would have $10x of disallowed business interest expense carryforward to Year 2. In Year 2, CFC2 disposes of one of its businesses at a substantial gain that gives rise to tested income (within the meaning of section 951A(c)(2)(A) and § 1.951A–2(b)(1)). As a result of the gain being included in the ATI of CFC2, absent the application of paragraph (g)(4)(i) of this section, CFC2 would be allowed to deduct the entire $10x of disallowed business interest expense carryforward and therefore reduce the amount of its tested income. Also, USP would pay residual U.S. tax on its GILTI inclusion amount in Year 2, without regard to the application of paragraph (g)(4)(i) of this section.

(ii) *Analysis.* The $10x of business interest expense paid in Year 1 is a payment amount described in paragraph (g)(4)(i) of this section because it is between specified group members, CFC1 and CFC2. Furthermore, the requirements of paragraphs (g)(4)(i)(A), (B), and (C) of this section are satisfied because the $10x of business interest expense is incurred with a principal

purpose of reducing USP's Federal income tax liability; absent the application of paragraph (g)(4)(i) of this section, the effect of CFC2 treating the $10x of business interest expense as disallowed business interest expense in Year 1 would be to reduce USP's Federal income tax liability in Year 2; and no CFC group election is in effect with respect to the specified group in Year 1. Because the requirements of paragraphs (g)(4)(i)(A), (B), and (C) of this section are satisfied, CFC2's ATI for Year 1 is increased by the ATI adjustment amount, or $33.33x, which is the amount equal to 3 ⅓ multiplied by $10x (the lesser of the payment amount of $10x and the disallowed business interest expense of $10x). As a result, the $10x of business interest expense is not disallowed business interest expense of CFC2 in Year 1, and therefore does not give rise to a disallowed business interest expense carryforward to Year 2.

(m) *Applicability dates*—(1) *General applicability date.* Except as provided in paragraph (m)(2) of this section, this section applies for a taxable year of a foreign corporation beginning on or after November 13, 2020.

(2) *Exception.* Paragraphs (a), (c)(1), (c)(2)(i) and (ii), and (c)(3) through (5), (d), (e), (f)(1), (g)(3) and (4), (h), and (k)(1) through (3), (6) through (8), and (10) through (32) of this section apply for a taxable year of a foreign corporation beginning on or after March 22, 2021.

(3) *Early application*—(i) *Rules for paragraphs (b) and (g)(1) and (2) of this section.* Taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in paragraphs (b) and (g)(1) and (2) of this section for a taxable year beginning after December 31, 2017, and before November 13, 2020, provided that those taxpayers and their related parties consistently apply all of those rules and the rules described in paragraph (m)(4) of this section for that taxable year. If a taxpayer and its related parties apply the rules described in paragraph (m)(4) of this section, as contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020), they will be considered as applying the rules described in paragraph (m)(4) of this section for purposes of this paragraph (m)(3)(i).

(ii) *Rules for certain other paragraphs in this section.* Taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in paragraphs (a), (c)(1), (c)(2)(i) and (ii), and (c)(3) through (5), (d), (e), (f)(1), (g)(3) and (4), (h), and (k)(1) through (3), (6) through (8), and (10) through (32) of this section for a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of those rules and the rules described in paragraph (m)(4) of this section for that taxable year and for each subsequent taxable year. If a taxpayer and its related parties apply the rules described in paragraph (m)(4) of this section, as contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021),they will be considered as applying the rules described in paragraph (m)(4) of this section for purposes of this paragraph (m)(3)(ii).

(4) *Additional rules that must be applied consistently.* The rules described in this paragraph (m)(4) are the section 163(j) regulations and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.382–7, 1.383–0, 1.383–1, 1.469–9, 1.469–11, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–36, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1) and 1.1504–4.

(5) *Election for prior taxable years and specified periods.* Notwithstanding paragraph (e)(5)(iii) or (h)(5)(i) of this section, in the case of a specified period of a specified group or a taxable year of a stand-alone applicable CFC that ends with or within a taxable year of a designated U.S. person ending before November 13, 2020, a CFC group election or a safe-harbor election may be made on an amended Federal income tax return filed on or before the due date (taking into account extensions, if any) of the original Federal income tax return for the first taxable year of each designated U.S. person ending on or after November 13, 2020.

■ **Par. 8.** Section 1.163(j)–10 is amended by:

■ 1. Redesignating paragraph (c)(5)(ii)(D) as paragraph (c)(5)(ii)(D)(*1*).

■ 2. Adding a subject heading for paragraph (c)(5)(ii)(D).

■ 3. Adding paragraph (c)(5)(ii)(D)(*2*).

■ 4. Redesignating paragraph (f) as paragraph (f)(1).

■ 5. Adding a subject heading for paragraph (f).

■ 6. Revising the subject heading for redesignated paragraph (f)(1).

■ 7. Adding paragraph (f)(2).

The revisions and additions read as follows:

§ 1.163 (j)–10 Allocation of interest expense, interest income, and other items of expense and gross income to an excepted trade or business.

* * * * *

(c) * * *

(5) * * *

(ii) * * *

(D) *Limitations on application of look-through rules.* * * *

(*2*) *Limitation on application of look-through rule to C corporations.* Except as provided in § 1.163(j)–9(h)(4)(iii) and (iv) (for a REIT or a partnership making the election under § 1.163(j)–9(h)(1) or (7), respectively), for purposes of applying the look-through rules in paragraph (c)(5)(ii)(B) and (C) of this section to a non-consolidated C corporation (upper-tier entity), that upper-tier entity may not apply these look-through rules to a lower-tier non-consolidated C corporation if a principal purpose for borrowing funds at the upper-tier entity level or adding an upper-tier or lower-tier entity to the ownership structure is increasing the amount of the taxpayer's basis allocable to excepted trades or businesses. For example, P wholly and directly owns S1 (the upper-tier entity), which wholly and directly owns S2. Each of S1 and S2 is a non-consolidated C corporation to which the small business exemption does not apply, and S2 is engaged in an excepted trade or business. With a principal purpose of increasing the amount of basis allocable to its excepted trades or businesses, P has S1 (rather than S2) borrow funds from a third party. S1 may not look through the stock of S2 (and may not apply the asset basis look-through rule described in paragraph (c)(5)(ii)(B)(*2*)(*iv*) of this section) for purposes of P's allocation of its basis in its S1 stock between excepted and non-excepted trades or businesses; instead, S1 must treat its stock in S2 as an asset used in a non-excepted trade or business for that purpose. However, S1 may look through the stock of S2 for purposes of S1's allocation of its basis in its S2 stock between excepted and non-excepted trades or businesses.

* * * * *

(f) *Applicability dates.*

(1) *In general.* * * *

(2) *Paragraph (c)(5)(ii)(D)(2).* The rules contained in paragraph (c)(5)(ii)(D)(*2*) of this section apply for taxable years beginning on or after March 22, 2021. However, taxpayers may choose to apply the rules in paragraph (c)(5)(ii)(D)(*2*) of this section to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently

apply all of the rules in the section 163(j) regulations as contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.383–0, 1.383–1, 1.469–9, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905 as modified by T.D. 9943, to that taxable year and each subsequent taxable year.

■ **Par. 9.** Section 1.469–4 is amended by adding paragraph (d)(6) to read as follows:

§ 1.469–4 Definition of activity.

* * * * *

(d) * * *

(6) *Activities described in section 163(d)(5)(A)(ii).* With respect to any taxpayer that is an individual, trust, estate, closely held C corporation or personal service corporation, an activity described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii) that involves the conduct of a trade or business which is not a passive activity of the taxpayer and with respect to which the taxpayer does not materially participate may not be grouped with any other activity or activities of the taxpayer, including any other activity described in § 1.469–1T(e)(6) and subject to section 163(d)(5)(A)(ii).

* * * * *

■ **Par. 10.** Section 1.469–9 is amended by adding paragraphs (b)(2)(ii)(A) and (B) to read as follows:

§ 1.469–9 Rules for certain rental real estate activities.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(A) *Real property development.* The term *real property development* means the maintenance and improvement of raw land to make the land suitable for subdivision, further development, or construction of residential or commercial buildings, or to establish, cultivate, maintain or improve timberlands (that is, land covered by timber-producing forest). Improvement of land may include any clearing (such as through the mechanical separation and removal of boulders, rocks, brush, brushwood, and underbrush from the land); excavation and gradation work; diversion or redirection of creeks, streams, rivers, or other sources or bodies of water; and the installation of roads (including highways, streets, roads, public sidewalks, and bridges), utility lines, sewer and drainage systems, and any other infrastructure that may be necessary for subdivision, further development, or construction of residential or commercial buildings, or for the establishment, cultivation, maintenance or improvement of timberlands.

(B) *Real property redevelopment.* The term *real property redevelopment* means the demolition, deconstruction, separation, and removal of existing buildings, landscaping, and infrastructure on a parcel of land to return the land to a raw condition or otherwise prepare the land for new development or construction, or for the establishment and cultivation of new timberlands.

* * * * *

■ **Par. 11.** Section 1.469–11 is amended by revising paragraphs (a)(1) and (4) to read as follows:

§ 1.469–11 Applicability date and transition rules.

(a) * * *

(1) The rules contained in §§ 1.469–1, 1.469–1T, 1.469–2, 1.469–2T, 1.469–3, 1.469–3T, 1.469–4, but not § 1.469–4(d)(6), 1.469–5 and 1.469–5T, apply for taxable years ending after May 10, 1992. The rules contained in § 1.469–4(d)(6) apply for taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in § 1.469–4(d)(6) to a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules in the section 163(j) regulations as contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.383–0, 1.383–1, 1.469–9, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4 contained in T.D. 9905 as modified by T.D. 9943, to that taxable year and each subsequent taxable year.

* * * * *

(4) The rules contained in § 1.469–9(b)(2), other than paragraphs (b)(2)(ii)(A) and (B), apply to taxable years beginning on or after November 13, 2020. Section 1.469–9(b)(2)(ii)(A) and (B) applies to taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in § 1.469–9(b)(2), other than paragraphs (b)(2)(ii)(A) and (B), to a taxable year beginning after December 31, 2017, and on or before November 13, 2020 and may choose to apply the rules in § 1.469–9(b)(2)(ii)(A) and (B) to taxable years beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules in the section 163(j) regulations contained in T.D. 9905 (§§ 1.163(j)–0 through 1.163(j)–11, effective November 13, 2020) as modified by T.D. 9943 (effective January 13, 2021), and, if applicable, §§ 1.263A–9, 1.263A–15, 1.381(c)(20)–1, 1.382–1, 1.382–2, 1.382–5, 1.382–6, 1.383–0, 1.383–1, 1.469–9, 1.704–1, 1.882–5, 1.1362–3, 1.1368–1, 1.1377–1, 1.1502–13, 1.1502–21, 1.1502–79, 1.1502–91 through 1.1502–99 (to the extent they effectuate the rules of §§ 1.382–2, 1.382–5, 1.382–6, and 1.383–1), and 1.1504–4, contained in T.D. 9905 as modified by T.D. 9943, to that taxable year and each subsequent taxable year.

* * * * *

■ **Par. 12.** Section 1.1256(e)–2 is added to read as follows:

§ 1.1256 (e)–2 Special rules for syndicates.

(a) *Allocation of losses.* For purposes of section 1256(e)(3), *syndicate* means any partnership or other entity (other than a corporation that is not an S corporation) if more than 35 percent of the losses of such entity during the taxable year are allocated to limited partners or limited entrepreneurs (within the meaning of section 461(k)(4)).

(b) *Determination of loss amount.* For purposes of section 1256(e)(3), the amount of losses to be allocated under paragraph (a) of this section is calculated without regard to section 163(j).

(c) *Example.* The following example illustrates the rules in this section:

(1) *Facts.* Entity is an S corporation that is equally owned by individuals A and B. A provides all of the goods and services provided by Entity. B provided all of the capital for Entity but does not participate in Entity's business. For the current taxable year, Entity has gross receipts of $5,000,000, non-interest expenses of $4,500,000, and interest expense of $600,000.

(2) *Analysis.* Under paragraph (b) of this section, Entity has a net loss of $100,000 ($5,000,000 minus $5,100,000) for the current taxable year. One half (50 percent) of this loss is allocated to B, a limited owner. Therefore, for the current taxable year, Entity is a syndicate within the meaning of section 1256(e)(3)(B).

(d) *Applicability date.* This section applies to taxable years beginning on or after March 22, 2021. However, taxpayers and their related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), may choose to apply the rules in this section for a taxable year beginning after December 31, 2017, and before March 22, 2021, provided that those taxpayers and their related parties consistently apply all of the rules of this section to that taxable year and each subsequent taxable year.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: December 30, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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Part V

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Section 199A Rules for Cooperatives and Their Patrons; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9947]

RIN 1545–B090

Section 199A Rules for Cooperatives and Their Patrons

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of final and temporary regulations.

SUMMARY: This document contains final regulations that provide guidance to cooperatives to which sections 1381 through 1388 of the Internal Revenue Code (Code) apply (Cooperatives) and their patrons regarding the deduction provided by section 199A(a) of the Code for qualified business income (QBI), as well as guidance to specified agricultural or horticultural cooperatives (Specified Cooperatives) and their patrons regarding the deduction provided by section 199A(g) of the Code for eligible domestic production activities undertaken by Specified Cooperatives. The final regulations also provide guidance on section 199A(b)(7), the statutory rule requiring patrons of Specified Cooperatives to reduce their QBI deduction under section 199A(a). In addition, the final regulations include a definition of *patronage and nonpatronage sourced items* under section 1388 of the Code, and revise existing regulations under section 1382 of the Code to reference this definition. Finally, this document removes the final and temporary regulations under former section 199. These final regulations affect Cooperatives as well as patrons that are individuals, partnerships, S corporations, trusts, and estates engaged in domestic trades or businesses.

DATES:

Effective date: These regulations are effective on January 14, 2021.

Applicability dates: For dates of applicability, see §§ 1.199A–7(h), 1.199A–8(h), 1.199A–9(k), 1.199A–10(i), 1.199A–11(h), 1.199A–12(j), 1.1382–3(e), and 1.1388–1(g).

FOR FURTHER INFORMATION CONTACT: Jason Deirmenjian at (202) 317–4470 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 199A, 1382, and 1388 of the Code.

Section 199A was enacted on December 22, 2017, by section 11011 of Public Law 115–97, 131 Stat. 2054, 2063, commonly referred to as the Tax Cuts and Jobs Act (TCJA). Parts of section 199A were amended on March 23, 2018, effective as if included in the TCJA, by section 101 of Division T of the Consolidated Appropriations Act, 2018, Public Law 115–141, 132 Stat. 348, 1151 (2018 Act). Section 199A applies to taxable years beginning after 2017 and before 2026. Unless otherwise indicated, all references to section 199A are to section 199A as amended by the 2018 Act.

In addition, section 13305 of the TCJA repealed section 199 (former section 199), which provided a deduction for income attributable to domestic production activities (section 199 deduction). Public Law 115–97, 131 Stat. 2054, 2126. The repeal of former section 199 is effective for all taxable years beginning after 2017.

Section 199A(a) provides taxpayers a deduction of up to 20 percent of QBI from a domestic business operated as a sole proprietorship or through a partnership, S corporation, trust, or estate, and up to 20 percent of qualified real estate investment trust (REIT) dividends and publicly traded partnership (PTP) income (section 199A(a) deduction). Section 199A(b)(7) requires patrons of Specified Cooperatives to reduce their section 199A(a) deduction if those patrons receive certain payments from Specified Cooperatives.

Section 199A(g) provides a deduction for Specified Cooperatives and their patrons (section 199A(g) deduction) that is based on the former section 199 deduction. Section 199A(g)(4)(A) defines a Specified Cooperative, in part, as an organization to which part I of subchapter T of chapter 1 of the Code (subchapter T) applies. Under section 1381(a)(2), subchapter T applies to any corporation operating on a cooperative basis, with certain exceptions not relevant here. Section 1382 provides rules regarding the taxable income of Cooperatives and section 1388 provides definitions applicable for purposes of subchapter T.

The Department of the Treasury (Treasury Department) and the IRS published proposed regulations (REG–107892–18) providing guidance on the section 199A(a) deduction in the **Federal Register** (83 FR 40884) on August 16, 2018. A second notice of proposed rulemaking providing guidance (REG–134652–18) and final regulations implementing the section 199A(a) deduction (TD 9847) were published in the **Federal Register** (84 FR 3015 and 84 FR 2952, respectively) on February 8, 2019, with corrections to TD 9847 published in the **Federal Register** (84 FR 15954) on April 17, 2019. TD 9847, which promulgated §§ 1.199A–1 through 1.199A–6 to implement the section 199A(a) deduction, does not include all the rules needed for patrons of Cooperatives to calculate their particular section 199A(a) deductions. Specifically, the rules included in TD 9847 do not address patrons' treatment of payments received from Cooperatives for purposes of section 199A(a) or the section 199A(g) deduction for Specified Cooperatives, though § 1.199A–1(e)(7) restates the reduction to a patron's section 199A(a) deduction required under section 199A(b)(7).

To address these matters, on June 19, 2019, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–118425–18) in the **Federal Register** (84 FR 28668) containing proposed regulations under sections 199A and 1388, with corrections published in the **Federal Register** (84 FR 38148) on August 6, 2019 (together, Proposed Regulations). The Proposed Regulations set forth rules to address patrons' treatment of payments received from Cooperatives for purposes of section 199A(a) and the section 199A(g) deduction for Specified Cooperatives in proposed §§ 1.199A–7 through 1.199A–12, as well as proposed rules under section 1388 regarding patronage and nonpatronage sources of income of Cooperatives. The Proposed Regulations also withdrew all proposed regulations issued under former section 199 that had not been finalized and proposed to remove the final and temporary regulations under former section 199.

The Summary of Comments and Explanation of Revisions of the final regulations summarizes the provisions of the Proposed Regulations, which are explained in greater detail in the preamble to the Proposed Regulations. After full consideration of the comments received on the Proposed Regulations, this Treasury decision adopts the Proposed Regulations with modifications in response to such comments as described in the Summary of Comments and Explanation of Revisions.

Summary of Comments and Explanation of Revisions

The purpose and scope of the final regulations is limited to providing guidance regarding the application of sections 199A(a), 199A(b)(7), 199A(g), 1382, and 1388. Section 199A(a) is generally applicable to patrons of all

Cooperatives, whereas sections 199A(b)(7) and 199A(g) apply only to Specified Cooperatives and their patrons. Section 1388 generally applies to all Cooperatives and their patrons.

The Treasury Department and the IRS received written comment submissions in response to the Proposed Regulations. All comments were considered and are available at *www.regulations.gov* or upon request. Most of the comments addressing the Proposed Regulations are summarized in this Summary of Comments and Explanation of Revisions. However, comments merely summarizing or interpreting the Proposed Regulations, recommending statutory revisions, or addressing issues which are outside the scope of the final regulations are not discussed in this Summary of Comments and Explanation of Revisions.

Commenters requested that the rules for section 199A as they apply to Cooperatives and patrons be simplified and clarified. Accordingly, while the final regulations adopt many of the rules described in the Proposed Regulations, they are revised in response to the comments received. Additionally, in response to the comments, the final regulations include clarifying language and additional examples.

Parts I through VII of this Summary of Comments and Explanation of Revisions discuss §§ 1.199A–7 through 1.199A–12, 1.1382–3, and 1.1388–1, respectively. Part VIII addresses the removal of all final and temporary regulations issued under former section 199. Part IX addresses comments on the proposed applicability date and the transition rule.

I. § 1.199A–7, Rules for Patrons of Cooperatives

A. In General

As noted in the Background, the section 199A(a) deduction allows taxpayers to deduct up to 20 percent of QBI from a domestic business operated as a sole proprietorship or through a partnership, S corporation, trust, or estate, and up to 20 percent of qualified REIT dividends and PTP income. Patrons that are individuals (as described in § 1.199A–1(a)(2)) are eligible for the section 199A(a) deduction. If patrons receive certain payments from Specified Cooperatives, then section 199A(b)(7) requires them to calculate a reduction to their section 199A(a) deduction. This part I.A provides a general outline of the rules of proposed § 1.199A–7, and the remainder of this part I addresses the specific comments received on proposed § 1.199A–7. Other than for modifications made in response to specific comments, the final regulations generally adopt the Proposed Regulations.

Proposed § 1.199A–7(a) provides special rules and definitions for patrons of cooperatives in applying §§ 1.199A–1 through –6, including definitions of patron, patronage and nonpatronage, qualified payment, and Specified Cooperative. Proposed § 1.199A–7(b) explains that patronage dividends or similar payments that a patron receives from a Cooperative are considered as generated from the trade or business the Cooperative conducts on behalf of the patron, and are therefore tested by the Cooperative at its trade or business level. Proposed § 1.199A–7(c) provides special rules for patrons and Cooperatives relating to the definition of QBI, the determination of QBI by patrons, and the determination and reporting by Cooperatives of the amount of qualified items of income, gain, deduction, and loss (collectively, qualified items) for qualified trades or businesses in distributions made to patrons. Proposed § 1.199A–7(d) provides special rules for patrons' determinations of specified service trades or businesses (SSTBs) and for Cooperatives' determination and reporting of SSTBs.

Under proposed § 1.199A–7(c)(3) and (d)(3), Cooperatives are required to report the amount of qualified items related to non-SSTBs and SSTBs in distributions made to patrons on an attachment to or on the Form 1099–PATR (or any successor form), unless the form instructions provide otherwise. Under proposed § 1.199A–7(c)(3), if a Cooperative fails to report the amount of qualified items from its non-SSTBs, then the amount of distributions from the Cooperative that may be included in the patron's QBI is presumed to be zero. Under proposed § 1.199A–7(d)(3), if a Cooperative fails to report the amount of qualified items from an SSTB (SSTB items), then only the amount of qualified items the Cooperative reports under proposed § 1.199A–7(c)(3) may be included in the patron's QBI, and the remaining amount of distributions from the Cooperative is presumed to not be included in the patron's QBI.

Proposed § 1.199A–7(e) provides special rules for patrons relating to the statutory limitations based on W–2 wages and unadjusted basis immediately after acquisition (UBIA) of qualified property. The Proposed Regulations provide that Cooperatives do not allocate their W–2 wages and UBIA of qualified property to patrons, and directs patrons to calculate the W–2 wage and UBIA of qualified property limitations at the patron level when calculating their section 199A(a) deduction.

Proposed § 1.199A–7(f) provides special rules for Specified Cooperatives and their patrons relating to calculating the section 199A(b)(7) reduction, including a requirement that Cooperatives report the amount of qualified payments (as defined in proposed § 1.199A–8(d)(2)(ii)) made to patrons on an attachment to or on the Form 1099–PATR (or any successor form). Proposed § 1.199A–7(g) provides examples that illustrate the rules in § 1.199A–7(a) through (f) for Specified Cooperatives and their patrons.

Lastly, proposed § 1.199A–7(h) generally provides that taxpayers may rely on the proposed rules in their entirety and as applied in a consistent manner until final regulations are published in the **Federal Register**. Proposed § 1.199A–7(h) also includes the transition rule relating to the repeal of the former section 199 deduction and the implementation of the new section 199A(a) deduction.

B. Comments Related to Proposed §§ 1.199A–7(c)(3) and (d)(3)

i. Requirements That Cooperative Determines Qualified Items From Non-SSTBs and Qualified Items From SSTBs

Under proposed §§ 1.199A–7(c)(3) and (d)(3), Cooperatives must separately determine the amounts of qualified items relating to non-SSTBs and qualified items relating to SSTBs in distributions made to patrons. Commenters asserted that whether income is a qualified item when earned at the Cooperative level should not be determinative of its treatment at the patron level, but that instead the determination of qualified items from non-SSTBs and SSTBs should be made by the patron based solely on whether a patronage dividend relates to a patron's trade or business. These commenters additionally asserted that the proposed rules burden Cooperatives by requiring additional information reporting and are not consistent with the provisions of subchapter T.

The final regulations do not adopt the commenters' suggestion for several reasons, including that the proposal does not comport with sections 199A(c)(3) and (d)(2). The rules of proposed §§ 1.199A–7(c)(3) and (d)(3) are consistent with the rules in TD 9847 implementing the section 199A(a) deduction generally. These rules arise from the statutory requirement that all items in the computation of the section 199A(a) deduction be qualified items as defined in section 199A(c)(3) and not

derived from an SSTB as defined in section 199A(d)(2). TD 9847 generally provides that an item of income, gain, deduction and loss is determined and reported for each trade or business by the entity or individual that directly conducts the trade or business. Patronage dividends and similar payments are considered to be directly generated from the trade or business that the Cooperative conducts on behalf of or with its patrons. For example, an individual patron must determine QBI for each trade or business it directly conducts. To the extent a patron receives patronage dividends or similar payments from a Cooperative, such patronage dividends or similar payments are considered generated from the trade or business the Cooperative conducts on behalf of or with its patron and are tested by the Cooperative at the level of its trade or business.

Failure to determine whether items of income, gain, deduction, and loss that are distributed to patrons are qualified items at the Cooperative level could result in patrons' circumvention of the statutory requirements for qualified items under section 199A(c)(3)(A) and (B), for example, that items be effectively connected with the conduct of a trade or business within the United States. Section 199A(c)(3)(B) lists items that are not treated as qualified items defined in section 199A(c)(3). All dividends, income equivalent to dividends, or payments in lieu of dividends described in section 954(c)(1)(G) are not qualified items. However, section 199A(c)(3)(B)(ii) also specifically provides that patronage dividends are not treated as dividends, income equivalent to dividends, or payments in lieu of dividends described in section 954(c)(1)(G), which means a patronage dividend can be taken into account as a qualified item to the extent otherwise qualified. The Joint Committee on Taxation report titled ''Technical Explanation of the Revenue Provisions of the House Amendment to the Senate Amendment to H.R. 1625 (Rules Committee Print 115–66)'' (JCX–6–18, released March 22, 2018) (Joint Committee Report) further clarified that other similar amounts received from Cooperatives can be included in QBI, provided those amounts are otherwise a qualified item. Joint Committee on Taxation, JCX–6–18, Technical Explanation of the Revenue Provisions of the House Amendment to the Senate Amendment to H.R. 1625 (Rules Committee Print 115–66) 25 (March 22, 2018). As a result, the Proposed Regulations define a qualified item as including a distribution for which a Cooperative is allowed a deduction under section 1382(b) or (c)(2) (including patronage dividends and other similar payments, such as money, property, qualified written notices of allocation, and qualified per-unit retain certificates, as well as money or property paid in redemption of a nonqualified written notice of allocation), provided the distribution is otherwise a qualified item. Therefore, to be a qualified item under section 199A(c)(3), patronage dividends and other similar payments must still be effectively connected (section 199A(c)(3)(A)(i)), included or allowed in income (section 199A(c)(3)(A)(ii)), and not represent amounts described in section 199A(c)(3)(B)(i) and (iii)–(vii). Additionally, items of income, gain, deduction, and loss from an SSTB are not includable in QBI with respect to individuals above the threshold amount and subject to the phase-in range under section 199A(d)(3). Any potential burden to the Cooperatives in making these determinations is outweighed by the patrons' need for this information to determine their section 199A(a) deduction.

Based upon these statutory requirements and because the Cooperative is better positioned than a patron to determine whether a patronage dividend or other similar payment is a qualified item as determined under the rules of § 199A(c)(3) and § 1.199A–3(b) and whether it is derived from an SSTB as defined in § 199A(d)(2) and § 1.199A–5, these determination rules are adopted in the final regulations without substantive change. The patron then determines if the qualified item is includible in the patron's QBI under § 1.199A–7(c)(2) and whether the qualified item from the SSTB is includible in the patron's QBI based on the threshold rules in § 199A(d)(3) and § 1.199A–5(a)(2)). There is no duplication in effort between the Cooperative and the patron with respect to these determinations. However, in response to commenters, the reporting requirements of Cooperatives have been modified to balance the burden on the Cooperatives and the patrons' need to receive information to determine their section 199A(a) deduction.

ii. Requirements That Cooperative Report Qualified Items From Non-SSTBs, Qualified Items From SSTBs, and Qualified Payments

Proposed §§ 1.199A–7(c)(3), (d)(3), and (f)(3) require Cooperatives to report qualified items from non-SSTBs, qualified items from SSTBs, and qualified payments (qualified payments are relevant only for Specified Cooperatives) to patrons. A commenter opposed these reporting requirements on the grounds that the requirements did not exist under former section 199 and do not exist under section 6044(b). In the commenter's view, Congress would have amended section 6044 to that effect if the reporting requirements were intended. The Treasury Department and the IRS agree that versions of Form 1099–PATR prior to the enactment of section 199A did not include a box for qualified payments and that section 6044(b) does not require reporting of these amounts. However, unlike former section 199, information concerning all of these amounts (qualified payments as applicable) are required for a patron to calculate its section 199A(a) deduction, including the reduction under section 199A(b)(7) for patrons of Specified Cooperatives, which did not exist under former section 199. Therefore, it is necessary for patrons to have this information, and it is most efficient for patrons to receive the information from Cooperatives on Form 1099–PATR (or any successor form). Additionally, section 199A(f)(4) authorizes the Treasury Department and the IRS to prescribe such regulations as are necessary to carry out the purposes of section 199A, including reporting requirements.

The commenter also requested removal of these reporting requirements on the grounds that Cooperatives should not be treated as relevant passthrough entities (RPEs). The Treasury Department and the IRS agree that Cooperatives are not RPEs. However, these reporting requirements emanate from the statutory requirements of section 199A and not the nature of the entities. These reporting requirements are imposed on Cooperatives because sections 199A(c) and (d) require that items of income, gain, deduction, and loss be of a certain character and from a qualified trade or business when determining the section 199A(a) deduction, and patrons need this information to determine their section 199A(a) deduction. Further, the reporting requirements applicable to Cooperatives are distinguishable from those imposed on RPEs because RPEs are required to engage in more detailed reporting, including reporting W–2 wages and UBIA of qualified property.

After consideration of the comments, the final regulations maintain a reporting requirement for Cooperatives, but the rules in proposed § 1.199A–7(c)(3) and (d)(3) are revised to simplify the Cooperative's reporting obligation with respect to qualified items from

non-SSTBs and qualified items from SSTBs. The proposed regulations required that the Cooperative report the amounts of qualified items with respect to each non-SSTB of the Cooperative, with a similar requirement for SSTBs. However, to reduce burden and clarify that Cooperatives do not make trade or business and corresponding aggregation determinations, the final regulations require the Cooperative to report the total net amount of qualified items from non-SSTBs in distributions to patrons without delineating these amounts business by business. A similar change was made to the reporting requirements for qualified items in distributions from SSTBs. Patrons then determine the extent that those payments are included in the QBI of the patrons' trade or business. For example, a patron will determine whether those payments are related to the patron's trade or business and whether any items in the SSTB distributions reported by the Cooperative are includible as qualified items of income, gain, deduction and loss at the patron's level after consideration of the threshold and phase-in amounts as applied to the patron's taxable income. In addition, the rules in proposed § 1.199A–7(b) are revised for consistency with the revision to proposed § 1.199A–7(c)(3) and (d)(3).

Commenter also suggested that the SSTB reporting requirements be revised to reflect that if a Cooperative provides services from SSTBs to patrons, the services are provided to patrons, not third parties. Therefore, any patronage dividends should be deemed a rebate, which would increase QBI of the patrons to its proper amount. Further, if the SSTBs conducted by the Cooperatives relate to personal expenses of a patron, then the SSTB patronage dividends should be excluded from the QBI calculation, but done so at the patron level, because only the patron would know whether the SSTB service is a personal expense.

Based on the commenter's suggestions, the Treasury Department and the IRS considered whether additional rules were needed and concluded that revisions are necessary to resolve certain questions raised by the commenter. Consider an example where a Cooperative provides a service to patrons as part of an SSTB of the Cooperative under section 199A(d)(2). Assume that a patron's use of that service is a deductible expense to its qualified trade or business. Patron pays the Cooperative $1,000 for the service. The Cooperative later pays the patron a patronage dividend of $50 related to the service. This patronage dividend is income under section 1385(a)(1) to the patron. Under the Proposed Regulations, assuming the patron's income is over the threshold amount (defined in section 199A(e)(2)), the patron would not be able to include the $50 in its calculation of QBI because it is SSTB income. Meanwhile, the patron would have a $1,000 expense that would reduce QBI. In substance, however, the patron would have only paid $950 for the service.

The Treasury Department and the IRS considered two approaches for resolving this asymmetry. One approach (suggested by a commenter) would permit a patron paying for services from an SSTB of the Cooperative for its trade or business to treat any patronage dividends related to those amounts as qualified items (or rebates that would reduce the expense), regardless of the threshold amounts, if the services were required or used in a qualified trade or business of the patron. A second approach would permit the allocation of part of the patron's expense to the non-qualified SSTB income. To reach the correct result, this second approach would limit the allocation of the expense to the amount of SSTB income of the Cooperative that relates to the patron's expense. Under the second approach, a patron could allocate expenses between its qualified trade or business income and the SSTB income up to the amount of the patronage dividend. Either approach reaches a similar end result with respect to the example—that is, the patron having a net $950 expense included within QBI. However, the first approach conflicts with section 199A(d)(2) in that SSTB income cannot be treated as QBI, unless the section 199A(d)(3) exception applies. The first approach also conflicts with section 1385(a)(1), which requires inclusion of patronage dividends in income, unless an exception is met under section 1385(b). In contrast, the second approach does not conflict with either the requirements of section 199A or section 1385(a)(1). Also, the commenter noted, the patron's exception to income from patronage dividends for personal, living, or family items is met under section 1385(b)(2). For clarification in that case, the patron will have to make that determination, and none of the expense or patronage dividend should be taken into account for purposes of QBI. Based on this analysis, the final regulations in § 1.199A–7(d)(3)(ii) adopt the second approach, and include an example illustrating the application of this approach.

iii. Relief From Zero-Presumption Rule

As discussed previously, if a Cooperative fails to timely report qualified items and SSTB items, proposed §§ 1.199A–7(c)(3) and (d)(3) provide that the amount of distributions from the Cooperative that may be included in the patron's QBI is presumed to be zero (zero-presumption rule). Commenters requested relief from the zero-presumption rule on the basis that Cooperatives may not be aware of the reporting requirements and may negligently fail to issue Forms 1099–PATR in a timely manner. For tax year 2019 filing, Cooperatives can report qualified payments on the Form 1099–PATR and can attach a supplemental schedule disclosing qualified items and SSTB items to patrons. For future filing years, the Form 1099–PATR will be updated to include boxes for qualified items and SSTB items. The final regulations do not provide relief from the zero-presumption rule, since the zero-presumption rule is a presumption that the patron may rebut with appropriate evidence or documentation. One example of appropriate evidence or documentation would be a corrected Form 1099–PATR received by the patron from the Cooperative.

C. Comments Related to Proposed § 1.199A–7(f), Special Rules for Patrons of Specified Cooperatives

i. Requirement for Patrons To Compute the Section 199A(b)(7) Reduction

The section 199A(b)(7) reduction is a statutory rule requiring, in the case of any qualified trade or business of a patron of a Specified Cooperative, that the amount determined under section 199A(b)(2) with respect to the trade or business be reduced by the lesser of (A) 9 percent of so much of the QBI with respect to the trade of business as is properly allocable to qualified payments (as defined in section 199A(g)(2)(E) and § 1.199A–8(d)(2)(ii)), or (B) 50 percent of so much of the W–2 wages with respect to the trade or business as are so allocable. Proposed § 1.199A–7(f)(1) provides that a patron of a Specified Cooperative that receives a qualified payment must reduce its section 199A(a) deduction as provided in § 1.199A–1(e)(7) (which follows the language of section 199A(b)(7)), and the reduction applies whether the Specified Cooperative passes through all, some, or none of the Specified Cooperative's section 199A(g) deduction to the patron in the taxable year.

Commenters requested an opt-out provision whereby patrons and Specified Cooperatives could elect out of the rules under sections 199A(b)(7)

and (g). The final regulations do not adopt this request. There is no statutory provision providing for an opt-out of these Code sections. In the parallel situation under former section 199, there also was no opt-out provision. Specifically, the no-double-counting rule under former § 1.199–6(l) precluded farmers from including qualified payments in their own former section 199 deduction. Further, permitting patrons and Specified Cooperatives to elect out of the rules under sections 199A(b)(7) and (g) would be difficult to administer and could result in patrons and Specified Cooperatives taking conflicting positions.

Some commenters have reasoned that turning off the section 199A(b)(7) reduction is justified based on the part of the qualified payment definition in section 199A(g)(2)(E)(iii), whereby the payment must be attributable to qualified production activities income (QPAI) with respect to which a deduction is allowed to the Specified Cooperative under section 199A(g)(1). However, section 199A(b)(7) applies when qualified payments are received by a patron in a qualified trade or business. The determination of whether a qualified payment was received is a different issue and is addressed in part II of this Summary of Comments and Explanation of Revisions.

ii. Comments on Interaction of Section 199A(b)(7) Reduction and § 1.199A–4

Commenters requested clarification on how the section 199A(b)(7) reduction operates with the aggregation rules in § 1.199A–4. In certain circumstances, an individual may aggregate two or more trades or businesses for purposes of the QBI component calculation in § 1.199A–1(d)(2)(iv), which includes application of the W–2 wage and UBIA of qualified property limitations under section 199A(b)(2). Aggregation is permitted but not required. Once an individual chooses to aggregate two or more trades or businesses, the individual must consistently report the aggregated trades or businesses in all subsequent taxable years. As commenters point out, aggregation of two or more trades or businesses may be favored by a taxpayer because it may provide better results when applying the W–2 wage and UBIA of qualified property limitations.

Commenters asked for clarification in two situations. First, commenters asked whether a patron who aggregates a rental real estate business and a farming business conducted with or through a Specified Cooperative may exclude the rental income from the section 199A(b)(7) reduction. This question relates to clarifying the rule in proposed § 1.199A–7(f)(2)(i), which provides that for purposes of calculating the section 199A(b)(7) reduction, a patron must use a reasonable method based on all the facts and circumstances to allocate between income that is from qualified payments and income that is not from qualified payments. As a clarification, income that is not related to qualified payments can be earned in transactions that do not involve Specified Cooperatives, for example, a grain sale to a noncooperative customer. This means that the rental income, which is not income related to qualified payments, should be excluded when calculating the section 199A(b)(7) reduction for the aggregated trade or business.

Second, commenters asked whether in that same situation a patron is permitted to allocate the rental expenses toward the income from the Specified Cooperative, thus possibly lowering the section 199A(b)(7) reduction. Proposed § 1.199A–7(f)(2)(i) provides that for purposes of calculating the section 199A(b)(7) reduction, a patron must use a reasonable method to allocate income items and related deductions. Thus, it would be reasonable to allocate that expense against qualified payments when calculating the section 199A(b)(7) reduction only to the extent the rental expense is related to the qualified payments from the Specified Cooperative. These aggregation principles are applied throughout the rules and examples of the final regulations and are consistent with the Proposed Regulations.

Commenters also inquired as to how negative QBI allocable to qualified payments affects the section 199A(b)(7) reduction. The Treasury Department and the IRS considered this comment and determined that there would be no section 199A(b)(7) reduction in such a case. An example illustrating this is a farmer conducting two types of agricultural businesses (A and B). Assume the farmer treats A and B as one trade or business for purposes of the section 199A(a) deduction. The farmer conducts A with non-Specified Cooperatives and B through a Specified Cooperative. The farmer generates $100 of qualifying income through A and receives $100 of qualifying income from a Specified Cooperative in B, all of which is also a qualified payment. The farmer has $180 of qualified expenses. For purposes of the section 199A(a) deduction, the farmer's QBI ($20) from the trade or business is used to calculate the deduction, resulting in a $4 deduction (assuming there is no limitation under section 199A(b)(2)(B)). The farmer then must determine if there is any section 199A(b)(7) reduction to this amount. The farmer reasonably allocates its qualified expenses under § 1.199A–7(f)(2)(i) for purposes of calculating the section 199A(b)(7) reduction, and determines $110 of the qualified expenses are allocable to B (and $70 to A). The farmer will use only QBI from B to calculate the section 199A(b)(7) reduction because that is the only QBI properly allocable to qualified payments. Farmer's QBI for purposes of section 199A(b)(7)(A) is negative $10, resulting in a $0 section 199A(b)(7) reduction (regardless of W–2 wages under section 199A(b)(7)(B)).

iii. Comments on Safe Harbor Allocation Method in Proposed § 1.199A–7(f)(2)(ii)

Proposed § 1.199A–7(f)(2)(ii) is a safe harbor providing a reasonable method for patrons with income under the threshold amount (set forth in section 199A(e)(2)) to allocate deductions and W–2 wages between income or gain related to qualified payments and income or gain that is not related to qualified payments when determining the section 199A(b)(7) reduction with respect to a patron's qualified trade or business. The method allows patrons to apportion deductions and W–2 wages ratably between income related to qualified payments and income not related to qualified payments. This means, for example, that the amount of deductions in QBI allocable to qualified payments is equal to the proportion of the total deductions that the amount of income or gain related to qualified payments bears to total income or gain used to determine QBI. The same proportion also applies when determining the amount of W–2 wages allocable to the portion of the trade or business that received qualified payments. In addition to considering the specific comments concerning proposed § 1.199A–7(f)(2)(ii) described in this preamble, revisions necessary to clarify the scope and application of the safe harbor were made in § 1.199A–7(f)(2)(ii) of the final regulations.

Commenters requested clarification on whether QBI under the safe harbor allocation method in proposed § 1.199A–7(f)(2)(ii) includes: Gross receipts from the sale of farm equipment, farm program payments (*i.e.,* Conservation Reserve Program, Market Facilitation Program, Dairy Program, etc.), section 1245 recapture, and commonly owned rental income. One commenter recommended that gross receipts from the sale of equipment and machinery should be included in the calculation and allocated based on past depreciation (in

the case of section 1245 recapture), and that gross receipts from farm programs be considered not related to qualified payments. Another commenter recommended that both gains from section 1245 recapture, crop insurance receipts, government subsidy payments, and income from aggregated rental income under § 1.199A–4 be not allocable to qualified payments received from Specified Cooperatives for purposes of section 199A(b)(7).

Section 199A(b)(7)(A) requires determining the QBI with respect to a trade or business that is properly allocable to qualified payments received from a Specified Cooperative, § 1.199A–7(f)(2)(i) requires a reasonable method be adopted for making this determination, and the safe harbor under § 1.199A–7(f)(2)(ii) allows patrons under the threshold amount to allocate the deductions and W–2 wages of a business between income related to qualified payments and income that is not related to qualified payments based on a ratio. The determination of whether the amounts mentioned by commenters are included in QBI of a trade or business, subject to the section 199A(b)(7) reduction, and how these amounts are allocated may change based on a patron's individual facts and circumstances and is not addressed in the final regulations.

One commenter also requested that the safe harbor method in proposed § 1.199A–7(f)(2)(ii) apply to patrons with a trade or business that has average annual total gross receipts equal to $25,000,000 or less. This amount is equal to the threshold for the small business simplified overall method under proposed § 1.199A–10(f)(1). Under the small business simplified overall method, a qualifying small Specified Cooperative may apportion total costs for the current taxable year between domestic production gross receipts (DPGR) and non-DPGR based on relative gross receipts for purposes of calculating the section 199A(g) deduction. The safe harbor in proposed § 1.199A–7(f)(2)(ii) is different from the safe harbor in proposed § 1.199A–10(f)(1). Proposed § 1.199A–7(f)(2)(ii) is applied as part of the patron's calculation of the section 199A(a) deduction. In calculating the section 199A(a) deduction, the threshold amount (described in section 199A(e)(2)) is used in other circumstances to determine when a taxpayer must engage in more complex calculations, specifically the W–2 wage and UBIA of qualified property limitations in section 199A(b)(2)(B). Thus, it is consistent with section 199A(e)(2) for the safe harbor in proposed § 1.199A–7(f)(2)(ii) to adopt the threshold amount. This contrasts with the small business simplified overall method in § 1.199A–10(f)(1), used to compute the section 199A(g) deduction by a Specified Cooperative, and for which the threshold amount in section 199A(e)(2) is not relevant. Therefore, the final regulations do not adopt this request.

The commenter also suggested cooperative and noncooperative farming expenses should be allocable based on sales. The commenter believes that if an allocation based on sales is not allowed, then it will be impossible for cash basis taxpayers to offset input expenses from the prior year to harvest revenues in the following year, because taxpayers would have already claimed the expenses in the prior year. Moreover, because farmers do not know if crops are sold to a Specified Cooperative or noncooperative until the crops are harvested, the potential exists for allocations to be understated/overstated as it relates to either Specified Cooperative/noncooperative revenues. The reasonable method approach in § 1.199A–7(f)(2)(i) of the Proposed Regulations, which is the approach adopted in the final regulations, accommodates these timing issues. A reasonable method is based on the facts and circumstances of the taxpayer and should provide the needed flexibility to accommodate this fact pattern.

D. Comments on Examples in Proposed § 1.199A–7(g)

Commenters requested corrections to proposed § 1.199A–7(g)(1), Example 1, because the allocation of W–2 wage expense is not proportional to the total expense allocation. This example illustrates that a reasonable method of allocation does not necessarily have to be proportional between W–2 wages and other expenses. This example is consistent with Example 1 in the Joint Committee Report. The Joint Committee Report in footnote 133 explains that example and the general rule by stating that ''[w]hich expenses are properly allocable in a given case will depend on all the facts and circumstances. The example assumes that the fraction of properly allocable W–2 wages differs from the fraction of other properly allocable expenses.'' Thus, a modification to the allocation in Example 1 of the proposed § 1.199A–7(g)(1) is not warranted.

II. § 1.199A–8, Deduction for Income Attributable to Domestic Production Activities of Specified Cooperatives

A. In General

Section 199A(g) provides a deduction for Specified Cooperatives and their patrons. This deduction is similar in many respects to the former section 199 deduction and, as provided in section 199A(g)(6), these regulations are based on the regulations applicable to Specified Cooperatives and their patrons under former section 199. The section 199A(g) deduction is calculated by the Specified Cooperative and is equal to 9 percent of the lesser of the Specified Cooperative's QPAI or taxable income (as modified by section 199A(g)(1)(C)) for the taxable year. There is a further limitation on the deduction equal to 50 percent of the Specified Cooperative's W–2 wages for the taxable year that are properly allocable to DPGR. Proposed § 1.199A–8 provides definitions relating to the section 199A(g) deduction, which includes establishing the criteria that a Specified Cooperative must satisfy to be eligible to claim the section 199A(g) deduction, and sets forth the necessary steps for a Specified Cooperative to calculate the section 199A(g) deduction. This part II.A provides a general outline of proposed § 1.199A–8, and the remainder of this part II addresses specific comments on proposed § 1.199A–8. Other than as described in response to the specific comments, the final regulations generally follow the Proposed Regulations.

Proposed § 1.199A–8(a), for purposes of section 199A(g), defines the terms patron (cross references proposed § 1.1388–1(e)), Specified Cooperative, and agricultural or horticultural products. The definition of Specified Cooperative is consistent with section 199A(g)(4) and the Joint Committee Report, and reflects the 2018 Act's amendment to the definition originally provided by section 11011(a) of the TCJA.; that is, a Specified Cooperative no longer includes a Cooperative solely engaged in the provision of supplies, equipment, or services to farmers or other Specified Cooperatives. The definition of agricultural or horticultural products in the Proposed Regulations is based upon the Cooperative Marketing Act of 1926, 44 Stat. 802 (1926).

Proposed § 1.199A–8(b) provides the four steps a Specified Cooperative that is not qualified as a farmer's cooperative organization under section 521 (nonexempt Specified Cooperative) performs to calculate its section 199A(g) deduction and includes definitions of relevant terms. Step 1, under proposed

§ 1.199A–8(b)(2)(i), requires a Specified Cooperative to identify its patronage and nonpatronage gross receipts, and related cost of goods sold (COGS), deductible expenses, W–2 wages, etc. (collectively, deductions) and allocate these deductions to the gross receipts from patronage and nonpatronage activity. Proposed § 1.199A–8(b)(2)(ii) directs a nonexempt Specified Cooperative to use only patronage gross receipts and related deductions when calculating the section 199A(g) deduction. Step 2, under proposed § 1.199A–8(b)(3), requires a nonexempt Specified Cooperative to determine the patronage gross receipts that qualify as DPGR. Proposed § 1.199A–9 provides rules for determining whether gross receipts are DPGR. Step 3, under proposed § 1.199A–8(b)(4), requires a Specified Cooperative to calculate QPAI (including oil-related QPAI) from only patronage DPGR and patronage deductions. Further rules for allocating COGS and other expenses, losses, or deductions to patronage DPGR are in proposed § 1.199A–10. A nonexempt Specified Cooperative calculates the section 199A(g) deduction using step 4, under proposed § 1.199A–8(b)(5). Proposed § 1.199A–8(b) also provides a definition of taxable income (including how to take net operating losses (NOLs) into account), rules on the use of the patronage section 199A(g) deduction, and special rules for nonexempt Specified Cooperatives that have oil-related QPAI.

Proposed § 1.199A–8(c) provides rules explaining the steps a Specified Cooperative that is qualified as a farmer's cooperative organization under section 521 (exempt Specified Cooperative) performs to calculate its section 199A(g) deduction. Generally, exempt Specified Cooperatives follow the same steps as nonexempt Specified Cooperatives, except that exempt Specified Cooperatives are not disallowed a section 199A(g) deduction based on nonpatronage gross receipts and related deductions. Instead, exempt Specified Cooperatives performs step 1 to identify patronage and nonpatronage gross receipts and related deductions, and then performs steps 2 through 4 in proposed § 1.199A–8(b) twice, to calculate a patronage section 199A(g) deduction and a nonpatronage section 199A(g) deduction. Proposed § 1.199A–8(c)(4)(ii) explains that the nonpatronage section 199A(g) deduction can be used only against nonpatronage income and cannot be passed through to patrons.

Proposed § 1.199A–8(d) provides rules for Specified Cooperatives passing through the section 199A(g) deduction to patrons. In general, under proposed § 1.199A–8(d)(1), a Specified Cooperative may pass through all, some, or none of the section 199A(g) deduction to patrons who are eligible taxpayers as defined in section 199A(g)(2)(D), that is, (i) a patron that is other than a corporation defined in section 1361(a)(2) (C corporation) or (ii) a patron that is a Specified Cooperative. Proposed § 1.199A–8(d)(2) limits the amount of the section 199A(g) deduction that a Specified Cooperative can pass through to the portion of the section 199A(g) deduction that is allowed with respect to the QPAI to which the qualified payments (defined in proposed § 1.199A–8(d)(2)(ii)) made to the eligible taxpayer are attributable. Proposed §§ 1.199A–8(d)(3) through (7) further outlines the written notice requirement to pass through the deduction to a patron, the patron's ability to deduct the section 199A(g) passed through (generally limited to the patron's taxable income), that a Specified Cooperative that is passed through a section 199A(g) deduction as an eligible taxpayer is limited to taking the deduction only against patronage gross income and related deductions, that the W–2 wage limitation is applied only at the Specified Cooperative level, and that a Specified Cooperative must reduce its section 1382 deduction by an amount equal to the section 199A(g) deduction passed through to its eligible patrons.

The remainder of proposed § 1.199A–8 covers a variety of issues. Proposed § 1.199A–8(e) provides examples that illustrate the rules in proposed § 1.199A–8(b) through (d). Proposed § 1.199A–8(f) provides guidance for Specified Cooperatives that are partners in a partnership. Proposed § 1.199A–8(g) provides guidance on the recapture of a claimed section 199A(g) deduction. Finally, proposed § 1.199A–8(h) generally provides that taxpayers may rely on the proposed rules in their entirety and as applied in a consistent manner until final regulations are published in the **Federal Register**.

B. Comments Related to Definition of "Agricultural or Horticultural Products"

i. General Comments on Definition

Section 199A(g)(3)(D) defines DPGR as the gross receipts of a taxpayer that are derived from any lease, rental, license, sale, exchange, or other disposition (collectively, disposition) of any agricultural or horticultural product that was manufactured, produced, grown, or extracted (MPGE) by the taxpayer in whole or significant part within the United States. Proposed § 1.199A–8(a)(4) defines *agricultural or horticultural products* as agricultural, horticultural, viticultural, and dairy products, livestock and the products thereof, the products of poultry and bee raising, the edible products of forestry, and any and all products raised or produced on farms and processed or manufactured products thereof within the meaning of the Cooperative Marketing Act of 1926, 44 Stat. 802 (1926). Agricultural or horticultural products also include aquatic products that are farmed whether by an exempt or a nonexempt Specified Cooperative. In addition, agricultural or horticultural products include fertilizer, diesel fuel, and other supplies used in agricultural or horticultural production that are MPGE by a Specified Cooperative. Agricultural or horticultural products, however, do not include intangible property (other than as provided in the exception in § 1.199A–9(b)(2)); for example, an agricultural or horticultural product includes a seed that is grown, but does not include the intangible property right to reproduce a seed for sale. This exclusion of intangible property does not apply to intangible characteristics of any particular agricultural or horticultural product. For example, gross receipts from the sale of different varieties of oranges would all qualify as DPGR from the disposition of agricultural or horticultural products (assuming all other requirements of section 199A(g) are met). However, gross receipts from the license of the right to produce and sell a certain variety of an orange would be considered separate from the orange and not from an agricultural or horticultural product.

One commenter requested that the definition be omitted on the premise that the meaning of farming and agricultural or horticultural product is generally understood by the agricultural community and their advisors, and argued that there was no current, comprehensive definition of these terms in the Code or regulations. Because section 199A(g) is focused solely on dispositions of agricultural or horticultural products, as opposed to the broader scope of former section 199, the Treasury Department and the IRS have determined a definition is necessary to provide guidance on the limits of the section 199A(g) deduction. As an alternative to removing the definition, the commenter recommended against referencing non-tax legislation or regulations because the definitions were developed independent of tax law. The Treasury Department and the IRS have determined that using

the definition from the Proposed Regulations, based on a pre-existing definition from non-tax cooperative law specifically referencing the type of cooperative at issue here, is the best alternative, but have made some modifications based on the commenter's suggested definition. The definition in the final regulations includes parts of the commenter's suggested definition, by providing examples (without limitation) of products that are considered agricultural or horticultural products, including specific agricultural or horticultural products, livestock products, edible forestry products, and farmed aquatic products.

ii. Comments on Exclusion of Intangible Property

A commenter requested that the definition of agricultural or horticultural products include intangible property. The commenter reasoned that because a license is a disposition under section 199A(g)(3)(D) for purposes of determining if gross receipts qualify as DPGR, an exploitation of intangible property is implied. However, the inclusion of the term license under section 199A(g)(3)(D) does not impact the definition of agricultural or horticultural products. The term license also appeared in former section 199(c)(4)(A)(i), which was the equivalent of section 199A(g)(3)(D) under former section 199. Under former section 199, DPGR generally meant the gross receipts of the taxpayer derived from qualifying production property (QPP) which was MPGE by the taxpayer in whole or significant part within the US. Income from the disposition of intangible property (with the specific exception of computer software, sound recordings under section 168(f)(4), and qualified films under former section 199(c)(6)) were generally excluded from DPGR. This was because intangible property was not QPP (as defined in former section 199(c)(5), also see former § 1.199–3(j)(2)(iii)). The proposed definition and rules reach a similar result for purposes of section 199A(g).

Also related to intangible property, the commenter specifically requested that gross receipts qualify as DPGR from the disposition of an agricultural or horticultural product when a Specified Cooperative enters into a long-term arrangement with an unrelated third party, under which (1) the Specified Cooperative develops a finished retail product with the unrelated third party, (2) the finished retail product contains a patron's product as an ingredient, and (3) the Specified Cooperative receives a royalty or license fee based on the sale of the finished retail product irrespective of whether the Specified Cooperative's brand, label, and/or tradename is featured on the finished retail product. The situation described by the commenter is very fact specific and raises multiple possible issues for purposes of section 199A(g). Among the issues to consider are what property or properties the Specified Cooperative is deriving gross receipts from in the normal course of business, and which party is the producer of the property. Because of the fact specific nature of the comment, and multiple possible outcomes, there is no rule or example to address this specific situation in the final regulations.

After consideration of the comments, the final regulations maintain the approach in the Proposed Regulations that the definition of agricultural or horticultural products does not include intangible property, but also provide language further clarifying the exclusion. The clarifying language provides that intangible rights include the rights to MPGE and sell an agricultural or horticultural product with certain characteristics protected by a patent and the trademark of a brand. Further examples 9 and 10 have been added to § 1.199A–8(e) to illustrate concepts related to intangible property transactions and the disposition of agricultural or horticultural products.

iii. Comments on ''Other Supplies''

Included in the definition of agricultural or horticultural products are other supplies that are MPGE by the Specified Cooperative. A commenter suggested that the MPGE requirement be removed from ''other supplies'' on the basis that Joint Committee Report footnote 120 cites § 1.199–6(f), which made no mention of a MPGE requirement as it pertained to ''other supplies'' being agricultural or horticultural products. However, footnote 120 explicitly mentions a MPGE requirement as it pertains to other supplies. The Joint Committee Report also explains that after the amendments to section 199A(g) made by the 2018 Act, ''[t]he definition of [specified agricultural or horticultural cooperative] no longer includes a [C]ooperative solely engaged in the provision of supplies, equipment, or services to farmers or other specified agricultural or horticultural cooperatives.'' Joint Committee Report, 23. Based upon these considerations, subjecting ''other supplies'' to a MPGE requirement before being considered agricultural or horticultural products is appropriate.

Commenters also requested that ''other supplies'' be further illustrated with examples. The final regulations include more examples of ''other supplies'' such as seed, feed, herbicides, and pesticides.

Finally, one commenter requested that language be added to the definition of agricultural or horticultural products to include supplies used in activities under § 1.199A–9(f)(2) and (3). Under proposed § 1.199A–9(f)(2) and (3), if the Specified Cooperative performs packaging, repackaging, labeling, or installation with respect to an agricultural or horticultural product and engages in no other MPGE activity with respect to that agricultural or horticultural product, the Specified Cooperative's activity does not qualify as MPGE with respect to that agricultural or horticultural product. Based on this rule, to the extent a Specified Cooperative performs MPGE activities with respect to an agricultural or horticultural product, and in conjunction performs a packaging, repackaging, labeling, or installation activity, the activities are treated as part of the MPGE of the agricultural production. The packaging or labeling materials used may also be treated as part of the agricultural or horticultural product. For example, if a Specified Cooperative packages an agricultural or horticultural product that the Specified Cooperative had MPGE, then the packaging activity is treated as part of the MPGE of the agricultural or horticultural product, and gross receipts from the sale of the packaged agricultural or horticultural product all qualify as DPGR, assuming all other requirements for such treatment are met. However, property packaged or offered with an agricultural or horticultural product that is not an agricultural or horticultural product (or packaging) is not considered part of the agricultural or horticultural product.

C. Identifying Patronage Items and Exclusion of Nonpatronage Items for Nonexempt Specified Cooperatives

As previously described, proposed § 1.199A–8(b) outlines a four-step process for nonexempt Specified Cooperatives to use in calculating the section 199A(g) deduction. Step 1, in proposed § 1.199A–8(b)(2)(i) and (ii), requires a nonexempt Specified Cooperative to identify its gross receipts, COGS, deductions, W–2 wages, etc. as patronage or nonpatronage, and allows only the patronage activities to be included in the calculation of the section 199A(g) deduction. One commenter described step 1 as burdensome and unnecessary, and suggested removal of that step. Further, the commenter asserted that both

patronage and nonpatronage activities should be included in the section 199A(g) deduction calculation for nonexempt Specified Cooperatives. The commenter provided, as an alternative to removal of that step, that these rules be reserved until the conclusion of litigation under former section 199 relating to the calculation of the former section 199 deduction by Specified Cooperatives.

The Treasury Department and the IRS decline to adopt these comments in the final regulations for the reasons described in the following paragraphs. However, the final regulations make revisions to the proposed regulations to benefit and reduce complexity for Specified Cooperatives with de minimis gross receipts from nonpatronage activities.

Section 199A(g)(4)(A) defines a Specified Cooperative, in part, as an organization to which part I of subchapter T applies. Under section 1381(a)(2), subchapter T applies to any corporation operating on a cooperative basis, with certain exceptions not relevant here. In the commenter's view, this means that if subchapter T applies, it applies to the entire corporation, and the benefits of the section 199A(g) deduction should follow that determination. In support of this position, the commenter argues that the plain language of the statute and the Joint Committee Report do not limit the deduction to patronage activities. The commenter's view fails to properly take into account how subchapter T applies to nonexempt Cooperatives that have both cooperative and noncooperative operations. This is an especially important consideration because of the exclusion of C corporations from the definition of eligible taxpayers under section 199A(g)(2)(D)(i), and the fact that section 199A as a general matter is not intended to benefit C corporations.

When a nonexempt Cooperative does not act entirely on a cooperative basis under subchapter T, its activities are characterized as patronage or nonpatronage, and accordingly, the tax items from these distinct activities receive different treatment. *See Buckeye Countrymark, Inc.* v. *Comm'r,* 103 T.C. 547, at 559 (1994) (explaining that ''subchapter T requires nonexempt cooperatives to separate income and deductions into two categories or baskets, one for patronage income and deductions and one for nonpatronage income and deductions'') and *Farm Service Coop.* v. *Comm'r,* 619 F.2d 718 (8th Cir. 1980) (subchapter T prohibits the netting of patronage losses against nonpatronage income). Cooperative activities generate patronage income and deductions and are taxed on a cooperative basis, generally resulting in a single-level of tax to the Cooperative or the patrons after application of the rules under subchapter T. *See* Joint Committee Report, 20 (explaining that ''excluding patronage dividends and per-unit retain allocations paid by the cooperative from the cooperative's taxable income in effect allows the cooperative to be a conduit with respect to profits derived from transactions with its patrons''). In contrast, noncooperative activities of a Cooperative generate nonpatronage income and deductions and are taxed like a for-profit business of a C corporation, resulting in a double-level of tax, that is, at both the Cooperative and patron levels. *See, for example, Farm Service* at 723, and *Conway Cty. Farmers Ass'n* v. *United States,* 588 F.2d 592, 596 (8th Cir. 1978) (describing nonpatronage income as being taxed as a for-profit business in case where organization found to be operating on a cooperative basis with more than 50 percent of business done with nonmembers).

There is limited guidance as to how much of an organization's activities must be conducted on a cooperative basis for the organization to qualify as a Cooperative under subchapter T, but the available guidance suggests a low threshold in certain cases. To the extent this is true, it allows for the noncooperative activities to be of substantial value relative to the organization's cooperative activities. For example, in *Columbus Fruit and Vegetable Coop. Ass'n, Inc.* v. *United States,* 7 Cl. Ct. 561 (March 27, 1985), the court held that an agricultural organization whose sales of members' merchandise accounted for only about 24 percent of value of its total sales for the tax years in question was nevertheless a corporation operating on a cooperative basis within the meaning of the Code, and thus was entitled to deduct patronage dividends paid to its members.

The Treasury Department and IRS compared how application of the rules of subchapter T aligned with the commenter's proposal and with the Proposed Regulations and found the subchapter T rules align better with the Proposed Regulations. Among the scenarios considered were C corporations engaged in the following: (1) An agricultural business with no cooperative activities (scenario 1); (2) an agricultural business operating entirely on a cooperative basis considered a nonexempt Specified Cooperative (scenario 2); and, (3) an agricultural business with a mixed percentage of business from cooperative and noncooperative activities that qualifies as a nonexempt Specified Cooperative (scenario 3).

In the first and second scenarios, both the commenter's proposal and the Proposed Regulations reach the same conclusions. In the first scenario, because none of the organization's activities are conducted on a cooperative basis, subchapter T does not apply to the organization, and the organization receives no benefits from the section 199A(g) deduction. In the second scenario, because all the organization's activities are conducted on a cooperative basis, the benefits of subchapter T apply to all of the organization's activities, and the organization can calculate the section 199A(g) deduction based on all its activities.

It is the third scenario where the conclusions under the commenter's proposal and the Proposed Regulations differ. Under the commenter's proposal, subchapter T applies to the organization and so the organization should calculate a single section 199A(g) deduction by aggregating the patronage income, deductions, etc., resulting from cooperative activities and the nonpatronage income, deductions, etc., resulting from noncooperative activities. The commenter's proposal would permit a Specified Cooperative to calculate and take the section 199A(g) deduction on its business activities that are not operated on a cooperative basis (those activities that generate income that is taxed as that of a C corporation). This would be the case even where a substantial portion of the income of the Specified Cooperative is generated from business activities not operated on a cooperative basis. In contrast, the Proposed Regulations allow the organization to calculate the section 199A(g) deduction based only on the patronage income, deductions, etc., resulting from the organization's cooperative activities.

The Proposed Regulations, and not the commenter's proposal, align with subchapter T and the structure and intent of section 199A. Under subchapter T, a nonexempt Cooperative with both cooperative and noncooperative activities receives beneficial single-level tax treatment only on its patronage income, and its income from operating as a C corporation (that is, nonpatronage income) receives double-level tax treatment. *Farm Service* at 723. Generally, section 199A was structured to give businesses that are not operating as C corporations a deduction that corresponds to the TCJA's reduction of

the top corporate rate of tax from 35 percent to 21 percent under section 11. Indeed, Congress needed to specifically clarify that Specified Cooperatives could benefit from the section 199A deduction because Cooperatives are C Corporations. See section 1382(a)(2). That is, Congress, in including section 199A(g), was making sure that Specified Cooperatives received a benefit when operating as Cooperatives. This also makes sense when considering that patronage distributions deductible under section 1382 to a Specified Cooperative, which enable the Specified Cooperative to act as a conduit for its patrons, are taxed to the patrons eligible for the section 199A(a) deduction at individual rates. The Proposed Regulations align with this intent because only the activities resulting in patronage income receive beneficial treatment under section 199A(g), and income arising from nonpatronage activities continues to be taxed as income from a C corporation. Were the result as requested by commenter, a C corporation conducting a portion of its business on a cooperative basis would receive the benefits of both the reduced corporate income tax rate and the section 199A(g) deduction with respect to its nonpatronage activities, giving it a competitive advantage relative to a regular C corporation.

The commenter also referred to section 199A(g)(6), which provides that the Secretary shall prescribe regulations as are necessary to carry out the purposes of section 199A(g), and that the regulations shall be based on the regulations applicable to Cooperatives and their patrons under section 199 (as in effect before its repeal). The commenter noted that the former section 199 regulations did not exclude nonpatronage income from the calculation of the former section 199 deduction. However, because there are material differences between former section 199 and section 199A, section 199A(g)(6) does not require that the section 199A(g) regulations replicate or duplicate the former section 199 regulations in their entirety. The former section 199 regulations did not specifically address an organization with cooperative and noncooperative operations because former section 199 applied to all categories of businesses, including C corporations, whether operating on a cooperative basis, noncooperative basis, or both. In contrast to the former section 199 deduction, the section 199A(g) deduction, which must be read in the context of section 199A, does not apply to C corporations generally. Unlike for the former section 199 regulations, clarification of this distinction is necessary to carry out the purposes of section 199A(g), which include providing the section 199A(g) deduction for the patronage activities of Specified Cooperatives. Clarification of this distinction is also necessary to assist taxpayers in complying with the law, as well as to aid the proper administration of section 199A(g).

The Treasury Department and the IRS also considered the recent opinions in *Ag Processing, Inc.* v. *Comm'r,* 153 T.C. No. 3 (2019), and *Growmark, Inc. & Subsidiaries* v. *Comm'r,* T.C. Memo. 2019–161. These cases are the litigation referred to by the commenter. In *Ag Processing* and *Growmark,* the Tax Court determined that under former section 199, a nonexempt agricultural Cooperative should calculate the section 199 deduction in the aggregate by combining patronage and nonpatronage items and then allocating the total section 199 deduction between the Cooperative's patronage and nonpatronage businesses. These cases do not support, and in fact, conflict with the commenter's proposal in that they require an allocation of the former section 199 deduction between patronage and nonpatronage businesses. At the same time, the Tax Court's approach in these cases allows the proceeds of the cooperative and noncooperative businesses to be combined to calculate an aggregate deduction before allocation. The allowance of an aggregate calculation highlights the difference between section 199A(g), benefitting solely cooperative activities, and former section 199, benefitting both cooperative and noncooperative activities. Thus, the cases do not necessitate that final regulations adopt an approach different from that of the Proposed Regulations. Based on the commenter's proposal, the Treasury Department and IRS considered calculating the section 199A(g) deduction on an aggregate basis and then disallowing the nonpatronage portion, but this would require unnecessary calculations and likely prove less accurate than the straightforward calculation provided in the Proposed Regulations.

Finally, the Treasury Department and IRS considered how the commenter's proposal would align with the treatment of exempt Specified Cooperatives. The commenter's proposal would allow both exempt and nonexempt Specified Cooperatives to calculate their section 199A(g) deductions based on both cooperative and noncooperative activities. The Proposed Regulations permit only exempt Specified Cooperatives to calculate their section 199A(g) deductions based on both cooperative and noncooperative activities. Under subchapter T, exempt Cooperatives can receive the beneficial single-level tax treatment with respect to both types of business activities while nonexempt Cooperatives cannot. In effect, by meeting the requirements of section 521, the entirety of an exempt organization's operations can be treated as done on a cooperative basis. Exempt Specified Cooperatives, thus, are effectively equivalent to the described scenario 2 (a nonexempt Specified Cooperative operating entirely on a cooperative basis). The commenter's proposal would provide the same benefits of the section 199A(g) deduction to nonexempt Specified Cooperatives without requiring those Cooperatives to meet the requirements of section 521.

In summary, the Treasury Department and the IRS have determined that retaining step 1 in proposed § 1.199A–8(b)(2)(i) and (ii) is the approach for calculating the section 199A(g) deduction that best reflects the law and is most consistent with the scope of section 199A(g) and the application of subchapter T to nonexempt Cooperatives.

The final regulations, however, revise the rule for applicable gross receipts in § 1.199A–8(b)(2)(ii) to allow a Specified Cooperative to include all nonpatronage gross receipts in non-DPGR for purposes of the de minimis rules in § 1.199A–9(c)(3), while also increasing the de minimis percentage in the de minimis rules in § 1.199A–9(c)(3) from 5 percent to 10 percent. These revisions expand the type of gross receipts eligible for the de minimis rules and should increase the number of Specified Cooperatives that can apply the de minimis rules. Applying the de minimis rule in § 1.199A–9(c)(3)(i) after these revisions means that a Specified Cooperative when calculating its patronage section 199A(g) deduction can treat all of its gross receipts as DPGR when the Specified Cooperative derives less than 10 percent of its total gross receipts from non-DPGR (with non-DPGR now possibly including all gross receipts from nonpatronage as well as other patronage non-DPGR). While this provides the benefit of increased DPGR, application of the de minimis rule in § 1.199A–9(c)(3)(i) also reduces complexity by simplifying the allocations needed to calculate the section 199A(g) deduction. Under § 1.199A–9(c)(3)(ii), the revisions also make it possible for any Specified Cooperative deriving less than 10 percent of their gross receipts from

DPGR to treat all of their gross receipts as non-DPGR. The final regulations also update § 1.199A–8(b)(5)(ii)(C), § 1.199A–8(c)(2) and (4), and § 1.199A–12(b)(1) to take these revisions into account.

D. Exempt Specified Cooperative Calculation of Nonpatronage Section 199A(g) Deduction

Rules for exempt Specified Cooperatives to calculate the section 199A(g) deduction were included in proposed § 1.199A–8(c). Specifically, under proposed § 1.199A–8(c)(2), an exempt Specified Cooperative calculates separate patronage and nonpatronage section 199A(g) deductions, as is consistent with the administration of former section 199. One commenter disputed that separate calculations were required under former section 199 and further stated that separate calculations are unnecessary since exempt Specified Cooperatives are permitted the section 199A(g) deduction on both their patronage and nonpatronage income. Contrary to the commenter's assertion, the instruction to line 25 for Agricultural and Horticultural Cooperatives on the Form 8903, Domestic Production Activities Deduction, makes clear that the calculations are made separately. This step is necessary because allowing an aggregate calculation and allocation results in less accurate patronage and nonpatronage deductions because alignment of the appropriate W–2 wages, COGS, and other expenses from an activity with the income from that activity is lost on aggregation, and difficult to rectify on allocation. For these reasons, the final regulations maintain the requirement of separate calculations of the patronage section 199A(g) deductions and nonpatronage section 199A(g) deductions by exempt Specified Cooperatives. However, the revisions in the final regulations to § 1.199A–8(b)(2)(ii) and the increase in the de minimis percentage under § 1.199A–9(c)(3) will simplify the allocations needed to calculate the section 199A(g) deduction for an exempt Specified Cooperative with de minimis nonpatronage gross receipts.

E. Definition of Taxable Income

i. General Definition Comments

Proposed § 1.199A–8(b)(5)(ii)(C) provides that taxable income is defined in section 1382 and § 1.1382–1 and § 1.1382–2. For purposes of determining the amount of the deduction allowed under § 1.199A–8(b)(5)(ii), taxable income is limited to taxable income and related deductions from patronage sources. Patronage NOLs reduce taxable income. Taxable income is determined without taking into account the section 199A(g) deduction or any deduction allowable under section 1382(b). Further, taxable income is determined using the same method of accounting used to determine distributions under section 1382(b) and qualified payments to eligible taxpayers.

One commenter stated that the definition of taxable income should refer to section 63, and take into account both patronage and nonpatronage income (including NOLs) on an aggregate basis. The Treasury Department and the IRS agree that section 63 generally defines taxable income. In response, the definition of taxable income in the final regulations has been modified so that it also includes a reference to section 63. However, consistent with the exclusion of nonpatronage items from the calculation of the section 199A(g) deduction, the final regulations continue to limit the definition to patronage taxable items for purposes of the limitation.

The commenter also stated that the requirement that Specified Cooperatives use the same method of accounting to determine taxable income, distributions under section 1382(b), and qualified payments is in error. Specifically, commenter stated that patronage dividends or other similar payments to patrons can be calculated on a book basis because it is a more accurate economic measure of income over time. The commenter provided an example where accelerated depreciation and other book/tax items often cause timing differences that may disproportionately benefit longer-term patrons over shorter-term patrons. Commenter further maintained that Cooperatives have been allowed to determine payments to patrons pursuant to methods other than on tax basis. The commenter pointed to section 1388(a)(3), which in defining patronage dividends, references the net earnings of the organization. In the commenter's view, the use of net earnings rather than taxable income means that net earnings do not necessarily correlate to taxable income. Further, the commenter pointed to Example 2 of former § 1.199–6(m) that included language indicating patronage distributions could be paid based on book or Federal income tax net earnings, as well as the requirement on Form 1120–C (U.S. Income Tax Form for Cooperative Associations) that a cooperative disclose the method of accounting used to compute distributable patronage income, with the choices being ''Book,'' Tax,'' and ''Other.''

In reviewing this part of the definition, the Treasury Department and the IRS determined it is unnecessary for defining taxable income to include the requirement that taxable income is determined using the same method of accounting used to determine distributions under section 1382(b) and qualified payments to eligible taxpayers. Accordingly, the final regulations do not include this requirement in § 1.199A–8(b)(5)(ii)(C) and also do not include a similar requirement in § 1.199A–8(c)(4)(i). The commenter's example and reasoning, however, relate more to the deductibility under section 1382 of distributions to patrons calculated on a book basis when there are book/tax differences, which is outside of the scope of the final regulations. No inference as to the deductibility of distributions to patrons under section 1382 is intended by removing this language (regardless of the method used to determine the payments).

ii. Comments on Net Operating Loss (NOL) Ordering Rules

Proposed § 1.199A–8(b)(5)(ii)(C) provides that patronage NOLs reduce taxable income. However, taxable income does not take into account the section 199A(g) deduction or any deduction allowable under section 1382(b). A commenter requested clarification on ordering rules concerning the interplay of NOLs, section 1382(b), and section 199A(g) deductions. Specifically, the commenter requested that final regulations clarify that the amount of an NOL that is taken into account for purposes of calculating the section 199A(g) deduction is the amount that the Specified Cooperative actually used in computing taxable income on its tax return for the year. The commenter further suggested that NOLs should not be regarded as having been used against any patronage dividends or per-unit retain allocations that are disregarded in computing taxable income for purposes of the section 199A(g) deduction limitation. The commenter provided an example where a nonexempt Specified Cooperative generated $100 of QPAI and taxable income, without taking account any of its deductions under section 1382(b) or section 199A(g), or an NOL carryover of $500. In the commenter's example, the nonexempt Specified Cooperative was able to calculate and use a $9 section 199A(g) deduction, pay out a $91 patronage dividend, and avoid using any of the $500 NOL carryover.

In consideration of the commenter's example, the Treasury Department and

the IRS reviewed Examples 1 and 2 in former § 1.199–1(b)(2), which illustrated that when calculating and using the former section 199 deduction, taxable income is reduced by any available NOL or NOL carryovers, before being reduced by the section 199 deduction. This avoided having the former section 199 deduction create or increase an NOL, but did not illustrate how section 1382 deductions impacted the calculation or use of the former section 199 deduction. Consistent with former section 199, taxable income for purposes of calculating the section 199A(g) deduction should take into account an NOL or NOL carryover. After calculation, the section 199A(g) deduction should not create or increase an NOL or NOL carryover. The section 199A(g) deduction also should not be used as a substitute for an NOL carryover when a Specified Cooperative has taxable income remaining after its section 1382 deductions, but before the section 199A(g) deduction is taken.

Using the facts of the commenter's example, this means that for purposes of calculating the section 199A(g) deduction, the $500 NOL carryover should reduce taxable income by $9, which is the amount that remains after the section 1382(b) deduction. Taxpayer would calculate a section 199A(g) deduction based on $91 (the lesser of QPAI ($100) or taxable income ($91), without taking section 1382(b) deduction into account). As a result under these facts, taxpayer would have $0 of taxable income after taking a section 1382 deduction of $91 and using $9 of the $500 NOL carryover (leaving a $491 NOL carryover). The Specified Cooperative could pass through the section 199A(g) deduction to patrons and reduce its section 1382 deduction accordingly. However, if the Specified Cooperative did not pass through the section 199A(g) deduction it would be lost because the deduction cannot increase an NOL carryover. In accordance with this analysis, the definition of taxable income in § 1.199A–8(b)(5)(ii)(C) and the rules in § 1.199A–8(b)(6) related to a Specified Cooperative using the section 199A(g) deduction have been updated. To illustrate this ordering rule, example 5 has also been added under § 1.199A–8(e). Based on this ordering rule and its reasoning, the Treasury Department and the IRS decline to adopt the commenter's approach permitting Specified Cooperatives to reduce taxable income by taking the section 199A(g) deduction before using an NOL, but clarify that NOLs are not used against taxable income that is the result of not taking into account section 1382 deductions when calculating the section 199A(g) deduction.

The commenter also stated that the examples in the proposed regulation (Examples 6 and 7 of proposed § 1.199A–8(e)) do not consider the more realistic case where the Specified Cooperative made payments to patrons that were deductible under section 1382(b). The Treasury Department and the IRS agree with this statement, and the new example in § 1.199A–8(e) replaces those examples from the Proposed Regulations.

F. Pass Through of Section 199A(g) Deduction

Sections 1.199A–8(d)(1) and (2) of the Proposed Regulations allow a Specified Cooperative, at its discretion, to pass through all, some, or none of its patronage section 199A(g) deduction to an eligible taxpayer (*i.e.,* a patron other than a C Corporation or a patron that is a Specified Cooperative), but the amount passed through to any eligible taxpayer is limited to the allowable portion of the section 199A(g) deduction with respect to the QPAI to which the qualified payments made to the eligible taxpayer are attributable. The intent of the proposed rule was to allow the Specified Cooperative the benefit of retaining and using the amounts equal to the section 199A(g) deduction attributable to non-eligible taxpayers (who will not be able to use the deduction) at the Specified Cooperative level, even when the Specified Cooperative chooses to pass through all or some of the section 199A(g) deduction attributable to patrons that are eligible taxpayers. Consistent with section 199A(g)(2)(A)(ii), proposed § 1.199A–8(d)(3) provides that a Specified Cooperative must identify in a written notice the amount of the deduction passed through to an eligible taxpayer, and the notice must be mailed by the Specified Cooperative to the eligible taxpayer no later than the 15th day of the ninth month following the close of the taxable year of the Specified Cooperative. The 15th day of the ninth month coincides with the end of the payment period as described in section 1382(d).

Commenters asked that the final regulations clarify that a Specified Cooperative will not be penalized if it passes through information relating to a section 199A(g) deduction to a non-eligible taxpayer, and that the ultimate determination of whether the deduction that is passed through can be used is the responsibility of the patron. One of these commenters indicated that section 199A(g)(2)(A) does not require the Specified Cooperative to determine the eligibility of all of its patrons. The Treasury Department and the IRS recognize that it may be difficult for a Specified Cooperative to determine the eligibility status of all patrons, and agree that the ultimate determination of eligibility should be made at the patron level. Therefore, the final regulations provide that a Specified Cooperative may pass through all, some, or none of the section 199A(g) deduction to all patrons, with appropriate adjustments to the section 1382 deduction depending on the amount passed through, but that only eligible taxpayers may claim the section 199A(g) deduction that is passed through. In considering this comment, the Treasury Department and the IRS also considered proposed § 1.199A–8(d)(5), which provides special rules for eligible taxpayers that are Specified Cooperatives, and that provides a Specified Cooperative that receives a section 199A(g) deduction can take the deduction only against patronage gross income and related deductions. The final regulations clarify the rule to be consistent with the nonpatronage disallowance for nonexempt Specified Cooperatives and also provide that only an exempt Specified Cooperative can take a section 199A(g) deduction passed through from another Specified Cooperative if the deduction relates to the patron Specified Cooperative's nonpatronage gross income and related deductions.

In addition to requesting that Specified Cooperatives not be required to identify the eligibility of all patrons, commenters requested that if a Specified Cooperative does obtain the tax status of its patrons so as not to pass through the section 199A(g) deduction to an non-eligible taxpayer, then the Specified Cooperative should be allowed to retain and use the section 199A(g) deduction from patrons that are non-eligible taxpayers while passing through the section 199A(g) deduction to patrons that are eligible taxpayers, subject to the section 199A(g)(1)(A)(ii) limitation. The Treasury Department and the IRS intended this result in the Proposed Regulations and have revised § 1.199A–8(d)(1) to clarify that if a Specified Cooperative obtains the tax status of a patron that is an non-eligible taxpayer, the Specified Cooperative may retain the section 199A(g) deduction attributable to that patron, even when passing through the deduction to other patrons. Example 11 under § 1.199A–8(e) has also been added to illustrate allocation rules for situations in which a Specified Cooperative retains the

section 199A(g) deduction attributable to non-eligible taxpayers.

Another commenter also requested relief from the notice requirements in proposed § 1.199A–8(d)(3) in the event that a Specified Cooperative wishes to pass through the section 199A(g) deduction to patrons but does not send the notice before the payment period ends, or passes through an incorrect amount of the section 199A(g) deduction during the payment period. Specifically, the commenter asked if there is a way to issue a late notice or to void or otherwise reissue a notice after the payment period. The requirement of identifying the amount passed through during the payment period is from section 199A(g)(2)(A)(ii). Further, no administrative remedies of this type existed under former section 199. The former section 199 rules required the notice to be provided during the payment period, and this notice worked in conjunction with the recapture provision in former § 1.199–6(k) and the no-double counting rule in former § 1.199–6(l). Finally, the payment period is also used in determining whether a distribution is deductible under section 1382(b), so a consistent interpretation is appropriate. Thus, no changes were made with respect to this comment.

G. Comments on Definition of Qualified Payments

Section 199A(g)(2)(E) defines *qualified payment,* with respect to any eligible taxpayer, as any amount which is (i) described in section 1385(a)(1) or (3), (ii) received by the taxpayer from a Specified Cooperative, and (iii) is attributable to QPAI with respect to which a deduction is allowed to the Specified Cooperative under section 199A(g)(1). Proposed § 1.199A–8(d)(2)(ii) defines qualified payment as ''any amount of a patronage dividend or per-unit retain allocation, as described in section 1385(a)(1) or (3) received by a patron from a Specified Cooperative that is attributable to the portion of the Specified Cooperative's QPAI, for which the cooperative is allowed a section 199A(g) deduction. For this purpose, patronage dividends include any advances on patronage and per-unit retain allocations include per-unit retains paid in money during the taxable year. A Specified Cooperative calculates its qualified payment using the same method of accounting it uses to calculate its taxable income.'' The inclusion of advances on patronage and per-unit retains paid in money during the taxable year is consistent with the definition in former § 1.199–6(e).

The commenter asserted that when a Specified Cooperative's section 199A(g) deduction is W–2 wage-limited under section 199A(g)(1)(B), section 199A(g)(2)(E)(iii) requires qualified payments to reflect the limitation for purposes of the section 199A(b)(7) reduction. The commenter provided an example where the Cooperative's W–2 wage-limited section 199A(g) deduction is $50, but would have been $100 absent the W–2 wage limitation, and so the commenter proposed that only 50 percent of patronage dividends (or per-unit retain allocations) would be ''qualified payments'' under section 199A(g)(2)(E).

The definition of qualified payment in former section 199 and section 199A is almost identical. Under former section 199, the definition in section 199(d)(3)(E)(iii) provided that a qualified payment is an amount which is attributable to QPAI with respect to which a deduction is allowed to such cooperative under section 199(a). Section 199(A)(g)(2)(E)(iii) provides the same except that it refers to the deduction allowed to such cooperative under section 199A(g)(1). In former section 199, the amount allowed under former section 199(a) did not consider the W–2 wage limitation, which was in section 199(b). Section 199A(g)(1) is organized so that section 199A(g)(1)(A) is equivalent to former section 199(a) and section 199A(g)(1)(B) is equivalent to former section 199(b).

The Proposed Regulations interpreted the definition of qualified payment as referring to payments that relate to gross receipts that are allowable in the QPAI of a Specified Cooperative for which a deduction is allowed under section 199A(g)(1)(A). This is consistent with the language used in section 199A(g)(1)(A), which provides that there shall be allowed a deduction equal to 9 percent of the lesser of (i) QPAI of the taxpayer for the taxable year, or (ii) the taxable income of the taxpayer for the taxable year. As relevant, this language parallels former section 199(a). This interpretation is directly supported by Example 1 of the Joint Committee Report, which illustrates that payments to the patron are considered qualified payments for purposes of the section 199A(b)(7) reduction when the issuing Specified Cooperative's section 199A(g) deduction was W–2 wage-limited. This is also consistent with the regulations under former section 199, which did not have a proportionality rule for qualified payments. Therefore, the final regulations do not incorporate this comment.

Commenters also requested clarification that the definition of qualified payments does not include amounts paid to patrons by Specified Cooperatives with respect to activities that do not qualify as producing DPGR from the sale of agricultural or horticultural products. When gross receipts of a Specified Cooperative are non-DPGR, and thus, are not includable in QPAI, payments based on these amounts do not meet the definition of qualified payments. The Treasury Department and the IRS agree with this comment and view this as consistent with the interpretation of qualified payment described earlier, but do not consider additional regulatory language necessary to clarify this point.

Commenters also suggested that the last sentence of the definition, indicating that a Specified Cooperative calculates its qualified payment using the same method of accounting it uses to calculate its taxable income, was added in error and should be removed. This sentence was not in the definition of qualified payment in former § 1.199–6(e), and the Treasury Department and the IRS have removed the sentence for consistency with former § 1.199–6(e). Further, the definition of qualified payments already encompasses this concept with its references to patronage dividends and per-unit retain allocations, as a Specified Cooperative calculates patronage dividends and per-unit retain allocations when determining taxable income.

H. Comments on Examples in Proposed § 1.199A–8(e)

Commenters requested clarification on Examples 1 and 2 of proposed § 1.199A–8(e), asking how both examples are based on the same facts, but the payment in Example 1 is deemed a per-unit retain allocation, while the payment in Example 2 is deemed a purchase. Commenters indicated that without further explanation, the examples were confusing. Example 2 has been removed to eliminate any confusion as Example 1 is consistent with Example 1 from the Joint Committee Report. Example 1 has also been slightly modified for clarity and to more closely track Example 1 from the Joint Committee Report. In general, the determination of whether a payment is a per-unit retain allocation is made based on the definition in section 1388(f). Section 1388(f) defines per-unit retain allocations as any allocation, by an organization to which part I of subchapter T apples, to a patron with respect to products marketed for the patron, the amount of which is fixed without reference to the net earnings of the organization pursuant to an agreement between the organization and

the patron. Per-unit retain allocations are qualified payments (to the extent all other requirements are met) under the definition in § 1.199A–8(d)(2)(ii).

One commenter also requested clarification on whether it is possible for a Specified Cooperative and its patrons to contractually agree that a payment is not a qualified payment. The Treasury Department and the IRS believe that an agreement to treat a payment that otherwise meets the definition of qualified payment as something else would be inappropriate and ineffective. A payment meeting the definition of a qualified payment should be characterized as a qualified payment.

Commenters also asked that Examples 1–3 from former § 1.199–6(m) be included in the final regulations. Similar to Example 2 of proposed § 1.199A–8(e), the facts of Examples 1 and 2 from former § 1.199–6(m) both treat the Cooperative payments to patrons as purchases rather than per-unit retain allocations. In order to avoid confusion, the examples were modified to be consistent with Example 1 from the Joint Committee Report. The final regulations include Examples 1–3 from former § 1.199–6(m) as Examples 6, 7, and 8 under § 1.199A–8(e).

I. Comments on Rules for Specific Cooperative Partners in Proposed § 1.199A–8(f)

Under proposed § 1.199A–8(f), a Specified Cooperative that is a partner in a partnership must determine which Schedule K–1 allocations (*i.e.,* gross receipts and related deductions) qualify as DPGR and use the items to calculate its corresponding section 199A(g) deduction. A commenter noted that W–2 wages generated by the partnership should be passed on to the Specified Cooperative partner, relying on section 199A(f)(1)(A)(iii) and former § 1.199–5(b)(1)(i). The Treasury Department and the IRS agree and have amended § 1.199A–8(f) accordingly. Section 1.199A–8(f) of the final regulations also includes the share of COGS to maintain consistency with former § 1.199–5(b)(1)(i), which allowed for the allocation of COGS to partners.

A commenter also requested that if a partnership conducts MPGE activities that result in DPGR, then a Specified Cooperative partner in that partnership should be treated as if the activities were directly conducted by the Specified Cooperative. The Treasury Department and IRS agree with the comment and § 1.199A–8(f) now allows for two-way attribution, meaning: (1) A partnership's activities alone with respect to an agricultural or horticultural product can qualify the gross receipts for the Specified Cooperative partner, and (2) a partnership can be attributed the activities of the Specified Cooperative partner (including those activities that a specified partner is attributed from patrons) so that the gross receipts can be DPGR.

III. § 1.199A–9, Domestic Production Gross Receipts

A. In General

Section 199A(g)(3)(D) defines the term *DPGR* to mean gross receipts of a Specified Cooperative derived from any lease, rental, license, sale, exchange, or other disposition (collectively, a disposition) of any agricultural or horticultural product which was MPGE (determined after application of section 199A(g)(4)(B)) by the Specified Cooperative in whole or significant part within the United States. DPGR does not include gross receipts of the Specified Cooperative derived from a disposition of land or from services. Section 199A(g)(4)(B) treats marketing Specified Cooperatives as having MPGE any agricultural or horticultural product in whole or significant part within the United States if their patrons have done so. Proposed § 1.199A–9 provides rules for determining whether gross receipts are DPGR, and provides methods of allocating gross receipts between DPGR and non-DPGR. Proposed § 1.199A–9 was based on § 1.199–3 of the former section 199 regulations, but also incorporated rules from former § 1.199–1(d)(1) through (3) and § 1.199–1(e). Former § 1.199–1(d)(1) through (3) and § 1.199–1(e) relate to the allocation of gross receipts between DPGR and non-DPGR, determining whether an allocation method is reasonable, treating de minimis gross receipts as DPGR or non-DPGR, and the use of historical data to allocate gross receipts for certain multiple-year transactions. The Proposed Regulations were intended to be interpreted in a manner consistent with the interpretation under former section 199. Other than as described in response to the specific comments, the final regulations generally follow the Proposed Regulations.

B. Reasonable Method of Allocating Gross Receipts Between DPGR and Non-DPGR

Under proposed § 1.199A–9(c)(1), Specified Cooperatives must use a reasonable method when allocating gross receipts between DPGR and non-DPGR. This reasonable method must be consistently applied from one taxable year to another, and must clearly reflect the portion of gross receipts for the taxable year that is DPGR and the portion of gross receipts that is non-DPGR. Proposed § 1.199A–9(c)(2) provides that if a Specified Cooperative has the information readily available and can, without undue burden or expense, specifically identify whether the gross receipts are derived from an item as defined in proposed § 1.199A–9(e)(1)(i) (and thus, are DPGR), then the Specified Cooperative must use that specific identification method to determine DPGR. If the Specified Cooperative does not have information readily available to specifically identify whether gross receipts are derived from an item or cannot, without undue burden or expense, specifically identify whether the gross receipts are derived from an item, then the Specified Cooperative can use a reasonable method. Among the seven factors listed for determining whether a method is reasonable is whether the Specified Cooperative applies the method consistently from year to year.

A commenter observed that former § 1.199–8(a) did not prevent taxpayers from choosing a reasonable method on a year-to-year basis, and that former § 1.199–8(a) provided that a taxpayer's change in allocating or apportioning items did not constitute a change in method of accounting to which the provisions of sections 446 and 481 and the regulations under sections 446 and 481 apply. The Treasury Department and the IRS agree with the commenter that any change to an allocation or apportionment of items should not constitute a change in method of accounting to which the provisions of sections 446 and 481 and the regulations under sections 446 and 481 apply. However, the final regulations maintain the rule from the Proposed Regulations. The Treasury Department and the IRS incorporated the ''consistently applied'' requirement into proposed § 1.199A–9(c)(1) to be consistent with the section 199A(a) regulations, specifically § 1.199A–3(b)(5). Further, if a method is not reasonable because it no longer clearly reflects the gross receipts from DPGR and non-DPGR, the method cannot continue to be used. The Specified Cooperative must choose a new method that is reasonable under the facts and circumstances and apply it consistently going forward.

The same commenter also claimed that former section 199 did not subject the ''any reasonable method'' determination to the § 1.199A–9(c)(2) factors. This is incorrect, as the proposed § 1.199A–9(c)(2) factors follow former § 1.199–1(d)(2), including the factor of whether the taxpayer applies

the method consistently from year to year. Therefore, the use of consistency as a factor (§ 1.199A–9(c)(2)) follows former § 1.199–1(d)(2).

C. Interaction of MPGE Rules in Proposed § 1.199A–9(f)(1) With (f)(2) and (3)

MPGE is defined under proposed § 1.199A–9(f)(1) as manufacturing, producing, growing, extracting, installing, developing, improving, and creating agricultural or horticultural products; making agricultural or horticultural products out of material by processing, manipulating, refining, or changing the form of an article, or by combining or assembling two or more articles; and cultivating soil, raising livestock, and farming aquatic products. MPGE also includes storage, handling, or other processing activities (other than transportation activities) within the United States related to the sale, exchange, or other disposition of agricultural or horticultural products only if the products are consumed in connection with or incorporated into the MPGE of agricultural or horticultural products, whether or not by the Specified Cooperative. The Specified Cooperative (or the patron if § 1.199A–9(a)(2) applies) must have the benefits and burdens of ownership of the agricultural or horticultural products under Federal income tax principles during the period the MPGE activity occurs in order for the gross receipts derived from the MPGE of the agricultural or horticultural products to qualify as DPGR. Under proposed § 1.199A–9(f)(2) and (3), if a Specified Cooperative engages in packaging, repackaging, labeling, or installation of an agricultural or horticultural product, and engages in no other MPGE activity with respect to the agricultural or horticultural product, then the activities of packaging, repackaging, labeling, or installation do not qualify as MPGE with respect to the agricultural or horticultural product.

A commenter suggested the removal of § 1.199A–9(f)(2) and (3) on the grounds that ''packaging, repackaging, or labelling, [and] installing'' cannot be distinguished from ''storage, handling, and other processing activities'' mentioned in proposed § 1.199A–9(f)(1).

The Joint Committee Report, in footnote 118, citing § 1.199–3(e)(1), provides that gross receipts of a Specified Cooperative may qualify as DPGR so long as the Specified Cooperative performs storage, handling, or other processing activities (other than transportation activities) within the United States, provided the products are consumed in connection with, or incorporated into, the MPGE of agricultural or horticultural products (whether or not by the Specified Cooperative). Thus, the Proposed Regulations' definition of MPGE included that language. However, § 1.199A–9(f)(2) and (3) effectively serve as minimum thresholds for purposes of MPGE qualification under § 1.199A–9(f)(1). These requirements were also part of the former section 199 regulations at the time of repeal (see former § 1.199–3(e)(2) and (3)). A logical reading of these paragraphs is that the storage, handling, and other processing activities that are described in § 1.199A–9(f)(1) are activities that are more extensive than those described in § 1.199A–9(f)(2) and (3). Thus, the final regulations do not adopt this suggestion.

Commenters requested the inclusion of Examples 1 and 2 of former § 1.199–3(e)(5) to affirm that the storage of farm products qualifies as MPGE. These examples deal with relevant fact patterns, but required modification to apply to Specified Cooperatives as the examples in former § 1.199–3(e)(5) explicitly state that all taxpayers are not Cooperatives. Therefore, Examples 1 and 2, with appropriate modifications, have been added under § 1.199A–9(f)(5).

IV. § 1.199A–10, Costs Allocable to DPGR

Section 1.199A–10 provides guidance on the allocation of costs to DPGR. This section provides rules for allocating a taxpayer's COGS, as well as other expenses, losses, and deductions properly allocable to DPGR. The Proposed Regulations were based on and follow the former section 199 regulations in § 1.199–4. No comments were received on this part of the Proposed Regulations, and so § 1.199A–10 of the Proposed Regulations is adopted without change by the final regulations.

V. § 1.199A–11, Wage Limitation

Section 1.199A–11 provides guidance regarding the W–2 wage limitation on the section 199A(g) deduction. No comments were received on this part of the Proposed Regulations, and so § 1.199A–11 of the Proposed Regulations is adopted without change by the final regulations.

A notice of proposed revenue procedure, Notice 2019–27, 2019–31 IRB, which proposed a draft revenue procedure providing three proposed methods that Specified Cooperatives may use for calculating W–2 wages, was issued concurrently with the Proposed Regulations. A revenue procedure is a statement of procedure that affects the rights or duties of taxpayers under the Code. Consistent with the general purpose of publishing revenue procedures in the Internal Revenue Bulletin, the methods that taxpayers may use for calculating W–2 wages are set forth in a revenue procedure to promote a uniform application of the laws administered by the IRS. The revenue procedure may be modified independently from the regulations under section 199A if, for example, changes unrelated to section 199A or the regulations thereunder are made to the underlying Form W–2, Wage and Tax Statement. No comments were received on Notice 2019–27. A revenue procedure that conforms with the draft, with one modification related to short taxable years, is being issued concurrently with the final regulations.

VI. § 1.199A–12, Expanded Affiliated Group (EAG) Rules

Proposed § 1.199A–12 provides guidance on the application of section 199A(g) to an expanded affiliated group (EAG) that includes a Specified Cooperative. Section 199A(g)(5)(A)(iii) defines an EAG as an ''affiliated group as defined in section 1504(a),'' except that the ownership threshold is ''more than 50 percent'' as opposed to ''at least 80 percent.'' Section 1504(a)(1) defines an affiliated group as ''1 or more chains of includible corporations connected through stock ownership with a common parent corporation which is an includible corporation . . . .'' Section 1504(b)(1) further provides that the term ''includible corporation'' excludes ''[c]orporations exempt from taxation under section 501.'' Thus, the final regulations clarify that exempt Specified Cooperatives are not eligible to be members of an EAG. See § 1.1381–2(a)(1) (treating farmers' cooperatives that are exempt from tax under section 521 (such as Specified Cooperatives) as exempt organizations under section 501 ''[f]or the purpose of any law that refers to organizations exempt from income taxes''). As a result, for purposes of section 199A(g), an EAG may include nonexempt Specified Cooperatives as well as other includible corporations.

The Proposed Regulations provide that the section 199A(g) deduction for an EAG is determined by separating patronage and nonpatronage gross receipts and related deductions of Specified Cooperatives that are members of the EAG. The section 199A(g) deduction is then computed solely with respect to patronage gross receipts and related deductions (patronage items). As explained in part VII of this Summary of Comments and Explanation of Revisions, patronage items are items of income or deduction

produced by a transaction that actually facilitates the accomplishment of the Specified Cooperative's marketing, purchasing, or services activities. See *Farmland Industries, Inc.* v. *Comm'r,* 78 T.C.M. 846 (CCH) (1999); § 1.1388–1(f).

Thus, the Proposed Regulations effectively have two specific rules addressing the computation of the section 199A(g) deduction for an EAG that includes a Specified Cooperative. First, the section 199A(g) deduction is computed using only patronage items (the EAG patronage limitation). Second, only members of an EAG that are Specified Cooperatives are taken into account in computing the section 199A(g) deduction (the Specified Cooperative limitation).

A commenter recommended that the final regulations eliminate the EAG patronage limitation. Specifically, as discussed in part II of this Summary of Comments and Explanation of Revisions, the commenter argued that the general requirement to distinguish income, deductions, and W–2 wages from patronage and nonpatronage activities conflicts with the policy of section 199A, and that such a requirement is equally inappropriate for EAGs that include Specified Cooperatives.

The Treasury Department and the IRS do not agree with the commenter's argument. Under subchapter T, patronage income of a nonexempt cooperative with both patronage and nonpatronage activities effectively receives single-level tax treatment, whereas nonpatronage income of such a cooperative is taxed at both the corporate level and the shareholder level. *Farm Service Coop.* v. *Comm'r,* 619 F.2d 718, 723 (8th Cir. 1980). Because the commenter's proposal would extend the benefits of the section 199A(g) deduction to nonpatronage activities, with respect to which a nonexempt cooperative is taxed as a C corporation, it is inconsistent with the purposes and structure of section 199A. Moreover, eliminating the patronage limitation solely in the context of an EAG would disadvantage nonexempt Specified Cooperatives that are not members of an EAG because such entities, unlike their counterparts in an EAG, would be prohibited from taking a section 199A(g) deduction on nonpatronage sourced gross receipts.

Thus, the final regulations do not adopt the commenter's recommendation to compute the section 199A(g) deduction using both patronage and nonpatronage items in either the standalone context (see part II of this Summary of Comments and Explanation of Revisions) or for EAGs. Instead, activities resulting in nonpatronage income continue to be taxed as income from a noncooperative C corporation.

The same commenter also recommended eliminating the Specified Cooperative limitation, specifically arguing that, because C corporations that are not Specified Cooperatives can be members of an EAG, such corporations also should be taken into account in computing the section 199A(g) deduction for an EAG. The commenter also stressed that the approach in proposed § 1.199A–12 is different from the approach in the former section 199 EAG rules, which provide the basis for the rules in proposed § 1.199A–12.

The final regulations also do not adopt this recommendation. Unlike the former section 199 deduction, which was broader in scope, section 199A(g) specifically provides that only a ''taxpayer which is a specified agricultural or horticultural cooperative'' (that is, a Specified Cooperative) may claim the section 199A(g) deduction. Moreover, as noted in part II of this Summary of Comments and Explanation of Revisions, C corporations are expressly prohibited under section 199A(a) from claiming a section 199A(a) deduction, and C corporations other than Specified Cooperatives under section 199A(g)(2)(D)(i) from claiming a section 199A(g) deduction as a patron of a Specified Cooperative. Although the statute does not expressly prohibit C corporations that are not Specified Cooperatives from being taken into account in computing an EAG's section 199A(g) deduction, the fact that the statute expressly limits this deduction to Specified Cooperatives, and the statute's general prohibition against C corporations that are not Specified Cooperatives benefiting from the section 199A(g) deduction, indicate that the Specified Cooperative limitation is consistent with the structure and intent of section 199A.

Additionally, eliminating the Specified Cooperative limitation would have no practical effect unless the EAG patronage limitation also were eliminated. Nonexempt Specified Cooperatives receive single-level tax treatment only to the extent of patronage income generated and distributed to their patrons; their nonpatronage income continues to be taxed at both the corporate level and the shareholder level. Accordingly, the net effect of the Specified Cooperative limitation is to exclude what otherwise would be nonpatronage income, because a C corporation that is not a Specified Cooperative cannot generate patronage income. Because the final regulations retain the EAG patronage limitation, removing the Specified Cooperative limitation would have no practical effect with respect to nonexempt Specified Cooperatives. As previously noted, removing the Specified Cooperative limitation would not affect the treatment of exempt Specified Cooperatives because they are not eligible to be members of an EAG. See section 1504(b)(1); § 1.1381–2(a)(1).

Finally, revisions necessary to clarify the scope and application of section 199A(g) to an EAG that includes a Specified Cooperative were made in § 1.199A–12 of the final regulations.

VII. § 1.1382–3, Taxable Income of Cooperatives; Special Deductions for Exempt Farmers' Cooperatives; and § 1.1388–1, Definitions and Special Rules

A. Comments on Definition of ''Patronage and Nonpatronage''

Section 1.1388–1 provides definitions and special rules applicable to Cooperatives. The Proposed Regulations added a definition of *patronage and nonpatronage* in proposed § 1.1388–1(f). Proposed § 1.1388–1(f) provides ''[w]hether an item of income or deduction is patronage or nonpatronage sourced is determined by applying the directly related use test. The directly related use test provides that if the income or deduction is produced by a transaction that actually facilitates the accomplishment of the cooperative's marketing, purchasing, or services activities, the income or deduction is from patronage sources. However, if the transaction producing the income or deduction does not actually facilitate the accomplishment of these activities but merely enhances the overall profitability of the cooperative, being merely incidental to the association's cooperative operation, the income or deduction is from nonpatronage sources. Patronage and nonpatronage income or deductions cannot be netted unless otherwise permitted by the Internal Revenue Code or regulations issued under the relevant section of the Internal Revenue Code, or guidance published in the Internal Revenue Bulletin (*see* § 601.601(d)(2) of this chapter).''

Commenters questioned the need for adopting a definition in connection with guidance under section 199A(g), as the definition will impact all Cooperatives. However, a common determination for all Cooperatives is identifying activities as patronage or nonpatronage. Prior to the Proposed Regulations, there was no single definition of patronage and

nonpatronage. The definition of *income derived from sources other than patronage* in § 1.1382–3(c)(2), which was often cited as part of the determination, is outdated. As it relates to section 199A(g), the requirement to identify patronage and nonpatronage to calculate the section 199A(g) deduction places additional importance on the determination. To assist taxpayers in distinguishing between patronage and nonpatronage, proposed § 1.1388–1(f) was added. The intent in adding § 1.1388–1(f) was to incorporate the ''directly related'' test, which is the current legal standard for making the determination.

Commenters requested citations relevant to the proposed definition to ensure the language complies with the current legal standard. Other than the last sentence, the language adopted in the Proposed Regulations closely follows the language used in Rev. Rul. 69–576, 1969–2 C.B. 166, which provides ''[t]he classification of an item of income as from either patronage or nonpatronage sources is dependent on the relationship of the activity generating the income to the marketing, purchasing, or service activities of the cooperative. If the income is produced by a transaction which actually facilitates the accomplishment of the cooperative's marketing, purchasing, or service activities, the income is from patronage sources. However, if the transaction producing the income does not actually facilitate the accomplishment of these activities but merely enhances the overall profitability of the cooperative, being merely incidental to the association's cooperative operation, the income is from nonpatronage sources.''

The language from Rev. Rul. 69–576 has been cited in numerous opinions, including *Farmland Industries, Inc.* v. *Comm'r,* 78 T.C.M. 846 (CCH) (1999), which provides a summary of published guidance and many of the cases relevant to the current legal standard. In the *Farmland* opinion, the court states that ''the 'directly related test' applied by the courts is traceable to published rulings issued by the Commissioner, such as Rev. Rul. 69–576, 1969–2 C.B. 166, and Rev. Rul. 74–160, 1974–1 C.B. 245, that interpreted patronage income broadly.'' *Farmland* at 865.

Commenters also suggested removal of § 1.1388–1(f) on the basis that patronage/nonpatronage determinations necessitate a facts and circumstances analysis, and, therefore § 1.1388–1(f) is inappropriate. Section 1.1388–1(f) provides a definition, it does not eliminate the necessity for factual analysis. Therefore, the final regulations do not adopt this comment.

Alternatively, one commenter requested that the definition in § 1.1388–1(f) be modified to provide that income is from patronage sources if the underlying transaction is either directly related or actually facilitates the cooperative's purpose. The final regulations do not adopt this comment. The definitional language of § 1.1388–1(f) follows the language from Rev. Rul. 69–576 and is also consistent with language in *Farmland.* However, revisions have been made to clarify the distinction between patronage and nonpatronage sourced items.

The commenter also suggested the removal of the last sentence of the definition, which prohibited the netting of patronage and nonpatronage items. The Treasury Department and the IRS agree that the ''netting'' rule is not needed to define patronage and nonpatronage. Therefore, the last sentence of proposed § 1.1388–1(f) is removed from the definition in the final regulations.

B. Comments on Removing the Definition of ''Income From Sources Other Than Patronage''

The commenter also requested that if a definition was finalized, then the definition of *income from sources other than patronage* in § 1.1382–3(c)(2) be removed. The Treasury Department and the IRS agree that this section should be revised. The final regulations revise this section so that it now cross-references the definition of *patronage and nonpatronage* in § 1.1388–1(f).

VIII. Removal of Section 199 Regulations

In light of the TCJA, the Treasury Department and the IRS proposed to remove the former section 199 regulations (§§ 1.199–0 through 1.199–9) and withdrew the 2015 proposed regulations because the regulations interpret a provision of the Code that has been repealed for taxable years beginning after December 31, 2017. No comments were received, and the final regulations remove the former section 199 final regulations (§§ 1.199–0 through 1.199–9, including expired temporary regulations published in the **Federal Register** as TD 9731).

The removal of these regulations is unrelated to the substance of the rules in the regulations, and no negative inference regarding the stated rules should be made. The regulations are removed from the Code of Federal Regulations (CFR) solely because they have no future applicability. Removal of these regulations is not intended to alter any non-regulatory guidance that cites to or relies upon these regulations. These regulations as contained in 26 CFR part 1, revised April 1, 2019, remain applicable to determining eligibility for the former section 199 deduction for any taxable year that began before January 1, 2018. The beginning date of the taxable year of a partnership, S corporation, or a non-grantor trust or estate, rather than the taxable year of a partner, shareholder, or beneficiary is used to determine items that are taken into account for purposes of calculating a former section 199 deduction.

IX. Comments on Proposed Applicability Date and Transition Rule

A commenter requested that the final regulations be made applicable to taxable years beginning after the publication date. The final regulations adopt the commenter's request.

Regarding the transition rule, proposed § 1.199A–7(h)(2) provides that no deductions under section 199A are allowed to patrons for any qualified payments that are attributable to QPAI with respect to which a deduction is allowable to the Specified Cooperative under former section 199 as in effect on and before December 31, 2017, for a taxable year of the Cooperative beginning before January 1, 2018. Additionally proposed § 1.199A–7(h)(3) provides that if a patron of a Cooperative cannot claim a deduction under section 199A(a) for any qualified payments described in the transition rule of § 1.199A–7(h)(2), the Cooperative must report this information on an attachment to or on the Form 1099–PATR (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the form.

The commenter also requested omission of references to the transition rule and confirmation that any reasonable application of the transition rule will be deemed appropriate. This request was based on the presumption that these regulations would not be finalized until after 2019, when the time period covered by the transition rule has passed, thus requiring the amendment of Forms 1099–PATR (and corresponding Forms 1040, U.S. Individual Income Tax Return). The commenter also suggested that Cooperatives have a common understanding of the transition rule to the extent that payments described under proposed § 1.199A–7(h)(2) would be properly identified and not included in patrons' section 199A(a) calculations. The commenter, however, did not identify a specific method that

Cooperatives primarily used. The final regulations amend the rule from proposed § 1.199A–7(h)(2) so that it now only cross-references section 101(c) of Division T of the 2018 Act. The final regulations also amend proposed § 1.199A–7(h)(3) to allow Cooperatives to use a reasonable method to identify the payments, and state that the method from the Proposed Regulations of reporting on an attachment to or on Form 1099–PATR (or successor form) is one reasonable method.

Applicability Dates

Section 7805(b)(1)(A) and (B) of the Code generally provide that no temporary, proposed, or final regulation relating to the internal revenue laws may apply to any taxable period ending before the earliest of (A) the date on which the regulation is filed with the **Federal Register**, or (B) in the case of a final regulation, the date on which a proposed or temporary regulation to which the final regulation relates was filed with the **Federal Register**.

Consistent with authority provided by section 7805(b)(1)(A), §§ 1.199A–7 through 1.199A–12, § 1.1382–3(c)(2) as revised, and § 1.1388–1(f) generally apply to taxable years beginning after January 19, 2021. However, taxpayers may choose to apply the rules set forth in §§ 1.199A–7 through 1.199A–12, § 1.1382–3(c)(2) as revised, and § 1.1388–1(f) for taxable years beginning on or before January 19, 2021, provided, in each case, the taxpayers follow the rules in their entirety and in a consistent manner. Alternatively, taxpayers may rely on the proposed regulations under §§ 1.199A–7 through 1.199A–12 issued on June 19, 2019 for taxable years beginning on or before January 19, 2021 and taxpayers may rely on the proposed regulations under § 1.1388–1(f) issued on June 19, 2019 for taxable years beginning on or before January 19, 2021, provided, in each case, taxpayers follow the proposed regulations in their entirety and in a consistent manner.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 13771, 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

These regulations have been designated by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. OIRA has determined that the final rulemaking is significant and subject to review under Executive Order 12866 and section 1(b) of the Memorandum of Agreement. Accordingly, the final regulations have been reviewed by the Office of Management and Budget.

A. Background and Overview

The TCJA repealed section 199 of the Code, which provided a deduction for income attributable to domestic production activities. In its place it created section 199A, which provides a deduction for qualified business income derived from passthrough businesses—such as sole proprietorships, partnerships, and S corporations—engaged in domestic trades or businesses. While the repealed section 199 deduction was generally available to all taxpayers, the section 199A(a) deduction is available only to taxpayers other than C corporations, including patrons of cooperatives to which sections 1381 through 1388 of the Code apply (Cooperatives). On March 23, 2018, section 101 of the 2018 Act amended section 199A(g) to provide deductions for Specified Cooperatives and their patrons that are substantially similar to the deductions allowed under the repealed section 199 deduction. Accordingly, these regulations generally formalize prior and current practices based on the rules under former section 199. The 2018 Act also added section 199A(b)(7), which requires patrons of Specified Cooperatives to reduce their section 199A(a) deduction if those patrons receive qualified payments from Specified Cooperatives.

The estimated number of Cooperatives affected by the 2018 Act and these final regulations is 9,200, including approximately 2,000 Specified Cooperatives, based on 2018 tax filings.

B. Need for Regulation

The final regulations provide guidance regarding the application of sections 199A(a), 199A(b)(7), and 199A(g) to Cooperatives, Specified Cooperatives, and their patrons. The final regulations are needed because the 2018 Act introduced a number of terms and calculations. Patrons, Cooperatives, and Specified Cooperatives would benefit from greater specificity regarding these and other items.

C. Economic Analysis

1. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

2. Economic Rationale for Issuing Guidance for the 2018 Act

The Treasury Department and the IRS anticipate that the issuance of guidance pertaining to sections 199A(a), 199A(b)(7), and 199A(g) of the 2018 Act to Cooperatives, Specified Cooperatives, and their patrons will provide a marginal net economic benefit to the overall U.S. economy.

The final regulations clarify a number of concepts for Cooperatives and their patrons, regarding the deduction provided by section 199A(a) for qualified business income, as well as for Specified Cooperatives and their patrons regarding the section 199A(g) deduction on income attributable to the domestic production activities of Specified Cooperatives. Specifically, the final regulations (i) clarify how Specified Cooperatives should determine their section 199A(g) deduction; (ii) define ''agricultural or horticultural products'' to clarify which Cooperatives qualify as Specified Cooperatives eligible for the section 199A(g) deduction; (iii) provide de minimis rules reducing compliance costs for certain Specified Cooperatives; (iv) require reporting from Cooperatives; (v) provide a safe harbor permitting certain patrons of Specified Cooperatives to use a simpler method to calculate the section 199A(b)(7) reduction to the section 199A(a) deduction; (vi) permit patrons to allocate their expenses to calculate the correct amount of qualified business income and their section 199A(a) deduction; (vii) permit, but do not require, Specified Cooperatives to identify the eligibility status of patrons to pass through the section 199A(g) deduction to them; and (viii) permit partnerships to pass through W–2 wages and cost of goods sold (COGS) to Specified Cooperative partners and permit attribution of a partnership's activities to a Specified Cooperative partner and a Specified Cooperative's partner's activities to a partnership. In the absence of guidance, affected

taxpayers would have to calculate their tax liability without the definitions and clarifications provided by the final regulations, a situation that is generally considered more burdensome and could lead to greater conflicts with tax administrators. Thus, the Treasury Department and the IRS project that the final regulations will marginally reduce taxpayer compliance burden and the costs of tax administration relative to not issuing any such guidance.

This guidance also ensures that section 199A deductions are calculated similarly across taxpayers, avoiding situations where one taxpayer receives preferential treatment over another for fundamentally similar economic activity. For example, in the absence of these final regulations, a Specified Cooperative may have uncertainty over what type of income is eligible for the section 199A(g) deduction. If a Specified Cooperative claimed the section 199A(g) deduction on income that is taxed similarly to a C corporation, this would confer an unintended economic benefit to the Specified Cooperative over other C corporations performing identical activities that only benefit from a lower corporate tax rate. As discussed further below, this guidance prevents the introduction of distortions of economic decisions in the agricultural or horticultural sector.

In the absence of these regulations, uncertainty over statutory interpretation could lead to economic losses to the extent that taxpayers interpret the statute in ways that are inconsistent with the statute's intents and purposes. For example, a Specified Cooperative may pursue a project involving a certain product that is only profitable if that product is deemed ''agricultural or horticultural'' and thus eligible for the section 199A(g) deduction. If, in fact, this product is ineligible for the deduction based on the intents and purposes of the statute, then the project should not have been pursued and this results in an economic loss. Alternatively, without a definition of ''agricultural or horticultural,'' a Specified Cooperative may incorrectly assume that a project is not eligible for the deduction and not pursue the project, which could also result in an economic loss. In such cases, guidance provides value by supporting decision-making that is economically efficient, contingent on the overall Code. While no guidance can fully curtail all inaccurate interpretations of the statute, the final regulations significantly mitigate the chance for such interpretations and thereby increase economic efficiency. Due to the lack of readily available data, the Treasury Department and the IRS have not estimated the increase in United States economic activity that would arise from the guidance.

The Treasury Department further projects that the issuance of guidance will reduce taxpayer compliance burden and the costs of tax administration relative to a no-action baseline. Due to the lack of readily available data, the Treasury Department has not estimated the decrease in taxpayer compliance burden nor tax administration costs arising from the issuance of guidance.

No comments were received on the economic analysis provided in the proposed regulations.

3. Economic Analysis of Specific Provisions

The final regulations embody certain regulatory decisions that reflect necessary regulatory discretion. These decisions specify more fully how the 2018 Act is to be implemented.

i. Determining Section 199A(g) Deduction for Specified Cooperatives

The final regulations outline the process by which Specified Cooperatives calculate their section 199A(g) deductions. The rules concern two types of Specified Cooperatives, those that are exempt (qualified as a Cooperative under section 521) and those that are nonexempt (qualified under subchapter T of the Code), and two sources of income, patronage and nonpatronage. The patronage and nonpatronage income of Specified Cooperatives is taxed differently depending on whether the Specified Cooperative is exempt or nonexempt. In the case of exempt Specified Cooperatives, patronage and nonpatronage source income is subject to a single level of tax at the patron level. Whereas, for nonexempt Specified Cooperatives only patronage source income is subject to a single level of tax at the patron level; nonpatronage source income is subject to a double level of tax, similar to other C corporation income.

Because the Code does not define *patronage and nonpatronage sourced items,* § 1.1388–1(f) of these final regulations sets forth a definition that is consistent with the current state of federal case law. Specifically, the definition adopts the directly related test, which is a fact specific test for determining whether income and deductions of a Cooperative are patronage or nonpatronage. The final regulations also make revisions to clarify patronage versus nonpatronage items. In response to a commenter, the final regulations remove the last sentence in the proposed definition, because the Treasury Department and the IRS agree that the sentence is not needed to define patronage and nonpatronage. Specifying a definition that is consistent with current case law will help to minimize the economic impacts of these regulations that may arise from lack of clarity.

The final regulations adopt the proposed rule requiring Specified Cooperatives to identify gross receipts, COGS, deductions, W–2 wages, etc. as patronage or nonpatronage, and only allows the patronage activities of nonexempt Specified Cooperatives to be included in the calculation of the section 199A(g) deduction, unless the Specified Cooperative falls under the expanded de minimis rules, which are discussed later. The TCJA reduced the corporate tax rate for C corporations under section 11 and provided the section 199A deduction for domestic businesses operating as sole proprietorships or through partnerships, S corporations, trusts, or estates. The TCJA also repealed section 199, which did not preclude deductions on income earned by C corporations. The 2018 Act amended section 199A to address concerns that the TCJA created an unintended incentive for farmers to sell their agricultural or horticultural products to Specified Cooperatives over independent buyers. Specifically, the 2018 Act amended section 199A(g) to allow Specified Cooperatives and their patrons a deduction similar to the former section 199 deduction. Because the section 199A(g) deduction is not intended to benefit C corporations and their shareholders, in general, the final regulations specify that the section 199A(g) deduction can be claimed only on income that can be subject to tax only at the patron level. Under the final regulations, a non-exempt Specified Cooperative may not claim the section 199A(g) deductions on income that cannot be paid to patrons and deducted under section 1382(b) and exempt Specified Cooperatives may not claim section 199A(g) deductions on income that cannot be paid to patrons and deducted under sections 1382(b) or 1382(c)(2).

In the absence of these regulations, a Specified Cooperative may have uncertainty as to whether nonpatronage source income, which would be taxed in the same manner as a C corporation, could receive both the lower corporate tax rate and be further offset by a section 199A(g) deduction. Other C corporations performing identical activities would only benefit from the lower corporate tax rate. This would

confer an unintended economic benefit to Specified Cooperatives over other C corporations and undermine the intent of the 2018 Act's amendments of section 199A to reduce competitive distortions between C corporations and Specified Cooperatives.

The Treasury Department and the IRS have determined that this potential uncertainty as to tax treatment could distort economic decisions in the agricultural or horticultural sector. The final regulations avoid this outcome, promoting a more efficient allocation of resources by providing more uniform incentives across taxpayers.

ii. Definition of Agricultural or Horticultural Products

The section 199A(g) deduction is focused solely on dispositions of agricultural or horticultural products. As a result, the Treasury Department and the IRS determined that it was necessary to provide a definition. Because there is no definition of *agricultural or horticultural products* in the Code or Income Tax Regulations, the Treasury Department and the IRS looked to the United States Department of Agriculture (USDA) for definitions because the USDA has expertise concerning Specified Cooperatives, and Specified Cooperatives are likely familiar with USDA law. The proposed regulations defined *agricultural or horticultural products* within the meaning of the Cooperative Marketing Act of 1926 as agricultural, horticultural, viticultural, and dairy products, livestock and the products thereof, the products of poultry and bee raising, the edible products of forestry, and any and all products raised or produced on farms and processed or manufactured products thereof. Agricultural or horticultural products also include aquatic products that are farmed as well as fertilizer, diesel fuel, and other supplies used in agricultural or horticultural production that are manufactured, produced, grown, or extracted by the Specified Cooperative. Agricultural or horticultural products, however, do not include intangible property, since agricultural or horticultural products were considered a subset of tangible property under former section 199. Intangible property (defined in § 1.199–3(j)(2)(iii)) was a separate category of property and gross receipts from intangible property did not qualify as domestic production gross receipts (DPGR).

The final regulations made clarifying changes to the definition of agricultural or horticultural products in response to commenters. The final regulations provide examples (without limitation) of products that are considered agricultural or horticultural products, including specific agricultural or horticultural products, livestock products, edible forestry products, and farmed aquatic products. The final regulations also provide language further clarifying that agricultural or horticultural products do not include intangible property. Finally, the final regulations include more examples of ''other supplies'' being agricultural or horticultural products.

The Treasury Department and the IRS considered a similar but alternative definition of *agricultural or horticultural* products within the meaning of the Agricultural Marketing Act of 1946 as agricultural, horticultural, viticultural, and dairy products, livestock and poultry, bees, forest products, fish and shellfish, and any products thereof, including processed and manufactured products, and any and all products raised or produced on farms and any processed or manufactured product thereof. While very similar to the definition in the rules adopted in these final regulations, the rules under the Agricultural Marketing Act of 1946 concern the marketing and distribution of agricultural products without reference to Cooperatives.

The Treasury Department and the IRS also considered an alternative definition of *agricultural or horticultural products* based on the definition of agricultural commodities within the meaning of general regulations under the Commodity Exchange Act. The Treasury Department and the IRS concluded that this definition was too narrow, because it is limited to products that can be commodities. The use of this narrow definition would have restricted the range of products for which the section 199A(g) deduction would be otherwise available.

The Treasury Department and the IRS did not attempt to provide quantitative estimates of the economic consequences of different designations of agricultural or horticultural products because suitable data are not readily available at this level of detail.

iii. De Minimis Threshold for Domestic Production Gross Receipts of Specified Cooperatives

In general, § 1.199A–9 of the final regulations requires that Specified Cooperatives allocate gross receipts between DPGR and non-DPGR. However, § 1.199A–9(c)(3) of the proposed regulations includes a de minimis provision that allows Specified Cooperatives to allocate total gross receipts to DPGR if less than 5 percent of total gross receipts are non-DPGR or to allocate total gross receipts to non-DPGR if less than 5 percent of total gross receipts are DPGR. The thresholds provided in the proposed regulations are based on the thresholds set forth in § 1.199–1(d)(3) under former section 199. The Treasury Department and the IRS chose to include a de minimis rule to reduce compliance costs and simplify tax filing relative to an alternative of no de minimis rule.

The Treasury Department and the IRS considered changes to the de minimis provisions in the proposed regulations, but determined that materially changing these rules from provisions that were previously available would lead to taxpayer confusion. The final regulations generally maintain the rules of the proposed regulations, but increase the threshold. Thus, under § 1.199A–9(c)(3) of the final regulations, Specified Cooperatives when calculating the patronage section 199A(g) deduction may allocate total gross receipts to DPGR if less than 10 percent of total gross receipts are non-DPGR (which now can include nonpatronage gross receipts as well as patronage non-DPGR pursuant to § 1.199A–8(b)(2)(ii)), or alternatively, may allocate total gross receipts to non-DPGR if less than 10 percent of total gross receipts are DPGR. The de minimis threshold modestly reduces compliance costs for businesses with relatively small amounts of non-DPGR or DPGR by allowing them to avoid allocating receipts between DPGR and non-DPGR activities. The de minimis threshold is unlikely to create any substantial effects on market activity because any change in the ratio of DPGR to non-DPGR will be localized around the threshold, meaning that the movement will be a small fraction of receipts to get below the de minimis threshold. Because the de minimis provision exempts taxpayers from having to perform certain allocations and therefore reporting these allocations, the Treasury Department and the IRS do not have information on taxpayers' use of this exemption under former section 199 to perform a quantitative analysis of the impacts of the de minimis provision.

iv. Reporting Requirements for Cooperatives

Final regulations § 1.199A–7(c) and (d) provide that, when a patron conducts a trade or business that receives distributions from a Cooperative, the Cooperative is required to provide the patron with qualified items of income, gain, deduction, and loss and specified service trade or business (SSTB) determinations with

respect to those distributions. This increases the compliance burden on such Cooperatives. However, in the absence of these regulations, the burden for determining of the amount of distributions from a Cooperative that constitute qualified items of income, gain, deduction, and loss from a non-SSTB and an SSTB would lie with the patron. Because patrons are less well positioned to acquire the relevant information to determine whether distributions from a Cooperative are qualified items of income, gain, deduction, and loss and whether items that would otherwise qualify are from an SSTB, the Treasury Department and the IRS expect that these regulations will reduce overall compliance costs relative to an alternative approach of not introducing a reporting requirement. After consideration of comments, the reporting requirements of Cooperatives have been modified to simplify the Cooperatives' reporting obligations in order to balance the burden on the Cooperatives and the patrons' need to receive information to determine their section 199A(a) deduction.

v. Allocation Safe Harbor

If a patron receives both income or gain related to qualified payments and income or gain that is not related to qualified payments in a qualified trade or business, the patron must allocate those items and related deductions, losses, and W–2 wages using a reasonable method based on all of the facts and circumstances. The final regulations provide a safe harbor that allows patrons who receive income or gain related to qualified payments in addition to income or gain that is not related to qualified payments to use a simpler method to allocate deductions, losses, and W–2 wages between income or gain related to qualified payments and income or gain that is not related to qualified payments to calculate the section 199A(b)(7) reduction to the section 199A(a) deduction. The safe harbor allocation method allows patrons to allocate by ratably apportioning deductions, losses, and W–2 wages based on the proportion that the amount of income or gain related to qualified payments bears to the total income or gain used to determine QBI. This safe harbor is available to patrons with taxable incomes below the threshold amounts set forth in section 199A(e)(2).

The Treasury Department and the IRS considered an alternative of not allowing a safe harbor but determined that a safe harbor could reduce compliance costs and simplify tax filing. The threshold was set at amounts set forth in section 199A(e)(2) to avoid a proliferation of thresholds applicable to taxpayers claiming a section 199A(a) deduction. Because the threshold amounts are relatively low, the Treasury Department and the IRS expect that the safe harbor would not distort business decisions or reduce revenue to any meaningful extent.

i. Patrons May Allocate Expenses to Specified Service Trade or Business Items of Income Reported by Cooperative

A commenter asked the Treasury Department and the IRS to revise proposed reporting requirements in circumstances where a Cooperative engages in a specified service trade or business (SSTB) business with patrons. In response to the commenter's request, the final regulations allow patrons to allocate expenses between qualified trade or business income and any SSTB income received from the Cooperative up to the amount of the income from the SSTB. The final regulations more accurately track the substance of the transaction. In the absence of these regulations, the patron may calculate lower qualified business income, resulting in a lower section 199A(a) deduction.

ii. Specified Cooperatives May Pass Through All, Some, or None of the Section 199A(g) Deduction

Section 199A(g) permits Specified Cooperatives to pass through their section 199A(g) deduction, and allows eligible taxpayers to claim the deduction passed through. The proposed regulations required Specified Cooperatives to identify whether the patrons are eligible taxpayers and only pass through the deduction to those patrons. Commenters requested that the rule be modified so that patrons, and not Specified Cooperatives, have to identify whether the patrons are eligible taxpayers for purposes of using the section 199A(g) deduction. The rules have been modified in the final regulations to provide Specified Cooperatives with maximum flexibility. If a Specified Cooperative does not identify the eligibility status of all of its patrons, it may pass through all, some, or none of the section 199A(g) deduction. Only patrons that are eligible taxpayers may use the section 199A(g) deduction passed through to them. If a Specified Cooperative does determine the eligibility status of its patrons, it has the discretion to retain the section 199A(g) deduction attributable to any ineligible taxpayer, and pass out the remainder to eligible taxpayers.

In the absence of these regulations, a Specified Cooperative may have uncertainty as to whether to distribute the section 199A(g) deduction to eligible taxpayers. The final regulations provide Specified Cooperatives with the option of retaining and using the amounts equal to the section 199A(g) deduction attributable to ineligible taxpayers, or passing out the deduction, which only eligible taxpayers may claim. This allows Specified Cooperatives to choose whether to engage in information gathering regarding patrons' eligibility to use the deduction. The Treasury Department and the IRS have determined that this increased flexibility promotes a more efficient allocation of resources by allowing Specified Cooperatives to choose the extent to which they engage in information gathering in relation to the use of the section 199A(g) deduction at the Specified Cooperative level or the patron level.

iii. Special Rule for Specified Cooperative Partners

The final regulations provide special rules for Specified Cooperatives that are partners in a partnership. A commenter recommended that the proposed regulations be modified to permit partnerships to pass through W–2 wages to Specified Cooperative partners, thereby increasing the Specified Cooperatives' section 199A(g) deduction. A commenter also recommended that, to the extent a partnership conducts activities that result in gross receipts, a Specified Cooperative partner in that partnership should be permitted to treat those activities as conducted directed by the Specified Cooperative. The Treasury Department and the IRS agree with these comments. The final regulations permit the partnerships to pass through W–2 wages and COGS to Specified Cooperative partners. Additionally, the final regulations allow for two-way attribution, meaning: (1) A partnership's activities alone with respect to an agricultural or horticultural product can qualify as gross receipts for the Specified Cooperative partner and (2) a partnership can be attributed the activities of the Specified Cooperative partner. These rules permit additional activities and the resulting income, as well as additional W–2 wages and COGS, to be considered in the calculation of the section 199A(g) deduction.

This stipulation allows for greater flexibility in determining deductions when Specified Cooperatives are partners. Flexibility will increase economic efficiency by making it more likely that Specified Cooperatives

comply with regulations by lowering the compliance burden.

The Treasury Department and the IRS anticipate that these regulations in aggregate will have a marginal impact on economic activity. Compared to the economic impacts resulting from the 2018 Act, the final regulations' primary impact will be through increasing comprehension of the tax code. Increased understanding will reduce the risk that firms and the IRS will disagree on tax reporting and allocation and therefore engage in costly legal transactions. Increased comprehension will also reduce the possibility that firms will engage in activities that would yield negative economic impacts if clarity were stronger. These final regulations also respond to commenters by adding additional examples to further increase comprehension.

II. Paperwork Reduction Act

The collection of information contained in these regulations has been revised and approved by the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control numbers 1545–0118 and 1545–0123.

Regulations in § 1.199A–7(c)(3), (d)(3), (f)(3), and (h)(3), as well as § 1.199A–8(d)(3) and (f), require the collection of information. The collections of information in § 1.199A–7(c)(3), (d)(3), (f)(3), and (h)(3), as well as § 1.199A–8(d)(3) will be conducted through Form 1099–PATR, Taxable Distributions Received From Cooperatives, while the collection of information in § 1.199A–8(f) will be conducted through Schedule K–1 to Form 1065, U.S. Return of Partnership Income.

A. Collections of Information Conducted Through Form 1099–PATR

Section 1.199A–7(c)(3) requires the Cooperative to inform its patron of the amount of any distribution to the patron that constitutes qualified items of income, gain, deduction, and loss from a non-specified service trade or business (SSTB) conducted directly by the Cooperative. Not all distributions to patrons are qualified items of income, gain, deduction, and loss because the source of the distribution may not be effectively connected with the conduct of a trade or business within the United States or may include interest income that is not properly allocable to the patron's trade or business. The Cooperative directly conducting the trade or business from which the distribution to the patron originates is in the best position to know how much of the distribution is qualified items of income, gain, deduction, and loss. The Cooperative is also in the best position to know if it is generating income from an SSTB. Accordingly, the collection of information is necessary for the patron to calculate correctly the patron's section 199A(a) deduction for the patron's trade or business.

Section 1.199A–7(d)(3) requires the Cooperative to inform its patron of the amount of any distributions to the patron that constitutes qualified items of income, gain, deduction, and loss from an SSTB conducted directly by the Cooperative. Accordingly, the collection of information is necessary for the patron to correctly calculate the patron's section 199A(a) deduction for the patron's qualified trade or business.

The collection of information in § 1.199A–7(f)(3) is essential for the eligible taxpayer's calculation of the reduction in the eligible taxpayer's section 199A(a) deduction for the eligible taxpayer's trade or business that is required by section 199A(b)(7). Section 199A(g)(2)(A) requires the Specified Cooperative to identify the amount of qualified payments being distributed to an eligible taxpayer and identify the portion of the section 199A(g) deduction allowed in a notice mailed to the eligible taxpayer during the payment period described in section 1382(d). Section 199A(b)(7) provides that an eligible taxpayer who receives qualified payments from a Specified Cooperative must reduce the eligible taxpayer's section 199A(a) deduction by an amount set forth in this section. Without the notice described in § 1.199A–7(f)(3), the eligible taxpayer cannot calculate the reduction required by section 199A(b)(7).

The collection of information in § 1.199A–8(d)(3) is necessitated by section 199A(g)(2)(A). Section 199A(g)(2)(A) permits a Specified Cooperative to pass through an amount of its section 199A(g) deduction to an eligible taxpayer. The amount of the section 199A(g) deduction that the Specified Cooperative is permitted to pass through is an amount that is allocable to the qualified production activities income (QPAI) generated from qualified payments distributed to the eligible taxpayer and identified by such cooperative in a written notice mailed to such taxpayer during the payment period described in section 1382(d). Without the notice required in § 1.199A–8(d)(3) the eligible taxpayer would not know that the Specified Cooperative is passing a portion of its section 199A(g) deduction to the eligible taxpayer.

The collections of information in § 1.199A–7(h)(3) are necessitated by a special transition rule in section 101 of the 2018 Act. Under this transition rule, the repeal of former section 199 for taxable years beginning after December 31, 2017, does not apply to a qualified payment received by a patron from a Specified Cooperative in a taxable year beginning after December 31, 2017, to the extent such qualified payment is attributable to QPAI with respect to which a deduction is allowable to the Specified Cooperative under former section 199 for a taxable year of the Specified Cooperative beginning before January 1, 2018. Such qualified payment remains subject to former section 199 and no deduction is allowed under section 199A(a) or (g) with respect to such qualified payment. Without these collections of information by the Specified Cooperative, the patron has no way of knowing that the patron is barred by the transition rule from using a qualified payment received that is QBI for the patron's trade or business to claim a section 199A(a) deduction for the patron's trade or business.

The collections of information in § 1.199A–7(c)(3), (d)(3), (f)(3), and (h)(3) as well as § 1.199A–8(d)(3) are satisfied by providing information about qualified items of income, SSTB determinations, qualified payments, the section 199A(g) deduction, and the use of qualified payments tied to the former section 199 deduction, as applicable, on an attachment to or on the Form 1099–PATR (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the Form.

For purposes of the Paperwork Reduction Act of 1995, (44 U.S.C. 3507(d)) (PRA), the reporting burden associated with proposed § 1.199A–7(c)(3), (d)(3), (f)(3), and (h)(3) as well as proposed § 1.199A–8(d)(3) will be reflected in the PRA Submission associated with Form 1099–PATR (OMB control number 1545–0118). As further discussed in this section, the estimated number of respondents for the reporting burden associated with these information collections is 9,200 based on 2018 tax filings.

B. Collections of Information Conducted Through Schedule K–1, Form 1065

The collection of information in § 1.199A–8(f) is required by section 199A(g)(5)(B). This section allows a Specified Cooperative that is a partner in a partnership to use its allocable share of gross receipts and related deductions, W–2 wages, and cost of goods sold to calculate its section 199A(g) deduction. Under these

regulations, the partnership must separately identify and report the allocable share of gross receipts and related deductions, W–2 wages, and cost of goods sold on or attached to the Schedule K–1 to the Form 1065 (or any successor form) issued to a Specified Cooperative partner, unless otherwise provided by the instructions to the Form. Without this reporting, the Specified Cooperative partner would not have the information necessary to calculate its section 199A(g) deduction from its activities with the partnership.

The Schedule K–1 to the Form 1065 will be modified to include a mechanism to report the Specified Cooperative partner's allocable share of gross receipts and related deductions. The collection of information in § 1.199A–8(f) is satisfied when the partnership provides the required information to its Specified Cooperative partners on or attached to the Schedule K–1 of Form 1065 (or any successor form), unless otherwise provided by the instructions to the Form. For purposes of the PRA, the reporting burden associated with proposed § 1.199A–8(f) will be reflected in the PRA Submission associated with Form 1065 (OMB control number 1545–0123). As provided in this section, the estimated number of respondents for the reporting burden associated with these information collections is 750 based on 2018 tax filings.

C. Revised Tax Forms

The revised tax forms are as follows:

	OMB No.	New	Revision of existing form	Number of respondents
Form 1099–PATR	1545–0118		✓	9,200
Schedule K–1 (Form 1065)	1545–0123		✓	750

The current status of the PRA submissions related to the tax forms that will be revised as a result of the information collections in the final regulations is provided in the accompanying table. As described previously, the burdens associated with § 1.199A–7(c)(3), (d)(3), (f)(3), and (h)(3) as well as § 1.199A–8(d)(3) will be included in the aggregated burden estimates for OMB control number 1545–0118, which represents a new total estimated burden time of 564,200 hours and total estimated monetized costs of $49.497 million ($2018). The burdens associated with the information collection in § 1.199A–8(f) will be included in the aggregated burden estimates for OMB control number 1545–0123, which represents a total estimated burden time for all forms and schedules of 3.344 billion hours and total estimated monetized costs of $61.558 billion ($2018). The overall burden estimates provided for 1545–0118 and 1545–0123 are aggregate amounts that relate to all information collections associated with the applicable OMB control number. These estimates are therefore unrelated to the future calculations needed to assess the burden imposed by these regulations. To guard against over-counting the burden imposed, the Treasury Department and the IRS urge readers to recognize that these burden estimates are aggregates for the applicable types of filers. With respect to the final regulations, the only relevant burden estimates are those associated with OMB control number 1545–0118. Future estimates under OMB control number 1545–0123 would capture both changes made by the 2018 Act and those that arise out of discretionary authority exercised in the regulations. In addition, when available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

One comment on the burden related to the Form 1099–PATR reporting requirements suggested the Proposed Regulations may have understated the regulatory burden, but provided no specific estimates. Without an alternative estimate to evaluate, the final regulations will rely on the new aggregated burden estimates for OMB control number 1545–0118. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the final regulations, including estimates for how much time it would take to comply with the paperwork burdens described above for each relevant form and ways for the IRS to minimize the paperwork burden.

Form	Type of filer	OMB No.(s)	Status
Form 1099–PATR	[Business (Legacy Model)]	1545–0118	Approved by OIRA through 6/30/2023.
	Link: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201602-1545-024*		
Form 1065, Schedule K–1	Business (NEW Model)	1545–0123	Approved by OIRA through 1/31/2021.
	Link: *https://www.federalregister.gov/documents/2018/10/09/2018-21846/proposed-collection-comment-request-for-forms-1065-1065-b-1066-1120-1120-c-1120-f-1120-h-1120-nd.*		

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

III. Regulatory Flexibility Act

As described in more detail in this section, pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. chapter 6, the Treasury Department and the IRS hereby certify that these regulations will not have a significant economic impact on a substantial number of small entities. In addition to the economic impact described, affected taxpayers, regardless of size will also need to spend time and resources to read and understand these regulations.

A. § 1.199A–7(c)(3) and (d)(3)

Although § 1.199A–7(c)(3) and (d)(3) will have an impact on a substantial number of small entities, the economic impact will not be significant. The IRS creates the Business Master File which

contains data from Form 1120–C, U.S. Income Tax Return for Cooperative Associations. According to the Business Master File data, in 2018, the IRS received approximately 9,200 Forms 1120–C from Cooperatives. The small business size standards of the U.S. Small Business Association (SBA) under 13 CFR 121.201 matched to the North American Industry Classification System (NAICS) were used in estimating the number of Cooperatives that are considered small businesses. Approximately 8,200 (90 percent) of the 9,200 filers of Forms 1120–C were estimated to be small businesses. Therefore, a substantial number of small entities are affected by the requirements in § 1.199A–7(c)(3) and (d)(3).

Section 1.199A–7 provides rules similar to those provided in § 1.199A–6. In § 1.199A–6, relevant passthrough entities (RPEs) are not permitted to take the section 199A deduction but are required to determine and report the information necessary for their direct and indirect owners to determine their individual section 199A(a) deductions. Section 1.199A–6 requires RPEs to determine and report on or attach to the RPEs' Schedule K–1s to the Form 1065 for each trade or business in which the RPE was directly engaged four items: (1) The amount of QBI, (2) W–2 wages, (3) UBIA of qualified property, and (4) SSTBs.

Although Cooperatives are not RPEs, Cooperatives make distributions to patrons that such patrons are permitted to include in calculating their individual section 199A(a) deductions. Section 1.199A–7(c) and (d) require the Cooperatives to determine and report to their patrons whether the distributions for which the Cooperatives take deductions under section 1382(b) and/or (c)(2), as applicable, constitute qualified items of income, gain, deduction, and loss and whether they are from an SSTB in which the Cooperative was directly engaged.

In TD 9847 the Treasury Department and the IRS determined that the reporting burden in § 1.199A–6 was estimated at 30 minutes to 20 hours, depending on individual circumstances, with an estimated average of 2.5 hours for all affected entities, regardless of size. The burden on entities with business receipts below $10 million was expected to be at the lower end of the range (30 minutes to 2.5 hours). The estimated compliance burden for passthrough entities that issue Schedules K–1 is $53 per hour. This estimate was derived from the Business Taxpayer Burden model developed by the IRS's Office of Research, Applied Analytics, and Statistics (RAAS), which relates time and out-of-pocket costs of business tax preparation, derived from survey data, to assets and receipts of affected taxpayers along with other relevant variables. *See* Tax Compliance Burden (John Guyton, et al., July 2018) at *https://www.irs.gov/pub/irs-soi/d13315.pdf.* Thus, the annual aggregate burden on businesses with gross receipts below $10 million was estimated to be between $19.50 and $132.50 per business. The Treasury Department and the IRS determined in TD 9847 that the requirements in § 1.199A–6 imposed no significant economic impact on affected entities.

The reporting requirements under § 1.199A–7(c)(3) and (d)(3) require Specified Cooperatives to report only two of the four pieces of information RPEs are required to report under § 1.199A–6: the amount of qualified items of income, gain, deduction, and loss and whether the distributions are from an SSTB in which the Cooperative was directly engaged. In addition, these final regulations, in response to comments, revise the proposed reporting requirements under § 1.199A–7(c)(3) and (d)(3) to reduce the Specified Cooperative's burden by requiring the Cooperative to report the total net amount of qualified items from non-SSTBs and SSTBs in distributions to patrons without delineating these amounts business by business.

Furthermore, the burden imposed by § 1.199A–7(c)(3) and (d)(3) only occurs when a Cooperative has net income that it may distribute to its patrons such that the income will qualify for the income tax deductions under section 1382(b) and/or (c), as applicable. With respect to this net income, Cooperatives already know the source of their income and deductions without which information they would not be able to determine the correct distributions to their patrons and to claim the income tax deduction for these distributions under section 1382(b) and/or (c)(2), as applicable. Finally, assuming that the approximately 8,200 filers of Forms 1120–C were estimated to be small businesses in 2018 and that each business incurred half of the higher figure of $132.50 ($66.25) determined for the § 1.199A–6 regulations to satisfy the reporting requirements under § 1.199A–7(c)(3) and (d)(3), the annual burden imposed by the reporting requirements would not exceed $66.25 per business. Accordingly, the Treasury Department and the IRS conclude that the requirements in § 1.199A–7(c)(3) and (d)(3) will not impose a significant economic impact on small entities.

B. § 1.199A–7(h)(3)

Although § 1.199A–7(h)(3) will have an impact on a substantial number of small entities, this economic impact will not be significant. As previously noted, in 2018, approximately 90 percent of Cooperatives filing Form 1120–C were estimated to be small businesses. Therefore, a substantial number of small entities are affected by § 1.199A–7(h)(3).

Section 1.199A–7(h)(3) requires Cooperatives to notify patrons if, pursuant to the transition rule in section 101 of the 2018 Act, the patron is barred from using certain qualified payments from a Cooperative to claim a section 199A(a) deduction in a taxable year because these qualified payments are attributable to QPAI with respect to which a deduction is allowable to the Cooperative under former section 199 in a taxable year beginning before January 1, 2018. The Cooperative knows which patrons are impacted since, in order to claim its deduction under former section 199, the Cooperative must identify which qualified payments to use. The Treasury Department and the IRS estimate that the annual burden imposed by the requirement in § 1.199A–7(h)(3) will be far less than the $66.25 per business estimated for the requirements in § 1.199A–7(c)(3) and (d)(3) discussed above, since the Cooperatives know which patrons are impacted and the reporting is limited to informing these patrons that they cannot use such qualified payments to calculate their section 199A(a) deduction. Further, the requirements under § 1.199A–7(h)(3), in response to a comment, have been revised to allow more flexibility by allowing the reporting to be made using any reasonable method.

In addition, absent notice from the Cooperatives, patrons would have no way of determining whether they were barred from claiming the section 199A(a) deduction using such qualified payments. Finally, Cooperatives are not able to claim a deduction under former section 199 for taxable years beginning after December 31, 2017. Therefore, the reporting required by § 1.199A–7(h)(3) will be for a short duration and have a limited impact on Cooperatives. Accordingly, for all these reasons, the requirements in § 1.199A–7(h)(3) will not impose a significant economic impact on small entities.

C. §§ 1.199A–7(f)(3) and 1.199A–8(d)(3)

Sections 1.199A–7(f)(3) and 1.199A–8(d)(3) will not have a significant economic impact on a substantial number of small entities. According to

the Business Master File filing data from the transcribed fields from the Forms 1120–C for 2018, of the approximately 9,200 Forms 1120–C filed by Cooperatives, approximately 2,000 filers identified their Cooperatives as involving agriculture or horticulture using the NAICS codes. Of the 2,000 filers of Forms 1120–C identifying as Specified Cooperatives, approximately 1,600 filers (80 percent) would qualify as small business under the SBA thresholds. However, the requirement under § 1.199A–7(f)(3) involving reporting of qualified payments should not impose a significant burden because qualified payments overlap with the section 1382 distributions a Cooperative uses to calculate the section 199A(g) deduction. Further, the notice requirement in § 1.199A–8(d)(3), which is imposed under section 199A(g)(2)(A)(ii), follows the same procedures that Cooperatives used under former section 199 so Cooperatives should already have a process in place. Accordingly, §§ 1.199A–7(f)(3) and 1.199A–8(d)(3) will not impose a significant economic impact on a substantial number of small entities.

D. § 1.199A–8(f)

Although § 1.199A–8(f) will have an impact on a substantial number of small entities, this impact will not be economically significant. According to the Business Master File filing data from the transcribed fields from the Forms 1065 for 2018, the IRS estimates that there were 4,100,000 partnerships reporting their partners' share of partnership items on Schedules K–1 (Form 1065). The IRS also identified 763 different partnerships that issued a Schedule K–1 to 654 different Cooperatives in 2018. The IRS does not have information as to whether the 654 Cooperatives all qualified as Specified Cooperatives.

Of the 763 different partnerships, the IRS estimated that 215 of the partnerships conducted activities in 2018 that would have required the partnerships to file under § 1.199A–8(f). The IRS does not have sufficient data to determine the type of business activities of the remaining partnerships. To be as comprehensive and transparent as possible in analyzing the potential impact of the final regulations, it is assumed that all of these partnerships would be required to file under § 1.199A–8(f) and would be considered small entities.

Of the 215 partnerships identified as having both issued a Schedule K–1 to a Cooperative and conducting eligible activities in 2018, the IRS determined that 158 of these partnerships conducted activities for which the SBA uses the number of employees to determine if an entity is a small entity using the NAICS. The IRS determined that 95 of these 97 partnerships would be small entities, while two would not be small entities based on the reported number of Forms W–2 filed in connection with the Forms 1065 the partnerships filed in 2018.

The SBA uses income to determine if an entity is a small entity for the reported business activities of the remaining 118 partnerships using the NAICS. Based upon the reported income for 2018, 84 of the remaining 118 partnerships are small entities, while 34 partnerships are not small entities. Therefore, a substantial number of small entities are affected by requirements in § 1.199A–8(f).

The economic impact of § 1.199A–8(f), however, will not be significant because the information required to be reported is gross receipts and related deductions. This information is readily available to each partnership and already known for the purpose of determining Federal income and other tax obligations. A commenter also requested that the partnerships be allowed to report further information, and the rules in § 1.199A–8(f) were broadened consistent with the request. Because the information required to be reported is already available and familiar to each partnership, the reporting required by § 1.199A–8(f) will not impose a significant economic impact on small entities.

Accordingly, the Treasury Department and the IRS hereby certify that these regulations will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f) of the Code, the Proposed Regulation preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business and no comments were received.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (titled *Federalism*) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. These rules do not have federalism implications, and do not impose substantial direct compliance costs on state and local governments or preempt state law, within the meaning of the Executive Order.

VI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of lnformation and Regulatory Affairs designated this rule as not a 'major rule', as defined by 5 U.S.C. 804(2).

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, Notices and other guidance cited in this document are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov*.

Drafting Information

The principal author of these regulations is Jason Deirmenjian, Office of Associate Chief Counsel (Passthroughs and Special Industries). Other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by:

■ 1. Removing the entries for §§ 1.199–0 through 1.199–9.

■ 2. Adding entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 1.199A–7 also issued under 26 U.S.C. 199A(f)(4) and (g)(6).

Section 1.199A–8 also issued under 26 U.S.C. 199A(g)(6).

Section 1.199A–9 also issued under 26 U.S.C. 199A(g)(6).

Section 1.199A–10 also issued under 26 U.S.C. 199A(g)(6).

Section 1.199A–11 also issued under 26 U.S.C. 199A(g)(6).

Section 1.199A–12 also issued under 26 U.S.C. 199A(g)(6).

* * * * *

§ § 1.199–0 through 1.199–9 [Removed]

■ **Par. 2.** Sections 1.199–0 through 1.199–9 are removed.

■ **Par. 3.** Sections 1.199A–7 through 1.199A–12 are added to read as follows:

* * * * *

§ 1.199A–7 Section 199A(a) Rules for Cooperatives and their Patrons.

(a) *Overview*—(1) *In general.* This section provides guidance and special rules on the application of the rules of §§ 1.199A–1 through 1.199A–6 regarding the deduction for qualified business income (QBI) under section 199A(a) (section 199A(a) deduction) of the Internal Revenue Code (Code) by patrons (patrons) of cooperatives to which Part I of subchapter T of chapter 1 of the Code (subchapter T) applies (Cooperatives). Unless otherwise provided in this section, all the rules in §§ 1.199A–1 through 1.199A–6 relating to calculating the section 199A(a) deduction apply to patrons and Cooperatives. Paragraph (b) of this section provides special rules for patrons relating to trades or businesses. Paragraph (c) of this section provides special rules for patrons and Cooperatives relating to the definition of QBI. Paragraph (d) of this section provides special rules for patrons and Cooperatives relating to specified service trades or businesses (SSTBs). Paragraph (e) of this section provides special rules for patrons relating to the statutory limitations based on W–2 wages and unadjusted basis immediately after acquisition (UBIA) of qualified property. Paragraph (f) of this section provides special rules for specified agricultural or horticultural cooperatives (Specified Cooperatives) and paragraph (g) of this section provides examples for Specified Cooperatives and their patrons. Paragraph (h) of this section sets forth the applicability date of this section and a special transition rule relating to Specified Cooperatives and their patrons.

(2) *At patron level.* The section 199A(a) deduction is applied at the patron level, and patrons who are individuals (as defined in § 1.199A–1(a)(2)) may take the section 199A(a) deduction.

(3) *Definitions.* For purposes of section 199A and § 1.199A–7, the following definitions apply—

(i) *Individual* is defined in § 1.199A–1(a)(2).

(ii) *Patron* is defined in § 1.1388–1(e).

(iii) *Patronage and nonpatronage* is defined in § 1.1388–1(f).

(iv) *Relevant Passthrough Entity (RPE)* is defined in § 1.199A–1(a)(9).

(v) *Qualified payment* is defined in § 1.199A–8(d)(2)(ii).

(vi) *Specified Cooperative* is defined in § 1.199A–8(a)(2) and is a subset of Cooperatives defined in § 1.199A–7(a)(1).

(b) *Trade or business.* A patron (whether the patron is an RPE or an individual), and not a Cooperative, must determine whether it has one or more trades or businesses that it directly conducts as defined in § 1.199A–1(b)(14). To the extent a patron operating a trade or business has income directly from that business, the patron must follow the rules of §§ 1.199A–1 through 1.199A–6 to calculate the section 199A(a) deduction. Patronage dividends or similar payments are considered to be generated from the trade or business the Cooperative conducts on behalf of or with the patron. A Cooperative that distributes patronage dividends or similar payments, as described in paragraph (c)(1) of this section, must determine and report information to its patrons relating to qualified items of income, gain, deduction, and loss in accordance with paragraphs (c)(3) and (d)(3) of this section. A patron that receives patronage dividends or similar payments, as described in paragraph (c)(1) of this section, from a Cooperative must follow the rules of paragraphs (c) through (e) of this section to calculate the section 199A(a) deduction.

(c) *Qualified Business Income*—(1) *In general.* QBI means the net amount of qualified items of income, gain, deduction, and loss with respect to any trade or business as determined under the rules of § 199A(c)(3) and § 1.199A–3(b). A qualified item of income includes distributions for which the Cooperative is allowed a deduction under section 1382(b) and (c)(2) (including patronage dividends or similar payments, such as money, property, qualified written notices of allocations, and qualified per-unit retain certificates, as well as money or property paid in redemption of a nonqualified written notice of allocation (collectively patronage dividends or similar payments)), provided such distribution is otherwise a qualified item of income, gain, deduction, or loss. *See* special rule in paragraph (d)(3) of this section relating to SSTBs that may affect QBI.

(2) *QBI determinations made by patron.* A patron must determine QBI for each trade or business it directly conducts. In situations where the patron receives distributions described in paragraph (c)(1) of this section, the Cooperative must determine whether those distributions include qualified items of income, gain, deduction, and loss as determined under rules of § 199A(c)(3) and § 1.199A–3(b). These distributions may be included in the QBI of the patron's trade or business to the extent that:

(i) The distributions are related to the patron's trade or business as defined in § 1.199A–1(b)(14);

(ii) The distributions are qualified items of income, gain, deduction, and loss as determined under rules of § 199A(c)(3) and § 1.199A–3(b) at the Cooperative's trade or business level;

(iii) The distributions are not items from an SSTB as defined in § 199A(d)(2) at the Cooperative's trade or business level (except as permitted by the threshold rules in § 199A(d)(3) and § 1.199A–5(a)(2)); and

(iv) Certain information is reported by the Cooperative about these payments as provided in paragraphs (c)(3) and (d)(3) of this section.

(3) *Qualified items of income, gain, deduction, and loss determinations made and reported by Cooperatives.* In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a patron, the Cooperative must determine the amount of qualified items of income, gain, deduction, and loss as determined under the rules of § 199A(c)(3) and § 1.199A–3(b) in those distributions. A patron must determine whether these qualified items relate to one or more trades or businesses that it directly conducts as defined in § 1.199A–1(b)(14). Pursuant to this paragraph (c)(3), the Cooperative must report the net amount of qualified items with respect to non-SSTBs of the Cooperative in the distributions made to the patron on an attachment to or on the Form 1099–PATR, Taxable Distributions Received From Cooperatives, (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the Form. If the Cooperative does not report on or before the due date of the Form 1099–PATR the amount of such qualified items of income, gain, deduction, and loss in the distributions to the patron, the amount of distributions from the Cooperative that

may be included in the patron's QBI is presumed to be zero. *See* special rule in paragraph (d)(3) of this section relating to reporting of qualified items of income, gain, deduction, and loss with respect to SSTBs of the Cooperative.

(d) *Specified Service Trades or Businesses*—(1) *In general.* This section provides guidance on the determination of SSTBs as defined in § 199A(d)(2) and § 1.199A–5. Unless otherwise provided in this section, all of the rules in § 1.199A–5 relating to SSTBs apply to patrons of Cooperatives.

(2) *SSTB determinations made by patron.* A patron (whether an RPE or an individual) must determine whether each trade or business it directly conducts is an SSTB.

(3) *SSTB determinations made and reported by Cooperatives*—(i) *In general.* In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a patron, the Cooperative must determine the amount of qualified items of income, gain, deduction, and loss as determined under the rules of § 199A(c)(3) and § 1.199A–3(b) with respect to SSTBs directly conducted by the Cooperative. A patron must determine whether these qualified items relate to one or more trades or businesses that it directly conducts as defined in § 1.199A–1(b)(14). The Cooperative must report the net amount of qualified items with respect to the SSTBs of the Cooperative in the distributions made to the patron on an attachment to or on the Form 1099–PATR, Taxable Distributions Received from Cooperatives, (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the Form. If the Cooperative does not report the amount on or before the due date of the Form 1099–PATR, then only the amount that a Cooperative reports as qualified items of income, gain, deduction, and loss under § 1.199A–7(c)(3) may be included in the patron's QBI, and the remaining amount of distributions from the Cooperative that may be included in the patron's QBI is presumed to be zero.

(ii) *Patron allocation of expenses paid to Cooperative for SSTB items of income reported by Cooperative*—(A) *In general.* When a Cooperative reports SSTB items to a patron, a patron may allocate a deductible expense that was paid to the Cooperative in connection with the patron's qualified trade or business between a patron's qualified trade or business income and the SSTB income reported to it by the Cooperative only if the SSTB income directly relates to the deductible expense. A patron can allocate the deductible expense paid by the patron to the Cooperative only up to the amount of SSTB income reported by the Cooperative.

(B) *Example. Patron allocating expenses between qualified trade or business and SSTB income from a Cooperative.* (*1*) Cooperative provides to its patrons a service that is an SSTB under section 199A(d)(2). P, a patron, runs a qualified trade or business under section 199A(d)(1) and incurs expenses for the service from the Cooperative in P's qualified trade or business. P pays the Cooperative $1,000 for the service. Cooperative later pays P a patronage dividend of $50 related to the service.

(i*2*) Cooperative reports the $50 as SSTB income on the Form 1099–PATR issued to P.

(*3*) Since P's deductible expense for services from the Cooperative was in connection with a qualified trade or business and the SSTB income directly relates to that expense, P may allocate the expense under paragraph (d)(3)(ii) of this section. Accordingly, $50 of the $1,000 expense is allocated to P's SSTB income, and $950 of the expense is allocated to P's qualified trade or business and is included in P's QBI calculation.

(e) *W–2 wages and unadjusted basis immediately after acquisition of qualified property*—(1) *In general.* This section provides guidance on calculating a trade or business's W–2 wages and the UBIA of qualified property properly allocable to QBI.

(2) *Determinations made by patron.* The determination of W–2 wages and UBIA of qualified property must be made for each trade or business by the patron (whether an RPE or individual) that directly conducts the trade or business before applying the aggregation rules of § 1.199A–4. Unlike RPEs, Cooperatives do not compute and allocate their W–2 wages and UBIA of qualified property to patrons.

(f) *Special rules for patrons of Specified Cooperatives*—(1) *Section 199A(b)(7) reduction.* A patron of a Specified Cooperative that receives a qualified payment must reduce its section 199A(a) deduction as provided in § 1.199A–1(e)(7). This reduction applies whether the Specified Cooperative passes through all, some, or none of the Specified Cooperative's section 199A(g) deduction to the patron in that taxable year. The rules relating to the section 199A(g) deduction can be found in §§ 1.199A–8 through 1.199A–12.

(2) *Reduction calculation*—(i) *Allocation method.* If in any taxable year, a patron receives income or gain related to qualified payments and income or gain that is not related to qualified payments in a trade or business, the patron must allocate the income or gain and related deductions, losses and W–2 wages using a reasonable method based on all the facts and circumstances for purposes of calculating the reduction in § 1.199A–1(e)(7). Different reasonable methods may be used for different items and related deductions of income, gain, deduction, and loss. The chosen reasonable method for each item must be consistently applied from one taxable year of the patron to another, and must clearly reflect the income and expenses of each trade or business. The overall combination of methods must also be reasonable based on all the facts and circumstances. The books and records maintained for a trade or business must be consistent with any allocations under this paragraph (f)(2)(i).

(ii) *Safe harbor.* A patron with taxable income under the threshold amount set forth in section 199A(e)(2) is eligible to use the safe harbor set forth in this paragraph (f)(2)(ii) to apportion its deductions, losses and W–2 wages instead of the allocation method set forth in paragraph (f)(2)(i) of this section for any taxable year in which the patron receives income or gain related to qualified payments and income or gain not related to qualified payments in a trade or business. Under the safe harbor the patron may apportion its deductions, losses and W–2 wages ratably between income or gain related to qualified payments and income or gain that is not related to qualified payments for purposes of calculating the reduction in paragraph (f)(1) of this section. Accordingly, the amount of deductions and losses apportioned to determine QBI allocable to qualified payments is equal to the proportion of the total deductions and losses that the amount of income or gain related to qualified payments bears to total income or gain used to determine QBI. The same proportion applies to determine the amount of W–2 wages allocable to the portion of the trade or business that received qualified payments.

(3) *Qualified payments notice requirement.* A Specified Cooperative must report the amount of the qualified payments made to the eligible taxpayer, as defined in section 199A(g)(2)(D), on an attachment to or on the Form 1099–PATR (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the Form.

(g) *Examples.* The following examples illustrate the provisions of paragraph (f) of this section. For purposes of these examples, assume that the Specified Cooperative has satisfied the applicable

written notice requirements in paragraphs (c)(3), (d)(3) and (f)(3) of this section.

(1) *Example 1. Patron of Specified Cooperative with W–2 wages.* (i) P, a grain farmer and patron of nonexempt Specified Cooperative C, delivered to C during 2020 2% of all grain marketed through C during such year. During 2021, P receives $20,000 in patronage dividends and $1,000 of allocated section 199A(g) deduction from C related to the grain delivered to C during 2020.

(ii) P has taxable income of $75,000 for 2021 (determined without regard to section 199A) and has a filing status of married filing jointly. P's QBI related to its grain trade or business for 2021 is $50,000, which consists of gross receipts of $150,000 from sales to an independent grain elevator, per-unit retain allocations received from C during 2021 of $80,000, patronage dividends received from C during 2021 related to C's 2020 net earnings of $20,000, and expenses of $200,000 (including $50,000 of W–2 wages).

(iii) The portion of QBI from P's grain trade or business related to qualified payments received from C during 2021 is $10,000, which consists of per-unit retain allocations received from C during 2021 of $80,000, patronage dividends received from C during 2021 related to C's 2020 net earnings of $20,000, and properly allocable expenses of $90,000 (including $25,000 of W–2 wages).

(iv) P's deductible amount related to the grain trade or business is 20% of QBI ($10,000) reduced by the lesser of 9% of QBI related to qualified payments received from C ($900) or 50% of W–2 wages related to qualified payments received from C ($12,500), or $9,100. As P does not have any other trades or businesses, the combined QBI amount is also $9,100.

(v) P's deduction under section 199A for 2021 is $10,100, which consists of the combined QBI amount of $9,100, plus P's deduction passed through from C of $1,000.

(2) *Example 2. Patron of Specified Cooperative without W–2 wages.* (i) C and P have the same facts for 2020 and 2021 as *Example 1,* except that P has expenses of $200,000 that include zero W–2 wages during 2021.

(ii) P's deductible amount related to the grain trade or business is 20% of QBI ($10,000) reduced by the lesser of 9% of QBI related to qualified payments received from C ($900) or 50% of W–2 wages related to qualified payments received from C ($0), or $10,000.

(iii) P's deduction under section 199A for 2021 is $11,000, which consists of the combined QBI amount of $10,000, plus P's deduction passed through from C of $1,000.

(3) *Example 3. Patron of Specified Cooperative—Qualified Payments do not equal QBI and no section 199A(g) passthrough.* (i) P, a grain farmer and a patron of a nonexempt Specified Cooperative C, during 2020, receives $60,000 in patronage dividends, $100,000 in per-unit retain allocations, and $0 of allocated section 199A(g) deduction from C related to the grain delivered to C. C notifies P that only $150,000 of the patronage dividends and per-unit retain allocations are qualified payments because $10,000 of the payments are not attributable to C's QPAI.

(ii) P has taxable income of $90,000 (determined without regard to section 199A) and has a filing status of married filing jointly. P's QBI related to its grain trade or business is $45,000, which consists of gross receipts of $95,000 from sales to an independent grain elevator, plus $160,000 from C (all payments from C qualify as qualified items of income, gain, deduction, and loss), less expenses of $210,000 (including $30,000 of W–2 wages).

(iii) The portion of QBI from P's grain trade or business related to qualified payments received from C is $25,000, which consists of the qualified payments received from C of $150,000, less the properly allocable expenses of $125,000 (including $18,000 of W–2 wages), which were determined using a reasonable method under paragraph (f)(2)(ii) of this section.

(iv) P's patron reduction is $2,250, which is the lesser of 9% of QBI related to qualified payments received from C, $2,250 (9% × $25,000), or 50% of W–2 wages related to qualified payments received from C, $9,000 (50% × $18,000). As P does not have any other trades or businesses, the combined QBI amount is $6,750 (20% of P's total QBI, $9,000 (20% × $45,000), reduced by the patron reduction of $2,250).

(v) P's deduction under section 199A is $6,750, which consists of the combined QBI amount of $6,750.

(4) *Example 4. Patron of Specified Cooperative—Reasonable Method under paragraph (f)(2)(i) of this section.* P is a grain farmer that has $45,000 of QBI related to P's grain trade or business in 2020. P's QBI consists of $105,000 of sales to an independent grain elevator, $100,000 of per-unit retain allocations, and $50,000 of patronage dividends from a nonexempt Specified Cooperative C, for which C reports $150,000 of qualified payments to P as required by paragraph (f)(3) of this section. P's grain trade or business has $210,000 of expenses (including $30,000 of W–2 wages). P delivered 65x bushels of grain to C and sold 35x bushels of comparable grain to the independent grain elevator. To allocate the expenses between qualified payments ($150,000) and other income ($105,000), P compares the bushels of grain delivered to C (65x) to the total bushels of grain delivered to C and sold to the independent grain elevator (100x). P determines $136,500 (65% × $210,000) of expenses (including $19,500 of W–2 wages) are properly allocable to the qualified payments. The portion of QBI from P's grain trade or business related to qualified payments received from C is $13,500, which consists of qualified payments of $150,000 less the properly allocable expenses of $136,500 (including $19,500 of W–2 wages). P's method of allocating expenses is a reasonable method under paragraph (f)(2)(i) of this section.

(5) *Example 5. Patron of Specified Cooperative using safe harbor to allocate.* (i) P is a grain farmer with taxable income of $100,000 for 2021 (determined without regard to section 199A) and has a filing status of married filing jointly. P's QBI related to P's grain trade or business for 2021 is $50,000, which consists of gross receipts of $180,000 from sales to an independent grain elevator, per-unit retain allocations received from a Specified Cooperative C during 2021 of $15,000, patronage dividends received from C during 2021 related to C's 2020 net earnings of $5,000, and expenses of $150,000 (including $50,000 of W–2 wages). C also passed through $1,800 of the section 199A(g) deduction to P, which related to the grain delivered by P to the Specified Cooperative during 2020. P uses the safe harbor in paragraph (f)(2)(ii) of this section to determine the expenses (including W–2 wages) allocable to the qualified payments.

(ii) Using the safe harbor to allocate P's $150,000 of expenses, P allocates $15,000 of the expenses to the qualified payments ($150,000 of expenses multiplied by the ratio (0.10) of qualified payments ($20,000) to total gross receipts ($200,000)). Using the same ratio, P also determines there are $5,000 of W–2 wages allocable ($50,000 multiplied by 0.10) to the qualified payments.

(iii) The portion of QBI from P's grain trade or business related to qualified payments received from C during 2021 is $5,000, which consists of per-unit retain allocations received from C during 2021 of $15,000, patronage dividends of $5,000, and properly

allocable expenses of $15,000 (including $5,000 of W–2 wages).

(iv) P's QBI related to the grain trade or business is 20% of QBI ($10,000) reduced by the lesser of 9% of QBI related to qualified payments received from C ($450) or 50% of W–2 wages related to qualified payments received from C ($2,500), or $9,550. As P does not have any other trades or businesses, the combined QBI amount is also $9,550.

(v) P's deduction under section 199A for 2021 is $11,350, which consists of the combined QBI amount of $9,550, plus P's deduction passed through from C of $1,800.

(h) *Applicability date*—(1) *General rule.* Except as provided in paragraph (h)(2) of this section, the provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided taxpayers apply the rules in their entirety and in a consistent manner.

(2) *Transition rule for qualified payments of patrons of Cooperatives.* See the transition rule for qualified payments of patrons of Cooperatives for a taxable year of a Cooperative beginning before January 1, 2018 in the Consolidated Appropriations Act, 2018 (Pub. L. 115–141, 132 Stat. 348) Division T, section 101(c).

(3) *Notice from the Cooperative.* If a patron of a Cooperative cannot claim a deduction under section 199A for any qualified payments described in the transition rule set forth in paragraph (h)(2) of this section, the Cooperative must use a reasonable method to identify the qualified payments to its patrons. A reasonable method includes reporting this information on an attachment to or on the Form 1099–PATR (or any successor form) issued by the Cooperative to the patron, unless otherwise provided by the instructions to the Form.

§ 1.199A–8 Deduction for income attributable to domestic production activities of specified agricultural or horticultural cooperatives

(a) *Overview*—(1) *In general.* This section provides rules relating to the deduction for income attributable to domestic production activities of a specified agricultural or horticultural cooperative (Specified Cooperative). This paragraph (a) provides an overview and definitions of certain terms. Paragraph (b) of this section provides rules explaining the steps a nonexempt Specified Cooperative performs to calculate its section 199A(g) deduction and includes definitions of relevant terms. Paragraph (c) of this section provides rules explaining the steps an exempt Specified Cooperative performs to calculate its section 199A(g) deduction. Paragraph (d) of this section provides rules for Specified Cooperatives passing through the section 199A(g) deduction to patrons. Paragraph (e) of this section provides examples that illustrate the provisions of paragraphs (b), (c), and (d) of this section. Paragraph (f) of this section provides guidance for Specified Cooperatives that are partners in a partnership. Paragraph (g) of this section provides guidance on the recapture of a claimed section 199A(g) deduction. Paragraph (h) of this section provides effective dates. For additional rules addressing an expanded affiliated group (EAG), to which the principles of this section apply, *see* § 1.199A–12. The provisions of this section apply solely for purposes of section 199A of the Internal Revenue Code (Code).

(2) *Specified Cooperative*—(i) *In general.* Specified Cooperative means a cooperative to which Part I of subchapter T of chapter 1 of the Code applies and which—

(A) Manufactures, produces, grows, or extracts (MPGE) in whole or significant part within the United States any agricultural or horticultural product, or

(B) Is engaged in the marketing of agricultural or horticultural products that have been MPGE in whole or significant part within the United States by the patrons of the cooperative.

(C) See § 1.199A–9 for rules to determine if a Specified Cooperative has MPGE an agricultural or horticultural product in whole or significant part within the United States.

(ii) *Types of Specified Cooperatives.* A Specified Cooperative that is qualified as a farmer's cooperative organization under section 521 is an *exempt Specified Cooperative,* while a Specified Cooperative not so qualified is a *nonexempt Specified Cooperative.*

(3) *Patron* is defined in § 1.1388–1(e).

(4) *Agricultural or horticultural products* are agricultural, horticultural, viticultural, and dairy products, livestock and the products thereof, the products of poultry and bee raising, the edible products of forestry, and any and all products raised or produced on farms and processed or manufactured products thereof within the meaning of the Cooperative Marketing Act of 1926, 44 Stat. 802 (1926). Agricultural or horticultural products also include aquatic products that are farmed. Some examples of agricultural or horticultural products include, but are not limited to, fruits, grains, oilseeds, rice, vegetables, legumes, grasses (including hay), plants of all kinds, flowers (including hops), seeds, tobacco, cotton, sugar cane and sugar beets. Some examples of livestock products include, but are not limited to, wool, fur, hides, eggs, down, honey, and silk. Some examples of edible forestry products include, but are not limited to, fruits, nuts, berries and mushrooms. Some examples of aquatic products include, but are not limited to, fish, crustaceans, shellfish and seaweed. In addition, agricultural or horticultural products include fertilizer, diesel fuel, and other supplies (for example, seed, feed, herbicides, and pesticides) used in agricultural or horticultural production that are MPGE by a Specified Cooperative. Agricultural or horticultural products, however, do not include intangible property other than when incorporated into a tangible agricultural or horticultural product (other than as provided in the exception in § 1.199A–9(b)(2)). Intangible property for this purpose includes, for example, the rights to MPGE and sell an agricultural or horticultural product with certain characteristics protected by a patent, or the rights to a trademark or tradename. This exclusion of intangible property does not apply to intangible characteristics of any particular agricultural or horticultural product. For example, gross receipts from the sale of different varieties of oranges would be considered from the disposition of agricultural or horticultural products. However, gross receipts from the license of the right to produce and sell a certain variety of an orange would be considered separate from the orange and not from an agricultural or horticultural product.

(b) *Steps for a nonexempt Specified Cooperative in calculating deduction*—(1) *In general.* Except as provided in paragraph (c)(3) of this section, this paragraph (b) applies only to nonexempt Specified Cooperatives.

(2) *Step 1—Gross receipts and related deductions*—(i) *Identify.* To determine the section 199A(g) deduction, a Specified Cooperative first identifies its patronage and nonpatronage gross receipts and related cost of goods sold (COGS), deductible expenses, W–2 wages, etc. (deductions) and allocates them between patronage and nonpatronage. A single definition for the term *patronage and nonpatronage* is found in § 1.1388–1(f).

(ii) *Applicable gross receipts and deductions.* Except as described in this paragraph (b)(ii), for all purposes of the section 199A(g) deduction, a Specified Cooperative can use only patronage gross receipts and related deductions to calculate qualified production activities

income (QPAI) as defined in paragraph (b)(4)(ii) of this section, oil-related QPAI as defined in paragraph (b)(7)(ii) of this section, the W–2 wage limitation in paragraph (b)(5)(ii)(B) of this section, or taxable income as defined in paragraph (b)(5)(ii)(C) of this section. A Specified Cooperative cannot use its nonpatronage gross receipts and related deductions to calculate its section 199A(g) deduction, other than treating all of its nonpatronage gross receipts as patronage non-DPGR for purposes of applying the de minimis rules in § 1.199A–9(c)(3). If a Specified Cooperative treats all nonpatronage gross receipts as DPGR under § 1.199A–9(c)(3)(i), then a Specified Cooperative shall also treat its deductions related to the nonpatronage gross receipts as patronage in calculating QPAI, oil-related QPAI, the W–2 wage limitation, or taxable income for purposes of the section 199A(g) deduction.

(iii) *Gross receipts* are the Specified Cooperative's receipts for the taxable year that are recognized under the Specified Cooperative's methods of accounting used for Federal income tax purposes for the taxable year. See § 1.199A–12 if the gross receipts are recognized in an intercompany transaction within the meaning of § 1.1502–13. Gross receipts include total sales (net of returns and allowances) and all amounts received for services. In addition, gross receipts include any income from investments and from incidental or outside sources. For example, gross receipts include interest (except interest under section 103 but including original issue discount), dividends, rents, royalties, and annuities, regardless of whether the amounts are derived in the ordinary course of the Specified Cooperative's trade or business. Gross receipts are not reduced by COGS or by the cost of property sold if such property is described in section 1221(a)(1), (2), (3), (4), or (5). Finally, gross receipts do not include amounts received by the Specified Cooperative with respect to sales tax or other similar state or local taxes if, under the applicable state or local law, the tax is legally imposed on the purchaser of the good or service and the Specified Cooperative merely collects and remits the tax to the taxing authority. If, in contrast, the tax is imposed on the Specified Cooperative under the applicable law, then gross receipts include the amounts received that are allocable to the payment of such tax.

(3) *Step 2—Determine gross receipts that are DPGR*—(i) *In general.* A Specified Cooperative examines its patronage gross receipts to determine which of these are DPGR. A Specified Cooperative does not use nonpatronage gross receipts to determine DPGR.

(ii) *DPGR* are the gross receipts of the Specified Cooperative that are derived from any lease, rental, license, sale, exchange, or other disposition of an agricultural or horticultural product that is MPGE by the Specified Cooperative or its patrons in whole or significant part within the United States. DPGR does not include gross receipts derived from services or the lease, rental, license, sale, exchange, or other disposition of land unless a de minimis or other exception applies. See § 1.199A–9 for additional rules on determining if gross receipts are DPGR.

(4) *Step 3—Determine QPAI*—(i) *In general.* A Specified Cooperative determines QPAI from patronage DPGR and patronage deductions identified in paragraphs (b)(3)(ii) and (b)(2)(i) of this section, respectively. A Specified Cooperative does not use nonpatronage gross receipts or deductions to determine QPAI.

(ii) *QPAI* for the taxable year means an amount equal to the excess (if any) of—

(A) DPGR for the taxable year, over

(B) The sum of—

(*1*) COGS that are allocable to DPGR, and

(*2*) Other expenses, losses, or deductions (other than the section 199A(g) deduction) that are properly allocable to DPGR.

(C) *QPAI computational rules.* QPAI is computed without taking into account the section 199A(g) deduction or any deduction allowed under section 1382(b). *See* § 1.199A–10 for additional rules on calculating QPAI.

(5) *Step 4—Calculate deduction*—(i) *In general.* From QPAI and taxable income, a Specified Cooperative calculates its section 199A(g) deduction as provided in paragraph (b)(5)(ii) of this section.

(ii) *Deduction*—(A) *In general.* A Specified Cooperative is allowed a deduction equal to 9 percent of the lesser of—

(*1*) QPAI of the Specified Cooperative for the taxable year, or

(*2*) Taxable income of the Specified Cooperative for the taxable year.

(B) *W–2 wage limitation.* The deduction allowed under paragraph (b)(5)(ii)(A) of this section for any taxable year cannot exceed 50 percent of the patronage W–2 wages attributable to DPGR for the taxable year. *See* § 1.199A–11 for additional rules on calculating the patronage W–2 wage limitation.

(C) *Taxable income.* Taxable income is defined in section 63, and adjusted under section 1382 and § 1.1382–1 and § 1.1382–2. For purposes of determining the amount of the deduction allowed under paragraph (b)(5)(ii) of this section, taxable income is limited to taxable income and related deductions from patronage sources, other than as allowed under paragraph (b)(2)(ii) of this section. Taxable income is computed without taking into account the section 199A(g) deduction or any deduction allowable under section 1382(b). Patronage net operating losses (NOLs) reduce taxable income in the amount that the Specified Cooperative would use to reduce taxable income (no lower than zero) before using the section 199A(g) deduction, but do not reduce taxable income that is the result of not taking into account any deduction allowable under section 1382(b).

(6) *Use of patronage section 199A(g) deduction.* Except as provided in § 1.199A–12(c)(2) related to the rules for EAGs, the patronage section 199A(g) deduction cannot create or increase a patronage or nonpatronage NOL or the amount of a patronage or nonpatronage NOL carryover or carryback, if applicable, in accordance with section 172. A patronage section 199A(g) deduction can be applied only against patronage income and deductions. A patronage section 199A(g) deduction that is not used in the appropriate taxable year is lost. To the extent that a Specified Cooperative passes through the section 199A(g) deduction to patrons and appropriately adjusts the section 1382 deduction under § 1.199A–8(d), the amount passed through is not considered to create or increase a patronage or nonpatronage NOL or the amount of a patronage or nonpatronage NOL carryover or carryback, if applicable, in accordance with section 172.

(7) *Special rules for nonexempt Specified Cooperatives that have oil-related QPAI*—(i) *Reduction of section 199A(g) deduction.* If a Specified Cooperative has oil-related QPAI for any taxable year, the amount otherwise allowable as a deduction under paragraph (b)(5)(ii) of this section must be reduced by 3 percent of the least of—

(A) Oil-related QPAI of the Specified Cooperative for the taxable year,

(B) QPAI of the Specified Cooperative for the taxable year, or

(C) Taxable income of the Specified Cooperative for the taxable year.

(ii) *Oil-related QPAI* means, for any taxable year, the patronage QPAI that is attributable to the production, refining, processing, transportation, or distribution of oil, gas, or any primary product thereof (within the meaning of section 927(a)(2)(C), as in effect before

its repeal) during such taxable year. Oil-related QPAI for any taxable year is an amount equal to the excess (if any) of patronage DPGR derived from the production, refining or processing of oil, gas, or any primary product thereof (oil-related DPGR) over the sum of—

(A) COGS of the Specified Cooperative that is allocable to such receipts; and

(B) Other expenses, losses, or deductions (other than the section 199A(g) deduction) that are properly allocable to such receipts.

(iii) *Special rule for patronage oil-related DPGR.* Oil-related DPGR does not include gross receipts derived from the transportation or distribution of oil, gas, or any primary product thereof. However, to the extent that the nonexempt Specified Cooperative treats gross receipts derived from transportation or distribution of oil, gas, or any primary product thereof as part of DPGR under § 1.199A–9(c)(3)(i), or under § 1.199A–9(j)(3)(i)(B), then the Specified Cooperative must treat those patronage gross receipts as oil-related DGPR.

(iv) *Oil* includes oil recovered from both conventional and non-conventional recovery methods, including crude oil, shale oil, and oil recovered from tar/oil sands. The *primary product from oil* includes all products derived from the destructive distillation of oil, including volatile products, light oils such as motor fuel and kerosene, distillates such as naphtha, lubricating oils, greases and waxes, and residues such as fuel oil. The *primary product from gas* means all gas and associated hydrocarbon components from gas wells or oil wells, whether recovered at the lease or upon further processing, including natural gas, condensates, liquefied petroleum gases such as ethane, propane, and butane, and liquid products such as natural gasoline. The primary products from oil and gas provided in this paragraph (b)(7)(iv) are not intended to represent either the only primary products from oil or gas, or the only processes from which primary products may be derived under existing and future technologies. Examples of non-primary products include, but are not limited to, petrochemicals, medicinal products, insecticides, and alcohols.

(c) *Exempt Specified Cooperatives*—(1) *In general.* This paragraph (c) applies only to exempt Specified Cooperatives.

(2) *Two section 199A(g) deductions.* The Specified Cooperative must calculate two separate section 199A(g) deductions, one patronage sourced and the other nonpatronage sourced, unless a Specified Cooperative treats all of its nonpatronage gross receipts and related deductions as patronage as described in paragraph (b)(2)(ii) of this section. Patronage and nonpatronage gross receipts, related COGS that are allocable to DPGR, and other expenses, losses, or deductions (other than the section 199A(g) deduction) that are properly allocable to DPGR (deductions), DPGR, QPAI, NOLs, W–2 wages, etc. are not netted to calculate these two separate section 199A(g) deductions.

(3) *Exempt Specified Cooperative patronage section 199A(g) deduction.* The Specified Cooperative calculates its patronage section 199A(g) deduction following steps 1 through 4 in paragraphs (b)(2) through (5) of this section as if it were a nonexempt Specified Cooperative.

(4) *Exempt Specified Cooperative nonpatronage section 199A(g) deduction*—(i) *In general.* The Specified Cooperative calculates its nonpatronage section 199A(g) deduction following steps 2 through 4 in paragraphs (b)(2) through (5) of this section using only nonpatronage gross receipts and related nonpatronage deductions, unless a Specified Cooperative treats all of its nonpatronage gross receipts and related deductions as patronage as described in paragraph (b)(2)(ii) of this section. For purposes of determining the amount of the nonpatronage section 199A(g) deduction allowed under paragraph (b)(5)(ii) of this section, taxable income is limited to taxable income and related deductions from nonpatronage sources. Nonpatronage NOLs reduce taxable income. Taxable income is computed without taking into account the section 199A(g) deduction or any deduction allowable under section 1382(c).

(ii) *Use of nonpatronage section 199A(g) deduction.* Except as provided in § 1.199A–12(c)(2) related to the rules for EAGs, the nonpatronage section 199A(g) deduction cannot create or increase a nonpatronage NOL or the amount of nonpatronage NOL carryover or carryback, if applicable, in accordance with section 172. A Specified Cooperative cannot pass through its nonpatronage section 199A(g) deduction under paragraph (d) of this section and can apply the nonpatronage section 199A(g) deduction only against its nonpatronage income and deductions. As is the case for the patronage section 199A(g) deduction, the nonpatronage section 199A(g) deduction that a Specified Cooperative does not use in the appropriate taxable year is lost.

(d) *Discretion to pass through deduction*—(1)(i) *In general.* A Specified Cooperative may, at its discretion, pass through all, some, or none of its patronage section 199A(g) deduction to all patrons. Only eligible taxpayers as defined in section 199A(g)(2)(D) may claim the section 199A(g) deduction that is passed through. A Specified Cooperative member of a federated cooperative may pass through the patronage section 199A(g) deduction it receives from the federated cooperative to its member patrons.

(ii) *Specified Cooperative identifies eligibility of patron.* If a Specified Cooperative determines that a patron is not an eligible taxpayer, then the Specified Cooperative may, at its discretion, retain any of the patronage section 199A(g) deduction attributable to the patron that would otherwise be passed through and lost under the general rule in paragraph (d)(1)(i) of this section.

(2) *Amount of deduction being passed through*—(i) *In general.* A Specified Cooperative is permitted to pass through an amount equal to the portion of the Specified Cooperative's section 199A(g) deduction that is allowed with respect to the portion of the cooperative's QPAI that is attributable to the qualified payments the Specified Cooperative distributed to the patron during the taxable year and identified on the notice required in § 1.199A–7(f)(3) on an attachment to or on the Form 1099–PATR, Taxable Distributions Received From Cooperatives (Form 1099–PATR), (or any successor form) issued by the Specified Cooperative to the patron, unless otherwise provided by the instructions to the Form. The notice requirement to pass through the section 199A(g) deduction is in paragraph (d)(3) of this section.

(ii) *Qualified payment* means any amount of a patronage dividend or per-unit retain allocation, as described in section 1385(a)(1) or (3) received by a patron from a Specified Cooperative that is attributable to the portion of the Specified Cooperative's QPAI, for which the cooperative is allowed a section 199A(g) deduction. For this purpose, patronage dividends include any advances on patronage and per-unit retain allocations include per-unit retains paid in money during the taxable year.

(3) *Notice requirement to pass through deduction.* A Specified Cooperative must identify in a written notice the amount of the section 199A(g) deduction being passed through to its patrons. This written notice must be mailed by the Specified Cooperative to the patron no later than the 15th day of the ninth month following the close of the taxable year of the Specified Cooperative. The Specified Cooperative may use the same written notice, if any,

that it uses to notify the patron of the patron's respective allocations of patronage distributions, or may use a separate timely written notice(s) to comply with this section. The Specified Cooperative must report the amount of section 199A(g) deduction passed through to the patron on an attachment to or on the Form 1099–PATR (or any successor form) issued by the Specified Cooperative to the patron, unless otherwise provided by the instructions to the Form.

(4) *Section 199A(g) deduction allocated to eligible taxpayer.* An eligible taxpayer may deduct the lesser of the section 199A(g) deduction identified on the notice described in paragraph (d)(3) of this section or the eligible taxpayer's taxable income in the taxable year in which the eligible taxpayer receives the timely written notice described in paragraph (d)(3) of this section. For this purpose, the eligible taxpayer's taxable income is determined without taking into account the section 199A(g) deduction being passed through to the eligible taxpayer and after taking into account any section 199A(a) deduction allowed to the eligible taxpayer. Any section 199A(g) deduction the eligible taxpayer does not use in the taxable year in which the eligible taxpayer receives the notice (received on or before the due date of the Form 1099–PATR) is lost and cannot be carried forward or back to other taxable years. The taxable income limitation for the section 199A(a) deduction set forth in section 199A(b)(3) and § 1.199A–1(a) and (b) does not apply to limit the deductibility of the section 199A(g) deduction passed through to the eligible taxpayer.

(5) *Special rules for eligible taxpayers that are Specified Cooperatives.* Any Specified Cooperative that receives a section 199A(g) deduction as an eligible taxpayer can take the deduction against patronage gross income and related deductions to the extent it relates to its patronage gross income and related deductions. Only a patron that is an exempt Specified Cooperative may take a section 199A(g) deduction passed through from another Specified Cooperative if the deduction relates to the patron Specified Cooperative's nonpatronage gross income and related deductions.

(6) *W–2 wage limitation.* The W–2 wage limitation described in paragraph (b)(5)(ii)(B) of this section is applied at the cooperative level whether or not the Specified Cooperative chooses to pass through some or all of the section 199A(g) deduction. Any section 199A(g) deduction that has been passed through by a Specified Cooperative to an eligible taxpayer is not subject to the W–2 wage limitation a second time at the eligible taxpayer's level.

(7) *Specified Cooperative denied section 1382 deduction for portion of qualified payments.* A Specified Cooperative must reduce its section 1382 deduction by an amount equal to the portion of any qualified payment that is attributable to the Specified Cooperative's section 199A(g) deduction passed through. This means the Specified Cooperative must reduce its section 1382 deduction in an amount equal to the section 199A(g) deduction passed through.

(8) *No double counting.* A qualified payment received by a Specified Cooperative that is a patron of a Specified Cooperative is not taken into account by the patron for purposes of section 199A(g).

(e) *Examples.* The following examples illustrate the application of paragraphs (a), (b), (c), and (d) of this section. The examples of this section apply solely for purposes of section 199A of the Code. Assume for each example that the Specified Cooperative sent all required notices to patrons on or before the due date of the Form 1099–PATR.

(1) *Example 1. Nonexempt Specified Cooperative calculating section 199A(g) deduction.* (i) C is a grain marketing nonexempt Specified Cooperative, with $5,250,000 in gross receipts during 2020 from the sale of grain grown by its patrons. C paid $4,000,000 to its patrons at the time the grain was delivered in the form of per-unit retain allocations and another $1,000,000 in patronage dividends after the close of the 2020 taxable year. C has other expenses of $250,000 during 2020, including $100,000 of W–2 wages.

(ii) C has DPGR of $5,250,000 and QPAI as defined in § 1.199A–8(b)(4)(ii) of $5,000,000 for 2020. C's section 199A(g) deduction is equal to the least of 9% of QPAI ($450,000), 9% of taxable income ($450,000), or 50% of W–2 wages ($50,000). C passes through the entire section 199A(g) deduction to its patrons. Accordingly, C reduces its $5,000,000 deduction allowable under section 1382(b) (relating to the $1,000,000 patronage dividends and $4,000,000 per-unit retain allocations) by $50,000.

(2) *Example 2. Nonexempt Specified Cooperative determines amounts included in QPAI and taxable income.* (i) C, a nonexempt Specified Cooperative, offers harvesting services and markets the grain of patrons and nonpatrons. C had gross receipts from harvesting services and grain sales, and expenses related to both. All of C's harvesting services were performed for their patrons, and 75% of the grain sales were for patrons.

(ii) C identifies 75% of the gross receipts and related expenses from grain sales and 100% of the gross receipts and related expenses from the harvesting services as patronage sourced. C identifies 25% of the gross receipts and related expenses from grain sales as nonpatronage sourced.

(iii) C does not include any nonpatronage gross receipts or related expenses from grain sales in either QPAI or taxable income when calculating the section 199A(g) deduction. C's QPAI includes the patronage DPGR, less related expenses (allocable COGS, wages and other expenses). C's taxable income includes the patronage gross receipts, whether such gross receipts are DPGR or non-DPGR.

(iv) C allocates and reports patronage dividends to its harvesting patrons and grain marketing patrons. C also notifies its grain marketing patrons (in accordance with the requirements of § 1.199A–7(f)(3)) that their patronage dividends are qualified payments used in C's section 199A(g) computation. The patrons must use this information for purposes of computing their section 199A(b)(7) reduction to their section 199A(a) deduction (*see* § 1.199A–7(f)).

(3) *Example 3. Nonexempt Specified Cooperative with patronage and nonpatronage gross receipts and related deductions.* (i) C, a nonexempt Specified Cooperative, markets corn grown by its patrons in the United States. For the calendar year ending December 31, 2020, C derives gross receipts from the marketing activity of $1,800. Such gross receipts qualify as DPGR. Assume C has $800 of expenses (including COGS, other expenses, and $400 of W–2 wages) properly allocable to DPGR, and a $1,000 deduction allowed under section 1382(b). C also derives gross receipts from nonpatronage sources in the amount of $500, and has nonpatronage deductions in the amount of $400 (including COGS, other expenses, and $100 of W–2 wages).

(ii) C does not include any gross receipts or deductions from nonpatronage sources when calculating the deduction under paragraph (b)(5)(ii) of this section. C's QPAI and taxable income both equal $1,000 ($1,800 − 800). C's deduction under paragraph (b)(5)(ii) of this section for the taxable year is equal to $90 (9% of $1,000), which does not exceed $200 (50% of C's W–2 wages properly allocable to DPGR). C passes through $90 of the deduction to patrons and C reduces its section 1382(b) deduction by $90.

(4) *Example 4. Exempt Specified Cooperative with patronage and nonpatronage income and deductions.* (i) C, an exempt Specified Cooperative, markets corn MPGE by its patrons in the United States. For the calendar year ending December 31, 2020, C derives gross receipts from the marketing activity of $1,800. For this activity assume C has $800 of expenses (including COGS, other expenses, and $400 of W–2 wages) properly allocable to DPGR, and a $1,000 deduction under section 1382(b). C also derives gross receipts from nonpatronage sources in the amount of $500. Assume the gross receipts qualify as DPGR. For this activity assume C has $400 of expenses (including COGS, other expenses, and $20 of W–2 wages) properly allocable to DPGR and no deduction under section 1382(c).

(ii) C calculates two separate section 199A(g) deduction amounts. C's section 199A(g) deduction attributable to patronage sources is the same as the deduction calculated by the nonexempt Specified Cooperative in *Example 1* in paragraph (e)(1) of this section.

(iii) C's nonpatronage QPAI and taxable income is equal to $100 ($500 − $400). C's deduction under paragraph (c)(4) of this section that directs C to use paragraph (b)(5)(ii) of this section attributable to nonpatronage sources is equal to $9 (9% of $100), which does not exceed $10 (50% of C's W–2 wages properly allocable to DPGR). C cannot pass through any of the nonpatronage section 199A(g) deduction amount to its patrons.

(5) *Example 5. NOL.* (i) In 2021, E, a nonexempt Specified Cooperative that is not part of an EAG, generates QPAI and taxable income of $100 (without taking into account any section 1382(b) deductions, NOLs, or the section 199A(g) deduction). E pays out patronage dividends of $91 that are deductible under section 1382(b). E has an NOL carryover of $500 attributable to losses incurred prior to 2018. While taxable income and QPAI do not take into account the section 1382(b) deduction, taxable income does take into account NOLs. When calculating its section 199A(g) deduction, E must take into account the NOL carryover when calculating taxable income, unless the taxable income is the result of not taking into account any deduction allowable under section 1382(b). In this case $91 of taxable income is the result of not taking into account the deduction allowed under section 1382(b) and the remaining $9 should be reduced by the NOL carryover so that taxable income equals $91. E calculates a section 199A(g) deduction of $8.19 (.09 × $91 (which is the lesser of $100 QPAI or $91 taxable income)).

(ii) E may pass through the entire $8.19 of section 199A(g) deduction to patrons (which will reduce its section 1382(b) deduction from $91 to $82.81). However, if E does not pass the deduction through, paragraph (b)(6) of this section prohibits E from claiming any of the section 199A(g) deduction in 2021.

(iii) If E passes through the deduction to patrons, E's taxable income under section 172(b)(2) for NOL absorption purposes is $9 ($100 − $82.81 − $9 NOL − $8.19 section 199A(g) deduction). If E does not pass through the deduction, then E's taxable income under section 172(b)(2) for NOL absorption purposes is $9 ($100 − $91 − $9 NOL).

(iv) Assuming E passes through the deduction to patrons, E would use $9 of the NOL carryover and have a $491 NOL carryover remaining. To the extent E does not pass through the deduction, E would still use $9 of the NOL carryover and have a $491 NOL carryover remaining.

(6) *Example 6. Nonexempt Specified Cooperative not passing through the section 199A(g) deduction to patrons.* (i) D, a nonexempt Specified Cooperative, markets corn grown by its patrons within the United States. For its calendar year ended December 31, 2020, D has gross receipts of $1,500,000, all derived from the sale of corn grown by its patrons within the United States. D pays $300,000 for its patrons' corn at the time the grain was delivered in the form of per-unit retain allocations and its W–2 wages (as defined in § 1.199A–11)) for 2020 total $200,000. D has no other costs. Patron A is a patron of D. Patron A is a cash basis taxpayer and files Federal income tax returns on a calendar year basis. All corn grown by Patron A in 2020 is sold through D and Patron A is eligible to share in patronage dividends paid by D for that year.

(ii) All of D's gross receipts from the sale of its patrons' corn qualify as DPGR (as defined paragraph (8)(b)(3)(ii) of this section). D's QPAI and taxable income is $1,300,000. D's section 199A(g) deduction for its taxable year 2020 is $117,000 (.09 × $1,300,000). Because this amount is less than 50% of Cooperative X's W–2 wages, the entire amount is allowed as a section 199A(g) deduction. D decides not to pass any of its section 199A(g) deduction to its patrons. The section 199A(g) deduction of $117,000 is applied to, and reduces, D's taxable income.

(7) *Example 7. Nonexempt Specified Cooperative passing through the section 199A(g) deduction to patrons paid a patronage dividend.* (i) The facts are the same as in Example 6 except that D decides to pass its entire section 199A(g) deduction through to its patrons. D declares a patronage dividend for its 2020 taxable year of $1,000,000, which it pays on March 15, 2021. Pursuant to paragraph (d)(3) of this section, D notifies patrons in written notices that accompany the patronage dividend notification that D is allocating to them the section 199A(g) deduction D is entitled to claim in the calendar year 2020. On March 15, 2021, Patron A receives a $10,000 patronage dividend that is a qualified payment under paragraph (d)(2)(ii) of this section from D. In the notice that accompanies the patronage dividend, Patron A is designated a $1,170 section 199A(g) deduction. Under paragraph (a) of this section, Patron A may claim a $1,170 section 199A(g) deduction for the taxable year ending December 31, 2021, subject to the limitations set forth under paragraph (d)(4) of this section. D must report the allowable amount of Patron A's section 199A(g) deduction on Form 1099–PATR, ''Taxable Distributions Received From Cooperatives,'' issued to Patron A for the calendar year 2021.

(ii) Under paragraph (d)(7) of this section, D is required to reduce its section 1382 deduction of $1,300,000 by the $117,000 section 199A(g) deduction passed through to patrons (whether D pays patronage dividends on book or Federal income tax net earnings). As a consequence, D is entitled to a section 1382 deduction for the taxable year ending December 31, 2020, in the amount of $1,183,000 ($1,300,000 − $117,000) and to a section 199A(g) deduction in the amount of $117,000 ($1,300,000 × .09). Its taxable income for 2020 is $0.

(8) *Example 8. Nonexempt Specified Cooperative passing through the section 199A(g) deduction to patrons paid a patronage dividend and advances on expected patronage net earnings.* (i) The facts are the same as in Example 6 except that D paid out $500,000 to its patrons as advances on expected patronage net earnings. In 2020, D pays its patrons a $500,000 ($1,000,000 − $500,000 already paid) patronage dividend in cash or a combination of cash and qualified written notices of allocation. Under paragraph (d)(7) of this section and section 1382, D is allowed a deduction of $1,183,000 ($1,300,000 − $117,000 section 199A(g) deduction), whether patronage net earnings are distributed on book or Federal income tax net earnings.

(ii) The patrons will have received a gross amount of $1,300,000 in qualified

payments under paragraph (d)(2)(ii) of this section from Cooperative D ($300,000 paid as per-unit retain allocations, $500,000 paid during the taxable year as advances, and the additional $800,000 paid as patronage dividends). If D passes through its entire section 199A(g) deduction to its patrons by providing the notice required by paragraph (d)(3) of this section, then the patrons will be allowed a $117,000 section 199A(g) deduction, resulting in a net $1,183,000 taxable distribution from D. Pursuant to paragraph (d)(8) of this section, any of the $1,300,000 received by patrons that are Specified Cooperatives from D is not taken into account for purposes of calculating the patrons' section 199A(g) deduction. Patrons that are not Specified Cooperatives must include those payments in the section 199A(b)(7) reduction when calculating a section 199A(a) deduction as applicable.

(9) *Example 9. Intangible property transaction as part of disposition of agricultural or horticultural products.* F, a Specified Cooperative, markets patrons' oranges by processing the oranges into orange juice, and then bottling and selling the orange juice to customers. F markets the orange juice under its own brand name, but F also licenses from G, an unrelated third party, the rights to use G's brand name on the bottled orange juice. F's gross receipts from the sale of both brands of orange juice qualify as DPGR, assuming all other requirements of this section are met.

(10) *Example 10. Intangible property transaction that is not a disposition of an agricultural or horticultural product.* H, a Specified Cooperative, licenses H's brand name to J, an unrelated third party. J purchases oranges, produces orange juice, and then bottles and sells the orange juice to customers. Gross receipts that H derives from the license of the brand name to J are not DPGR from the disposition of an agricultural or horticultural product.

(11) *Example 11. Allocation rules when Specified Cooperative retains the section 199A(g) deduction attributable to non-eligible taxpayers.* K, a Specified Cooperative, for the taxable year has $200 of taxable income and QPAI ($100 is attributable to business done for patrons that are C corporation patrons and $100 is attributable to business done for patrons that are eligible taxpayers). K calculates an $18 section 199A(g) deduction. K passes through $9 to its patrons that are eligible taxpayers, distributes $191 to patrons in distributions that are deductible under section 1382(b) (including patronage dividends that were paid out in the same amounts to C corporation patrons and eligible taxpayer patrons because the value of their business,$100 each, was the same), and adjusts its deduction under section 1382 by $9 (the amount of the section 199A(g) deduction passed through). K's taxable income after the section 199A deduction and distributions is $0.

(f) *Special rule for Specified Cooperative partners.* In the case described in section 199A(g)(5)(B), where a Specified Cooperative is a partner in a partnership, the partnership must separately identify and report on the Schedule K–1 of the Form 1065, U.S. Return of Partnership Income (or any successor form) issued to the Specified Cooperative partner the cooperative's share of gross receipts and related deductions, unless otherwise provided by the instructions to the Form. The Specified Cooperative partner determines what gross receipts reported by the partnership qualify as DPGR and includes these gross receipts and related deductions, W–2 wages, and COGS to calculate one section 199A(g) deduction (in the case of a nonexempt Specified Cooperative) or two section 199A(g) deductions (in the case of an exempt Specified Cooperative) using the steps set forth in paragraphs (b) and (c) of this section. For purposes of determining whether gross receipts are DPGR, the MPGE activities of the Specified Cooperative partner may be attributed to the partnership, and the partnership's MPGE activities may be attributed to the Specified Cooperative partner.

(g) *Recapture of section 199A(g) deduction.* If the amount of the section 199A(g) deduction that was passed through to eligible taxpayers exceeds the amount allowable as a section 199A(g) deduction as determined on examination or reported on an amended return, then recapture of the excess will occur at the Specified Cooperative level in the taxable year the Specified Cooperative took the excess section 199A(g) deduction.

(h) *Applicability date.* Except as provided in paragraph (h)(2) of § 1.199A–7, the provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided the taxpayers apply the rules in their entirety and in a consistent manner.

§ 1.199A–9 Domestic production gross receipts.

(a) *Domestic production gross receipts*—(1) *In general.* The provisions of this section apply solely for purposes of section 199A(g) of the Internal Revenue Code (Code). The provisions of this section provide guidance to determine what gross receipts (defined in § 1.199A–8(b)(2)(iii)) are domestic production gross receipts (DPGR) (defined in § 1.199A–8(b)(3)(ii)). DPGR does not include gross receipts derived from services or the lease, rental, license, sale, exchange, or other disposition of land unless a de minimis or other exception applies. Partners, including partners in an EAG partnership described in § 1.199A–12(i)(1), may not treat guaranteed payments under section 707(c) as DPGR.

(2) *Application to marketing cooperatives.* For purposes of determining DPGR, a Specified Cooperative (defined in § 1.199A–8(a)(2)) will be treated as having manufactured, produced, grown, or extracted (MPGE) (defined in paragraph (f) of this section) in whole or significant part (defined in paragraph (h) of this section) any agricultural or horticultural product (defined in § 1.199A–8(a)(4)) within the United States (defined in paragraph (i) of this section) marketed by the Specified Cooperative which its patrons (defined in § 1.1388–1(e)) have so MPGE.

(b) *Related persons*—(1) *In general.* Pursuant to section 199A(g)(3)(D)(ii), DPGR does not include any gross receipts derived from agricultural or horticultural products leased, licensed, or rented by the Specified Cooperative for use by any related person. A person is treated as related to another person if both persons are treated as a single employer under either section 52(a) or (b) (without regard to section 1563(b)), or section 414(m) or (o). Any other person is an unrelated person for purposes of the section 199A(g) deduction.

(2) *Exceptions.* Notwithstanding paragraph (b)(1) of this section, gross receipts derived from any agricultural or horticultural product leased or rented by the Specified Cooperative to a related person may qualify as DPGR if the agricultural or horticultural product is held for sublease or rent, or is subleased or rented, by the related person to an unrelated person for the ultimate use of the unrelated person. Similarly, notwithstanding paragraph (b)(1) of this section, gross receipts derived from a license of the right to reproduce an agricultural or horticultural product to a related person for reproduction and sale, exchange, lease, or rental to an unrelated person for the ultimate use of the unrelated person are treated as gross receipts from a disposition of an

agricultural or horticultural product and may qualify as DPGR.

(c) *Allocating gross receipts*—(1) *In general.* A Specified Cooperative must determine the portion of its gross receipts for the taxable year that is DPGR and the portion of its gross receipts that is non-DPGR using a reasonable method based on all the facts and circumstances. Applicable Federal income tax principles apply to determine whether a transaction is, in substance, a lease, rental, license, sale, exchange, or other disposition the gross receipts of which may constitute DPGR, whether it is a service the gross receipts of which may constitute non-DPGR, or some combination thereof. For example, if a Specified Cooperative sells an agricultural or horticultural product and, in connection with that sale, also provides services, the Specified Cooperative must allocate its gross receipts from the transaction using a reasonable method based on all the facts and circumstances that accurately identifies the gross receipts that constitute DPGR and non-DPGR in accordance with the requirements of § 1.199A–8(b) and/or (c). The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the portion of gross receipts for the taxable year that is DPGR and the portion of gross receipts that is non-DPGR. The books and records maintained for gross receipts must be consistent with any allocations under this paragraph (c)(1).

(2) *Reasonable method of allocation.* If a Specified Cooperative has the information readily available and can, without undue burden or expense, specifically identify whether the gross receipts are derived from an item (and thus, are DPGR), then the Specified Cooperative must use that specific identification to determine DPGR. If the Specified Cooperative does not have information readily available to specifically identify whether gross receipts are derived from an item or cannot, without undue burden or expense, specifically identify whether gross receipts are derived from an item, then the Specified Cooperative is not required to use a method that specifically identifies whether the gross receipts are derived from an item but can use a reasonable allocation method. Factors taken into consideration in determining whether the Specified Cooperative's method of allocating gross receipts between DPGR and non-DPGR is reasonable include whether the Specified Cooperative uses the most accurate information available; the relationship between the gross receipts and the method used; the accuracy of the method chosen as compared with other possible methods; whether the method is used by the Specified Cooperative for internal management or other business purposes; whether the method is used for other Federal or state income tax purposes; the time, burden, and cost of using alternative methods; and whether the Specified Cooperative applies the method consistently from year to year.

(3) *De minimis rules*—(i) *DPGR.* A Specified Cooperative's applicable gross receipts as provided in § 1.199A–8(b) and/or (c) may be treated as DPGR if less than 10 percent of the Specified Cooperative's total gross receipts are non-DPGR (after application of the exceptions provided in § 1.199A–9(j)(3)). If the amount of the Specified Cooperative's gross receipts that are non-DPGR equals or exceeds 10 percent of the Specified Cooperative's total gross receipts, then, except as provided in paragraph (c)(3)(ii) of this section, the Specified Cooperative is required to allocate all gross receipts between DPGR and non-DPGR in accordance with paragraph (c)(1) of this section. If a Specified Cooperative is a member of an expanded affiliated group (EAG) (defined in § 1.199A–12), but is not a member of a consolidated group, then the determination of whether less than 10 percent of the Specified Cooperative's total gross receipts are non-DPGR is made at the Specified Cooperative level. If a Specified Cooperative is a member of a consolidated group, then the determination of whether less than 10 percent of the Specified Cooperative's total gross receipts are non-DPGR is made at the consolidated group level. *See* § 1.199A–12(d).

(ii) *Non-DPGR.* A Specified Cooperative's applicable gross receipts as provided in §§ 1.199A–8(b) and/or (c) may be treated as non-DPGR if less than 10 percent of the Specified Cooperative's total gross receipts are DPGR. If a Specified Cooperative is a member of an EAG, but is not a member of a consolidated group, then the determination of whether less than 10 percent of the Specified Cooperative's total gross receipts are DPGR is made at the Specified Cooperative level. If a Specified Cooperative is a member of a consolidated group, then the determination of whether less than 10 percent of the Specified Cooperative's total gross receipts are DPGR is made at the consolidated group level.

(d) *Use of historical data for multiple-year transactions.* If a Specified Cooperative recognizes and reports gross receipts from upfront payments or other similar payments on a Federal income tax return for a taxable year, then the Specified Cooperative's use of historical data in making an allocation of gross receipts from the transaction between DPGR and non-DPGR may constitute a reasonable method. If a Specified Cooperative makes allocations using historical data, and subsequently updates the data, then the Specified Cooperative must use the more recent or updated data, starting in the taxable year in which the update is made.

(e) *Determining DPGR item-by-item*—(1) *In general.* For purposes of the section 199A(g) deduction, a Specified Cooperative determines, using a reasonable method based on all the facts and circumstances, whether gross receipts qualify as DPGR on an item-by-item basis (and not, for example, on a division-by-division, product line-by-product line, or transaction-by-transaction basis). The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the portion of gross receipts that is DPGR. The books and records maintained for gross receipts must be consistent with any allocations under this paragraph (e)(1).

(i) The term *item* means the agricultural or horticultural product offered by the Specified Cooperative in the normal course of its trade or business for lease, rental, license, sale, exchange, or other disposition (for purposes of this paragraph (e), collectively referred to as disposition) to customers, if the gross receipts from the disposition of such product qualify as DPGR; or

(ii) If paragraph (e)(1)(i) of this section does not apply to the product, then any component of the product described in paragraph (e)(1)(i) of this section is treated as the item, provided that the gross receipts from the disposition of the product described in paragraph (e)(1)(i) of this section that are attributable to such component qualify as DPGR. Each component that meets the requirements under this paragraph (e)(1)(ii) must be treated as a separate item and a component that meets the requirements under this paragraph (e)(1)(ii) may not be combined with a component that does not meet these requirements.

(2) *Special rules.* (i) For purposes of paragraph (e)(1)(i) of this section, in no event may a single item consist of two or more products unless those products are offered for disposition, in the normal course of the Specified Cooperative's trade or business, as a single item (regardless of how the products are packaged).

(ii) In the case of agricultural or horticultural products customarily sold

by weight or by volume, the item is determined using the most common custom of the industry (for example, barrels of oil).

(3) *Exception.* If the Specified Cooperative MPGE agricultural or horticultural products within the United States that it disposes of, and the Specified Cooperative leases, rents, licenses, purchases, or otherwise acquires property that contains or may contain the agricultural or horticultural products (or a portion thereof), and the Specified Cooperative cannot reasonably determine, without undue burden and expense, whether the acquired property contains any of the original agricultural or horticultural products MPGE by the Specified Cooperative, then the Specified Cooperative is not required to determine whether any portion of the acquired property qualifies as an item for purposes of paragraph (e)(1) of this section. Therefore, the gross receipts derived from the disposition of the acquired property may be treated as non-DPGR. Similarly, the preceding sentences apply if the Specified Cooperative can reasonably determine that the acquired property contains agricultural or horticultural products (or a portion thereof) MPGE by the Specified Cooperative, but cannot reasonably determine, without undue burden or expense, how much, or what type, grade, etc., of the agricultural or horticultural MPGE by the Specified Cooperative the acquired property contains.

(f) *Definition of manufactured, produced, grown, or extracted (MPGE)*—(1) *In general.* Except as provided in paragraphs (f)(2) and (3) of this section, the term *MPGE* includes manufacturing, producing, growing, extracting, installing, developing, improving, and creating agricultural or horticultural products; making agricultural or horticultural products out of material by processing, manipulating, refining, or changing the form of an article, or by combining or assembling two or more articles; cultivating soil, raising livestock, and farming aquatic products. The term MPGE also includes storage, handling, or other processing activities (other than transportation activities) within the United States related to the sale, exchange, or other disposition of agricultural or horticultural products only if the products are consumed in connection with or incorporated into the MPGE of agricultural or horticultural products, whether or not by the Specified Cooperative. The Specified Cooperative (or the patron if § 1.199A–9(a)(2) applies) must have the benefits and burdens of ownership of the agricultural or horticultural products under Federal income tax principles during the period the MPGE activity occurs for the gross receipts derived from the MPGE of the agricultural or horticultural products to qualify as DPGR.

(2) *Packaging, repackaging, or labeling.* If the Specified Cooperative packages, repackages, or labels agricultural or horticultural products and engages in no other MPGE activity with respect to those agricultural or horticultural products, the packaging, repackaging, or labeling does not qualify as MPGE with respect to those agricultural or horticultural products.

(3) *Installing.* If a Specified Cooperative installs agricultural or horticultural products and engages in no other MPGE activity with respect to the agricultural or horticultural products, the Specified Cooperative's installing activity does not qualify as an MPGE activity. Notwithstanding paragraph (j)(3)(i)(A) of this section, if the Specified Cooperative installs agricultural or horticultural products MPGE by the Specified Cooperative and the Specified Cooperative has the benefits and burdens of ownership of the agricultural or horticultural products under Federal income tax principles during the period the installing activity occurs, then the portion of the installing activity that relates to the agricultural or horticultural products is an MPGE activity.

(4) *Consistency with section 263A.* A Specified Cooperative that has MPGE agricultural or horticultural products for the taxable year must treat itself as a producer under section 263A with respect to the agricultural or horticultural products unless the Specified Cooperative is not subject to section 263A. A Specified Cooperative that currently is not properly accounting for its production activities under section 263A, and wishes to change its method of accounting to comply with the producer requirements of section 263A, must follow the applicable administrative procedures issued under § 1.446–1(e)(3)(ii) for obtaining the Commissioner's consent to a change in accounting method (for further guidance, for example, *see* Rev. Proc. 2015–13, 2015–5 IRB 419, or any applicable subsequent guidance (*see* § 601.601(d)(2) of this chapter)).

(5) *Examples.* The following examples illustrate the application of paragraphs (f)(1), (2), and (3) of this section.

(i) *Example 1. MPGE activities conducted within United States.* A, B, and C are unrelated persons. A is a Specified Cooperative, B is an individual patron of A, and C is a C corporation. B grows agricultural products outside of the United States and A markets those agricultural products for B. A stores the agricultural products in agricultural storage bins in the United States and has the benefits and burdens of ownership under Federal income tax principles of the agricultural products while they are being stored. A sells the agricultural products to C, who processes them into refined agricultural products in the United States. The gross receipts from A's activities are DPGR from the MPGE of agricultural products.

(ii) *Example 2. MPGE activities conducted within and outside United States.* The facts are the same as in Example 1 except that B grows the agricultural products outside the United States and C processes them into refined agricultural products outside the United States. Pursuant to paragraph (f)(1) of this section, the gross receipts derived by A from its sale of the agricultural products to C are DPGR from the MPGE of agricultural products within the United States.

(g) *By the taxpayer.* With respect to the exception of the rules applicable to an EAG and EAG partnerships under § 1.199A–12, only one Specified Cooperative may claim the section 199A(g) deduction with respect to any qualifying activity under paragraph (f) of this section performed in connection with the same agricultural or horticultural product. If an unrelated party performs a qualifying activity under paragraph (f) of this section pursuant to a contract with a Specified Cooperative (or its patron as relevant under paragraph (a)(2) of this section), then only if the Specified Cooperative (or its patron) has the benefits and burdens of ownership of the agricultural or horticultural product under Federal income tax principles during the period in which the qualifying activity occurs is the Specified Cooperative (or its patron) treated as engaging in the qualifying activity.

(h) *In whole or significant part defined*—(1) *In general.* Agricultural or horticultural products must be MPGE in whole or significant part by the Specified Cooperative (or its patrons in the case described in paragraph (a)(2) of this section) and in whole or significant part within the United States to qualify under section 199A(g)(3)(D)(i). If a Specified Cooperative enters into a contract with an unrelated person for the unrelated person to MPGE agricultural or horticultural products for the Specified Cooperative and the Specified Cooperative has the benefits and burdens of ownership of the

agricultural or horticultural products under applicable Federal income tax principles during the period the MPGE activity occurs, then, pursuant to paragraph (g) of this section, the Specified Cooperative is considered to MPGE the agricultural or horticultural products under this section. The unrelated person must perform the MPGE activity on behalf of the Specified Cooperative in whole or significant part within the United States in order for the Specified Cooperative to satisfy the requirements of this paragraph (h)(1).

(2) *Substantial in nature.* Agricultural or horticultural products will be treated as MPGE in whole or in significant part by the Specified Cooperative (or its patrons in the case described in paragraph (a)(2) of this section) within the United States for purposes of paragraph (h)(1) of this section. However, MPGE of the agricultural or horticultural products by the Specified Cooperative within the United States must be substantial in nature taking into account all the facts and circumstances, including the relative value added by, and relative cost of, the Specified Cooperative's MPGE within the United States, the nature of the agricultural or horticultural products, and the nature of the MPGE activity that the Specified Cooperative performs within the United States. The MPGE of a key component of an agricultural or horticultural product does not, in itself, meet the substantial-in-nature requirement with respect to an agricultural or horticultural product under this paragraph (h)(2). In the case of an agricultural or horticultural product, research and experimental activities under section 174 and the creation of intangible assets are not taken into account in determining whether the MPGE of the agricultural or horticultural product is substantial in nature.

(3) *Safe harbor*—(i) *In general.* A Specified Cooperative (or its patrons in the case described in paragraph (a)(2) of this section) will be treated as having MPGE an agricultural or horticultural product in whole or in significant part within the United States for purposes of paragraph (h)(1) of this section if the direct labor and overhead of such Specified Cooperative to MPGE the agricultural or horticultural product within the United States account for 20 percent or more of the Specified Cooperative's COGS of the agricultural or horticultural product, or in a transaction without COGS (for example, a lease, rental, or license), account for 20 percent or more of the Specified Cooperative's unadjusted depreciable basis (as defined in paragraph (h)(3)(ii) of this section) in property included in the definition of agricultural or horticultural products. For Specified Cooperatives subject to section 263A, overhead is all costs required to be capitalized under section 263A except direct materials and direct labor. For Specified Cooperatives not subject to section 263A, overhead may be computed using a reasonable method based on all the facts and circumstances, but may not include any cost, or amount of any cost, that would not be required to be capitalized under section 263A if the Specified Cooperative were subject to section 263A. Research and experimental expenditures under section 174 and the costs of creating intangible assets are not taken into account in determining direct labor or overhead for any agricultural or horticultural product. In the case of agricultural or horticultural products, research and experimental expenditures under section 174 and any other costs incurred in the creation of intangible assets may be excluded from COGS or unadjusted depreciable basis for purposes of determining whether the Specified Cooperative meets the safe harbor under this paragraph (h)(3). For Specified Cooperatives not subject to section 263A, the chosen reasonable method to compute overhead must be consistently applied from one taxable year to another and must clearly reflect the Specified Cooperative's portion of overhead not subject to section 263A. The method must also be reasonable based on all the facts and circumstances. The books and records maintained for overhead must be consistent with any allocations under this paragraph (h)(3)(i).

(ii) *Unadjusted depreciable basis.* The term unadjusted depreciable basis means the basis of property for purposes of section 1011 without regard to any adjustments described in section 1016(a)(2) and (3). This basis does not reflect the reduction in basis for—

(A) Any portion of the basis the Specified Cooperative properly elects to treat as an expense under sections 179 or 179C; or

(B) Any adjustments to basis provided by other provisions of the Code and the regulations under the Code (for example, a reduction in basis by the amount of the disabled access credit pursuant to section 44(d)(7)).

(4) *Special rules*—(i) *Contract with an unrelated person.* If a Specified Cooperative enters into a contract with an unrelated person for the unrelated person to MPGE an agricultural or horticultural product within the United States for the Specified Cooperative, and the Specified Cooperative is considered to MPGE the agricultural or horticultural product pursuant to paragraph (f)(1) of this section, then, for purposes of the substantial-in-nature requirement under paragraph (h)(2) of this section and the safe harbor under paragraph (h)(3)(i) of this section, the Specified Cooperative's MPGE activities or direct labor and overhead must include both the Specified Cooperative's MPGE activities or direct labor and overhead to MPGE the agricultural or horticultural product within the United States as well as the MPGE activities or direct labor and overhead of the unrelated person to MPGE the agricultural or horticultural product within the United States under the contract.

(ii) *Aggregation.* In determining whether the substantial-in-nature requirement under paragraph (h)(2) of this section or the safe harbor under paragraph (h)(3)(i) of this section is met at the time the Specified Cooperative disposes of an agricultural or horticultural product—

(A) An EAG member must take into account all the previous MPGE activities or direct labor and overhead of the other members of the EAG;

(B) An EAG partnership as defined in § 1.199A–12(i)(1) must take into account all of the previous MPGE activities or direct labor and overhead of all members of the EAG in which the partners of the EAG partnership are members (as well as the previous MPGE activities of any other EAG partnerships owned by members of the same EAG); and

(C) A member of an EAG in which the partners of an EAG partnership are members must take into account all of the previous MPGE activities or direct labor and overhead of the EAG partnership (as well as those of any other members of the EAG and any previous MPGE activities of any other EAG partnerships owned by members of the same EAG).

(i) *United States defined.* For purposes of section 199A(g), the term *United States* includes the 50 states, the District of Columbia, the territorial waters of the United States, and the seabed and subsoil of those submarine areas that are adjacent to the territorial waters of the United States and over which the United States has exclusive rights, in accordance with international law, with respect to the exploration and exploitation of natural resources. Consistent with its definition in section 7701(a)(9), the term *United States* does not include possessions and territories of the United States or the airspace or space over the United States and these areas.

(j) *Derived from the lease, rental, license, sale, exchange, or other disposition*—(1) *In general*—(i) *Definition.* The term *derived from the lease, rental, license, sale, exchange, or other disposition* is defined as, and limited to, the gross receipts directly derived from the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products even if the Specified Cooperative has already recognized receipts from a previous lease, rental, license, sale, exchange, or other disposition of the same agricultural or horticultural products. Applicable Federal income tax principles apply to determine whether a transaction is, in substance, a lease, rental, license, sale, exchange, or other disposition, whether it is a service, or whether it is some combination thereof.

(ii) *Lease income.* The financing and interest components of a lease of agricultural or horticultural products are considered to be derived from the lease of such agricultural or horticultural products. However, any portion of the lease income that is attributable to services or non-qualified property as defined in paragraph (j)(3) of this section is not derived from the lease of agricultural or horticultural products.

(iii) *Income substitutes.* The proceeds from business interruption insurance, governmental subsidies, and governmental payments not to produce are treated as gross receipts derived from the lease, rental, license, sale, exchange, or other disposition to the extent they are substitutes for gross receipts that would qualify as DPGR.

(iv) *Exchange of property*—(A) *Taxable exchanges.* The value of property received by the Specified Cooperative in a taxable exchange of agricultural or horticultural products MPGE in whole or in significant part by the Specified Cooperative within the United States is DPGR for the Specified Cooperative (assuming all the other requirements of this section are met). However, unless the Specified Cooperative meets all of the requirements under this section with respect to any additional MPGE by the Specified Cooperative of the agricultural or horticultural products received in the taxable exchange, any gross receipts derived from the sale by the Specified Cooperative of the property received in the taxable exchange are non-DPGR, because the Specified Cooperative did not MPGE such property, even if the property was an agricultural or horticultural product in the hands of the other party to the transaction.

(B) *Safe harbor.* For purposes of paragraph (j)(1)(iv)(A) of this section, the gross receipts derived by the Specified Cooperative from the sale of eligible property (as defined in paragraph (j)(1)(iv)(C) of this section) received in a taxable exchange, net of any adjustments between the parties involved in the taxable exchange to account for differences in the eligible property exchanged (for example, location differentials and product differentials), may be treated as the value of the eligible property received by the Specified Cooperative in the taxable exchange. For purposes of the preceding sentence, the taxable exchange is deemed to occur on the date of the sale of the eligible property received in the taxable exchange by the Specified Cooperative, to the extent the sale occurs no later than the last day of the month following the month in which the exchanged eligible property is received by the Specified Cooperative. In addition, if the Specified Cooperative engages in any further MPGE activity with respect to the eligible property received in the taxable exchange, then, unless the Specified Cooperative meets the in-whole-or-in-significant-part requirement under paragraph (h)(1) of this section with respect to the property sold, for purposes of this paragraph (j)(1)(iv)(B), the Specified Cooperative must also value the property sold without taking into account the gross receipts attributable to the further MPGE activity.

(C) *Eligible property.* For purposes of paragraph (j)(1)(iv)(B) of this section, eligible property is—

(*1*) Oil, natural gas, or petrochemicals, or products derived from oil, natural gas, or petrochemicals; or

(*2*) Any other property or product designated by publication in the Internal Revenue Bulletin (*see* § 601.601(d)(2)(ii)(b) of this chapter).

(*3*) For this purpose, the term *natural gas* includes only natural gas extracted from a natural deposit and does not include, for example, methane gas extracted from a landfill. In the case of natural gas, production activities include all activities involved in extracting natural gas from the ground and processing the gas into pipeline quality gas.

(2) *Hedging transactions*—(i) *In general.* For purposes of this section, if a transaction is a hedging transaction within the meaning of section 1221(b)(2)(A) and § 1.1221–2(b), is properly identified as a hedging transaction in accordance with § 1.1221–2(f), and the risk being hedged relates to property described in section 1221(a)(1) that gives rise to DPGR or to property described in section 1221(a)(8) that is consumed in an activity that gives rise to DPGR, then—

(A) In the case of a hedge of purchases of property described in section 1221(a)(1), income, deduction, gain, or loss on the hedging transaction must be taken into account in determining COGS;

(B) In the case of a hedge of sales of property described in section 1221(a)(1), income, deduction, gain, or loss on the hedging transaction must be taken into account in determining DPGR; and

(C) In the case of a hedge of purchases of property described in section 1221(a)(8), income, deduction, gain, or loss on the hedging transaction must be taken into account in determining DPGR.

(ii) *Allocation.* The income, deduction, gain and loss from hedging transactions described in paragraph (j)(2) of this section must be allocated between the patronage and nonpatronage (defined in § 1.1388–1(f)) sourced income and related deductions of the Specified Cooperatives consistent with the cooperative's method for determining patronage and nonpatronage income and deductions.

(iii) *Effect of identification and nonidentification.* The principles of § 1.1221–2(g) apply to a Specified Cooperative that identifies or fails to identify a transaction as a hedging transaction, except that the consequence of identifying as a hedging transaction a transaction that is not in fact a hedging transaction described in paragraph (j)(2) of this section, or of failing to identify a transaction that the Specified Cooperative has no reasonable grounds for treating as other than a hedging transaction described in paragraph (j)(2) of this section, is that deduction or loss (but not income or gain) from the transaction is taken into account under paragraph (j)(2) of this section.

(iv) *Other rules.* See § 1.1221–2(e) for rules applicable to hedging by members of a consolidated group and § 1.446–4 for rules regarding the timing of income, deductions, gains or losses with respect to hedging transactions.

(3) *Allocation of gross receipts to embedded services and non-qualified property*—(i) *Embedded services and non-qualified property*—(A) *In general.* Except as otherwise provided in paragraph (j)(3)(i)(B) of this section, gross receipts derived from the performance of services do not qualify as DPGR. In the case of an embedded service, that is, a service the price of which, in the normal course of the business, is not separately stated from the amount charged for the lease, rental, license, sale, exchange, or other disposition of agricultural or

horticultural products, DPGR includes only the gross receipts derived from the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products (assuming all the other requirements of this section are met) and not any receipts attributable to the embedded service. In addition, DPGR does not include gross receipts derived from the lease, rental, license, sale, exchange, or other disposition of property that does not meet all of the requirements under this section (non-qualified property). The allocation of the gross receipts attributable to the embedded services or non-qualified property will be deemed to be reasonable if the allocation reflects the fair market value of the embedded services or non-qualified property.

(B) *Exceptions.* There are five exceptions to the rules under paragraph (j)(3)(i)(A) of this section regarding embedded services and non-qualified property. A Specified Cooperative may include in DPGR, if all the other requirements of this section are met with respect to the underlying item of agricultural or horticultural products to which the embedded services or non-qualified property relate, the gross receipts derived from—

(1) A qualified warranty, that is, a warranty that is provided in connection with the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products if, in the normal course of the Specified Cooperative's business—

(i) The price for the warranty is not separately stated from the amount charged for the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products; and

(ii) The warranty is neither separately offered by the Specified Cooperative nor separately bargained for with customers (that is, a customer cannot purchase the agricultural or horticultural products without the warranty);

(2) A qualified delivery, that is, a delivery or distribution service that is provided in connection with the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products if, in the normal course of the Specified Cooperative's business—

(i) The price for the delivery or distribution service is not separately stated from the amount charged for the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products; and

(ii) The delivery or distribution service is neither separately offered by the Specified Cooperative nor separately bargained for with customers (that is, a customer cannot purchase the agricultural or horticultural products without the delivery or distribution service).

(3) A qualified operating manual, that is, a manual of instructions that is provided in connection with the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products if, in the normal course of the Specified Cooperative's business—

(i) The price for the manual is not separately stated from the amount charged for the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products;

(ii) The manual is neither separately offered by the Specified Cooperative nor separately bargained for with customers (that is, a customer cannot purchase the agricultural or horticultural products without the manual); and

(iii) The manual is not provided in connection with a training course for customers.

(4) A qualified installation, that is, an installation service for agricultural or horticultural products that is provided in connection with the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products if, in the normal course of the Specified Cooperative's business—

(i) The price for the installation service is not separately stated from the amount charged for the lease, rental, license, sale, exchange, or other disposition of the agricultural or horticultural products; and

(ii) The installation is neither separately offered by the Specified Cooperative nor separately bargained for with customers (that is, a customer cannot purchase the agricultural or horticultural products without the installation service).

(5) A *de minimis* amount of gross receipts from embedded services and non-qualified property for each item of agricultural or horticultural products may qualify. For purposes of this exception, a *de minimis* amount of gross receipts from embedded services and non-qualified property is less than 5 percent of the total gross receipts derived from the lease, rental, license, sale, exchange, or other disposition of each item of agricultural or horticultural products. In the case of gross receipts derived from the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products that are received over a period of time (for example, a multi-year lease or installment sale), this *de minimis* exception is applied by taking into account the total gross receipts for the entire period derived (and to be derived) from the lease, rental, license, sale, exchange, or other disposition of the item of agricultural or horticultural products. For purposes of the preceding sentence, if a Specified Cooperative treats gross receipts as DPGR under this *de minimis* exception, then the Specified Cooperative must treat the gross receipts recognized in each taxable year consistently as DPGR. The gross receipts that the Specified Cooperative treats as DPGR under paragraphs (j)(3)(i)(B)(1) through (4) of this section are treated as DPGR for purposes of applying this *de minimis* exception. This *de minimis* exception does not apply if the price of a service or non-qualified property is separately stated by the Specified Cooperative, or if the service or non-qualified property is separately offered or separately bargained for with the customer (that is, the customer can purchase the agricultural or horticultural products without the service or non-qualified property).

(ii) *Non-DPGR.* Applicable gross receipts as provided in §§ 1.199A–8(b) and/or (c) derived from the lease, rental, license, sale, exchange or other disposition of an item of agricultural or horticultural products may be treated as non-DPGR if less than 5 percent of the Specified Cooperative's total gross receipts derived from the lease, rental, license, sale, exchange or other disposition of that item are DPGR (taking into account embedded services and non-qualified property included in such disposition, but not part of the item). In the case of gross receipts derived from the lease, rental, license, sale, exchange, or other disposition of agricultural or horticultural products that are received over a period of time (for example, a multi-year lease or installment sale), this paragraph (j)(5)(ii) is applied by taking into account the total gross receipts for the entire period derived (and to be derived) from the lease, rental, license, sale, exchange, or other disposition of the item of agricultural or horticultural products. For purposes of the preceding sentence, if the Specified Cooperative treats gross receipts as non-DPGR under this *de minimis* exception, then the Specified Cooperative must treat the gross receipts recognized in each taxable year consistently as non-DPGR.

(k) *Applicability date.* The provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided the

taxpayers apply the rules in their entirety and in a consistent manner.

§ 1.199A–10 Allocation of cost of goods sold (COGS) and other deductions to domestic production gross receipts (DPGR), and other rules.

(a) *In general.* The provisions of this section apply solely for purposes of section 199A(g) of the Internal Revenue Code (Code). The provisions of this section provide additional guidance on determining qualified production activities income (QPAI) as described and defined in § 1.199A–8(b)(4)(ii).

(b) *COGS allocable to DPGR*—(1) *In general.* When determining its QPAI, the Specified Cooperative (defined in § 1.199A–8(a)(2)) must subtract from its DPGR (defined in § 1.199A–8(b)(3)(ii)) the COGS allocable to its DPGR. The Specified Cooperative determines its COGS allocable to DPGR in accordance with this paragraph (b)(1) or, if applicable, paragraph (f) of this section. In the case of a sale, exchange, or other disposition of inventory, COGS is equal to beginning inventory of the Specified Cooperative plus purchases and production costs incurred during the taxable year and included in inventory costs by the Specified Cooperative, less ending inventory of the Specified Cooperative. In determining its QPAI, the Specified Cooperative does not include in COGS any payment made, whether during the taxable year, or included in beginning inventory, for which a deduction is allowed under section 1382(b) and/or (c), as applicable. *See* § 1.199A–8(b)(4)(ii)(C). COGS is determined under the methods of accounting that the Specified Cooperative uses to compute taxable income. *See* sections 263A, 471, and 472. If section 263A requires the Specified Cooperative to include additional section 263A costs (as defined in § 1.263A–1(d)(3)) in inventory, additional section 263A costs must be included in determining COGS. COGS also include the Specified Cooperative's inventory valuation adjustments such as write-downs under the lower of cost or market method. In the case of a sale, exchange, or other disposition (including, for example, theft, casualty, or abandonment) by the Specified Cooperative of non-inventory property, COGS for purposes of this section includes the adjusted basis of the property.

(2) *Allocating COGS*—(i) *In general.* A Specified Cooperative must use a reasonable method based on all the facts and circumstances to allocate COGS between DPGR and non-DPGR. Whether an allocation method is reasonable is based on all the facts and circumstances, including whether the Specified Cooperative uses the most accurate information available; the relationship between COGS and the method used; the accuracy of the method chosen as compared with other possible methods; whether the method is used by the Specified Cooperative for internal management or other business purposes; whether the method is used for other Federal or state income tax purposes; the availability of costing information; the time, burden, and cost of using alternative methods; and whether the Specified Cooperative applies the method consistently from year to year. Depending on the facts and circumstances, reasonable methods may include methods based on gross receipts (defined in § 1.199A–8(b)(2)(iii)), number of units sold, number of units produced, or total production costs. Ordinarily, if a Specified Cooperative uses a method to allocate gross receipts between DPGR and non-DPGR, then the use of a different method to allocate COGS that is not demonstrably more accurate than the method used to allocate gross receipts will not be considered reasonable. However, if a Specified Cooperative has information readily available to specifically identify COGS allocable to DPGR and can specifically identify that amount without undue burden or expense, COGS allocable to DPGR is that amount irrespective of whether the Specified Cooperative uses another allocation method to allocate gross receipts between DPGR and non-DPGR. A Specified Cooperative that does not have information readily available to specifically identify COGS allocable to DPGR and that cannot, without undue burden or expense, specifically identify that amount is not required to use a method that specifically identifies COGS allocable to DPGR. The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the portion of COGS between DPGR and non-DPGR. The method must also be reasonable based on all the facts and circumstances. The books and records maintained for COGS must be consistent with any allocations under this paragraph (b)(2).

(ii) *Gross receipts recognized in an earlier taxable year.* If the Specified Cooperative (other than a Specified Cooperative that uses the small business simplified overall method of paragraph (f) of this section) recognizes and reports gross receipts on a Federal income tax return for a taxable year, and incurs COGS related to such gross receipts in a subsequent taxable year, then regardless of whether the gross receipts ultimately qualify as DPGR, the Specified Cooperative must allocate the COGS to—

(A) DPGR if the Specified Cooperative identified the related gross receipts as DPGR in the prior taxable year; or

(B) Non-DPGR if the Specified Cooperative identified the related gross receipts as non-DPGR in the prior taxable year or if the Specified Cooperative recognized under the Specified Cooperative's methods of accounting those gross receipts in a taxable year to which section 199A(g) does not apply.

(iii) *COGS associated with activities undertaken in an earlier taxable year*—(A) *In general.* A Specified Cooperative must allocate its COGS between DPGR and non-DPGR under the rules provided in paragraphs (b)(2)(i) and (iii) of this section, regardless of whether certain costs included in its COGS can be associated with activities undertaken in an earlier taxable year (including a year prior to the effective date of section 199A(g)). A Specified Cooperative may not segregate its COGS into component costs and allocate those component costs between DPGR and non-DPGR.

(B) *Example.* The following example illustrates an application of paragraph (b)(2)(iii)(A) of this section.

(*1*) *Example 1.* During the 2020 taxable year, nonexempt Specified Cooperative X grew and sold Horticultural Product A. All of the patronage gross receipts from sales recognized by X in 2020 were from the sale of Horticultural Product A and qualified as DPGR. Employee 1 of X was involved in X's production process until he retired in 2013. In 2020, X paid $30 directly from its general assets for Employee 1's medical expenses pursuant to an unfunded, self-insured plan for retired X employees. For purposes of computing X's 2020 taxable income, X capitalized those medical costs to inventory under section 263A. In 2020, the COGS for a unit of Horticultural Product A was $100 (including the applicable portion of the $30 paid for Employee 1's medical costs that was allocated to COGS under X's allocation method for additional section 263A costs). X has information readily available to specifically identify COGS allocable to DPGR and can identify that amount without undue burden and expense because all of X's gross receipts from sales in 2020 are attributable to the sale of Horticultural Product A and qualify as DPGR. The inventory cost of each unit of Horticultural Product A sold in 2020, including the applicable portion of retiree medical costs, is related to X's gross receipts from the

sale of Horticultural Product A in 2020. X may not segregate the 2020 COGS by separately allocating the retiree medical costs, which are components of COGS, to DPGR and non-DPGR. Thus, even though the retiree medical costs can be associated with activities undertaken in prior years, $100 of inventory cost of each unit of Horticultural Product A sold in 2020, including the applicable portion of the retiree medical expense cost component, is allocable to DPGR in 2020.

(3) *Special allocation rules.* Section 199A(g)(3)(C) provides the following two special rules—

(i) For purposes of determining the COGS that are allocable to DPGR, any item or service brought into the United States (defined in § 1.199A–9(i)) is treated as acquired by purchase, and its cost is treated as not less than its value immediately after it entered the United States. A similar rule applies in determining the adjusted basis of leased or rented property where the lease or rental gives rise to DPGR.

(ii) In the case of any property described in paragraph (b)(3)(i) of this section that has been exported by the Specified Cooperative for further manufacture, the increase in cost or adjusted basis under paragraph (b)(3)(i) of this section cannot exceed the difference between the value of the property when exported and the value of the property when brought back into the United States after the further manufacture. For the purposes of this paragraph (b)(3), the value of property is its customs value as defined in section 1059A(b)(1).

(4) *Rules for inventories valued at market or bona fide selling prices.* If part of COGS is attributable to the Specified Cooperative's inventory valuation adjustments, then COGS allocable to DPGR includes inventory adjustments to agricultural or horticultural products that are MPGE in whole or significant part within the United States. Accordingly, a Specified Cooperative that values its inventory under § 1.471–4 (inventories at cost or market, whichever is lower) or § 1.471–2(c) (subnormal goods at bona fide selling prices) must allocate a proper share of such adjustments (for example, write-downs) to DPGR based on a reasonable method based on all the facts and circumstances. Factors taken into account in determining whether the method is reasonable include whether the Specified Cooperative uses the most accurate information available; the relationship between the adjustment and the allocation base chosen; the accuracy of the method chosen as compared with other possible methods; whether the method is used by the Specified Cooperative for internal management or other business purposes; whether the method is used for other Federal or state income tax purposes; the time, burden, and cost of using alternative methods; and whether the Specified Cooperative applies the method consistently from year to year. If the Specified Cooperative has information readily available to specifically identify the proper amount of inventory valuation adjustments allocable to DPGR, then the Specified Cooperative must allocate that amount to DPGR. The Specified Cooperative that does not have information readily available to specifically identify the proper amount of its inventory valuation adjustments allocable to DPGR and that cannot, without undue burden or expense, specifically identify the proper amount of its inventory valuation adjustments allocable to DPGR, is not required to use a method that specifically identifies inventory valuation adjustments to DPGR. The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect inventory adjustments. The method must also be reasonable based on all the facts and circumstances. The books and records maintained for inventory adjustments must be consistent with any allocations under this paragraph (b)(4).

(5) *Rules applicable to inventories accounted for under the last-in, first-out inventory method*—(i) *In general.* This paragraph (b)(5) applies to inventories accounted for using the specific goods last-in, first-out (LIFO) method or the dollar-value LIFO method. Whenever a specific goods grouping or a dollar-value pool contains agricultural or horticultural products that produce DPGR and goods that do not, the Specified Cooperative must allocate COGS attributable to that grouping or pool between DPGR and non-DPGR using a reasonable method based on all the facts and circumstances. Whether a method of allocating COGS between DPGR and non-DPGR is reasonable must be determined in accordance with paragraph (b)(2) of this section. In addition, this paragraph (b)(5) provides methods that a Specified Cooperative may use to allocate COGS for a Specified Cooperative's inventories accounted for using the LIFO method. If the Specified Cooperative uses the LIFO/FIFO ratio method provided in paragraph (b)(5)(ii) of this section or the change in relative base-year cost method provided in paragraph (b)(5)(iii) of this section, then the Specified Cooperative must use that method for all of the Specified Cooperative's inventory accounted for under the LIFO method. The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the inventory method. The method must also be reasonable based on all the facts and circumstances. The books and records maintained for the inventory method must be consistent with any allocations under this paragraph (b)(5).

(ii) *LIFO/FIFO ratio method.* The LIFO/FIFO ratio method is applied with respect to the LIFO inventory on a grouping-by-grouping or pool-by-pool basis. Under the LIFO/FIFO ratio method, a Specified Cooperative computes the COGS of a grouping or pool allocable to DPGR by multiplying the COGS of agricultural or horticultural products (defined in § 1.199A–8(a)(4)) in the grouping or pool that produced DPGR computed using the FIFO method by the LIFO/FIFO ratio of the grouping or pool. The LIFO/FIFO ratio of a grouping or pool is equal to the total COGS of the grouping or pool computed using the LIFO method over the total COGS of the grouping or pool computed using the FIFO method.

(iii) *Change in relative base-year cost method.* A Specified Cooperative using the dollar-value LIFO method may use the change in relative base-year cost method. The change in relative base-year cost method for a Specified Cooperative using the dollar-value LIFO method is applied to all LIFO inventory on a pool-by-pool basis. The change in relative base-year cost method determines the COGS allocable to DPGR by increasing or decreasing the total production costs (section 471 costs and additional section 263A costs) of agricultural or horticultural products that generate DPGR by a portion of any increment or liquidation of the dollar-value pool. The portion of an increment or liquidation allocable to DPGR is determined by multiplying the LIFO value of the increment or liquidation (expressed as a positive number) by the ratio of the change in total base-year cost (expressed as a positive number) of agricultural or horticultural products that will generate DPGR in ending inventory to the change in total base-year cost (expressed as a positive number) of all goods in ending inventory. The portion of an increment or liquidation allocable to DPGR may be zero but cannot exceed the amount of the increment or liquidation. Thus, a ratio in excess of 1.0 must be treated as 1.0.

(6) *Specified Cooperative using a simplified method for additional section 263A costs to ending inventory.* A

Specified Cooperative that uses a simplified method specifically described in the section 263A regulations to allocate additional section 263A costs to ending inventory must follow the rules in paragraph (b)(2) of this section to determine the amount of additional section 263A costs allocable to DPGR. Allocable additional section 263A costs include additional section 263A costs included in the Specified Cooperative's beginning inventory as well as additional section 263A costs incurred during the taxable year by the Specified Cooperative. Ordinarily, if the Specified Cooperative uses a simplified method specifically described in the section 263A regulations to allocate its additional section 263A costs to its ending inventory, the additional section 263A costs must be allocated in the same proportion as section 471 costs are allocated.

(c) *Other deductions properly allocable to DPGR or gross income attributable to DPGR*—(1) *In general.* In determining its QPAI, the Specified Cooperative must subtract from its DPGR (in addition to the COGS), the deductions that are properly allocable and apportioned to DPGR. A Specified Cooperative generally must allocate and apportion these deductions using the rules of the section 861 method provided in paragraph (d) of this section. In lieu of the section 861 method, an eligible Specified Cooperative may apportion these deductions using the simplified deduction method provided in paragraph (e) of this section. Paragraph (f) of this section provides a small business simplified overall method that may be used by a qualifying small Specified Cooperative. A Specified Cooperative using the simplified deduction method or the small business simplified overall method must use that method for all deductions. A Specified Cooperative eligible to use the small business simplified overall method may choose at any time for any taxable year to use the small business simplified overall method or the simplified deduction method for a taxable year.

(2) *Treatment of net operating losses.* A deduction under section 172 for a net operating loss (NOL) is not allocated or apportioned to DPGR or gross income attributable to DPGR.

(3) *W–2 wages.* Although only W–2 wages as described in § 1.199A–11 are taken into account in computing the W–2 wage limitation, all wages paid (or incurred in the case of an accrual method taxpayer) in the taxable year are taken into account in computing QPAI for that taxable year.

(d) *Section 861 method.* Under the section 861 method, the Specified Cooperative must allocate and apportion its deductions using the allocation and apportionment rules provided under the section 861 regulations under which section 199A(g) is treated as an operative section described in § 1.861–8(f). Accordingly, the Specified Cooperative applies the rules of the section 861 regulations to allocate and apportion deductions (including, if applicable, its distributive share of deductions from passthrough entities) to gross income attributable to DPGR. If the Specified Cooperative applies the allocation and apportionment rules of the section 861 regulations for section 199A(g) and another operative section, then the Specified Cooperative must use the same method of allocation and the same principles of apportionment for purposes of all operative sections. Research and experimental expenditures must be allocated and apportioned in accordance with § 1.861–17 without taking into account the exclusive apportionment rule of § 1.861–17(b). Deductions for charitable contributions (as allowed under section 170 and section 873(b)(2) or 882(c)(1)(B)) must be ratably apportioned between gross income attributable to DPGR and gross income attributable to non-DPGR based on the relative amounts of gross income.

(e) *Simplified deduction method*—(1) *In general.* An eligible Specified Cooperative (defined in paragraph (e)(2) of this section) may use the simplified deduction method to apportion business deductions between DPGR and non-DPGR. The simplified deduction method does not apply to COGS. Under the simplified deduction method, the business deductions (except the NOL deduction) are ratably apportioned between DPGR and non-DPGR based on relative gross receipts. Accordingly, the amount of deductions for the current taxable year apportioned to DPGR is equal to the proportion of the total business deductions for the current taxable year that the amount of DPGR bears to total gross receipts.

(2) *Eligible Specified Cooperative.* For purposes of this paragraph (e), an eligible Specified Cooperative is—

(i) A Specified Cooperative that has average annual total gross receipts (as defined in paragraph (g) of this section) of $100,000,000 or less; or

(ii) A Specified Cooperative that has total assets (as defined in paragraph (e)(3) of this section) of $10,000,000 or less.

(3) *Total assets.*—(i) *In general.* For purposes of the simplified deduction method, total assets mean the total assets the Specified Cooperative has at the end of the taxable year.

(ii) *Members of an expanded affiliated group.* To compute the total assets of an *expanded affiliated group* (EAG) at the end of the taxable year, the total assets at the end of the taxable year of each member of the EAG at the end of the taxable year that ends with or within the taxable year of the computing member (as described in § 1.199A–12(g)) are aggregated.

(4) *Members of an expanded affiliated group*—(i) *In general.* Whether the members of an EAG may use the simplified deduction method is determined by reference to all the members of the EAG. If the average annual gross receipts of the EAG are less than or equal to $100,000,000 or the total assets of the EAG are less than or equal to $10,000,000, then each member of the EAG may individually determine whether to use the simplified deduction method, regardless of the cost allocation method used by the other members.

(ii) *Exception.* Notwithstanding paragraph (e)(4)(i) of this section, all members of the same consolidated group must use the same cost allocation method.

(f) *Small business simplified overall method*—(1) *In general.* A qualifying small Specified Cooperative may use the small business simplified overall method to apportion COGS and deductions between DPGR and non-DPGR. Under the small business simplified overall method, a Specified Cooperative's total costs for the current taxable year (as defined in paragraph (f)(3) of this section) are apportioned between DPGR and non-DPGR based on relative gross receipts. Accordingly, the amount of total costs for the current taxable year apportioned to DPGR is equal to the proportion of total costs for the current taxable year that the amount of DPGR bears to total gross receipts.

(2) *Qualifying small Specified Cooperative.* For purposes of this paragraph (f), a qualifying small Specified Cooperative is a Specified Cooperative that has average annual total gross receipts (as defined in paragraph (g) of this section) of $25,000,000 or less.

(3) *Total costs for the current taxable year.* For purposes of the small business simplified overall method, total costs for the current taxable year means the total COGS and deductions for the current taxable year. Total costs for the current taxable year are determined under the methods of accounting that the Specified Cooperative uses to compute taxable income.

(4) *Members of an expanded affiliated group*—(i) *In general.* Whether the

members of an EAG may use the small business simplified overall method is determined by reference to all the members of the EAG. If the average annual gross receipts of the EAG are less than or equal to $25,000,000 then each member of the EAG may individually determine whether to use the small business simplified overall method, regardless of the cost allocation method used by the other members.

(ii) *Exception.* Notwithstanding paragraph (f)(4)(i) of this section, all members of the same consolidated group must use the same cost allocation method.

(g) *Average annual gross receipts*—(1) *In general.* For purposes of the simplified deduction method and the small business simplified overall method, average annual gross receipts means the average annual gross receipts of the Specified Cooperative for the 3 taxable years (or, if fewer, the taxable years during which the taxpayer was in existence) preceding the current taxable year, even if one or more of such taxable years began before the effective date of section 199A(g). In the case of any taxable year of less than 12 months (a short taxable year), the gross receipts of the Specified Cooperative are annualized by multiplying the gross receipts for the short period by 12 and dividing the result by the number of months in the short period.

(2) *Members of an expanded affiliated group*—(i) *In general.* To compute the average annual gross receipts of an EAG, the gross receipts for the entire taxable year of each member that is a member of the EAG at the end of its taxable year that ends with or within the taxable year are aggregated. For purposes of this paragraph (g)(2), a consolidated group is treated as one member of an EAG.

(ii) *Exception.* Notwithstanding paragraph (g)(1)(i) of this section, all members of the same consolidated group must use the same cost allocation method.

(h) *Cost allocation methods for determining oil-related QPAI*—(1) *Section 861 method.* A Specified Cooperative that uses the section 861 method to determine deductions that are allocated and apportioned to gross income attributable to DPGR must use the section 861 method to determine deductions that are allocated and apportioned to gross income attributable to oil-related DPGR.

(2) *Simplified deduction method.* A Specified Cooperative that uses the simplified deduction method to apportion deductions between DPGR and non-DPGR must determine the portion of deductions allocable to oil-related DPGR by multiplying the deductions allocable to DPGR by the ratio of oil-related DPGR to DPGR from all activities.

(3) *Small business simplified overall method.* A Specified Cooperative that uses the small business simplified overall method to apportion total costs (COGS and deductions) between DPGR and non-DPGR must determine the portion of total costs allocable to oil-related DPGR by multiplying the total costs allocable to DPGR by the ratio of oil-related DPGR to DPGR from all activities.

(i) *Applicability date.* The provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided the taxpayers apply the rules in their entirety and in a consistent manner.

§ 1.199A–11 Wage limitation for the section 199A(g) deduction.

(a) *Rules of application*—(1) *In general.* The provisions of this section apply solely for purposes of section 199A(g) of the Internal Revenue Code (Code). The provisions of this section provide guidance on determining the W–2 wage limitation as defined in § 1.199A–8(b)(5)(ii)(B). Except as provided in paragraph (d)(2) of this section, the Form W–2, Wage and Tax Statement, or any subsequent form or document used in determining the amount of W–2 wages, are those issued for the calendar year ending during the taxable year of the Specified Cooperative (defined in § 1.199A–8(a)(2)) for wages paid to employees (or former employees) of the Specified Cooperative for employment by the Specified Cooperative. Employees are limited to employees defined in section 3121(d)(1) and (2) (that is, officers of a corporate taxpayer and employees of the taxpayer under the common law rules). See paragraph (a)(5) of this section for the requirement that W–2 wages must have been included in a return filed with the Social Security Administration (SSA) within 60 days after the due date (including extensions) of the return. *See also* section 199A(a)(4)(C).

(2) *Wage limitation for section 199A(g) deduction.* The amount of the deduction allowable under section 199A(g) to the Specified Cooperative for any taxable year cannot exceed 50 percent of the W–2 wages (as defined in section 199A(g)(1)(B)(ii) and paragraph (b) of this section) for the taxable year that are attributable to domestic production gross receipts (DPGR), defined in § 1.199A–8(b)(3)(ii), of agricultural or horticultural products defined in § 1.199A–8(a)(4).

(3) *Wages paid by entity other than common law employer.* In determining W–2 wages, the Specified Cooperative may take into account any W–2 wages paid by another entity and reported by the other entity on Forms W–2 with the other entity as the employer listed in Box c of the Forms W–2, provided that the W–2 wages were paid to common law employees or officers of the Specified Cooperative for employment by the Specified Cooperative. In such cases, the entity paying the W–2 wages and reporting the W–2 wages on Forms W–2 is precluded from taking into account such wages for purposes of determining W–2 wages with respect to that entity. For purposes of this paragraph (a)(4), entities that pay and report W–2 wages on behalf of or with respect to other taxpayers can include, but are not limited to, certified professional employer organizations under section 7705, statutory employers under section 3401(d)(1), and agents under section 3504.

(4) *Requirement that wages must be reported on return filed with the Social Security Administration*—(i) *In general.* Pursuant to section 199A(g)(1)(B)(ii) and section 199A(b)(4)(C), the term W–2 wages does not include any amount that is not properly included in a return filed with SSA on or before the 60th day after the due date (including extensions) for such return. Under § 31.6051–2 of this chapter, each Form W–2 and the transmittal Form W–3, Transmittal of Wage and Tax Statements, together constitute an information return to be filed with SSA. Similarly, each Form W–2c, Corrected Wage and Tax Statement, and the transmittal Form W–3 or W–3c, Transmittal of Corrected Wage and Tax Statements, together constitute an information return to be filed with SSA. In determining whether any amount has been properly included in a return filed with SSA on or before the 60th day after the due date (including extensions) for such return, each Form W–2 together with its accompanying Form W–3 is considered a separate information return and each Form W–2c together with its accompanying Form W–3 or Form W–3c is considered a separate information return. Section 6071(c) provides that Forms W–2 and W–3 must be filed on or before January 31 of the year following the calendar year to which such returns relate (but see the special rule in § 31.6071(a)–1T(a)(3)(1) of this chapter for monthly returns filed under § 31.6011(a)–5(a) of this chapter). Corrected Forms W–2 are required to be filed with SSA on or before January 31

of the year following the year in which the correction is made.

(ii) *Corrected return filed to correct a return that was filed within 60 days of the due date.* If a corrected information return (Return B) is filed with SSA on or before the 60th day after the due date (including extensions) of Return B to correct an information return (Return A) that was filed with SSA on or before the 60th day after the due date (including extensions) of the information return (Return A) and paragraph (a)(5)(iii) of this section does not apply, then the wage information on Return B must be included in determining W–2 wages. If a corrected information return (Return D) is filed with SSA later than the 60th day after the due date (including extensions) of Return D to correct an information return (Return C) that was filed with SSA on or before the 60th day after the due date (including extensions) of the information return (Return C), then if Return D reports an increase (or increases) in wages included in determining W–2 wages from the wage amounts reported on Return C, such increase (or increases) on Return D is disregarded in determining W–2 wages (and only the wage amounts on Return C may be included in determining W–2 wages). If Return D reports a decrease (or decreases) in wages included in determining W–2 wages from the amounts reported on Return C, then, in determining W–2 wages, the wages reported on Return C must be reduced by the decrease (or decreases) reflected on Return D.

(iii) *Corrected return filed to correct a return that was filed later than 60 days after the due date.* If an information return (Return F) is filed to correct an information return (Return E) that was not filed with SSA on or before the 60th day after the due date (including extensions) of Return E, then Return F (and any subsequent information returns filed with respect to Return E) will not be considered filed on or before the 60th day after the due date (including extensions) of Return F (or the subsequent corrected information return). Thus, if a Form W–2c is filed to correct a Form W–2 that was not filed with SSA on or before the 60th day after the due date (including extensions) of the Form W–2 (or to correct a Form W–2c relating to a Form W–2 that had not been filed with SSA on or before the 60th day after the due date (including extensions) of the Form W–2), then this Form W–2c is not to be considered to have been filed with SSA on or before the 60th day after the due date (including extensions) for this Form W–2c, regardless of when the Form W–2c is filed.

(b) *Definition of W–2 wages*—(1) *In general.* Section 199A(g)(1)(B)(ii) provides that the W–2 wages of the Specified Cooperative must be determined in the same manner as under section 199A(b)(4) (without regard to section 199A(b)(4)(B) and after application of section 199A(b)(5)). Section 199A(b)(4)(A) provides that the term W–2 wages means with respect to any person for any taxable year of such person, the amounts described in paragraphs (3) and (8) of section 6051(a) paid by such person with respect to employment of employees by such person during the calendar year ending during such taxable year. Thus, the term W–2 wages includes the total amount of wages as defined in section 3401(a); the total amount of elective deferrals (within the meaning of section 402(g)(3)); the compensation deferred under section 457; and the amount of designated Roth contributions (as defined in section 402A).

(2) *Section 199A(g) deduction.* Pursuant to section 199A(g)(3)(A), W–2 wages do not include any amount which is not properly allocable to DPGR for purposes of calculating qualified production activities income (QPAI) as defined in § 1.199A–8(b)(4)(ii). The Specified Cooperative may determine the amount of wages that is properly allocable to DPGR using a reasonable method based on all the facts and circumstances. The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the wages allocable to DPGR for purposes of QPAI. The books and records maintained for wages allocable to DPGR for purposes of QPAI must be consistent with any allocations under this paragraph (b)(2).

(c) *Methods for calculating W–2 wages.* The Secretary may provide for methods that may be used in calculating W–2 wages, including W–2 wages for short taxable years by publication in the Internal Revenue Bulletin (*see* § 601.601(d)(2)(ii)(b) of this chapter).

(d) *Wage limitation—acquisitions, dispositions, and short taxable years*—(1) *In general.* For purposes of computing the deduction under section 199A(g) of the Specified Cooperative, in the case of an acquisition or disposition (as defined in section 199A(b)(5) and paragraph (d)(3) of this section) that causes more than one Specified Cooperative to be an employer of the employees of the acquired or disposed of Specified Cooperative during the calendar year, the W–2 wages of the Specified Cooperative for the calendar year of the acquisition or disposition are allocated between or among each Specified Cooperative based on the period during which the employees of the acquired or disposed of Specified Cooperatives were employed by the Specified Cooperative, regardless of which permissible method is used for reporting predecessor and successor wages on Form W–2, Wage and Tax Statement.

(2) *Short taxable year that does not include December 31.* If the Specified Cooperative has a short taxable year that does not contain a calendar year ending during such short taxable year, wages paid to employees for employment by the Specified Cooperative during the short taxable year are treated as W–2 wages for such short taxable year for purposes of paragraph (a) of this section (if the wages would otherwise meet the requirements to be W–2 wages under this section but for the requirement that a calendar year must end during the short taxable year).

(3) *Acquisition or disposition.* For purposes of paragraph (d)(1) and (2) of this section, the terms *acquisition* and *disposition* include an incorporation, a liquidation, a reorganization, or a purchase or sale of assets.

(e) *Application in the case of a Specified Cooperative with a short taxable year.* In the case of a Specified Cooperative with a short taxable year, subject to the rules of paragraph (a) of this section, the W–2 wages of the Specified Cooperative for the short taxable year can include only those wages paid during the short taxable year to employees of the Specified Cooperative, only those elective deferrals (within the meaning of section 402(g)(3)) made during the short taxable year by employees of the Specified Cooperative, and only compensation actually deferred under section 457 during the short taxable year with respect to employees of the Specified Cooperative.

(f) *Non-duplication rule.* Amounts that are treated as W–2 wages for a taxable year under any method cannot be treated as W–2 wages of any other taxable year. Also, an amount cannot be treated as W–2 wages by more than one taxpayer. Finally, an amount cannot be treated as W–2 wages by the Specified Cooperative both in determining patronage and nonpatronage W–2 wages.

(g) *Wage expense safe harbor*—(1) *In general.* A Specified Cooperative using either the section 861 method of cost allocation under § 1.199A–10(d) or the simplified deduction method under § 1.199A–10(e) may determine the amount of W–2 wages that are properly allocable to DPGR for a taxable year by multiplying the amount of W–2 wages determined under paragraph (b)(1) of

this section for the taxable year by the ratio of the Specified Cooperative's wage expense included in calculating QPAI for the taxable year to the Specified Cooperative's total wage expense used in calculating the Specified Cooperative's taxable income for the taxable year, without regard to any wage expense disallowed by section 465, 469, 704(d), or 1366(d). A Specified Cooperative that uses either the section 861 method of cost allocation or the simplified deduction method to determine QPAI must use the same expense allocation and apportionment methods that it uses to determine QPAI to allocate and apportion wage expense for purposes of this safe harbor. For purposes of this paragraph (g)(1), the term wage expense means wages (that is, compensation paid by the employer in the active conduct of a trade or business to its employees) that are properly taken into account under the Specified Cooperative's method of accounting.

(2) *Wage expense included in cost of goods sold.* For purposes of paragraph (g)(1) of this section, a Specified Cooperative may determine its wage expense included in cost of goods sold (COGS) using a reasonable method based on all the facts and circumstances, such as using the amount of direct labor included in COGS or using section 263A labor costs (as defined in § 1.263A–1(h)(4)(ii)) included in COGS. The chosen reasonable method must be consistently applied from one taxable year to another and must clearly reflect the portion of wage expense included in COGS. The method must also be reasonable based on all the facts and circumstances. The books and records maintained for wage expense included in COGS must be consistent with any allocations under this paragraph (g)(2).

(3) *Small business simplified overall method safe harbor.* The Specified Cooperative that uses the small business simplified overall method under § 1.199A–10(f) may use the small business simplified overall method safe harbor for determining the amount of W–2 wages determined under paragraph (b)(1) of this section that is properly allocable to DPGR. Under this safe harbor, the amount of W–2 wages determined under paragraph (b)(1) of this section that is properly allocable to DPGR is equal to the same proportion of W–2 wages determined under paragraph (b)(1) of this section that the amount of DPGR bears to the Specified Cooperative's total gross receipts.

(h) *Applicability date.* The provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided the taxpayers apply the rules in their entirety and in a consistent manner.

§ 1.199A–12 Expanded affiliated groups.

(a) *In general.* The provisions of this section apply solely for purposes of section 199A(g) of the Internal Revenue Code (Code). Except as otherwise provided in the Code or regulations issued under the relevant section of the Code (for example, sections 199A(g)(3)(D)(ii) and 267, § 1.199A–8(c), paragraph (a)(3) of this section, and the consolidated return regulations under section 1502), each nonexempt Specified Cooperative (defined in § 1.199A–8(a)(2)(ii)) that is a member of an expanded affiliated group (EAG) (defined in paragraph (a)(1) of this section) computes its own taxable income or loss, qualified production activities income (QPAI) (defined in § 1.199A–8(b)(4)(ii)), and W–2 wages (defined in § 1.199A–11(b)). For purposes of this section unless otherwise specified, the term *Specified Cooperative* means a nonexempt Specified Cooperative. If a Specified Cooperative is also a member of a consolidated group, see paragraph (d) of this section.

(1) *Definition of an expanded affiliated group.* An EAG is an affiliated group as defined in section 1504(a), determined by substituting ''more than 50 percent'' for ''at least 80 percent'' in each place it appears and without regard to section 1504(b)(2) and (4).

(2) *Identification of members of an expanded affiliated group*—(i) *In general.* Each Specified Cooperative must determine if it is a member of an EAG on a daily basis.

(ii) *Becoming or ceasing to be a member of an expanded affiliated group.* If a Specified Cooperative becomes or ceases to be a member of an EAG, the Specified Cooperative is treated as becoming or ceasing to be a member of the EAG at the end of the day on which its status as a member changes.

(3) *Attribution of activities*—(i) *In general.* Except as provided in paragraph (a)(3)(iv) of this section, if a Specified Cooperative that is a member of an EAG (disposing member) derives gross receipts (defined in § 1.199A–8(b)(2)(iii)) from the lease, rental, license, sale, exchange, or other disposition (defined in § 1.199A–9(j)) of agricultural or horticultural products (defined in § 1.199A–8(a)(4)) that were manufactured, produced, grown or extracted (MPGE) (defined in § 1.199A–9(f)), in whole or significant part (defined in § 1.199A–9(h)), in the United States (defined in § 1.199A–9(i)) by another Specified Cooperative, then the disposing member is treated as conducting the previous activities conducted by such other Specified Cooperative with respect to the agricultural or horticultural products in determining whether its gross receipts are domestic production gross receipts (DPGR) (defined in § 1.199A–8(b)(3)(ii)) if—

(A) Such property was MPGE by such other Specified Cooperative, and

(B) The disposing member is a member of the same EAG as such other Specified Cooperative at the time that the disposing member disposes of the agricultural or horticultural products.

(ii) *Date of disposition for leases, rentals, or licenses.* Except as provided in paragraph (a)(3)(iv) of this section, with respect to a lease, rental, or license, the disposing member described in paragraph (a)(3)(i) of this section is treated as having disposed of the agricultural or horticultural products on the date or dates on which it takes into account the gross receipts derived from the lease, rental, or license under its methods of accounting.

(iii) *Date of disposition for sales, exchanges, or other dispositions.* Except as provided in paragraph (a)(3)(iv) of this section, with respect to a sale, exchange, or other disposition, the disposing member is treated as having disposed of the agricultural or horticultural products on the date on which it ceases to own the agricultural or horticultural products for Federal income tax purposes, even if no gain or loss is taken into account.

(iv) *Exception.* A Specified Cooperative is not attributed nonpatronage activities conducted by another Specified Cooperative. *See* § 1.199A–8(b)(2)(ii).

(4) *Marketing Specified Cooperatives.* A Specified Cooperative is treated as having MPGE in whole or significant part any agricultural or horticultural product within the United States marketed by the Specified Cooperative which its patrons have so MPGE. Patrons are defined in § 1.1388–1(e).

(5) *Anti-avoidance rule.* If a transaction between members of an EAG is engaged in or structured with a principal purpose of qualifying for, or increasing the amount of, the section 199A(g) deduction of the EAG or the portion of the section 199A(g) deduction allocated to one or more members of the EAG, the Secretary may make adjustments to eliminate the effect of the transaction on the computation of the section 199A(g) deduction.

(b) *Computation of EAG's section 199A(g) deduction.*—(1) *In general.* The section 199A(g) deduction for an EAG is determined by separately computing the section 199A(g) deduction from the patronage sources of Specified Cooperatives that are members of the EAG. The section 199A(g) deduction from patronage sources of Specified Cooperatives is determined by aggregating the income or loss, QPAI, and W–2 wages, if any, of each patronage source of a Specified Cooperative that is a member of the EAG. For purposes of this determination, a member's QPAI may be positive or negative. A Specified Cooperative's taxable income or loss and QPAI is determined by reference to the Specified Cooperative's method of accounting. For purposes of determining the section 199A(g) deduction for an EAG, taxable income or loss, QPAI, and W–2 wages of a Specified Cooperative from nonpatronage sources are considered to be zero, other than as allowed under § 1.199A–8(b)(2)(ii).

(2) *Example.* The following example illustrates the application of paragraph (b)(1) of this section.

(i) *Facts.* Nonexempt Specified Cooperatives X, Y, and Z, calendar year taxpayers, are the only members of an EAG and are not members of a consolidated group. X has patronage source taxable income of $50,000, QPAI of $15,000, and W–2 wages of $0. Y has patronage source taxable income of ($20,000), QPAI of ($1,000), and W–2 wages of $750. Z has patronage source taxable income of $0, QPAI of $0, and W–2 wages of $3,000.

(ii) *Analysis.* In determining the EAG's section 199A(g) deduction, the EAG aggregates each member's patronage source taxable income or loss, QPAI, and W–2 wages. Thus, the EAG has patronage source taxable income of $30,000, the sum of X's patronage source taxable income of $50,000, Y's patronage source taxable income of ($20,000), and Z's patronage source taxable income of $0. The EAG has QPAI of $14,000, the sum of X's QPAI of $15,000, Y's QPAI of ($1,000), and Z's QPAI of $0. The EAG has W–2 wages of $3,750, the sum of X's W–2 wages of $0, Y's W–2 wages of $750, and Z's W–2 wages of $3,000. Accordingly, the EAG's section 199A(g) deduction equals $1,260, 9% of $14,000, the lesser of the QPAI and patronage source taxable income, but not greater than $1,875, 50% of its W–2 wages of $3,750. This result would be the same if X had a nonpatronage source income or loss, because nonpatronage source income of a nonexempt Specified Cooperative is not taken into account in determining the section 199A(g) deduction.

(3) *Net operating loss carryovers/carrybacks.* In determining the taxable income of an EAG, if a Specified Cooperative has a net operating loss (NOL) from its patronage sources that may be carried over or carried back (in accordance with section 172) to the taxable year, then for purposes of determining the taxable income of the Specified Cooperative, the amount of the NOL used to offset taxable income cannot exceed the taxable income of the patronage source of that Specified Cooperative.

(4) *Losses used to reduce taxable income of an expanded affiliated group.* The amount of an NOL sustained by a Specified Cooperative member of an EAG that is used in the year sustained in determining an EAG's taxable income limitation under § 1.199A–8(b)(5)(ii)(C) is not treated as an NOL carryover to any taxable year in determining the taxable income limitation under § 1.199A–8(b)(5)(ii)(C). For purposes of this paragraph (b)(4), an NOL is considered to be used if it reduces an EAG's aggregate taxable income from patronage sources or nonpatronage sources, as the case may be, regardless of whether the use of the NOL actually reduces the amount of the section 199A(g) deduction that the EAG would otherwise derive. An NOL is not considered to be used to the extent that it reduces an EAG's aggregate taxable income from patronage sources to an amount less than zero. If more than one Specified Cooperative has an NOL used in the same taxable year to reduce the EAG's taxable income from patronage sources, the respective NOLs are deemed used in proportion to the amount of each Specified Cooperative's NOL.

(5) *Example.* The following example illustrates the application of paragraph (b)(4) of this section.

(i) *Facts.* Nonexempt Specified Cooperatives A and B are the only two members of an EAG. A and B are both calendar year taxpayers and they do not join in the filing of a consolidated Federal income tax return. Neither A nor B had taxable income or loss prior to 2020. In 2020, A has patronage QPAI and patronage taxable income of $1,000 and B has patronage QPAI of $1,000 and a patronage NOL of $1,500. A also has nonpatronage income of $3,000. B has no activities other than from its patronage activities. In 2021, A has patronage QPAI of $2,000 and patronage taxable income of $1,000 and B has patronage QPAI of $2,000 and patronage taxable income prior to the NOL deduction allowed under section 172 of $2,000. Neither A nor B has nonpatronage activities in 2021. A's and B's patronage activities have aggregate W–2 wages in excess of the section 199A(g)(1)(B) wage limitation in both 2020 and 2021.

(ii) *Section 199A(g) deduction for 2020.* In determining the EAG's section 199A(g) deduction for 2020, A's $1,000 of QPAI and B's $1,000 of QPAI are aggregated, as are A's $1,000 of taxable income from its patronage activities and B's $1,500 NOL from its patronage activities. A's nonpatronage income is not included. Thus, for 2020, the EAG has patronage QPAI of $2,000 and patronage taxable income of ($500). The EAG's section 199A(g) deduction for 2020 is 9% of the lesser of its patronage QPAI or its patronage taxable income. Because the EAG has a taxable loss from patronage sources in 2020, the EAG's section 199A(g) deduction is $0.

(iii) *Section 199A(a) deduction for 2021.* In determining the EAG's section 199A deduction for 2021, A's patronage QPAI of $2,000 and B's patronage QPAI of $2,000 are aggregated, resulting in the EAG having patronage QPAI of $4,000. Also, $1,000 of B's patronage NOL from 2020 was used in 2020 to reduce the EAG's taxable income from patronage sources to $0. The remaining $500 of B's patronage NOL from 2020 is not considered to have been used in 2020 because it reduced the EAG's patronage taxable income to less than $0. Accordingly, for purposes of determining the EAG's taxable income limitation under § 1.199A–8(b)(5) in 2021, B is deemed to have only a $500 NOL carryover from its patronage sources from 2020 to offset a portion of its 2021 taxable income from its patronage sources. Thus, B's taxable income from its patronage sources in 2021 is $1,500, which is aggregated with A's $1,000 of taxable income from its patronage sources. The EAG's taxable income limitation in 2021 is $2,500. The EAG's section 199A(g) deduction is 9% of the lesser of its patronage sourced QPAI of $4,000 and its taxable income from patronage sources of $2,500. Thus, the EAG's section 199A(g) deduction in 2021 is 9% of $2,500, or $225. The results for 2021 would be the same if neither A nor B had patronage sourced QPAI in 2020.

(c) *Allocation of an expanded affiliated group's section 199A(g) deduction among members of the expanded affiliated group*—(1) *In general.* An EAG's section 199A(g) deduction from its patronage sources, as determined in paragraph (b) of this section, is allocated among the Specified Cooperatives that are members of the EAG in proportion to

each Specified Cooperative's patronage QPAI, regardless of whether the Specified Cooperative has patronage taxable income or W–2 wages for the taxable year. For these purposes, if a Specified Cooperative has negative patronage QPAI, such QPAI is treated as zero. Pursuant to § 1.199A–8(b)(6), a patronage section 199A(g) deduction can be applied only against patronage income and deductions.

(2) *Use of section 199A(g) deduction to create or increase a net operating loss.* If a Specified Cooperative that is a member of an EAG has some or all of the EAG's section 199A(g) deduction allocated to it under paragraph (c)(1) of this section and the amount allocated exceeds patronage taxable income, determined as described in this section and prior to allocation of the section 199A(g) deduction, the section 199A(g) deduction will create an NOL for the patronage source. Similarly, if a Specified Cooperative that is a member of an EAG, prior to the allocation of some or all of the EAG's section 199A(g) deduction to the member, has a patronage NOL for the taxable year, the portion of the EAG's section 199A(g) deduction allocated to the member will increase such NOL.

(d) *Special rules for members of the same consolidated group*—(1) *Intercompany transactions.* In the case of an intercompany transaction between consolidated group members S and B (as the terms intercompany transaction, S, and B are defined in § 1.1502–13(b)(1)), S takes the intercompany transaction into account in computing the section 199A(g) deduction at the same time and in the same proportion as S takes into account the income, gain, deduction, or loss from the intercompany transaction under § 1.1502–13.

(2) *Application of the simplified deduction method and the small business simplified overall method.* For purposes of applying the simplified deduction method under § 1.199A–10(e) and the small business simplified overall method under § 1.199A–10(f), a Specified Cooperative that is part of a consolidated group determines its QPAI using its members' DPGR, non-DPGR, cost of goods sold (COGS), and all other deductions, expenses, or losses (hereinafter deductions), determined after the application of § 1.1502–13.

(3) *Determining the section 199A(g) deduction*—(i) *Expanded affiliated group consists of consolidated group and non-consolidated group members.* In determining the section 199A(g) deduction, if an EAG includes Specified Cooperatives that are members of the same consolidated group and Specified Cooperatives that are not members of the same consolidated group, the consolidated taxable income or loss, QPAI, and W–2 wages, from patronage sources, if any, of the consolidated group (and not the separate taxable income or loss, QPAI, and W–2 wages from patronage sources of the members of the consolidated group), are aggregated with the taxable income or loss, QPAI, and W–2 wages, from patronage sources, if any, of the non-consolidated group members. For example, if A, B, C, S1, and S2 are Specified Cooperatives that are members of the same EAG, and A, S1, and S2 are members of the same consolidated group (the A consolidated group), then the A consolidated group is treated as one member of the EAG. Accordingly, the EAG is considered to have three members—the A consolidated group, B, and C. The consolidated taxable income or loss, QPAI, and W–2 wages from patronage sources, if any, of the A consolidated group are aggregated with the taxable income or loss from patronage sources, QPAI, and W–2 wages, if any, of B and C in determining the EAG's section 199A(g) deduction from patronage sources. Pursuant to § 1.199A–8(b)(6), a patronage section 199A(g) deduction can be applied only against patronage income and deductions.

(ii) *Expanded affiliated group consists only of members of a single consolidated group.* If all of the Specified Cooperatives that are members of an EAG are also members of the same consolidated group, the consolidated group's section 199A(g) deduction is determined using the consolidated group's consolidated taxable income or loss, QPAI, and W–2 wages, from patronage sources rather than the separate taxable income or loss, QPAI, and W–2 wages from patronage sources of its members.

(4) *Allocation of the section 199A(g) deduction of a consolidated group among its members.* The section 199A(g) deduction from patronage sources of a consolidated group (or the section 199A(g) deduction allocated to a consolidated group that is a member of an EAG) is allocated among the patronage sources of Specified Cooperatives in proportion to each Specified Cooperative's patronage QPAI, regardless of whether the Specified Cooperative has patronage separate taxable income or W–2 wages for the taxable year. In allocating the section 199A(g) deduction of a patronage source of a Specified Cooperative that is part of a consolidated group among patronage sources of other members of the same group, any redetermination of a member's patronage receipts, COGS, or other deductions from an intercompany transaction under § 1.1502–13(c)(1)(i) or (c)(4) is not taken into account for purposes of section 199A(g). Also, for purposes of this allocation, if a patronage source of a Specified Cooperative that is a member of a consolidated group has negative QPAI, the QPAI of the patronage source is treated as zero.

(e) *Examples.* The following examples illustrate the application of paragraphs (a) through (d) of this section.

(i) *Example 1.* Specified Cooperatives X, Y, and Z are members of the same EAG but are not members of a consolidated group. X, Y, and Z each files Federal income tax returns on a calendar year basis. None of X, Y, or Z have activities other than from its patronage sources. Prior to 2020, X had no taxable income or loss. In 2020, X has taxable income of $0, QPAI of $2,000, and W–2 wages of $0, Y has taxable income of $4,000, QPAI of $3,000, and W–2 wages of $500, and Z has taxable income of $4,000, QPAI of $5,000, and W–2 wages of $2,500. Accordingly, the EAG's patronage source taxable income is $8,000, the sum of X's taxable income of $0, Y's taxable income of $4,000, and Z's taxable income of $4,000. The EAG has QPAI of $10,000, the sum of X's QPAI of $2,000, Y's QPAI of $3,000, and Z's QPAI of $5,000. The EAG's W–2 wages are $3,000, the sum of X's W–2 wages of $0, Y's W–2 wages of $500, and Z's W–2 wages of $2,500. Thus, the EAG's section 199A(g) deduction for 2020 is $720 (9% of the lesser of the EAG's patronage source taxable income of $8,000 and the EAG's QPAI of $10,000, but no greater than 50% of its W–2 wages of $3,000, that is $1,500). Pursuant to paragraph (c)(1) of this section, the $720 section 199A(g) deduction is allocated to X, Y, and Z in proportion to their respective amounts of QPAI, that is $144 to X ($720 × $2,000/$10,000), $216 to Y ($720 × $3,000/$10,000), and $360 to Z ($720 × $5,000/$10,000). Although X's patronage source taxable income for 2020 determined prior to allocation of a portion of the EAG's section 199A(g) deduction to it was $0, pursuant to paragraph (c)(2) of this section, X will have an NOL from its patronage source for 2020 equal to $144, which will be a carryover to 2021.

(ii) *Example 2.* (A) *Facts.* Corporation X is the common parent of a consolidated group, consisting of X and Y, which has filed a consolidated Federal income tax return for many years. Corporation P is the common parent of a consolidated group, consisting of P and S, which has filed

a consolidated Federal income tax return for many years. The X and P consolidated groups each file their consolidated Federal income tax returns on a calendar year basis. X, Y, P, and S are each Specified Cooperatives, and none of X, Y, P, or S has ever had activities other than from its patronage sources. The X consolidated group and the P consolidated group are members of the same EAG in 2021. In 2020, the X consolidated group incurred a consolidated net operating loss (CNOL) of $25,000. Neither P nor S (nor the P consolidated group) has ever incurred an NOL. In 2021, the X consolidated group has (prior to the deduction under section 172) taxable income of $8,000 and the P consolidated group has taxable income of $20,000. X's QPAI is $8,000, Y's QPAI is ($13,000), P's QPAI is $16,000 and S's QPAI is $4,000. There are sufficient W–2 wages to exceed the section 199A(g)(1)(B) limitation.

(B) *Analysis.* The X consolidated group uses $8,000 of its CNOL from 2020 to offset the X consolidated group's taxable income in 2021. None of the X consolidated group's remaining CNOL may be used to offset taxable income of the P consolidated group under paragraph (b)(3) of this section. Accordingly, for purposes of determining the EAG's section 199A(g) deduction for 2021, the EAG has taxable income of $20,000 (the X consolidated group's taxable income, after the deduction under section 172, of $0 plus the P consolidated group's taxable income of $20,000). The EAG has QPAI of $15,000 (the X consolidated group's QPAI of ($5,000) (X's $8,000 + Y's ($13,000)), and the P consolidated group's QPAI of $20,000 (P's $16,000 + S's $4,000)). The EAG's section 199A(g) deduction equals $1,350, 9% of the lesser of its taxable income of $20,000 and its QPAI of $15,000. The section 199A(g) deduction is allocated between the X and P consolidated groups in proportion to their respective QPAI. Because the X consolidated group has negative QPAI, all of the section 199A(g) deduction of $1,350 is allocated to the P consolidated group. This $1,350 is allocated between P and S, the members of the P consolidated group, in proportion to their QPAI. Accordingly, P is allocated $1,080 ($1,350 × ($16,000/$20,000) and S is allocated $270 ($1,350 × $4,000/$20,000)).

(f) *Allocation of patronage income and loss by a Specified Cooperative that is a member of the expanded affiliated group for only a portion of the year*—(1) *In general.* A Specified Cooperative that becomes or ceases to be a member of an EAG during its taxable year must allocate its taxable income or loss, QPAI, and W–2 wages between the portion of the taxable year that the Specified Cooperative is a member of the EAG and the portion of the taxable year that the Specified Cooperative is not a member of the EAG. This allocation of items is made by using the pro rata allocation method described in this paragraph (f)(1). Under the pro rata allocation method, an equal portion of patronage taxable income or loss, QPAI, and W–2 wages is assigned to each day of the Specified Cooperative's taxable year. Those items assigned to those days that the Specified Cooperative was a member of the EAG are then aggregated.

(2) *Coordination with rules relating to the allocation of income under § 1.1502–76(b).* If § 1.1502–76(b) (relating to items included in a consolidated return) applies to a Specified Cooperative that is a member of an EAG, then any allocation of items required under this paragraph (f) is made only after the allocation of the items pursuant to § 1.1502–76(b).

(g) *Total section 199A(g) deduction for a Specified Cooperative that is a member of an expanded affiliated group for some or all of its taxable year*—(1) *Member of the same EAG for the entire taxable year.* If a Specified Cooperative is a member of the same EAG for its entire taxable year, the Specified Cooperative's section 199A(g) deduction for the taxable year is the amount of the section 199A(g) deduction allocated to it by the EAG under paragraph (c)(1) of this section.

(2) *Member of the expanded affiliated group for a portion of the taxable year.* If a Specified Cooperative is a member of an EAG for only a portion of its taxable year and is either not a member of any EAG or is a member of another EAG, or both, for another portion of the taxable year, the Specified Cooperative's section 199A(g) deduction for the taxable year is the sum of its section 199A(g) deductions for each portion of the taxable year.

(3) *Example.* The following example illustrates the application of paragraphs (f) and (g) of this section.

(i) *Facts.* Specified Cooperatives X and Y, calendar year taxpayers, are members of the same EAG for the entire 2020 taxable year. Specified Cooperative Z, also a calendar year taxpayer, is a member of the EAG of which X and Y are members for the first half of 2020 and not a member of any EAG for the second half of 2020. None of X, Y, or Z have activities other than from its patronage sources. Assume that X, Y, and Z each has W–2 wages in excess of the section 199A(g)(1)(B) wage limitation for all relevant periods. In 2020, X has taxable income of $2,000 and QPAI of $600, Y has taxable loss of $400 and QPAI of ($200), and Z has taxable income of $1,400 and QPAI of $2,400.

(ii) *Analysis.* Pursuant to the pro rata allocation method, $700 of Z's 2020 taxable income and $1,200 of its QPAI are allocated to the first half of the 2020 taxable year (the period in which Z is a member of the EAG) and $700 of Z's 2020 taxable income and $1,200 of its QPAI are allocated to the second half of the 2020 taxable year (the period in which Z is not a member of any EAG). Accordingly, in 2020, the EAG has taxable income from patronage sources of $2,300 ($2,000 + ($400) + $700) and QPAI of $1,600 ($600 + ($200) + $1,200). The EAG's section 199A(g) deduction for 2020 is $144 (9% of the lesser of the EAG's taxable income of $2,300 or QPAI of $1,600). Pursuant to § 1.199A–12(c)(1), this $144 deduction is allocated to X, Y, and Z in proportion to their respective QPAI. Accordingly, X is allocated $48 of the EAG's section 199A(g) deduction ($144 × ($600/($600 + $0 + $1,200))), Y is allocated $0 of the EAG's section 199A(g) deduction ($144 × ($0/($600 + $0 + $1,200))), and Z is allocated $96 of the EAG's section 199A(g) deduction ($144 × ($1,200/($600 + $0 + $1,200))). For the second half of 2020, Z has taxable income of $700 and QPAI of $1,200. Therefore, for the second half of 2020, Z has a section 199A(g) deduction of $63 (9% of the lesser of its taxable income of $700 or its QPAI of $1,200). Accordingly, X's 2020 section 199A(g) deduction is $48 and Y's 2020 section 199A(g) deduction is $0. Z's 2020 section 199A(g) deduction is $159, the sum of $96, the portion of the EAG's section 199A(g) deduction allocated to Z for the first half of 2020 and Z's $63 section 199A(g) deduction for the second half of 2020.

(h) *Computation of section 199A(g) deduction for members of an expanded affiliated group with different taxable years*—(1) *In general.* If Specified Cooperatives that are members of an EAG have different taxable years, in determining the section 199A(g) deduction of a member (the computing member), the computing member is required to take into account the taxable income or loss, determined without regard to the section 199A(g) deduction, QPAI, and W–2 wages of each other group member that are both—

(i) Attributable to the period that each other member of the EAG and the computing member are members of the EAG; and

(ii) Taken into account in a taxable year that begins after the effective date of section 199A(g) and ends with or within the taxable year of the computing

member with respect to which the section 199A(g) deduction is computed.

(2) *Example.* The following example illustrates the application of this paragraph (h).

(i) *Facts.* Specified Cooperatives X, Y, and Z are members of the same EAG. Neither X, Y, nor Z is a member of a consolidated group. X and Y are calendar year taxpayers and Z is a June 30 fiscal year taxpayer. Z came into existence on July 1, 2020. None of X, Y, or Z have activities other than from its patronage sources. Each Specified Cooperative has taxable income that exceeds its QPAI and W–2 wages in excess of the section 199A(g)(1)(B) wage limitation. For the taxable year ending December 31, 2020, X's QPAI is $8,000 and Y's QPAI is ($6,000). For its taxable year ending June 30, 2021, Z's QPAI is $2,000.

(ii) *2020 Computation.* In computing X's and Y's respective section 199A(g) deductions for their taxable years ending December 31, 2020, X's taxable income or loss, QPAI and W–2 wages and Y's taxable income or loss, QPAI, and W–2 wages from their respective taxable years ending December 31, 2020, are aggregated. The EAG's QPAI for this purpose is $2,000 (X's QPAI of $8,000 + Y's QPAI of ($6,000)). Accordingly, the EAG's section 199A(g) deduction is $180 (9% × $2,000). The $180 deduction is allocated to each of X and Y in proportion to their respective QPAI as a percentage of the QPAI of each member of the EAG that was taken into account in computing the EAG's section 199A(g) deduction. Pursuant to paragraph (c)(1) of this section, in allocating the section 199A(g) deduction between X and Y, because Y's QPAI is negative, Y's QPAI is treated as being $0. Accordingly, X's section 199A(g) deduction for its taxable year ending December 31, 2020, is $180 ($180 × $8,000/($8,000 + $0)). Y's section 199A(g) deduction for its taxable year ending December 31, 2020, is $0 ($180 × $0/($8,000 + $0)).

(iii) *2021 Computation.* In computing Z's section 199A(g) deduction for its taxable year ending June 30, 2021, X's and Y's items from their respective taxable years ending December 31, 2020, are taken into account. Therefore, X's taxable income or loss and Y's taxable income or loss, determined without regard to the section 199A(g) deduction, QPAI, and W–2 wages from their taxable years ending December 31, 2020, are aggregated with Z's taxable income or loss, QPAI, and W–2 wages from its taxable year ending June 30, 2021. The EAG's QPAI is $4,000 (X's QPAI of $8,000 + Y's QPAI of ($6,000) + Z's QPAI of $2,000). The EAG's section 199A(g) deduction is $360 (9% × $4,000). A portion of the $360 deduction is allocated to Z in proportion to its QPAI as a percentage of the QPAI of each member of the EAG that was taken into account in computing the EAG's section 199A(g) deduction. Pursuant to paragraph (c)(1) of this section, in allocating a portion of the $360 deduction to Z, Y's QPAI is treated as being $0 because Y's QPAI is negative. Z's section 199A(g) deduction for its taxable year ending June 30, 2021, is $72 ($360 × ($2,000/($8,000 + $0 + $2,000))).

(i) *Partnership owned by expanded affiliated group*—(1) *In general.* For purposes of section 199A(g)(3)(D) relating to DPGR, if all of the interests in the capital and profits of a partnership are owned by members of a single EAG at all times during the taxable year of such partnership (EAG partnership), then the EAG partnership and all members of that EAG are treated as a single taxpayer during such period.

(2) *Attribution of activities*—(*i*) *In general.* If a Specified Cooperative which is a member of an EAG (disposing member) derives gross receipts from the lease, rental, license, sale, exchange, or other disposition of property that was MPGE by an EAG partnership, all the partners of which are members of the same EAG to which the disposing member belongs at the time that the disposing member disposes of such property, then the disposing member is treated as conducting the MPGE activities previously conducted by the EAG partnership with respect to that property. The previous sentence applies only for those taxable years in which the disposing member is a member of the EAG of which all the partners of the EAG partnership are members for the entire taxable year of the EAG partnership. With respect to a lease, rental, or license, the disposing member is treated as having disposed of the property on the date or dates on which it takes into account its gross receipts from the lease, rental, or license under its method of accounting. With respect to a sale, exchange, or other disposition, the disposing member is treated as having disposed of the property on the date it ceases to own the property for Federal income tax purposes, even if no gain or loss is taken into account. Likewise, if an EAG partnership derives gross receipts from the lease, rental, license, sale, exchange, or other disposition of property that was MPGE by a member (or members) of the same EAG (the producing member) to which all the partners of the EAG partnership belong at the time that the EAG partnership disposes of such property, then the EAG partnership is treated as conducting the MPGE activities previously conducted by the producing member with respect to that property. The previous sentence applies only for those taxable years in which the producing member is a member of the EAG of which all the partners of the EAG partnership are members for the entire taxable year of the EAG partnership. With respect to a lease, rental, or license, the EAG partnership is treated as having disposed of the property on the date or dates on which it takes into account its gross receipts derived from the lease, rental, or license under its method of accounting. With respect to a sale, exchange, or other disposition, the EAG partnership is treated as having disposed of the property on the date it ceases to own the property for Federal income tax purposes, even if no gain or loss is taken into account.

(*ii*) *Attribution between expanded affiliated group partnerships.* If an EAG partnership (disposing partnership) derives gross receipts from the lease, rental, license, sale, exchange, or other disposition of property that was MPGE by another EAG partnership (producing partnership), then the disposing partnership is treated as conducting the MPGE activities previously conducted by the producing partnership with respect to that property, provided that each of these partnerships (the producing partnership and the disposing partnership) is owned for its entire taxable year in which the disposing partnership disposes of such property by members of the same EAG. With respect to a lease, rental, or license, the disposing partnership is treated as having disposed of the property on the date or dates on which it takes into account its gross receipts from the lease, rental, or license under its method of accounting. With respect to a sale, exchange, or other disposition, the disposing partnership is treated as having disposed of the property on the date it ceases to own the property for Federal income tax purposes, even if no gain or loss is taken into account.

(j) *Applicability date.* The provisions of this section apply to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of §§ 1.199A–7 through 1.199A–12 for taxable years beginning on or before that date, provided the taxpayers apply the rules in their entirety and in a consistent manner.

■ **Par. 5.** Section 1.1382–3 is amended by

■ 1. Revising paragraph (c)(2).

■ 2. Adding paragraph (e).

The revisions and additions read as follows:

§ 1.1382–3 Taxable income of cooperatives; special deductions for exempt farmers' cooperatives.

* * * * *

(c) * * *

(2) *Definition.* The term *income derived from sources other than patronage* used in this paragraph (c) means income from nonpatronage sources within the meaning of § 1.1388–1(f)(3).

* * * * *

(e) *Applicability date.* Paragraph (c)(2) of this section applies to taxable years beginning after January 19, 2021. For taxable years beginning on or before January 19, 2021, taxpayers, however, may choose to apply the rules of paragraph (c)(2) of this section, provided the taxpayers apply the rules in their entirety and in a consistent manner.

■ **Par. 6.** Section 1.1388–1 is amended by adding paragraphs (f) and (g).

The additions read as follows:

§ 1.1388–1 Definitions and special rules.

* * * * *

(f) *Patronage and nonpatronage sourced items*—(1) *Directly related use test.* Whether an item of income or deduction is patronage or nonpatronage sourced is determined by applying the directly related use test.

(2) *Patronage sourced income or deductions.* If the income or deduction is produced by a transaction that actually facilitates the accomplishment of the cooperative's marketing, purchasing, or services activities, the income or deduction is from patronage sources.

(3) *Nonpatronage sourced income or deductions.* If the transaction producing the income or deduction does not actually facilitate the accomplishment of the cooperative's marketing, purchasing, or services activities but merely enhances the overall profitability of the cooperative, being merely incidental to the association's cooperative operation, the income or deduction is from nonpatronage sources.

(g) *Applicability date.* Paragraph (f) of this section applies to taxable years beginning after January 19, 2021. Taxpayers, however, may choose to apply the rules of paragraph (f) of this section for taxable years beginning on or before that date, provided the taxpayers apply the rules in their entirety and in a consistent manner.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: January 8, 2021.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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Part VI

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 990

Establishment of a Domestic Hemp Production Program; Final Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 990

[Doc. No. AMS–SC–19–0042; SC19–990–2 FR]

Establishment of a Domestic Hemp Production Program

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This final rule supersedes the interim final rule that established the Domestic Hemp Production Program, as mandated by the Agriculture Improvement Act of 2018 (2018 Farm Bill). This rule includes regulations used by the Department of Agriculture (USDA) to approve plans submitted by States and Indian Tribes for the domestic production of hemp. This rule also includes regulations on the Federal hemp production plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plans. The program provides requirements for maintaining records about the land where hemp is produced, testing the levels of total delta-9 tetrahydrocannabinol, disposing of non-compliant plants, licensing hemp producers, and ensuring compliance under the new program.

DATES: This rule is effective March 22, 2021.

FOR FURTHER INFORMATION CONTACT: Bill Richmond, Branch Chief, U.S. Domestic Hemp Production Program, Specialty Crops Program, AMS, USDA; 1400 Independence Ave. SW, Stop 0237, Washington, DC, 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *William.Richmond@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under the authority of section 10113 of the 2018 Farm Bill (Pub. L. 115–334; December 20, 2018), which amended the Agricultural Marketing Act of 1946, as previously amended (7 U.S.C. 1621 *et seq.*) (AMA), by adding Subtitle G (sections 297A through 297E). Section 297B of the AMA requires the Secretary of Agriculture (Secretary) to evaluate and approve or disapprove State or Tribal plans regulating the production of hemp. Section 297C of the AMA requires the Secretary to establish a Federal plan for producers in States and territories of Indian Tribes not covered by plans approved under section 297B. Section 297D of the AMA requires the Secretary to promulgate regulations and guidelines relating to the production of hemp under sections 297B and 297C in consultation with the U.S. Attorney General.

AMS issued an interim final rule (IFR) on October 31, 2019 (84 FR 58522), and began its initial implementation of the program. To date, USDA has approved approximately 45 State and Tribal hemp plans. However, not all of the States and Tribes have implemented their plans for various reasons, including the need to take additional steps to complete State legislative or rulemaking processes or to establish the regulatory scheme as well as the extension of the 2014 Farm Bill Program. Thus, as of November 2020, twenty States and nine Tribes have submitted reports on their respective programs. Based on the reports submitted by States and Tribes in 2020, producers have planted 6,166 acres under the 2018 Farm Bill hemp plans, of which approximately 730 acres were subject to disposal.

As of the effective date of this final rule, the interim final rule is superseded. This final rule replaces the IFR at 7 CFR part 990, effective March 22, 2021. The Agricultural Marketing Service (AMS), which has been delegated authority to administer the U.S. Domestic Hemp Production Program, provided multiple opportunities for public comment. AMS accepted comments during an initial comment period from October 31, 2019, through December 31, 2019. This initial comment period was extended for an additional 30 days on December 18, 2019 (84 FR 69295), ending January 29, 2020. AMS reopened the comment period for 30 additional days on September 8, 2020 (85 FR 55363), ending October 8, 2020. A total of approximately 5,900 comments were received during all comment periods from States; Indian Tribes; industry and agricultural organizations; private citizens; members of Congress, the scientific community; agencies; and individuals involved in the growing, processing, transporting and marketing of hemp. A summary of the public comments received and AMS's responses appear under ''Comment Analysis'' in section IX of this document.

I. Introduction

Hemp is a commodity with numerous industrial and horticultural uses including fabric, paper, construction materials, food products, cosmetics, production of cannabinoids (such as cannabidiol or CBD), and other products.[1] While hemp was produced previously in the United States (U.S.) for hundreds of years, its use diminished in favor of alternatives. Hemp fiber, for instance, which had been used to make rope and clothing, was replaced by less expensive jute and abaca imported from Asia. Rope made from these materials was lighter, more buoyant, and more resistant to saltwater than hemp rope, which required tarring. Improvements in technology further contributed to the decline in hemp use. The cotton gin, for example, simplified the processing of cotton, which replaced hemp in the manufacture of textiles.

The hemp industry continued in the U.S. until the Marihuana Tax Act of 1938. This Act ended the legal production of hemp in the United States, and hemp was added to Schedule I of the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* Prior to the 2018 Farm Bill, all *Cannabis sativa* L., regardless of delta-9 tetrahydrocannabinol (THC) concentration level, fell within the CSA definition of ''marihuana'' unless the product fell under a narrow range of exceptions (*e.g.,* the ''mature stalks'' of the plant).[2] As a result, many aspects of domestic production of what is now defined as hemp was limited to persons registered under the CSA to do so.

Under the Agricultural Act of 2014 (2014 Farm Bill), Public Law 113–79, State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes. The authority for hemp production provided in the 2014 Farm Bill was extended until January 1, 2022, by the Continuing Appropriations Act, 2021, and Other Extensions Act (Pub. L. 116–260) (2021 Continuing Appropriations Act).

Hemp production in the U.S. has seen a resurgence in the last several years.

Since importation of seed is covered under USDA's Animal and Plant Health Inspection Service (APHIS) regulations, this final rule does not regulate hemp

[1] Section 297D(c) of the AMA explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to promulgate regulations and guidance related to the production of hemp under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) (FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (PHS Act). *See* section 297D(c)(1) (''Nothing in this subchapter shall affect or modify . . . the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); section 351 of the Public Health Service Act (42 U.S.C. 262); or the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services . . . '' under those Acts).

[2] Although the statutory spelling is ''marihuana'' in the Controlled Substances Act, this rule uses the more commonly used spelling of marijuana.

seed imports. APHIS regulates the importation of all seeds for planting to ensure safe agricultural trade. Hemp seeds can be imported into the U.S. from Canada if accompanied by either: (1) A phytosanitary certification from Canada's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected; or (2) a Federal Seed Analysis Certificate (SAC, PPQ Form 925) for hemp seeds grown in Canada. Hemp seeds imported into the U.S. from countries other than Canada may be accompanied by a phytosanitary certificate from the exporting country's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected.

This final rule does not address the exportation of hemp. Should there be sufficient public interest in exporting hemp in the future, USDA will work with industry and other Federal agencies to help facilitate this process.

The 2018 Farm Bill requires USDA to promulgate regulations and guidelines to establish and administer a program for the production of hemp in the United States. Under this new authority, a State or Indian Tribe that wants to have primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. For States or Indian Tribes without an approved plan, the Secretary is directed to establish a Departmental plan to monitor and regulate hemp production in those areas.

The 2018 Farm Bill specifies requirements that all hemp producers must meet. These include licensing requirements; recordkeeping requirements for maintaining information about the land where hemp is produced; procedures for testing the THC concentration levels for hemp; procedures for disposing of non-compliant plants; compliance provisions; and procedures for handling violations.

For the purposes of 7 CFR part 990, and as defined in the 2018 Farm Bill, the term ''hemp'' means the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Delta-9 tetrahydrocannabinol, or THC, is the primary intoxicating component of cannabis. Cannabis with a THC level exceeding 0.3 percent is considered marijuana, which remains classified as a Schedule I controlled substance regulated by the Drug Enforcement Administration (DEA) under the CSA.

The term ''State'' means any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The term ''Indian Tribe'' or ''Tribe'' has the same definition as in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). This final rule also includes the definition of ''territory of an Indian Tribe'' to provide clarity to the term because the AMA does not define it. The final rule defines ''territory of the Indian Tribe'' as (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction. Under an approved Tribal plan, the Indian Tribe will have regulatory authority over hemp production within its Territory.[3] A full list of terms and definitions relating to part 990 can be found under ''Definitions'' in section IV.

This rule is divided into several sections. The first section provides a general introduction to the rule. This section does not go into a detailed description of all parts of the rule or about the provisions of the rule that are discussed later on in other sections. Sections for State and Tribal plans as well as the USDA plan contain general information on land use, tribal jurisdiction authority, sampling, testing, disposal and remediation, compliance provisions, information sharing, certification of resources, and State and Tribal plan approvals. The USDA section also includes USDA hemp license provisions and suspension. These two sections provide general provisions that are discussed in more detail in the comment analysis section. Sections containing definitions, severability and the regulatory analysis are included before the regulatory language. The reader may be best served by reading the comment section to determine the changes made to this rule.

[3] We note that if an Alaskan Native Corporation wants to produce hemp on land it owns in fee simple, it would need to have a State or USDA license, whichever is applicable, because that land does not qualify as Indian Country and the Corporation does not have jurisdiction over that land.

II. State and Tribal Plans

Section 297B (7 U.S.C. 1639p) of the AMA requires that States or Indian Tribes seeking primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe, submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. State or Tribal plans must be submitted to USDA and approved prior to their implementation. Nothing preempts or limits any law of a State or Tribe that regulates the production of hemp and is more stringent than the provisions in Subtitle G of the AMA.

AMS received extensive public input on the regulatory requirements for State and Tribal hemp plans. Incorporating the input received, the following sections explain the changes to the regulatory requirements for State and Tribal hemp plans.

A. Land Used for Production

The 2018 Farm Bill and the IFR required that plans include a process by which relevant information regarding the land used for hemp production in their jurisdiction is collected and maintained. Certain information on mailing addresses and hemp production sites must be collected for each licensee covered by the State or Tribal plan.

The information required to be collected includes a legal description of the land and geospatial location for each field, greenhouse, or other site where hemp is produced. Geospatial location is necessary because many rural locations do not have specific addresses, and these coordinates will assist with the proper identification of hemp production locations.

In addition to the land information required to be collected by the appropriate State or Indian Tribe, AMS chose to require licensed producers, including those under the USDA plan, to report their hemp crop acreage to the Farm Service Agency (FSA). Although many commenters opposed this requirement based on costs around the time and travel expense necessary to physically visit the appropriate FSA County Office, AMS has determined that maintaining the FSA reporting

requirement is essential for several reasons. AMS recognizes that in some cases producers may travel to FSA offices miles away incurring additional time and cost. These costs are incorporated in the expected burden of this program.

First, USDA is statutorily required to provide law enforcement with certain ''real-time'' information about who is growing hemp, whether their license is in good standing with the regulatory body issuing the license, and the location(s) where hemp is being grown. Having FSA collect the necessary information enables USDA to provide the most accurate and ''real-time'' information to law enforcement, as required by Subtitle G of the AMA. Second, FSA offices serve as useful resources to all farmers and, in collaboration with other USDA agencies, can provide a wide range of insurance, risk management, and conservation program guidance and information. These offices currently serve the agricultural industry within their communities, where producers can establish farm and producer records, record their licensing information, and report crop acreage. The producer may also, with supporting documentation, update their FSA farm records for leases, sub-leases, or land ownership. Requiring farmers to visit the FSA office ensures that they receive information on the availability of these helpful tools and programs. This is particularly important for new farmers, who may not be aware of the wide range of programs and services offered by USDA.

Further, FSA maintains the technology necessary for data collection and geographical land identification. These tools will provide easy access to information needed for law enforcement and for other agricultural programs. AMS has determined, for these reasons, to continue to require the reporting of hemp crop acreage to FSA.

Based on input from commenters, USDA is also clarifying the distinction between the term ''lot'' as defined in the IFR, and the term ''subfield'' as it relates to FSA reporting. Although this final rule uses the term ''lot'' to discuss the land where hemp is grown, when a producer visits the FSA office to report hemp crop acreage, FSA staff will help producers determine the applicable FSA-specific term for designating the location(s) where hemp is being grown. The terminology used by FSA to denote land areas include terms like ''farm,'' ''tract,'' ''field,'' and ''subfield,'' which are equivalent to AMS's term ''lot.'' FSA staff will not provide a ''lot number'' to producers as described in the IFR. FSA will use designations that they currently use such as track, field, or subfield, depending on the specific area. This designation does not change the requirements or the information submitted for law enforcement. AMS will amend the form to reflect these terms. When reporting to FSA, producers must provide their State or Tribe-issued license or authorization number. A link to FSA information on how to report hemp crop acreage to FSA is available at *https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/FactSheets/2019/crop-acreage-reporting-19.pdf* and is available on the USDA hemp production program website.

As described in the IFR, certain State hemp pilot programs operating under the 2014 Farm Bill authority developed ''seed certification'' programs to help producers identify hemp strains with potentially lower THC concentrations. The term ''certification'' in this context means tested or verified, but it does not necessarily mean certified for varietal purity. USDA acknowledges that this remains a significant hurdle to the hemp industry and is committed to assisting with the research and development of compliant hemp varietals. Although AMS encourages States and Tribes to develop seed-certification programs if sufficient data is available, AMS has determined, at this time, that requiring the use of certain ''compliant'' varietals or establishing National rules for State-level certification programs is inappropriate. AMS will look at best practices from States and Tribes to evaluate if a program would be applicable to a USDA plan. If applicable, USDA may develop a performance-based sampling program. Such a program will require USDA to conduct rulemaking and comment procedures.

The term ''seed certification,'' as found in the Federal Seed Act and its Regulations, refers to a third-party verification process that assures seed customers that they are receiving pure varieties and high-quality seed for planting purposes. The Federal Seed Act grants authority to seed certifying agencies in each State to administer varietal seed certification standards for all major agricultural crops, including hemp. Recognized seed certifying agencies are members of the Association of Official Seed Certifying Agencies (AOSCA), and they administer uniform AOSCA standards and inspect crops being grown for seed throughout the production process to maintain varietal purity. These activities protect seed customers in both domestic and export markets. Seed produced under these types of certification programs ensure a distinct, recognized variety that is properly tested and legally labeled. Seed certification under the Federal Seed Act is concerned with many varietal characteristics, not solely THC concentration. This enables farmers to confidently purchase seed of a suitable variety, by purchasing seed certified as to variety. Using certified seed, as described in the Federal Seed Act regulations and AOSCA standards, is an option for states and tribes if they have the data to support that the seed would work in their environment. While varietal certification does not absolutely ensure a specific THC content, the fact is that THC content (or at least a range) is a reliable varietal characteristic. Therefore, if the farmer is able to confidently purchase seed of a suitable variety by purchasing seed certified to variety, they at least know what to expect from the variety in their area.

For this reason, AMS recommends the use of hemp seed from varieties that have undergone varietal certification, following the process outlined in the Federal Seed Act Regulations, and produced following AOSCA standards. This recommendation will assist hemp farmers to purchase recognized hemp varieties that have been tested for purity and are properly labeled.

Additionally, AMS administers the Plant Variety Protection Office (PVPO) that is actively accepting applications of seed-propagated hemp for plant variety protection. The PVPO provides intellectual property protection to breeders of new varieties of seeds, tubers, and asexually reproduced plants. Under the U.S. Plant Variety Protection Act, PVPO examines new applications and grants certificates that protect varieties for 20 years (25 years for vines and trees). Certificate owners have rights to exclude others from marketing and selling their varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work. This work, however, does not certify seeds for THC content.

B. Tribal Jurisdictional Authority

The final rule clarifies the extent of a Tribe's regulatory authority over hemp production within its Territory. Several commenters stated that language in the IFR raised uncertainty as to whether Indian Tribes could regulate hemp production by non-Indians operating on fee lands within a Tribe's Territory. To address this uncertainty, § 990.4(b)(4) of the final rule now provides that ''[u]pon USDA approval of a Tribal plan, a Tribe may exercise jurisdiction and therefore primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent

regulatory authority.'' Thus, as long as the land at issue qualifies as land within the territory of an Indian Tribe under § 990.1 of the final rule, an Indian Tribe with a USDA-approved plan may regulate all hemp production on that land. USDA determined that this additional language is consistent with Congressional intent in the 2018 Farm Bill and best ensures that hemp production is managed consistently throughout the Territory of an Indian Tribe.

If an Indian Tribe desires to have primary regulatory authority over the production of hemp in its Territory, under the 2018 Farm Bill, the Tribe may submit a plan to USDA. Section 297C of the AMA provides that ''In the case of a State or Indian Tribe for which a State or Tribal plan is not approved under section 297B, the production of hemp in that State or the territory of that Indian Tribe shall be subject to a plan established by the Secretary to monitor and regulate that production.'' Hence if a Tribe does not regulate hemp production within its Tribal Territory, USDA, not a State with an approved plan, will regulate hemp production program within that Territory.

Sections 297B and C plainly show that Congress chose to take a territorial approach to the Tribal regulation of hemp production under the AMA. If Congress only wanted Indian Tribes to assume primary regulatory authority over hemp production in areas within their inherent jurisdictional authority it could have stated this. Instead, Congress opted for a land-based approach and delegated to Tribes the authority to assume hemp production regulatory authority throughout their territories. In consideration of the statutory language and the overall statutory scheme of the 2018 Farm Bill, USDA has determined that an Indian Tribe with an approved plan may regulate hemp production throughout its territory without regard to the Indian Tribe's ability to demonstrate inherent regulatory authority under the factors set forth in *Montana* v. *United States,* 450 U.S. 544 (1981). Because Congress did not define Territory of the Indian Tribe in the AMA and did not include discussion in the legislative history of the meaning of this term, USDA is exercising its authority to issue regulations to implement the provisions in the 2018 Farm Bill to define this term in this manner.

USDA's decision is in-line with agency determinations where the agency determined that Congress delegated a Tribe with authority to exercise regulatory authority over non-Tribal fee land within reservations. EPA Interpretive Rule: Revised Interpretation of Clean Water Act Tribal Provision, 81 FR 30183 (May 16, 2016); EPA Final Rule: Indian Tribes—Air Quality Planning and Management, 63 FR 7254 (Feb. 12, 1998); *Arizona Public Serv. Co.* v. *EPA,* 211 F.3d 1280 (D.C. Cir. 2000).

Moreover, USDA's decision is practicable and prevents piecemeal licensing by Tribes and USDA within a single Tribal Territory. If a Tribe was only able to exercise primary regulatory authority over hemp production within its Territory when it could demonstrate the inherent authority to do so, USDA could be required to regulate some hemp production within the Territory—for example, it could foreseeably be required to regulate hemp production by non-Indians operating on fee lands in certain cases. Such a system would be confusing for producers and regulators alike.

For the foregoing reasons, the final rule now clearly explains that upon USDA approval of a Tribal plan, a Tribe may exercise primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent regulatory authority, as reflected in §§ 990.2 and 990.4 of the final rule.

C. Sampling for Total THC

AMS is changing certain aspects of the sampling requirements. This section addresses performance-based sampling, how to sample hemp plants, sampling agents, and the harvest window after sampling takes place.

Sampling Requirements

AMS received significant input from commenters on how hemp sampling procedures and requirements should be changed. When referring to ''sampling,'' we mean the process of collecting cuttings from hemp plants for purposes of compliance testing.

Performance Based Sampling

The IFR required State and Tribal hemp programs to collect samples from the flower material of the cannabis plant. The IFR also required State and Tribal hemp programs to collect enough samples to ensure at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. Guidance issued concurrently with the IFR explained these requirements in greater detail. The sampling requirements in the IFR did not consider geography, environmental factors, State or Tribal level seed certification programs, or other factors faced by States and Tribes when developing sampling requirements for their hemp programs. AMS is modifying the sampling provisions as presented in the IFR to allow States and Tribes to develop performance-based sampling requirements. Performance-based sampling achieves defined objectives and focuses on results. It differs significantly from a prescriptive action in which licensees are provided detailed direction on how those results are to be obtained. A performance-based approach would simply set a performance objective (*e.g.,* reliability of 95 percent) and allow the States and Tribes considerable freedom in how to achieve that reliability objective with their sampling methodology.

Some State hemp regulators have successfully developed sampling requirements that ensure adherence to State and Federal regulations, while allowing for flexibilities due to limited State resources and State and Tribal differences. States expressed extensive concerns about the requirements in the IFR that all lots must be sampled and tested, due to significant logistical and fiscal impacts. They explained that, since most hemp in a given region is harvested at the same time, sampling must be completed within a very short time frame by only a few individuals. Several States also explained how sampling occurs under established State programs and described the different ways that perceived risk determines State requirements. Some States utilize different sampling requirements for broad end-use categories like ''fiber/grain'' hemp versus ''cannabinoid'' hemp, while others base their requirements on historical THC concentrations of certain varietals or on the characteristics and growing history of a certain farm or producer. While these States' plans have not been approved under the 2018 Farm Bill regulations, we believe that providing States and Tribes the flexibility to develop sampling plans based on data they gather during an extended period of time may be an effective method at ensuring the overall acceptable hemp THC level of hemp grown in the State or Tribe. AMS agrees that sampling requirements should allow States and Indian Tribes more flexibility in the management of their hemp regulatory programs.

AMS agrees that requiring sampling from every lot may be burdensome and expensive for State and Tribal regulatory entities and producers. AMS also finds compelling the arguments presented by States' regulatory agencies and other commenters that there are different risk factors for hemp used for fiber and grain versus hemp used for cannabinoids. Data submitted with

comments show that the THC levels of hemp used for cannabinoids are frequently higher than those of hemp for fiber and grain. The FDA authorizes the marketing of few types of cannabinoid products. This final rule does not cover cannabinoid products.

AMS also acknowledges that research institutions face special circumstances when conducting hemp research. Accordingly, this rule provides sampling and testing flexibility to these institutions and producers working with them to conduct hemp research. Producers that produce hemp for research, along with the research institution itself, must obtain a license from a State, Tribal Government, or USDA. However, the hemp that is produced for research is not subject to the same sampling requirements provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. Research institutions and producers growing hemp for research purposes shall ensure the disposal of all non-compliant plants. Research institutions and producers growing hemp for research purposes shall also comply with the reporting requirements including reporting disposal of non-compliant plants. Research institutions that handle ''hot'' hemp must follow CSA requirements for handling marijuana.

States and Indian Tribes are allowed to develop performance-based requirements for these institutions. However, the alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level.

AMS views this flexibility as necessary to help support research and development as it relates to hemp production. This decision allows these types of research facilities and institutions to confidently oversee the study of hemp through trialing and genetics research, which AMS believes to be critical to the growth of industry, particularly in its infancy. Over time, the flexibility provided by this final rule will help to stabilize industry by providing greater understanding of hemp genetics and how certain varietals respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as they will be made aware of the more stable and consistently reliable hemp varietals. Any non-compliant plants produced by research institutions as a result of research and development will still need to be disposed and verified through documentation. Research and development facilities are still required to be licensed by States and Tribes. Research institutions must follow licensing and reporting requirements.

In performance-based approaches, measurable or calculable parameters are available to determine whether the performance standard is met. These performance parameters are identified to provide measures of performance and the opportunity to take corrective action if performance is lacking. In the case of hemp, the performance parameter is the 0.3 percent THC level and other measures are included in this final rule if the parameter is not achieved such as disposal and remediation.

USDA finds that in order to increase regulatory effectiveness, it makes sense to allow States and Indian Tribes to consider performance-based alternatives when developing sampling plans. If the objective or intended result can be achieved by setting a readily measurable standard that is enforceable, the proposed requirement should merely specify the objective or result to be obtained rather than prescribe to the licensee how the objective or result is to be attained. In other words, requirements should be performance-based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary.

The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp growing facilities under their jurisdiction. Sampling protocols must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, the final rule allows States and Indian Tribes to adopt a performance-based sampling protocol. A performance-based protocol must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plants will not test above the acceptable hemp THC level. USDA encourages the alternative protocol to consider seed certification processes or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe, whether the producer is conducting research on hemp at an institution of higher learning, whether a producer has consistently produced compliant hemp plants over an extended period of time, and other similar factors. AMS believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. Sampling protocols submitted by States and Indian Tribes must comply with the thresholds established by the 2018 Farm Bill and this final rule. If performance-based sampling requirements are not included in a State or Tribal plan, the method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected from every lot, and thereby every producer must be sampled and tested. When evaluating sampling protocols submitted by States and Indian Tribes, USDA will evaluate the risk of producing non-compliant material to determine approval or disapproval. In evaluating the risk, USDA will take into consideration whether the performance-based factors the State or Indian Tribe used have the potential to assure compliance at a 95 percent confidence level.

Since USDA cannot develop performance metrics that would be applicable independently from where the producer is located, producers licensed under the USDA plan are subject to the sampling requirements in the rule. USDA guidelines provided on the USDA website at *https://www.ams.usda.gov/rules-regulations/hemp/information-sampling* describe best practices for complying with those requirements.

USDA recognizes that several States and Tribes may include performance-based sampling in their plans and that their experience could demonstrate that their sampling procedures may be adaptable to the USDA plan. If USDA finds this to be the case, USDA will explore a performance-based sampling scheme for producers under the USDA plan in the future through notice and comment rulemaking.

Where To Take Samples on the Hemp Plant

AMS will retain the requirement that pre-harvest samples be taken from the flower material of hemp plants. However, this rule clarifies the number

of inches of plant material needed for the sample and provides greater detail as to where exactly on the plant to make a cutting. The IFR required that samples be taken from the ''flower material'' of hemp plants. Further, in guidance material issued concurrently with the IFR, AMS explained in greater detail where exactly on the plant to make a cutting by recommending samples be taken from the top third of the plant, ''just underneath a flowering material.'' Many commenters argued that samples should be taken from the ''whole plant'' or that a ''homogenized'' sample should be taken to include the stem, stalk, leaves, and seeds along with flower material. Alternatively, some commenters proposed that samples be taken post-harvest from shredded whole plant material, otherwise known as ''biomass.'' Advocates of these positions asserted that THC levels of the whole hemp plant are better represented by samples collected from the entire plant, and not just from floral material. Other commenters advocated for sampling of a certain size or length of cutting. Such commenters advocated adoption of the sampling methods they or others had used under pilot programs. Many State agriculture departments suggested AMS continue to require samples taken from flower material.

Even though many commenters felt that whole plant sampling should be allowed, AMS is of the opinion that since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. AMS will modify the sampling requirement to state that the sample shall be approximately five to eight inches from the ''main stem'' (that includes the leaves and flowers), ''terminal bud'' (that occurs at the end of a stem), or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant. This change is consistent with the sampling practices in several States that established hemp programs pursuant to the 2014 Farm Bill authority. AMS determined that this standard strikes an appropriate balance between the need to collect a sufficiently large portion of the plant's flower (where THC and other cannabinoids are at their most concentrated), and the need to avoid cutting a portion that is so large that it would be logistically difficult to transport, dry, and prepare for lab testing. Based on the information discussed above and the experience and expertise of States and other commenters already engaged in hemp production pursuant to the 2014 Farm Bill authority, AMS is including new requirements herein.

AMS is publishing updated sampling guidance concurrently with this final rule. This guidance describes how to comply with this requirement regarding where to take the sample from the plant as well as other sampling requirements in the final rule. While the sampling guidance provides best practices for meeting the requirements, States, Indian Tribes, and USDA licensees may adopt sampling procedures that differ from the guidance so long as those procedures meet the standards in this final rule.

Sampling Agents

The IFR required a Federal, State, local, or Tribal law enforcement agency or other Federal, State, or Tribal designated person to collect hemp samples for the purposes of testing THC levels in hemp. Comments in response to the IFR presented several concepts concerning how sampling agents should be designated and/or trained. Comments mostly suggested the need for enhanced training requirements for sampling agents to promote consistency in the ways that samples are collected nationwide. Based on comments received regarding sampling agents, AMS will provide additional training resources for sampling agents. These training documents will explain how sampling agents can meet the sampling requirements of this regulation. States and Indian Tribes with an approved plan may require the sampling agents used in their jurisdiction to take the USDA training, or they may develop their own custom training incorporating USDA requirements with additional State or Tribal requirements. States and Tribes must maintain information, available to producers, about trained sampling agents.

Other comments on the topic of sampling agents spoke to the strain on State and Tribal resources of requiring agents to take samples instead of producers. Commenters presented two proposals to alleviate this strain—allowing producers to collect their own samples and reducing the volume of farms and plants from which samples are collected. AMS is retaining the requirement that only designated agents can collect samples. This ensures that there is consistency in sampling throughout the industry. The flexibilities provided to States and Indian Tribes with primary regulatory authority over hemp in their jurisdiction will likely reduce the number of samples required to be collected and thus reduce the burden on designated sampling agents.

Harvest Window

The IFR required harvest within 15 days of sampling. AMS received comments regarding the challenges presented by the 15-day harvest requirement, including the logistical challenges to State and Tribal agencies charged with overseeing the collection of samples in this short timeframe, the logistical challenges to producers in harvesting hemp crops in this short timeframe, and testing challenges faced by laboratories in having to conduct compliance analyses in this short timeframe. Commenters suggested lengthening the 15-day harvest requirement to a longer period of time—with some asking for up to 60 days.

AMS agrees with the arguments presented by commenters and recognizes the challenges imposed on the industry by the 15-day harvest requirement. AMS must also balance the logistical challenges of a harvest window requirement with the fact that THC concentration in hemp generally increases the longer the plant is in the ground. AMS now understands from data provided in comments that THC concentration does not increase linearly and is impacted by a myriad of environmental factors including moisture, wind, temperature, disease, sunlight, and soil, as discussed in the Comment Analysis section of this rule. The regulatory objective is to ensure, as best as possible, harmonization of the THC levels in the pre-harvest sample and that of the harvested material. Requiring that samples be taken prior to harvest is the best way to judge the THC concentration of the plant and the lot the sample represents. AMS recognizes that the most accurate measurement would be at time of harvest, but also understands the logistical practicalities discussed above and therefore has determined the most balanced approach is 30 days. For these reasons, AMS is expanding the window within hemp must be harvested after sampling to 30 days.

Under this final rule, no more than 30 days prior to the anticipated harvest of cannabis plants, a ''sampling agent'' must collect samples for compliance testing. If producers do not harvest within 30 days of sampling, the plant will likely have a higher THC level at harvest than the sample that is being tested. This requirement balances the need for accuracy with the logistical realities faced in the sampling and testing processes and will yield the most accurate measurement of the THC level at the point of harvest. Increasing the window within hemp must be harvested after sampling from 15 to 30 days will

better allow for variables such as testing, weather, agricultural practices, and equipment delays.

D. Testing Laboratories

The IFR introduced regulatory requirements for laboratories testing hemp for compliance purposes. AMS also issued guidance with the IFR to explain best practices for hemp testing laboratories (*www.ams.usda.gov/rules-regulations/hemp*). Based on comments to the IFR, AMS is changing certain parts of these regulations and updating the accompanying testing guideline. While the testing guidance provides best practices for meeting the regulatory requirements, States, Indian Tribes, and USDA licensees may use test procedures that differ from the guidance so long as those procedures meet the standards in the final rule.

Registration With DEA

The IFR required all hemp testing laboratories to be registered with the DEA in accordance with the CSA (21 U.S.C. 823(f)). On February 27, 2020, AMS announced a delay in enforcement of this requirement until October 31, 2020, or the publication of a final rule, whichever came first (USDA, DEA Provide Options for Labs, Disposal of Non-Compliant Hemp Plants. Thursday, Feb. 27, 2020) [4] AMS announced this enforcement delay to allow additional time to increase DEA registered analytical lab capacity and avoid potential delays to producers in receiving test results. Although AMS received comments in opposition to this requirement, AMS is retaining the requirement in this final rule that any laboratory testing hemp for purposes of regulatory compliance must be registered with DEA to conduct chemical analysis of controlled substances in accordance with 21 CFR 1301.13. This requirement also applies to any laboratory testing hemp throughout the growing season to informally monitor THC concentration. Registration is necessary because laboratories could potentially handle cannabis that tests above 0.3 percent THC on a dry weight basis, which is, by definition, marijuana and a Schedule 1 controlled substance. Instructions for laboratories to obtain DEA registration, along with a list of approved laboratories, are available on the USDA Domestic Hemp Production Program website. AMS is aware that there are still not enough DEA-registered hemp testing facilities in some States or territories of Indian Tribes. However, since the IFR was published, numerous laboratories have applied for registration and DEA is working diligently to process these requests. Given the limited number of DEA-registered labs available to hemp producers, delay in enforcement of this requirement is continued until December 31, 2022. AMS anticipates this delay will provide adequate time for testing facilities to obtain DEA registration.

Laboratory Testing Requirements

Section 297B(a)(2)(A)(ii) of the AMA requires that State and Tribal plans for primary regulatory jurisdiction include a ''procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian Tribe.'' Since not all testing methods include decarboxylation, AMS is requiring that the total THC, which includes the potential conversion of tetrahydrocannabinolic acid (THCA) into THC, be reported and used for purposes of determining the THC content of a hemp sample.

The IFR included requirements on how laboratories conduct hemp testing for the purposes of regulatory compliance to assure that total THC levels were measured. Commenters provided extensive input on testing requirements, particularly the requirement to test for ''total'' THC instead of only ''delta-9'' THC. AMS is retaining this requirement.

AMS looked at current testing methodologies that would meet the decarboxylation requirement set in the 2018 Farm Bill. In gas chromatography (GC) testing, heat is applied to the sample, which decarboxylates THCA, producing delta-9 THC, so that the final delta-9 THC result is actually a total THC result. GC is the more traditional technique used for THC testing and was the technique used by Dr. Small [5] in his research that derived the 0.3 percent threshold that was used as a basis for the 2018 Farm Bill requirement and is used by law enforcement as the threshold to differentiate hemp from marijuana. In his research papers, the 0.3 percent threshold is based on *total available* delta-9 THC, which is the sum of THCA and delta-9 THC in the plant material.

Liquid chromatography (LC) testing does not involve the use of significant heat, so that the THCA in a sample does not generally decarboxylate. Results can be reported for THCA and delta-9 THC separately. When LC is used, the total THC needs to be calculated post-testing in order to report results as a ''post-decarboxylation'' delta-9 THC value. The requirement to report the total THC value as the THC content regardless of testing methodology used ensures testing consistency across the program.

Samples must be tested using post-decarboxylation or other similarly reliable analytical methods by which the total THC concentration level reported accounts for the conversion of THCA into THC. Acceptable testing methodologies currently include gas or liquid chromatography with detection.

The total THC, derived from the sum of the THC and THCA content, shall be determined and reported on a dry weight basis. In order to provide flexibility to States and Tribes in administering their own hemp production programs, alternative testing protocols will be considered if they are comparable to and similarly reliable as the baseline mandated by section 297B(a)(2)(A)(ii) of the AMA and established under USDA regulations and procedures. Updated USDA procedures for sampling and testing will be issued concurrently with this rule and will be provided on the USDA website.

Reporting requirements for laboratories are discussed later in Section X (Regulatory Analysis) of this final rule. To clarify these requirements, laboratories conducting testing for purposes of monitoring THC concentration throughout the growing season are not subject to these reporting requirements. These tests are for the producer to monitor his or her production as it grows and not to comply with pre-harvest testing requirements in this rule. Only laboratories conducting the ''final'' test that will be used to determine whether a sample is compliant are subject to reporting requirements.

Measurement of Uncertainty

This final rule requires that laboratories calculate and include the Measurement of Uncertainty (MU) when they report THC test results. ''Measurement of uncertainty'' is defined as ''the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.'' This definition is based on the definition of ''uncertainty (of measurement)'' in section 2.2.3 of the Joint Committee for

[4] *www.ams.usda.gov/press-release/usda-dea-provide-options-labs-disposal-non-compliant-hemp-plants.*

[5] Small, E.; Beckstead, H.D.; Chan, A. The Evolution of Cannabinoid Phenotypes in Cannabis. *Economic Botany, 29,* 219–232, 1975.

Guides in Metrology[6] 100:800, Evaluation of measurement data—''Guide to the Expression of Uncertainty in Measurement'' (JCGM Guide). The National Institute of Standards and Technology (NIST) Technical Note 1297, ''Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results'' (TN 1297), is based on the JCGM Guide. AMS also relied on the Eurachem/Co-Operation on International Traceability in Analytical Chemistry's ''Guide on Use of Uncertainty Information in Compliance Assessment, First Edition 2007''. Colloquially, the measurement of uncertainty is similar to a margin of error. When the measurement of uncertainty, normally expressed as a +/− with a number (*e.g.* +/- 0.05), is combined with the reported measurement, it produces a range, and the actual measurement has a known probability of falling within that range (typically 95%). Laboratories should meet the AOAC International[7] standard method performance requirements for selecting an appropriate method to determine the MU.

This final rule requires that laboratories report the MU as part of any hemp test results. The rule also includes a definition of ''acceptable hemp THC level'' to account for the uncertainty in the test results. The reported THC concentration of a sample may not be the actual concentration level in the sample. However, the actual THC concentration is expected to be within the distribution or range calculated when the reported THC concentration is combined with the measurement of uncertainty.

The use of MU for purposes of determining the acceptable hemp THC level does not alter Federal law with regard to the definition of hemp or marijuana. As stated above, the 2018 Farm Bill defines hemp as the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC of not more than 0.3 percent on a dry weight basis. Likewise, the Federal (CSA) definition of marijuana continues to include those parts of the cannabis plant as specified in 21 U.S.C. 802(16) (and derivatives thereof) that contain more than 0.3 percent THC on a dry weight basis. The foregoing provisions of Federal law remain in effect for purposes of Federal criminal prosecutions, as well as Federal, civil, and administrative proceedings arising under the CSA.

The definition of ''acceptable hemp THC level'' is also retained in this final rule. States and Indian Tribes shall adopt this concept in their plans. This definition explains how to interpret test results that include the MU with an example. The application of the MU to the reported delta-9 tetrahydrocannabinol concentration on a dry weight basis produces a distribution, or range. If 0.3 percent or less is within the distribution or range, then the sample will be considered to be hemp for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans. For example, if a laboratory reports a result as 0.35 percent with a measurement of uncertainty of +/−0.06, the distribution or range is 0.29 percent to 0.41percent. Because 0.3 percent is within that distribution or range, the sample, and the lot it represents, is considered hemp for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans. However, if the MU for that sample was 0.02 percent, the distribution or range is 0.33 percent to 0.37 percent. Because 0.3 percent or less is not within that distribution or range, the sample is not considered hemp for the purpose of plan compliance, and the lot it represents will be subject to disposal. Thus the ''acceptable hemp THC level'' is the application of the MU to the reported delta-9 tetrahydrocannabinol content on a dry weight basis producing a distribution or range that includes 0.3 percent or less. As such, the regulatory definition of ''acceptable hemp THC level'' describes how State, Tribal, and USDA plans must account for uncertainty in test results in their treatment of cannabis. This definition affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of ''marihuana,'' 21 U.S.C. 802(16), in the CSA.

Sections 297B(a)(2)(A)(iii) and 297C(a)(2)(C) of the AMA require that cannabis plants that have a THC concentration level of greater than 0.3 percent on a dry weight basis be disposed of in accordance with the applicable State, Tribal, or USDA plan. Because of this requirement, producers whose cannabis crop is not hemp will likely lose most of the economic value of their investment. Thus, AMS believes that there must be a high degree of certainty that the THC concentration level is accurately measured and is in fact above 0.3 percent on a dry weight basis before requiring disposal of the crop.

The NIST Reference on Constants, Units, and Uncertainty states that ''measurement result is complete only when accompanied by a quantitative statement of its uncertainty. The uncertainty is required in order to decide if the result is adequate for its intended purpose and to ascertain if it is consistent with other similar results.''[8] Simply stated, knowing the measurement of uncertainty is necessary to evaluate the accuracy of test results.

Comments to the IFR generally expressed support for requiring that the measurement of uncertainty (MU) be accounted for when testing the THC concentration of hemp, due to the variability in laboratory testing equipment and complex mathematical principles involved. Comments also provided several suggestions on ways to improve the calculation of MU. Many comments advocated specifying an MU to create uniformity in testing across the nation.

USDA does not recommend establishing an MU upper limit (maximum) because (1) MU is typically not standardized, but is controlled using standard test methods, and (2) USDA does not have the data to set an upper limit so setting it would be arbitrary, not scientific. The hemp and scientific industries are just beginning to discuss standard test methods and the final rule does not establish an explicit test method. Setting an upper limit or maximum MU does not resolve the core issue and would not encourage or drive labs to improve accuracy and precision.

Setting an upper limit would in effect be setting a maximum or absolute MU. This may encourage labs to adopt the maximum MU as their MU, rather than drive for a smaller uncertainty. USDA may allow for establishing limits in the future, if needed, once methods are established and USDA has access to Proficiency Testing results and the reported MUs. We encourage States and Tribes to monitor, review and evaluate MU to evaluate trends and outliers, which may indicate ''lab shopping'' for higher MUs. The requirement for hemp

[6] The Joint Committee for Guides in Metrology is composed of international organizations working in the field of metrology. Its membership includes the Bureau International des Poids et Mesures, the Organisation Internationale de Métrologie Légale, the International Organization for Standardization, the International Electrotechnical Commission, the International Union of Pure and Applied Chemistry, the International Union of Pure and Applied Physics, the International Federation of Clinical Chemistry and Laboratory Medicine, and the International Laboratory Accreditation Cooperation.

[7] USDA established the Association of Official Agricultural Chemists in 1884. In 1965, it changed its name to the Association of Official Analytical Chemists and became an independent organization in 1979. In 1991, it adopted its current, legal name as AOAC International.

[8] *https://physics.nist.gov/cuu/Uncertainty/international1.html.*

testing laboratories to incorporate a MU is being retained in this regulation.

Laboratory Accreditation

In the IFR, AMS requested input on establishing a fee-for-service hemp laboratory approval process or a requirement for laboratories to obtain ISO 17025 accreditation for labs that wish to offer THC testing services. Comments reflected a range of views across the industry, both in support of and in opposition to additional laboratory certification requirements. In general, commenters preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory certification/registration/accreditation requirements. Other commenters were opposed to accreditation requirements due to the cost. While AMS strongly encourages laboratories to be accredited to ISO/IEC 17025 (by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) signatory accreditation body), we also acknowledge that ISO 17025 accreditation requires significant time and financial commitment to pursue and maintain. The time and cost involved is most challenging for smaller and start-up labs. The initial accreditation can cost $5,000–$10,000 (and in some case more) and yearly ongoing costs are $3,000–$8,000. Smaller labs may not have the resources to pursue accreditation in a timely manner or they may have to spend additional time and money for consultants to assist them in setting up a quality management system and to navigate the application and audit processes.

Based on insufficient laboratory capacity at this time and the cost involved in adding this requirement, AMS will not provide an AMS administered lab approval program or require ISO 17025 accreditation. However, AMS remains committed to assisting the hemp laboratory testing community and is available to assist in the development of a laboratory approval program in the future. As explained in the IFR, if such hemp laboratory approval program is developed by AMS, such process will be conducted by USDA, AMS Laboratory Approval Service, which administers the Laboratory Approval Program (LAP). State and Tribal plans are free to include certain additional requirements for hemp testing laboratories, including ISO accreditation or other proficiency schemes.

E. Disposal and Remediation of Non-Compliant Plants

State and Tribal plans are currently required to include procedures for ensuring effective disposal or remediation of plants produced in violation of part 990. Plants that are removed as a result of poor plant health, pests, disease, or weather events, along with removal of male or hermaphrodite plants as part of a cross-pollination prevention plan, are not subject to the disposal requirements herein. This final rule retains the disposal requirements explained in the IFR but clarifies what ''disposal'' means and explains how the process must be conducted. This final rule also includes remediation as an option to remove non-compliant plants.

As explained in the IFR, if a producer grows cannabis exceeding the legal 0.3 percent THC level, the material must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under the CSA. The material must be collected for disposal by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, Tribal, or local law enforcement officer. In the final rule, AMS is incorporating flexibilities for disposal that were announced on February 27, 2020 (*https://www.ams.usda.gov/rules-regulations/hemp/enforcement*). Some of these new options include, but are not limited to, plowing under non-compliant plants, composting into ''green manure'' for use on the same land, tilling, disking, burial, or burning. These methods are intended to allow producers to apply common on-farm practices for the disposal of non-compliant plants. One of the top considerations in making this change was to minimize, to the extent possible, the resource impact to State, Tribal, and local law enforcement in handling hemp that is out of compliance. In addition, we are confident that any disposal options make the product unusable and therefore is not at risk for entering any streams of commerce. Based on comments received, AMS is permanently retaining these on-farm disposal flexibilities.

AMS received comments on this requirement describing the expense associated with destroying cannabis in accordance with the CSA, primarily the requirement that disposal be conducted offsite by a reverse distributor or other law enforcement officer. Based on this input, AMS, in coordination with DEA partners, delayed enforcement of the disposal requirements in the IFR. In the final rule, producers have several options on how to handle non-compliant plants. Producers do not need to use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants. Producers may dispose of the plants using one or more of the means described by AMS at *https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities.* It is the Agency's intent that these methods allow producers to apply common on-farm practices as a means of disposal while rendering the controlled substance non-retrievable or non-ingestible. Under this final rule, State and Tribal plans must still include procedures to verify disposal. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements the direct growers to provide pictures, videos, or other proof that disposal occurred successfully. Producers under the USDA plan must document the disposal of all non-compliant plants. States and Indian Tribes operating under approved hemp production plans and producers under the USDA plan must notify USDA of any occurrence of non-conforming plants or plant material and provide the disposal record of those plants and materials monthly.

State and Tribal plans must include procedures to verify disposal, whether through the use of in-person verification by State or Tribal representatives, or requirements for producers to provide pictures, videos, or other proof that disposal did in fact occur. State and Tribal plans must also include requirements to submit to AMS the monthly disposal and remediation report documenting any on-farm disposals or remediations that occurred during the prior month. As of November 2020, twenty States and nine Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, there were 231 disposals representing 730 acres disposed due to not meeting the 0.3 percent acceptable hemp THC level.

AMS did not provide additional remediation options in the IFR. The only remediation alternative was to completely dispose of the non-compliant material. AMS is adding remediation to this final rule based on comment. AMS received many comments suggesting the inclusion of procedures to allow for non-compliant cannabis to be ''remediated.'' AMS agrees with this suggestion and is publishing remediation techniques concurrently with this rule that can be

followed to remediate non-compliant plant material into compliant form. As described in the IFR, hemp exceeding the acceptable THC level may not be further handled, processed, or enter the stream of commerce. AMS believes that hemp producers should have the opportunity to remediate non-compliant crops in order to minimize financial risk associated with the loss of investment in their hemp crop. For this reason, this final rule allows remediation activities, either disposing of flower materials and salvaging the remainder of the plant or blending the entire plant into biomass plant material. Through both forms of remediation, producers may be able to minimize losses, and in some cases produce a return on investment while ensuring that non-compliant material does not enter commerce.

If a producer elects to perform remediation activities as allowable under this final rule's provisions (referenced above), an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels. Only those successfully remediated crops will be allowed to enter the stream of commerce, and all other remaining non-compliant crops must then be disposed.

AMS believes the inclusion of remediation and post-harvest sampling into the final rule provides the additional flexibility requested by commenters that expressed the need for producers to have greater opportunity for success as established and beginning farmers entering hemp production.

F. Compliance With Enforcement Procedures, Including Determination of Negligence and Annual Inspection of Hemp Producers

The IFR required State and Tribal plans to include compliance procedures to ensure hemp was being produced in accordance with the requirements of this part. Comments to the IFR were generally opposed to the compliance requirements, particularly as they relate to the definition of negligence. Producers, along with State and Tribal regulatory agencies, found the negligence requirements in the IFR overly harsh and strict. This final rule changes these compliance procedures, particularly how ''negligence'' is determined. In the context of this regulation, negligence is defined as a failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulation. The definition employed in this rule is derived from the definition of negligence in Black's Law Dictionary. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (defining *negligence* as ''[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation'').

This final rule increases the negligence threshold from 0.5 to 1.0 percent THC and clarifies how States and Indian Tribes determine when to suspend or revoke a producer's license. AMS believes that raising the negligence threshold from 0.5 percent to 1.0 percent THC will increase flexibility to farmers as they learn more about how to grow compliant hemp and as the availability of stable hemp genetics improves. In developing the compliance requirements for State and Tribal plans, AMS recognizes that there may be significant differences across States and Indian Tribes in how they will administer their respective hemp programs. This final rule provides that a producer shall not be subject to more than one negligent violation per calendar year.

State and Tribal hemp plans must still include requirements to conduct annual inspections of, at a minimum, a random sample of hemp producers to verify hemp is not being produced in violation of this rule, along with a procedure for handling violations.

In accordance with the 2018 Farm Bill, States and Indian Tribes with their own hemp production plans have certain flexibilities in determining whether hemp producers have violated their approved plans. However, there are certain compliance requirements that all State and Tribal plans must contain. This includes procedures to identify and attempt to correct certain negligent acts, such as failing to provide a legal description of the land on which the hemp is produced, not obtaining a license or other required authorizations from the State or Tribal government, or producing plants exceeding 0.3 percent total THC. States and Indian Tribes may include additional requirements in their plans.

This final rule specifies that hemp producers do not commit a negligent violation if they produce plants that exceed the acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 1.0 percent on a dry weight basis. AMS recognizes that hemp producers may take the necessary steps and precautions to produce hemp, such as using certified seed, using other seed that has reliably grown compliant plants in other parts of the country, or engaging in other best practices, yet still produce plants that exceed the acceptable hemp THC level. AMS believes that a hemp producer in that scenario has exercised a level of care that a reasonably prudent person would exercise if the plant does not have a THC concentration of more than 1.0 percent on a dry weight basis. AMS arrived at this increased tolerance based on input from commenters, particularly State agriculture departments that operated hemp research programs under the 2014 Farm Bill, along with data provided by laboratories testing hemp subject to 2018 Farm Bill requirements. The 0.5 percent was based on data from three states participating in the 2014 Farm Bill pilot program. AMS believes raising the negligent violation threshold from 0.5 percent to 1.0 percent in the final rule provides a greater buffer and reduces farmers' exposure to risk of violation accrual and license suspension.

AMS recognizes the violation threshold may incentivize (or disincentivize) innovation by research institutions and producers. AMS acknowledges more innovation and research across industry will bring more stability to stakeholders. AMS believes the 1.0 percent threshold incentivizes innovation across industry more so than a 0.5 percent violation threshold. Further, comments addressed the negative impact of the accrual of negligent violations on the financial stability of the individual business. They described how a hemp grower's access to credit and insurance is jeopardized when negligent violations accumulate and lead to a determination of culpable negligence. Comments explained that lending institutions and insurance providers look for risk factors. They also raised questions about how the accrual of negligent violations may be interpreted by lender or providers. Comments said that many insurers will not cover crop losses if losses are due to the growers' negligence.

AMS acknowledges institutional lenders view violations as risk factors in decision making. AMS also notes that not all culpable violations are derived from the accrual of negligent violations. Culpable violations may be the result of producers violating other parts of the 2018 Farm Bill. However, the 2018 Farm Bill explicitly considers certain actions as constituting negligent violations. AMS's intention is to provide a threshold between 0.3 percent THC level and what would be considered a negligent violation so not all hemp that tests over the 0.3 percent be considered a negligent violation. Because a producer will not have committed a negligent violation every time he or she grows hemp with a concentration of hemp above the 0.3 percent level, this will assist producers when requesting loans or other financial assistance.

Several comments suggested that a 0.5 percent negligence threshold threatens the survival of farmers in an emerging industry. Comments suggested that the low threshold is a barrier to entry for new farmers or farmers with no experience growing hemp, who risk high initial capital investments to establish operations. Comments argued that the low threshold favors larger farms using industrialized hemp varieties and production practices, and that the low negligence threshold in the IFR would unnecessarily criminalize farmers working with a legal agricultural commodity. Increasing this threshold to 1.0 percent benefits producers, including small and new farmers, that intended to grow hemp but whose crops tested ''hot'' even though they made reasonable efforts to grow hemp.

In cases where a State or Indian Tribe determines a negligent violation has occurred, a corrective action plan shall be established. The corrective action plan must include a reasonable date by which the producer will correct the negligent violation. Producers operating under a corrective action plan must also periodically report to the State or Tribal government, as applicable, on their compliance with the plan for a period of not less than two calendar years following the violation. A producer who negligently violates a State or Tribal plan three times in a five-year period will be ineligible to produce hemp for a period of five years from the date of the third violation.

Several comments explained how these requirements as written in the IFR were confusing and difficult to administer. Particularly, commenters explained how a producer could easily receive three negligent violations during one growing season, which would lead to an automatic licensing revocation for the following five years. For example, a producer may grow hemp in three different locations. If the hemp becomes non-compliant cannabis, all in one season, the producer would lose the license in one season. Commenters described this as too strict and too severe a penalty for honest mistakes that many first-year hemp producers will certainly make. AMS agrees and wishes to clarify that this is not the intent of the regulation. AMS acknowledges that producers may have more than one production area and that they may harvest at different times. Tests results may be over the allowable limit on those production areas but the planting was performed at the same time using the same seeds. Allowing for only one violation per season would help minimize duplication of enforcement. This final rule provides that a producer shall not be subject to more than one negligent violation per calendar year. As it is customary in agriculture, practices vary due to many factors such as weather, availability of labor, transportation and storage capacity and more. Due to many factors, producers make determinations about planting and harvest cycles. In certain circumstances, producers may plant before the first cycle has been harvested specially when they plant in multiple locations. Calendar year is easier to administer and will allow for various growing seasons.

Each geographical area has a growing season based on specific temperature, weather, soil or other factors in that region, therefore this rule is defining growing season as a calendar year. This will allow flexibility, including a year-round season if States and Indian Tribes have a warmer climate or greenhouse growing.

Negligent violations are still not subject to criminal enforcement action by local, Tribal, State, or Federal government authorities under this regulation.

State and Tribal plans also must contain provisions relating to producer violations made with a culpable mental state greater than negligence, meaning acts made intentionally, knowingly, or with recklessness. This definition is derived from the definition of negligence in Black's Law Dictionary. See BLACK'S LAW DICTIONARY (10th ed. 2014) (giving as a definition of *negligence* ''[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation''). If it is determined a violation was committed with a culpable mental state greater than negligence, the State agriculture department or Tribal government, as applicable, shall immediately report the producer to the Attorney General, USDA, and the chief law enforcement officer of the State or Indian Tribe.

State and Tribal plans also must prohibit any person convicted of a felony related to a controlled substance under State or Federal law from participating in the State or Tribal plan and from producing hemp for 10-years following the date of conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date. This exemption language must be included in all State and Tribal hemp plans, whether they administered a 2014 Farm Bill research pilot program or not.

The 2018 Farm Bill does not define what it means to ''participate in the [State or Tribal] program.'' AMS is not requiring States and Indian Tribes to adopt a specific definition. Instead, they must define who those persons are in their plan. The definition must include one individual for whom a criminal history records check can be conducted for each license or authorization that the State or Indian Tribe issues. The final rule identifies and defines ''key participants'' as those participating in the USDA plan. State and Tribes may, but are not required, to adopt this definition for their plans.

The State or Indian Tribe will need to review criminal history reports for each individual identified as participating in its program. The final rules defines ''criminal history report'' as the Federal Bureau of Investigation's Identity History Summary. The State or Indian Tribe may review additional reports or checks to determine whether an individual may participate in its plan. Finally, any person found by the USDA, State, or Tribal government to have materially falsified any information submitted to the program will be ineligible to participate.

G. Information Sharing

The IFR included requirements for State and Tribal plans to contain procedures for reporting specific information to USDA. Limited comments were received on these requirements. This information has been transmitted already by many States and Tribes to USDA. This information meets the requirements set in the 2018 Farm Bill. Therefore, the following requirements are the same as required under the IFR and are in subpart F of this final rule. This is separate from the requirement to report hemp crop acreage with FSA as discussed above.

The information required includes contact information for each hemp producer covered under the plan, including name, address, telephone number, and email address (if available). If the producer is a business entity, the information must include the full name of the business, address of the principal business location, full name and title of each employee for whom the entity is required to submit a criminal history report, and an email address if available, and Employee Identification Number (''EIN'') of the business entity. Producers must report the legal description and geospatial location for each hemp production area, including each field, greenhouse, or other site used by them, as stated in section A of this preamble. The report also shall include the status of the license or other

required authorization from the State or Tribal government, as applicable, for each producer under a hemp production plan. States and Indian Tribes will submit this information to USDA not later than 30 days after the date it is received using the appropriate reporting requirements as determined by USDA.

These reporting requirements are found at § 990.70 in this final rule. Further explanation of the specific information to be submitted, the appropriate format, and the specific due dates for the information is discussed in Section X (Regulatory Analysis) of this final rule. This information submitted from each State and Tribal plan, along with the equivalent information collected from individuals participating under the USDA plan, will be assembled and maintained by USDA and made available in real time to Federal, State, Tribal, and local law enforcement, as required by the 2018 Farm Bill. All information supporting, verifying, or documenting the information submitted to USDA must be maintained by the States and Indian Tribes for at least three years.

Under § 990.70(c), States and Indian Tribes must also submit annual reports regarding the total planted, harvested, and disposed acreage. Additionally, because the final rule provides for remediation of plants, the final rule requires all remediated acreage to be reported as well. Similarly, under § 990.71(c), all USDA hemp plan producers must submit annual reports to USDA detailing total planted acreage, total acreage disposed and remediated, and total harvested acreage.

H. Certification of Resources

All State and Tribal plans submitted for USDA approval must also have a certification stating the State or Indian Tribe has the resources and personnel necessary to carry out the practices and procedures described in their plan. Section 297B of the AMA requires this certification, and the information is important to USDA's approval of State and Tribal plans, in that all such plans must be supported by adequate resources to effectively administer them. This section has not changed from the IFR.

I. State and Tribal Plan Approval, Technical Assistance and USDA Oversight

Since the publication of the IFR, AMS has worked extensively with States and Indian Tribes in developing hemp production plans. As States and Indian Tribes begin the work of modifying their plans to incorporate the changes herein, we encourage States and Indian Tribes to continue working with and sharing information with AMS. States and Tribes may need to change plans based on changes in this final rule because their State or Tribal laws may no longer match the requirements in this final rule. Even though some of the changes in this final rule are less burdensome, State and Tribal plans must follow their own legislations. Accordingly. They must amend their plans. During the plan development and/or revision process, States and Indian Tribes are encouraged to contact USDA so we may provide technical assistance in developing plan specifics. Since the publication of the IFR, USDA approved over 60 State and Tribal plans within the 60-day requirement. USDA approved plans that comply with the 2018 Farm Bill and with the provisions of the IFR. For the 2021 planting season, the 2018 Farm Bill, amended by the Continuing Resolution (CR) (Agriculture Improvement Act of 2018 (7 U.S.C. 5940 note; Pub. L. 116–260)), provided that States and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill until January 1, 2022. AMS clarified the avenues for Tribal participation under authorities in the 2014 Farm Bill to grow industrial hemp for research purposes. This clarification is available on the AMS website: *https://www.ams.usda.gov/content/usda-clarifies-industrial-hemp-production-indian-Tribes.*

Due to this extension, many States decided to remain under the 2014 Farm Bill provisions and rescinded their previously approved plans. All States are eligible to remain or start programs under the 2014 Farm Bill provisions. As a result, USDA will oversee 20 State and 20 Tribal plans under the 2018 Farm Bill until new States and Tribes submit more plans under the 2018 Farm Bill provisions.

As of November 2020, States and Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, there were 231 disposals representing 730 acres disposed due to not meeting the 0.3 percent acceptable hemp THC level. This data is limited because even though many States and Tribes have approved plans, they have not all been fully implemented. USDA expects more data will be available as the 2021 season begins and States and Tribes implement their programs.

USDA will use the procedures in this rule, which are substantively similar to those in the IFR, to review and approve State and Tribal plans. If a plan does not comply with the requirements of the Act and this regulation, it will not be approved. However, USDA has worked with many States and Tribes submitting plans to assist them in meeting the requirements and obtaining approval for their plans.

If a plan is not approved, USDA provides a letter of notification outlining the deficiencies identified. The State or Tribal government may then submit an amended plan for review. If the State or Tribe disagrees with the determination made by USDA regarding the plan, a request for reconsideration can be submitted to USDA using the appeal process as outlined in section V of this document. Plans submitted by States and Indian Tribes must be approved by USDA before they can be implemented.

States and Indian Tribes can submit their plans to USDA through electronic mail at *farmbill.hemp@usda.gov* or by postal carrier to USDA. The specific mailing address is provided on the USDA Domestic Hemp Production Program website.

If the State or Tribal plan application is complete and meets the criteria of this part, USDA issues an approval letter. Approved State and Tribal plans, including their respective rules, regulations, and procedures, are posted on USDA's hemp program website.

A USDA-approved State or Tribal plan will remain in effect, unless approval is revoked by USDA pursuant to the revocation procedures discussed in this section or unless the State or Tribe makes substantive revisions to their plan or their laws that alter the way the plan meets the requirements of this regulation. Additionally, changes to the provisions or procedures under this rule or to the language in the 2018 Farm Bill may require plan revision and resubmission to USDA for approval. Changes to applicable Federal and State or Tribal statutes may also require plan revision and resubmission to USDA for approval and may lead to plan revocation if the plan is not amended. Should States or Indian Tribes have questions regarding the need to resubmit their plans, they should contact USDA for guidance.

A State or Tribal government may submit an amended plan to USDA for approval if: (1) The Secretary disapproves a State or Tribal plan; or (2) the State or Tribe makes substantive revisions to their plan or to their laws that alter the way the plan meets the requirements of this regulation, or as necessary to bring the plan into compliance with changes in other applicable law or regulations.

If the plan previously approved by USDA needs to be amended because of

changes to the State's or Tribe's laws or regulations, such resubmissions should be provided to USDA within 60 days from when the new State or Tribal law or regulations are effective. Producers will be held to the requirements of the previous plan until such modifications are approved by USDA. If State or Tribal government regulations in effect under the USDA-approved plan change, but the State or Tribal government does not resubmit a modified plan within 60 days of the effective date of the change, USDA will issue a notification to the State or Tribal government that approval of its plan will be revoked. The revocation will be effective no earlier than the beginning of the next calendar year. If a plan is revoked, producers previously subject to an approved plan would be eligible to apply to USDA for a license. This is a change from the IFR that allowed for resubmission because of a change in State or Tribal law or regulations within a calendar year. This modification is due to USDA's need to know in a timelier manner, since such laws and regulations are the foundations of the hemp plans. The words of the plans do not have meaning if they are not aligned with current authorities.

USDA has the authority to audit States and Tribes to determine if they are in compliance with the terms and conditions of their approved plans. If a State or Indian Tribe is noncompliant with their plan, USDA will work with that State or Indian Tribe to develop a corrective action plan. However, if additional instances of noncompliance occur, USDA has the authority to revoke the approval of the State or Tribal plan for one year or until the State or Tribe become compliant. AMS still believes that one year is sufficient time for a noncompliant State or Indian Tribe to evaluate problems with their plan and make the necessary adjustments. Should USDA determine the approval of a State or Tribal plan should be revoked, such a revocation would begin after the end of the current calendar year, so producers will have the opportunity to adjust their operations as necessary. This will allow producers to apply for a license under the USDA plan so that their operations do not become disrupted due to the revocation of the State or Tribal plan.

III. Department of Agriculture Plan

The 2018 Farm Bill requires USDA to administer a hemp production plan for producers in jurisdictions where hemp production is legal but is not covered by an approved State or Tribal plan. The USDA licensing remains available to producers in States and Tribal territories without a USDA-approved hemp plan. All hemp produced in a jurisdiction without an approved State or Tribal plan must meet the requirements of the USDA plan. The requirements for producers operating under the USDA plan are similar to those operating under approved State and Tribal plans.

Regulatory requirements for producers licensed under the USDA plan in this final rule differ in some cases from corresponding requirements in the IFR and are explained in the following section. Comments submitted to the IFR generally did not address these requirements specifically; rather they focused on the broader requirements around sampling, testing, and disposal, to which all hemp producers are subject, whether licensed by a State, a Tribe, or USDA.

A. USDA Hemp Producer License and Criminal History Report

To produce hemp under the USDA plan, producers must apply for and be issued a license from USDA. USDA has been accepting applications from producers since October 2019. Any license issued by USDA prior to publication of this final rule will remain in effect and subject to the original expiration date. As of the issuance of this final rule, USDA has issued 380 licenses under the USDA plan.

While a State or Tribal government has a draft hemp production plan pending for USDA approval, USDA will not issue USDA hemp production licenses to individual producers located within that State or Tribal territory. Once USDA approves a hemp production plan from a State or Tribe, it will deny any license applications from individuals located in the applicable State or Tribal territory. If USDA disapproves a State or Tribal hemp production plan, individual producers located in the State or Tribal territory may apply for a USDA hemp production license, unless hemp production is illegal in the State or Tribal territory where they intend to produce hemp.

Comments to the IFR described confusion around the application window for when USDA would receive and process applications as described in the IFR. The IFR said that for the first year after USDA began to accept applications, applications could be submitted any time. For all subsequent years, license applications and license renewal applications would have to be submitted between August 1 and October 31. AMS requested input on this application window, and commenters were generally opposed. Under this final rule, USDA will accept applications for USDA hemp production licenses on a rolling basis to better accommodate the needs of producers. AMS continues to encourage the submission of applications well before the planting season so AMS has adequate time to process the applications. All applications must comply with the requirements as described below. The license application is available online at the USDA Domestic Hemp Production Program website at *https://www.ams.usda.gov/rules-regulations/hemp/information-producers.* Applications may be submitted electronically or by mail.

The producer license application requires contact information such as name, address, telephone number, and email address (if available). If the applicant represents a business entity, and that entity will be the producer, the application will require the full name of the business, address of the principal business location, full name and title of the key participants on behalf of the entity, an email address if available, and EIN of the business entity. All applications must be accompanied by a completed criminal history report. Several comments to the IFR expressed opposition to this requirement. AMS is retaining this requirement since verification of compliance with the felony restriction is a statutory requirement. If the application is for a business entity, a completed criminal history report must be provided for each key participant.

Some commenters expressed concern with the requirements pertaining to ''key participants,'' particularly with the requirement that all key participants undergo a background check. To the extent the commenters equated a criminal history check with a background check, AMS is retaining this requirement, since key participants are those individuals responsible for ensuring compliance with the regulatory requirements contained herein. If key participants are not subject to criminal history checks, AMS cannot ensure statutory restrictions on individuals with felony convictions related to controlled substances are met per Section 297B(e)(3)(B)(i) of the AMA. AMS notes that it will not conduct any other checks into the background of key participants.

Key participants are a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes a person in a corporate entity at executive levels including the chief executive officer, chief operating officer, and chief financial officer. This does not

include other management positions like farm, field, or shift managers. The final rule also specifies that the definition of key participant does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader, except when that member exercises executive managerial control over hemp production. AMS added this specification to address concerns raised by Indian Tribes regarding issues that can arise when a Tribal leader is also involved in the production of hemp in their capacity as a Tribal leader. While AMS understands the issues that can arise when a Tribal leader is subject to the felony conviction restriction, AMS must also ensure that all required entities operating under a USDA plan comply with Section 297B(e)(3)(B) of the AMA. Therefore, the definition of key participants still encompasses Tribal leaders who exercise executive managerial control over hemp production.

USDA will not accept criminal history reports completed more than 60 days before the submission of an application, because the 60-day window provides USDA with an expectation that the findings of the report are reasonably current and accurate.

The criminal history report must indicate the applicant has not been convicted of a State or Federal felony related to a controlled substance for the 10 years prior to the date of when the report was completed. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

In addition to providing the information specified, the application will also require license applicants to certify they will adhere to the provisions of the plan.

Once all the necessary information has been provided, applications will be reviewed by USDA for completeness and to determine an applicant's eligibility. USDA will approve or deny license applications unless the applicant is intending to produce hemp in a jurisdiction that has submitted a plan to USDA or has a plan approved by USDA, in which case the application for a USDA license will be denied. Applicants will be notified if they have been granted or denied a license either by mail or email.

If an application is denied, the applicant will receive a notification letter or email specifying why the application was denied. If an application is denied because it is incomplete, the applicant will have the option of resubmitting a revised application. If the application was denied for other reasons, the applicant will have the opportunity to appeal USDA's decision in accordance with the appeals process outlined in the regulation in subpart D.

Once a license application has been approved, USDA will issue the producer license. Licenses are not transferrable in any manner. An applicant whose application has been approved will not be considered a licensed producer under the USDA plan until the applicant receives their producer license. Licenses do not renew automatically and must be renewed every three years.

Applications for renewal will be subject to the same terms and approved under the same criteria as initial applications unless there has been an intervening change in the applicable law or regulations since approval of the initial or last application. In such a case, the subsequently enacted law or regulation shall govern renewal of the license. Licenses will be valid until December 31 of the year that is at least three years after the license is issued. This date is not tied to the harvest and planting season. For example, if a producer applies for a license on August 1, 2021, and is granted a license on September 15, 2021, the license would expire December 31, 2024. A December 31 expiration date will allow licensed producers time to apply for a license renewal prior to their prior license's expiration and prevent a gap in licensing.

A producer licensed by USDA must report their hemp crop acreage to FSA. Producers must provide specific information to FSA, including, but not limited to, USDA license number, the specific location where hemp is produced and the acreage, greenhouse, building, or site where hemp is produced. The specific location where hemp is produced must be identified, to the extent practicable, by the geospatial location. FSA will provide assistance in identifying the hemp growing location. Please refer to the Section II of this document on State and Tribal hemp production program requirements for further discussion on FSA reporting requirements.

If at any time there is a change to the information submitted in the license application, a license modification is required. A license modification is required if, for example, the licensed business is sold to a new owner or hemp will be produced in a new location not described on the original application. Producers must notify USDA immediately should there be any change in the information provided on the license application.

B. Sampling for THC

The IFR stated that all hemp production must be sampled and tested for THC concentration levels. It is the responsibility of the licensed producer to pay any fees associated with sampling. AMS issued guidance on sampling procedures that meet the sampling requirements to coincide with publication of the IFR and will update the guidance with this final rule. AMS is requiring that all samples tested for THC concentration levels be conducted in DEA-registered laboratories. However, this requirement will not be applicable until December 31, 2022.

Significant input was received on the IFR sampling requirements. Please refer to section B under State and Tribal plans above and the discussion of comments below for a summary of findings. Producers under the USDA plan are subject to the sampling and testing requirements as outlined in the USDA guidelines for sampling and testing. Since USDA cannot develop a one size fits all performance-based sampling program, all producers licensed under the USDA plan must comply with the USDA sampling guidelines. USDA licensed producers are responsible for obtaining the services of sampling agents and hemp testing laboratories themselves. USDA is updating guidance on sampling procedures and training for sampling agents with this rule. USDA does not provide sampling or testing services and will not pay for those services.

State and Tribal hemp regulators have successfully developed sampling requirements that ensure adherence to State and Federal regulations, while allowing for flexibilities due to limited State resources and State and Tribal differences. They explained that, since most hemp in a given region is harvested at the same time, sampling must be completed within a very short time frame by only a few individuals. Several States also explained that perceived risk determines State requirements. Some States utilize different sampling requirements for broad end-use categories like ''fiber/grain'' hemp versus ''cannabinoid'' hemp, while others base their requirements on historical THC concentrations of certain varietals or on the characteristics and growing history of a certain farm or producer. AMS agrees that sampling requirements should allow States and Indian Tribes more flexibility in the management of their hemp regulatory programs.

AMS agrees that requiring sampling from every lot may be burdensome and expensive for State and Tribal regulatory entities and producers.

AMS finds that it makes sense to allow States and Indian Tribes to consider performance-based alternatives when developing sampling plans that take into account unique sampling protocols for hemp growing facilities under their jurisdiction. The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp growing facilities under their jurisdiction. Sampling protocols must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, States and Indian Tribes may adopt a performance-based sampling protocol. A performance-based protocol must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plants will not test above the acceptable hemp THC level. USDA encourages that the alternative protocol consider seed certification processes or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe, whether the producer is conducting research on hemp at an institution of higher learning or that is funded by a Federal, State, or Tribal government, whether a producer has consistently produced compliant hemp plants over an extended period of time, and other similar factors. AMS believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. If a State or Tribal plan lacks a sampling protocol, every lot, and thereby every producer must be sampled and tested.

When evaluating sampling protocols submitted by States and Indian Tribes, USDA will evaluate the risk of producing non-compliant material to determine approval or disapproval. In evaluating the risk, USDA will take into consideration whether the performance-based factors the State or Tribe used have the potential to ensure compliance at a 95 percent confidence level.

Since USDA cannot develop performance metrics that would be applicable independently from where the producer is located, producers licensed under the USDA plan are subject to the sampling requirements in the rule. USDA guidelines provided on the USDA website at *https://www.ams.usda.gov/rules-regulations/hemp/information-sampling* describe best practices for complying with those requirements. However, USDA would consider a performance-based sampling scheme for producers under the USDA plan, and amend the sampling requirements accordingly, if information collected by USDA in the future is sufficient to make this determination. Data must be reliable and able to be applicable across the production areas in the U.S.

Samples must be collected by a USDA-approved sampling agent, or a Federal, State, Tribal, or local law enforcement agent authorized by USDA to collect samples. As explained above, USDA is expanding the training requirements for sampling agents and will provide a list of authorized sampling agents on the USDA website. It is the responsibility of the licensed producer to pay any fees associated with sampling and testing. Sampling and testing guideline documents are being updated as part of this proceeding and are available on the USDA website.

The sampling procedures are designed to produce a representative sample for testing. They describe procedures for entering a growing area and collecting the minimum number of plant specimens necessary to accurately represent the THC content, through laboratory testing, of the sample to be tested.

C. Testing Laboratories

The THC level in representative samples must be at or below the acceptable hemp THC level. Testing must be conducted using post-decarboxylation or other similarly reliable methods where the total THC concentration level measured includes the potential to convert THCA into THC. Further, test results should be determined and reported on a dry weight basis, meaning the percentage of THC, by weight, in a cannabis sample, after excluding moisture from the sample. The moisture content is expressed as the ratio of the amount of moisture in the sample to the amount of dry solid in the sample.

Based on AMS's review of scientific studies, internal research and information gathered from the *United Nations Office on Drugs and Crime:* ''*Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products*'' (ISBN 978–92–1–148242–3), AMS has determined that testing methodologies meeting these requirements include gas or liquid chromatography with detection. As discussed earlier and stated in § 990.25(g), if a testing laboratory utilizes alternative testing methods, they must be reviewed and approved by USDA to assess their reliability, accuracy, and compliance with the requirements.

As explained earlier in this document, AMS is requiring that all testing of samples for THC concentration levels be conducted in DEA-registered laboratories. Enforcement of this requirement has been delayed until December 31, 2022. Non-DEA-registered labs can continue testing hemp for THC concentration until that time. Labs testing hemp for THC must meet standards of performance described in this regulation. Standards of performance ensure the validity and reliability of test results; that analytical method selection, validation, and verification are appropriate (fit for purpose); and that the laboratory can successfully perform the testing. Furthermore, the standards ensure consistent, accurate, analytical performance and that the analytical tests performed are sufficiently sensitive for the purposes of the detectability requirements under this final rule.

Laboratories conducting THC testing must also be registered with DEA to handle controlled substances under the CSA (21 U.S.C. 822 and 21 U.S.C. 844) and DEA regulations (21 CFR part 1301). USDA is adopting this requirement because of the potential for these laboratories to handle cannabis products testing above 0.3 percent THC. Such products are, by definition, marijuana, and a controlled substance. DEA registration requirements verify a laboratory's ability to properly handle controlled substances.

As previously explained in the requirements for State and Tribal plans, AMS is not adopting requirements that hemp testing laboratories be approved under a USDA Laboratory Approval Program or undergo ISO accreditation.

It is the responsibility of the licensed producer to select the DEA-registered laboratory that will conduct the testing and to pay any fees associated with testing. Laboratories performing THC testing for hemp produced under this program are required to share test results with the licensed producer and USDA. USDA will provide instructions to all approved labs on how to electronically submit test results to USDA. Laboratories may provide test results to licensed producers in whatever manner best aligns with their business practices, but producers must

be able to produce a copy of test results. For this reason, providing test results to producers through a web portal or through electronic mail, so the producer will have ready access to print the results when needed, is preferred.

Samples exceeding the acceptable hemp THC level are marijuana and will be handled in accordance with the procedures discussed in section C below.

Any licensee may request that the laboratory retest pre-harvest samples, if it is believed the original THC concentration level test results were in error. The licensee requesting the retest of the second sample would pay the cost of the test. The retest results would be issued to the licensee requesting the retest, and a copy would be provided to USDA or its agent.

Research Institutions Sampling and Testing

AMS also acknowledges that research institutions face special circumstances when conducting hemp research. Under the IFR, researchers and research institutions were required to comply with the same production requirements as commercial producers. Under this final rule, and as described in detail below, research institutions and the producers working with them are afforded greater sampling and testing flexibility to facilitate continued hemp research. Producers that produce hemp for research must obtain a USDA license. However, the hemp that is produced for research is not subject to the same sampling requirements provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. The rule includes a performance-based standard for sampling for all licensed producers in section 990.24: ''at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level.'' The performance-based standard for research is a modification of that standard: ''the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level.'' We are comfortable with this modification to recognize that researchers may need flexibility to conduct their research and because the research hemp cannot enter the stream of commerce. USDA will monitor researchers' compliance with this standard as part of its normal oversight and compliance program.

USDA licensees shall ensure the disposal of all non-compliant plants. USDA licensees shall also comply with the reporting requirements including reporting disposal of non-compliant plants. Research institutions that handle ''hot'' hemp must follow CSA requirements for handling marijuana.

Performance based plans from research institutions where a State or Tribal plan is not in place will be reviewed by USDA. Notice and comment requirements under the PRA process will be followed before a final determination is made by USDA to move forward with approving performance-based plans for those producers under the USDA plan.

States and Indian Tribes are allowed to develop performance-based requirements for these institutions. However, the alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level.

The research institutions must follow reporting requirements. AMS believes this exception is necessary to help support research and development as it relates to hemp production. This decision allows these types of research facilities and institutions to confidently oversee the study of hemp plants through trialing and genetics research. AMS believes this exception to be critical to the growth of industry, particularly in its infancy. Over time, the exception provided by this final rule will help to stabilize the industry by providing greater understanding of hemp genetics and how certain varietals respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as they will be made aware of the more stable and consistently reliable hemp varietals. Any non-compliant plants produced by research institutions as a result of research and development will still need to be disposed and verified through documentation. Research institutions must follow licensing and reporting requirements.

D. Disposal of Non-Compliant Product

Under the IFR, non-compliant product was required to be disposed of by persons authorized to do so under the CSA and had to be destroyed. As explained below, under this final rule, producers may handle non-compliant product disposal on the farm, and they have greater flexibility in remediating that product. USDA producers are required to follow procedures for ensuring effective disposal of cannabis plants produced in violation of this rule. Plants that are removed as a result of poor plant health, pests, disease, weather events, along with removal of male or hermaphrodite plants as part of a cross-pollination prevention plans, are not subject to the disposal requirements herein. This final rule retains the disposal requirements explained in the IFR, but clarifies what ''disposal'' means and explains how the process must be conducted. If a producer grew cannabis exceeding the acceptable hemp THC level, the IFR required that the material be disposed of in accordance with the CSA and DEA regulations because such material is marijuana, a Schedule I controlled substance under the CSA. The IFR required that material be collected for disposal by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, Tribal, or local law enforcement officer.

As explained earlier, AMS is now allowing the flexibility to conduct on-farm disposals and also allowing for remediation options.

If the results of a test conclude that the THC levels exceed the acceptable hemp THC level, the laboratory will promptly notify the producer and USDA or its authorized agent. If a licensed producer is notified that they have produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of in accordance with the on-farm disposal options described herein.

Licensed producers notified they have produced cannabis plants exceeding the acceptable hemp THC level must arrange for disposal or remediation of the lot represented by the sample in accordance with the procedures as specified above and described on the USDA website at *https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities.*

Producers must document the disposal or remediation of all non-compliant cannabis. This can be accomplished by providing USDA with a copy of the documentation of disposal or remediation using the reporting requirements established by USDA. These reports must be submitted to USDA following the completion of the disposal or remediation process.

E. Compliance

As described below, this final rule changes the THC threshold for a negligent violation from 0.5 percent

under the IFR to 1.0 percent. Further, rather than being liable for multiple negligent violations in each growing season as under the IFR, this final rule provides that producers can only incur one negligent violation in each growing season, which prevents producers from accumulating multiple negligent violations and losing program eligibility after a single growing season.

USDA will maintain oversight of USDA-licensed hemp producers by conducting audits of USDA licensees and working with licensees with negligent violations to establish corrective action plans. Negligent violations by a producer may lead to suspension or revocation of a producer's license.

While USDA has not yet conducted any random audits, the department may conduct random audits of licensees to verify hemp is being produced in accordance with Subtitle G of the AMA no more frequently than every three years, based on available resources. The format of the audit will vary and may include a ''desk-audit'' where USDA requests records from a licensee, or the audit may be a physical visit to a licensee's facility. When USDA visits a licensee's facility, the licensee must provide access to any fields, greenhouses, storage facilities, or other locations where the licensee produces hemp. USDA may also request records from the licensee, to include production and planting data, testing results, and other information as determined by USDA.

USDA will issue a summary of the audit to the licensee after the completed audit. Licensees who are found to have a negligent violation will be subject to a corrective action plan. Negligent violations include: (1) Failure to provide a legal description of the land on which the hemp is produced; (2) not obtaining a license before engaging in production; or (3) producing plants exceeding the acceptable hemp THC level. Similar to the requirements for State and Tribal plans, USDA will not consider hemp producers as committing a negligent violation if they produce plants exceeding the acceptable hemp THC level if they use reasonable efforts to grow hemp and the cannabis plant does not have a THC concentration of more than 1.0 percent on a dry weight basis. AMS believes that increasing the negligence threshold from 0.5 percent to 1.0 percent will increase flexibility to farmers as they learn more about how to grow compliant hemp and as the availability of stable hemp genetics improves. Further, producers may only receive one negligent violation per growing season, as determined by USDA based on a review of producer records. USDA will use a calendar year as a growing season.

When USDA determines that a negligent violation has occurred, USDA will issue a Notice of Violation. This Notice of Violation will include a corrective action plan. The corrective action plan will include a reasonable date by which the producer will correct the negligent violation or violations and will require the producer to periodically report to USDA on its compliance with the plan for a period of not less than the next two calendar years. A producer who has negligently violated the provisions of this rule three times in a five-year period is ineligible to produce hemp for a period of five years from the date of the third violation. Negligent violations are not subject to criminal enforcement.

Hemp found to be produced in violation of this regulation, such as hemp produced on a property not disclosed by the licensed producer or without a license, would be subject to the same disposal provisions as for cannabis testing above the acceptable hemp THC level. Further, if it is determined a violation was committed with a culpable mental state greater than negligence, USDA will report the violation to law enforcement.

The 2018 Farm Bill limited the participation of certain convicted felons in hemp production. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Act. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

F. Suspension of a USDA License

There are no changes to the IFR provisions related to suspension of USDA licenses in this final rule.

A USDA license may be suspended if USDA receives credible information that a USDA licensee has either: (1) Engaged in conduct violating a provision of this regulation; or (2) failed to comply with a written order from the AMS Administrator related to a negligent violation of this regulation. Examples of credible information are information from local authorities of harvested plants without testing or planting of hemp in non-licensed locations.

Any person whose license has been suspended shall not produce hemp during the period of suspension. A suspended license may be restored after a waiting period of one year. A producer whose license has been suspended may be required to comply with a corrective action plan to fully restore their license.

A USDA license shall be immediately revoked if the USDA licensee: (1) Pleads guilty to, or is convicted of, any felony related to a controlled substance; [9] (2) made any materially false statement with regard to this regulation to USDA or its representatives with a culpable mental state greater than negligence; or (3) was found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence or negligently violated the provisions of this regulation three times in five years.

If the licensed producer wants to appeal any suspension or revocation decision made by USDA as described in this section, they can do so using the appeal process explained in section V of this document.

G. Reporting and Recordkeeping

The 2018 Farm Bill requires USDA to develop a process to maintain relevant information regarding the land where hemp is produced. Reporting requirements under this final rule, particularly the requirement to report hemp crop acreage to FSA, are discussed extensively in Section B of the State and Tribal plan requirements and the same requirements are applicable to USDA licensed producers.

In general, changes from the IFR allow producers more flexibility in defining for FSA the areas (instead of ''lots'') they use for hemp production. USDA hemp production licensees can apply for licenses on a rolling basis under this final rule, in contrast to the limited period provided under the IFR. Reporting requirements under this final rule are revised slightly to allow producers to account for on-farm disposal of non-compliant product.

USDA's FSA is well suited to collect this information for the domestic hemp production program. FSA has staff throughout the United States who are trained to work with farmers to verify land uses. Many hemp producers are likely to be familiar with the FSA since they already operate traditional farms, and therefore already provide data to FSA on acres and crops planted. Producers may benefit from information to participate in other USDA programs through FSA offices. Licensed producers will be required to report their hemp crop acreage with FSA, and to provide FSA with specific

[9] For a corporation, if a key participant has a disqualifying felony conviction, the corporation may remove that person from a key participant position. Failure to remove that person will result in a license revocation.

information regarding field acreage, greenhouse, or indoor square footage of hemp planted. This information must include street address, geospatial location or other comparable identification method specifying where the hemp will be produced, and the legal description of the land. Geospatial location or other methods of identifying the production locations are necessary, as not all rural locations have specific addresses. This information is required for each field, greenhouse, building, or site where hemp will be grown. USDA will use this information to assemble and maintain the data USDA must make available in real time to Federal, State, Tribal and local law enforcement as required by the 2018 Farm Bill and as described in section G below.

Specific procedures for reporting hemp acreage to FSA will be posted on the USDA Domestic Hemp Production Program website. All information will be maintained by USDA for at least three calendar years. FSA will assist producers in identifying the hemp growing locations since they have maps that allow for better identification. This is a procedure that FSA employees are very familiar with since it is used for other USDA programs. This rule also revises the definition of ''lot'' to include other terms used by FSA with the same meaning. FSA uses terms like ''farm,'' ''tract,'' ''field,'' and ''subfield.'' FSA staff will not provide a ''lot number'' to producers as described in the IFR. Instead, FSA will assist producers to identify the area where hemp is grown. More details are provided under the States and Tribal plan Section B earlier in this final rule.

Licensed producers are required to maintain copies of all records and reports necessary to demonstrate compliance with the program. These records include those that support, document, or verify the information provided in the forms submitted to USDA. Records and reports must be kept for a minimum of three years. Because the final rule allows producers to remediate plants, the final rule also requires producers to maintain records on all remediated cannabis plants.

Under the USDA plan, there will be additional reporting requirements for licensed producers. These include information requested in the application for a license and the record and reporting requirements needed to document disposal or remediation of cannabis produced in violation of the provisions of this rule. Specific reporting requirements are detailed in § 990.71.

H. Information Sharing With Law Enforcement

USDA is working to develop and maintain a database of all relevant and required information regarding hemp as specified by the 2018 Farm Bill. This database will be accessible in real time to Federal, State, local, and Tribal law enforcement officers through a Federal government law enforcement system. USDA AMS will administer and populate this database, which will include information submitted by States, Tribes, laboratories, and USDA licensed producers and information submitted to FSA. States and Tribes must provide information to USDA in a format that is compatible with USDA's information sharing system. USDA will work with States and Indian Tribes on system format and other information necessary to share information.

USDA will use this information to create a comprehensive list of all domestic hemp producers. USDA will also gather the information related to the land used to produce domestic hemp. This information will be comprehensive and include data from both State and Tribal plans and will include a legal description of the land on which hemp is grown by each hemp producer and the corresponding geospatial location or other identifiable location. Finally, USDA will also gather information regarding the status of all licenses issued under State and Tribal government plans and under the USDA plan.

This information will be made available in real time to Federal, State, local and Tribal law enforcement as required by the 2018 Farm Bill.

IV. Definitions

The following terms are integral to implementing Subtitle G of the AMA and establish the scope and applicability of the regulations of this final rule.

The term ''Act'' refers to the Agricultural Marketing Act of 1946. The 2018 Farm Bill amended the Agricultural Marketing Act of 1946 by adding Subtitle G, which is a new authority for the Secretary of Agriculture to administer a national hemp production program. Section 297D of Subtitle G authorizes and directs USDA to promulgate regulations to implement this program.

The ''Agricultural Marketing Service'' or ''AMS'' is the Agricultural Marketing Service of the U.S. Department of Agriculture is the agency the Secretary of Agriculture has been charged with the responsibility to oversee the administration of this new program.

The term ''applicant'' means any State or Indian Tribe that has applied for USDA approval of a State or Tribal hemp production plan for the State or Indian Tribe they represent. This term also applies to any person or business in a State or territory of an Indian Tribe not subject to a State or Tribal plan, who applies for a hemp production license under the USDA plan established under this part.

The term ''cannabis'' is the Latin name of the plant that, depending on its THC concentration level, is further defined as either ''hemp'' or ''marijuana.'' *Cannabis* is a genus of flowering plants in the family Cannabaceae, of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. For the purposes of this part, cannabis refers to any form of the plant where the delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined. This term is important in describing regulations that apply to plant production, sampling, or handling prior to determining its THC content.

The ''Controlled Substances Act'' is the statute, codified in 21 U.S.C. 801–971, establishing Federal U.S. drug policy under which the manufacture, importation, exportation, possession, use, and distribution of certain substances are regulated. Because cannabis with THC content concentration levels of higher than 0.3 percent is deemed to be marijuana, a Schedule I controlled substance, its regulation falls under the CSA. Therefore, for compliance purposes, the requirements of the CSA are relied upon for the disposal of cannabis that contains THC concentrations above the stated limit of this final rule.

The rule includes a definition of ''conviction'' to explain what is considered a conviction and what is not. Specifically, a plea of guilty or nolo contendere or any finding of guilt is a conviction. However, if the finding of guilt is subsequently overturned on appeal, pardoned, or expunged, then it is not considered a conviction for purposes of part 990. This definition of ''conviction'' is consistent with how some other agencies conducting criminal history record searches determine disqualifying crimes.

A ''corrective action plan'' is a plan agreed to by a State, Tribal government, or USDA for a licensed hemp producer, to correct a negligent violation or non-compliance with a hemp production plan, its terms, the applicable law(s) or this regulation. Corrective action plans may also be a plan set forth by a State or Tribal government with an approved

hemp production plan to correct a non-compliance of their program with their USDA-approved plan. This term is defined in accordance with the 2018 Farm Bill, which mandates certain non-compliant actions to be addressed through corrective action plans.

''Culpable mental state greater than negligence'' is a term used in the 2018 Farm Bill to determine when certain actions would be subject to specific consequences. This term means to act intentionally, knowingly, willfully, recklessly, or with criminal negligence.

The term ''decarboxylated'' refers to the completion of the chemical reaction that converts THCA into delta-9 THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a molecular mass conversion ratio that sums delta-9 THC and eighty-seven and seven tenths (87.7) percent of THC-acid ((delta-9 THC) + (0.877*THCA)).

''Delta-9 tetrahydrocannabinol,'' also referred to as ''Delta-9 THC'' or ''THC'' is the primary psychoactive component of cannabis, and its regulation forms the basis for the regulatory action of this part. As mandated by the Act, legal hemp production must be verified as having THC concentration levels of 0.3 percent on a dry weight basis or below. For the purposes of this part, delta-9 THC and THC are interchangeable.

The term ''disposal'' means the action or process of getting rid of cannabis that is non-compliant.

''DEA'' is an acronym for the ''Drug Enforcement Administration,'' a United States Federal law enforcement agency under the United States Department of Justice. The DEA is the lead agency for domestic enforcement of the Controlled Substances Act. The DEA plays an important role in the oversight of the disposal of marijuana, a Schedule I controlled substance, under the regulations of this part. The DEA is also instrumental in registering laboratories to legally handle controlled substances, including cannabis samples that test above the 0.3 THC concentration level.

''Dry weight basis'' refers to a method of determining the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

The ''Farm Service Agency (FSA)'' is an agency of the U.S. Department of Agriculture that provides services to farm operations including loans, commodity price supports, conservation payments, and disaster assistance. For the purposes of this program, FSA will assist in information collection of land being used for hemp production.

''Gas chromatography'' or GC, is a scientific method (specifically, a type of chromatography technique) used in analytical chemistry to separate, detect, and quantify each component in a mixture. It relies on the use of heat for separating and analyzing compounds that can be vaporized without decomposition. Under the terms of this part, GC is one of the valid methods by which laboratories may test for THC concentration levels.

For the purposes of this part, the term ''geospatial location'' means a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

The term ''handle'' is commonly understood by AMS and used across many of its administered programs. For the purposes of this part, ''handle'' refers to the actions of cultivating or storing hemp plants or hemp plant parts prior to the delivery of such plant or plant part for further processing. In cases where cannabis plants exceed the acceptable hemp THC level, handle may also refer to the disposal of those plants.

''Hemp'' is defined by the 2018 Farm Bill as ''the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

''Liquid chromatography (LC)'' is a scientific method (specifically, a type of chromatography) used in analytical chemistry used to separate, identify, and quantify each component in a mixture. It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds. Under the terms of this part, LC is one of the valid methods by which laboratories may test for THC concentration levels. Ultra-Performance Liquid Chromatography (UPLC) is an additional method that may also be used as well as other liquid or gas chromatography with detection.

''Indian Tribe or Tribe'' is defined in the 2018 Farm Bill by reference to section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

A ''key participant'' is a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes persons in a corporate entity, including tribally-owned corporation individuals, at executive levels, including chief executive officer, chief operating officer, and chief financial officer. This does not include such management personnel as farm, field, or shift managers. This definition also does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.

''Law enforcement agency'' refers to all Federal, State, Tribal, or local law enforcement agencies. Under the 2018 Farm Bill, State and Tribal submissions of proposed hemp production plans to USDA must be made in consultation with their respective Governors and chief law enforcement officers. Moreover, the 2018 Farm Bill contemplates the involvement of law enforcement in compliance actions related to offenses identified as being made under a ''culpable mental state greater than negligence.'' To assist law enforcement in the fulfillment of these duties, the 2018 Farm Bill also mandates information sharing that provides law enforcement with real-time data.

The term ''lot'' refers to a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout. In addition, ''lot'' is a common term in agriculture that refers to the batch or contiguous, homogeneous whole of a product being sold to a single buyer at a single time. Under the terms of this part, ''lot'' is to be defined by the producer in terms of farm location, field acreage, and variety (*i.e.,* cultivar) and to be reported as such to FSA. For FSA reporting purposes, FSA staff will determine the appropriate designation for the specific location(s) where hemp is being grown using FSA terminology such as ''farm,'' ''tract,'' ''field,'' and ''subfield'' to mean ''lot'' for the purpose of this rule.

''Marijuana,'' or, as defined in the CSA, ''marihuana,'' means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin. The term ''marihuana'' does not include hemp, as defined in section 297A of the Agricultural Marketing Act

of 1946, and does not include the mature stalks of such plant; fiber produced from such stalks; oil or cake made from the seeds of such plant; any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake; or the sterilized seed of such plant which is incapable of germination (7 U.S.C. 1639o(1)). ''Marihuana'' also means all cannabis that tests as having a THC concentration level on a dry weight basis of higher than 0.3 percent.

''Negligence'' is a term used in the 2018 Farm Bill to describe when certain actions are subject to specific compliance actions. For the purposes of this rule, the term means failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this final rule.

Used in relation to the other terms and regulations in this part, ''phytocannabinoids'' are cannabinoid chemical compounds found in the cannabis plant, two of which are Delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD). Testing methodologies under this part will refer to the presence of ''phytocannabinoids'' as either THC or CBD.

Under the terms of this program, ''plan'' refers to a set of criteria or regulations under which a State or Tribal government, or USDA, monitors and regulates the production of hemp. ''Plan'' may refer to a State or Tribal plan, whether approved by USDA or not, or the USDA hemp production plan.

The 2018 Farm Bill mandates that all cannabis be tested for THC concentration levels using ''post-decarboxylation'' or similar methods. In the context of this part, ''post-decarboxylation'' means testing methodologies for THC concentration levels in hemp, where the total potential delta-9-tetrahydrocannabinol content, derived from the sum of the THC and THCA content, is determined and reported on a dry weight basis. The post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, known as gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. The result of this test calculates total potential THC. The post-decarboxylation value of THC, or total THC, can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact, and requires a conversion calculation of that THCA to calculate total potential THC. See also the definitions for decarboxylation and total THC.

The term ''produce,'' when used as a verb, is a common agricultural term that is often used synonymously with ''grow,'' and means to propagate plants for market, or for cultivation for market, in the United States. In the context of this part, ''produce'' refers to the propagation of cannabis to produce hemp.

''Producer'' means a producer as defined in 7 CFR 718.2 specifically of hemp. The 2018 Farm Bill mandates that USDA maintain a real-time informational database that identifies registered hemp production sites, whether under a State, Tribal, or USDA plan, for the purposes of compliance and tracking with law enforcement. AMS will maintain this system with the information collection assistance of FSA. In order to maintain consistency and uniformity of hemp production locations, USDA is using FSA to collect this information through their crop acreage reporting system. In this context, a common use of the term ''producer'' is essential to maintaining a substantive database. For this reason, the definition of ''producer'' incorporates the FSA definition of ''producer'' with the additional qualifier that they are a producer specifically of hemp. All producers are required to be licensed or authorized to produce hemp under the USDA Domestic Hemp Production Program.

''Remediation'' refers to techniques utilized to transform non-compliant cannabis into something useful and compliant while disposing of non-compliant parts. Remediation can occur by removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds. Remediation can also occur by shredding the entire plant into a bio-mass like material, then re-testing the shredded biomass material for compliance.

''Secretary'' means the Secretary of Agriculture of the United States Department of Agriculture.

Section 297A of the Act defines ''State'' as any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The term ''State department of agriculture'' is defined by the 2018 Farm Bill as the agency, commission, or department of a State government responsible for agriculture in the State. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The term ''store'' is related to the term ''handle'' under this part and means to deposit hemp plants or hemp plant product in a storehouse, warehouse, or other identified location by a producer for safekeeping prior to delivery to a recipient for further processing.

The term ''Territory of the Indian Tribe'' means (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

The IFR defined the Territory of the Indian Tribe as ''Indian Country'' in 18 U.S.C. 1151 because section 1151 is a commonly acceptable approach to determine a Tribal government's jurisdiction. The final rule retains the language of section 1151, but adds item (d) to the definition of ''Territory of the Indian Tribe.'' This addition does not significantly expand the definition because many of the lands encompassed by item (d) were already considered as ''Territory of the Indian Tribe'' under the IFR. For example, off-reservation trust land, if not considered part of a reservation under section 1151(a), is generally considered within a dependent Indian community under section 1151(b). *See Club One Casino, Inc.* v. *Bernhardt,* 959 F.3d 1142, 1149–50 (9th Cir. 2020); Felix Cohen, Cohen's Handbook of Federal Indian Law, section 3.04 (Nell Jessup Newton ed. 2012). Also, restricted fee lands outside of a reservation are often considered part of a dependent Indian community, provided the lands satisfy the two requirements of a dependent Indian community—lands that are (1) set aside by the Federal Government for the use of the Indians and (2) under federal superintendence. *Citizens Against Casino Gambling in Erie Cty.* v. *Chaudhuri,* 802 F.3d 267, 281 (2d Cir. 2015).

However, because ''dependent Indian communities'' is an oft-litigated term that is interpreted varyingly amongst the courts, USDA decided to add item (d) to the definition of ''Territory of the Indian Tribe'' to add clarity and ensure nationwide consistency regarding the jurisdictional boundaries of regulatory authority over the production of hemp.

''Total THC'' is the post-decarboxylation value of THC, either after testing with gas chromatography or LC after using a conversion factor. LC does not use decarboxylation as part of the process and this addition is to account for the conversion of THCA into THC if decarboxylation was part of the process. The addition of 87.7 percent of THCA is applicable if the testing laboratory uses LC with detection to measure the THC. Total THC is the measured THC plus 87.7 percent of THCA.

As defined by the 2018 Farm Bill, the term ''Tribal government'' means the governing body of an Indian Tribe. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The ''U.S. Attorney General'' is the Attorney General of the United States.

''USDA'' is an acronym that stands for the ''United States Department of Agriculture.''

V. Appeals

The following paragraphs explain when and how to appeal a USDA decision. State or Tribal plans may include similar appeal procedures. No changes were made to this section based on comments.

An applicant for a USDA hemp production program license may appeal a license denial to the AMS Administrator. USDA licensees can appeal denials of license renewals, license suspensions, or license revocations to the AMS Administrator. All appeals must be submitted in writing and received within 30 days of the denial. Appeals may be submitted by mail or electronic form. This submission deadline should provide adequate time to prepare the necessary information required for the appeal. The Administrator will take into account the applicant or USDA licensee's justification for why the license should not be denied, suspended, or revoked, and then issue a final determination. Determinations made by the Administrator under the appeals process will be final unless the applicant or USDA licensee requests a formal adjudicatory proceeding to review the decision, which will be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H, which USDA will amend to add the Domestic Hemp Production Program. If the applicant or USDA licensee does not request that the Administrator initiate a formal adjudicatory proceeding within 30 days of the Administrator's adverse ruling, such ruling becomes final.

Appeals Under a State or Tribal Hemp Production Plan

A State or Tribe can appeal the denial of a proposed hemp production plan, or the proposed suspension or revocation of a plan by USDA. USDA will consult with States and Tribes to help ensure their draft plans meet statutory requirements, and that existing plan requirements are monitored and enforced by States and Indian Tribes. If, however, a proposed State or Tribal plan is not approved, or an existing plan is suspended or revoked the decision may be appealed.

If the AMS Administrator grants a State or Indian Tribe's appeal of a disapproval of its hemp plan, the proposed State or Tribal hemp production plan shall be approved as proposed. If the AMS Administrator denies an appeal, prospective producers located in the State or Tribal Territory can apply directly to USDA for a hemp license. Similarly, if an appeal of a denied proposed State or Tribal plan is denied, producers located in the impacted State or Tribal territory may apply for licenses under the USDA plan.

A State or Tribe appealing the suspension or revocation of their hemp production plan must explain the reasoning for the appeal and the appeal must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. This timeframe should be adequate for the assembly of the information required to be submitted as part of the appeal.

VI. Interstate Commerce

Nothing in this rule prohibits the interstate commerce of hemp. No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with this part and with section 7606 of the 2014 Farm Bill (expires January 1, 2022) through the State or the territory of the Indian Tribe, as applicable.[10]

[10] *See* section 10114 of the 2018 Farm Bill and the USDA General Counsel's Legal Opinion on the Authorities for Hemp Production at *https://www.ams.usda.gov/content/legal-opinion-authorities-hemp-production.*

VII. Outreach

As part of this rulemaking process, AMS held numerous meetings with State and Tribal governments and their representatives, industry organizations, groups and individuals with experience in the hemp industry, and representatives of law enforcement, as well as other Federal agencies.

In addition, USDA also conducted a listening session on March 13, 2019, that had more than 2,100 participants, and included comments from 46 separate speakers representing States, Tribes, producers, end-users, hemp organizations, and others. The recording of the listening session is available on the USDA website at *https://www.ams.usda.gov/rules-regulations/hemp.* On May 1 and 2, 2019, USDA also participated in Tribal consultation meetings for a total of 52 and 38 participants, respectively. On September 24, 2020, AMS conducted another Tribal Consultation with approximately 90 participants.

AMS published an interim final rule on October 31, 2019 (84 FR 58522), that established a temporary hemp production program and invited public comments on the program's provisions. The initial 60-day comment period was extended by 30 days on December 18, 2019 (84 FR 69295). The comment period was reopened for another 30 days on September 8, 2020 (85 FR 55363). A total of approximately 5,900 comments were submitted by States, Tribes, farmers, industry associations, and other interested groups and individuals during the combined comment periods expressing their views on the provisions of the IFR and suggesting modifications, many of which have been incorporated into this final rule.

Finally, in November 2019, AMS posted an informational webinar about the domestic hemp production program on its website (in English and Spanish) at *https://www.ams.usda.gov/rules-regulations/hemp.* AMS has also posted additional useful information for regulated entities and other interested persons on its website at *https://www.ams.usda.gov/rules-regulations/hemp.*

As required by the Farm Bill, the Secretary developed this final rule and related guidelines in consultation with the U.S. Attorney General. In addition, USDA has submitted information to, and consulted with, the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate regarding updates on the

implementation of the hemp requirements in the Farm Bill.

VIII. Severability

This final rule includes a severability provision. This provision helps address the status of the regulations should a court vacate a particular provision. This section provides that if any provision of part 990 is found to be invalid, the remainder of the part shall not be affected.

IX. Comment Analysis

AMS accepted comments during an initial comment period from October 31, 2019 through December 31, 2019. On December 18, 2019 (84 FR 69295), this initial comment period was extended for an additional 30 days, ending January 29, 2020. AMS reopened the comment period for 30 additional days on September 8, 2020 (85 FR 55363), ending October 8, 2020. Comments may be accessed through *Regulations.gov*.[11] Reopening the comment period gave interested persons an additional opportunity to comment on the IFR. Comments were solicited from all stakeholders, notably those who were subject to the regulatory requirements of the IFR during the 2020 production cycle.

AMS specifically requested comments on the 15-day sampling and harvest timeline; the possibility of establishing a fee-for-service hemp laboratory approval process for labs that wish to offer THC testing services; the possibility of requiring all laboratories testing hemp to have ISO 17025 accreditation; the number of labs already ISO 17025 accredited; additional examples of reasonable efforts to illustrate actions hemp producers can take in order to avoid committing a negligent violation under the program; the sufficiency of the hemp license application period; whether the information collection for the program is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; the ways to enhance the quality, utility, and clarity of the information to be collected; the ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; whether there is information or data that may inform whether or not the market will experience a significant shift, either positive or negative, in the developing hemp market and on consumers; any data or information on what impacts the regulation may have on current and future innovation in the areas of industrial hemp usages and how much such impacts on innovation may affect rural communities; the potential for innovation and the uncertainty and its impact on the hemp market vis a vis steady State; and additional reliable data sources on the annual receipts of industrial hemp producers.

AMS received approximately 5,900 comments. Comments represented the views of States, Indian Tribes, hemp farmers and processors, universities, laboratories, trade associations, carriers, non-profit associations, other Federal government agencies, consumers, and other interested individuals. A summary of the comments and AMS's analysis and response follows.

Extention of Comment Period

Several commenters urged AMS to extend the public comment period to allow for small businesses to meaningfully participate in this rulemaking process. One reason given was that the comment period fell in the middle of the harvest season for much of the mid-Atlantic and southern hemp growers, excluding those who grow indoors, and therefore were too busy to comment. Other reasons given were the ongoing global pandemic as well as many other ongoing natural disasters nation-wide that have presented additional strains and unique challenges to agricultural operations.

AMS Response: AMS provided an initial 60-day comment period and a 30-day extension and then reopened the comment period for 30 additional days in order to receive feedback from stakeholders thus giving ample time to interested parties to submit comments. In order to finalize the Domestic Hemp Promotion Program before the 2021 production cycle begins, AMS decided not to extend the comment period and to finalize this rule.

Extension of 2014 Pilot Program

Under the 2014 Farm Bill, State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes. Congress extended this authority under the 2021 Continuing Appropriations Act until January 1, 2022. After January 1, 2022, domestic hemp production must comply with Subtitle G of the AMA and this final rule.

Comments: Numerous comments praised the hemp production regulatory schemes established by States and Universities under the 2014 Farm Bill authority. Many comments reflected on the perceived increase in regulatory burden under the IFR, as opposed to the regulatory scheme that has been applied to domestic hemp production until now. Many comments, while making recommendations with regards to specific aspects of the IFR provisions, also encouraged USDA to continue to regulate domestic hemp production under the 2014 Farm Bill until satisfactory resolution of industry concerns can be achieved. Further, several comments stated that the extension of the pilot programs under the 2014 Farm Bill for another two to three years would give the industry time to adjust to the new requirements and to develop hemp genetics to more easily comply with the regulations.

A few comments opposed extension of the 2014 Farm Bill pilot program, asserting that States now operating under the more restrictive 2018 Farm Bill provisions are placed at a disadvantage.

AMS response: The extension of the 2014 Farm Bill authority is not within the authority of USDA. Congress only extended this authority under the 2021 Continuing Appropriations Act (Pub. L. 116–260), until January 1, 2022.

THC Limit

The IFR adopts the 2018 Farm Bill definition of hemp as the plant species *Cannabis sativa* L. and any part of that plant with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Further, the IFR requires that THC levels in representative samples test at or below the acceptable hemp THC level. Testing must be conducted using post-decarboxylation or other similarly reliable methods, where the total THC concentration level measured includes the potential to convert THCA into THC. Finally, the IFR provides that hemp testing higher than the acceptable hemp THC level is considered a controlled substance and requires disposal.

Comments: Some comments supported the 2018 Farm Bill's hemp THC level of 0.3 percent, and some explained that States had successfully incorporated that limit into programs authorized under the 2014 Farm Bill. Some comments thanked USDA for clearly defining the delta-9 THC standard in the IFR, which commenters

[11] *https://www.regulations.gov/searchResults?rpp=25&po=0&s=AMS-SC-19-0042&fp=true&ns=true..*

said would foster uniformity across hemp production in all States.

However, a greater number of comments from various stakeholder groups, including producers, States, Indian Tribes, and hemp organizations, asserted that the 0.3 percent threshold is too low and impractical in a program intended for multiple end uses of hemp. Comments argued that individuals interested in obtaining cannabis for intoxication purposes are unlikely to be interested in material containing 1.0 percent THC—or perhaps higher, and that setting the threshold at even 1.0 percent THC would give farmers, breeders, and researchers a lot more flexibility and confidence in producing compliant crops. One commenter reported that their State recognizes hemp with THC concentrations of up to 0.39 percent, with most crops testing between 0.31 and 0.39 percent THC, and no end products testing higher than 0.3 percent THC. The comment suggested USDA should raise the THC limit to at least 0.39, if not up to 0.5 percent. Other comments recommended revising the threshold to a higher level, asserting that there is no scientific evidence that supports use of the 0.3 percent level. Some comments recommended increasing the threshold to 0.8 or 1.0 percent, while some suggested 2.0 percent and others as much as 5.0 percent. Comments explained that a THC concentration of 5 percent is not viable for recreational marijuana markets and that USDA should consider the end-use potential when determining a threshold. One comment recommending a THC threshold of at least 2.0 percent included a news story reporting that marijuana plants confiscated by law enforcement routinely have THC concentrations of 12 percent or higher.[12]

Several comments suggested that the IFR's level of 0.3 percent delta-9 THC on a dry-weight basis is ''more aspirational than practical.'' Comments explained that THC levels vary with plant maturity and other factors. Comments urged USDA to build greater flexibility into the rule so producers don't unwittingly become illegal marijuana farmers as a result of factors beyond their control. One comment suggested USDA establish a wider gap between the THC levels that define controlled substances and agricultural commodities such as hemp to create an environment where hemp producers are presumed innocent until proven guilty of intentionally producing a controlled substance. Several comments recommended that university and other research programs be given more leeway as they work toward developing more compliant, regionally appropriate varieties through breeding.

Some comments noted that hemp containing more than 0.3 percent THC is not eligible for crop loss or replant payments under USDA Risk Management Agency regulations. Comments said further that if USDA is not certifying seed because of the regional effects of growing conditions on genetics, farmers are at risk and should be able to obtain comprehensive insurance coverage for crops with negligible overage above the acceptable THC level.

Comments explained that while the genetics of most U.S. crops have been developed over many years, hemp has not enjoyed that history, and it will take time to develop compliant but commercially viable crops with marketable CBD content for different regions. Comments asserted farmers will have fewer planting options because of the lack of a national hemp seed certification protocol and limited agronomic research on hemp varietals and production practices. Comments inferred that the 0.3 percent THC threshold would effectively demand that farmers plant a nationwide monoculture with little genetic diversity, which they said would leave U.S. hemp crops vulnerable to pests and diseases.

Many comments questioned the selection by Congress of the 0.3 percent THC threshold to legally distinguish hemp from marijuana.[13] Comments frequently referenced a 1976 publication, *A Practical and Natural Taxonomy for Cannabis,* in which horticulturalists Dr. Ernest Small and Arthur Cronquist used 0.3 percent THC as a threshold to distinguish hemp from marijuana in their scientific study on cannabis.[14] Comments highlighted statements made by Small and Cronquist, saying the researchers openly acknowledged that they ''arbitrarily adopt a concentration of 0.3 percent delta-9 THC (dry weight basis) in young, vigorous leaves of relatively mature plants as a guide to discriminating two classes of plants,'' and that the number was never intended to define hemp from a legal perspective. According to the comment, Small and Cronquist made no conclusionary statement on the use of the 0.3 percent THC threshold.

Several comments reported that countries determined to compete in the global marketplace, including Switzerland, Australia, Thailand, Uruguay, and Ecuador, recognize an acceptable hemp THC limit of 1.0 percent. According to comments, the international market settled on the 1.0 percent THC limit after numerous countries tested hemp over many years. Comments recommended the IFR incorporate the same standard.

Comments asserted that the rights of Indian Tribes and small Tribal farmers should be protected by allowing greater flexibility in the hemp production regulations overall, consistent with Tribal self-government. For example, comments said that Indian nations should be recognized to have authority to grow hemp with up to 1.5 percent THC and should not be restricted to 0.3 percent.

One comment explained that their company has focused on breeding efforts to develop genetics that produce CBD-rich hemp with the lowest possible THC concentrations. The commenter claimed their company has harvested millions of pounds of hemp compliant with the 0.3 percent total THC standard since 2017. The comment said they produced 25 million rooted cuttings this spring—enough, according to the comment, to produce biomass for the entire country, and the commenter assumed they were not the only ones who had done so. The comment asserted further that the global standard for THC concentration is 0.2 percent and that to be competitive, U.S. production must adhere to a similarly strict standard.

Although asserting that the IFR hemp THC level of 0.3 percent is not commercially reasonable, some comments acknowledged that only Congress could change the statute to allow a higher limit, and some commenters offered to serve as resources in that effort. Other comments urged USDA to work with Congress to raise the THC threshold.

AMS response: Congress defined hemp in the 2018 Farm Bill as *Cannabis sativa* L. with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Any change to the statutorily established threshold of THC concentration requires an amendment to the statute. The CSA defines marijuana as cannabis that is over the 0.3 percent THC level. AMS has no discretion to change the THC level or to treat States and Tribes differently as the 2018 Farm Bill applies to all production of hemp in

[12] McCullough, Jolie. ''Marijuana Prosecutions in Texas Have Dropped by More than Half Since Lawmakers Legalized Hemp.'' *The Texas Tribune,* 3 January 2020; *www.texastribune.org/2020/01/03/texas-marijuana-prosecution-drop-testinghemp/.*

[13] Johnson, Renee. ''Hemp as an agricultural commodity.'' Congressional Research Service (2014).

[14] Small, Ernest, and Arthur Cronquist. ''A practical and natural taxonomy for Cannabis.'' *Taxon* (1976): 405–435.

the U.S. Tribes do not have the authority to grow hemp with up to 1.5 percent THC as this would violate the 2018 Farm Bill and the CSA. Tribes' powers of self-government may be constrained by acts of Congress in accordance with Congress' constitutional authority to regulate commerce with Indian Tribes.

AMS notes that there seems to be confusion amongst some commenters on the THC level stated in the 2018 Farm Bill and the IFR's definition of acceptable hemp THC level. The acceptable hemp THC level in this final rule includes the 0.3 percent established in the Farm Bill plus any measure of uncertainty due to laboratory testing.

Regarding the comment citing the news story, AMS believes the commenter misconstrued the article's meaning. The article cited by the commenter explained that following passage of Texas's law that legalized hemp in early 2019, the number of marijuana prosecutions in the State plummeted, due in part to the lack of adequate and affordable criminal laboratory resources. According to the article, prosecutors were less likely to expend resources on low-level marijuana charges where the likelihood of conviction is low. The article described anticipated release of a new lab testing method that only determines whether THC concentration is above or below 2 percent for criminal testing purposes. According to the article, even though 2 percent is higher than the State's legal hemp limit of 0.3 percent, such testing would nevertheless be adequate for Texas law enforcement purposes, since nearly all marijuana plant prosecutions in the State involve THC concentrations of 12 percent or more. AMS believes neither the article nor the State are advocating legalization of hemp THC concentrations of up to 2 percent, but that Texas law enforcement is merely using that limit as a convenient way to determine whether to pursue criminal prosecution.

In response to concerns that producers could unwittingly become illegal marijuana farmers without greater flexibility in the rule, AMS has modified the negligent violation threshold as explained in the section responding to comments on the negligent violation threshold. AMS also notes, however, that it does not have any authority over how the DEA chooses to enforce compliance with the CSA.

In the final rule, AMS is implementing a nation-wide domestic hemp production program as contemplated by the 2018 Farm Bill. It is not amending Risk Management Agency's regulations regarding crop loss or repayment payments. Thus, comments regarding those regulations are outside the scope of this rule.

Testing for Total THC

The IFR requires that when hemp THC levels are measured using post-decarboxylation or other similarly reliable methods, the total THC concentration level measured must include the potential to convert THCA into THC.

Comments: Some comments agreed that the measurement of delta-9 THCA should be added to the measurement of delta-9 THC and reported as total THC used for determining compliance with the hemp program requirements, as this is what many hemp producing States are already doing under State programs. A comment from an association of Departments of Agriculture reported that many States responding to their survey supported testing for total THC in this manner.

Other commenters disagreed. According to one comment, only 22 of 47 States with State-level hemp programs test for total THC. The comment said that 18 States do not currently test for total THC, and that 7 States' rules are ambiguous on this point. Other comments reported that State programs currently testing for only delta-9 THC are confident that producers are not selling ''hot'' crops.

One comment said it is irrational to subject hemp biomass to decarboxylation when most biomass harvested for processing into increasingly popular consumer goods or industrial products will never even be decarboxylated.

Another comment explained how USDA cannot alter the definition of hemp as set forth in the 2018 Farm Bill. The comment said that there should not be a ''total'' THC mandate and, rather, the plain reading of the 2018 Farm Bill establishes that delta-9 THC is actually the determinative factor. The comment went on to explain how other State and Federal agencies also rely only on delta-9 THC when making critical distinctions with respect to hemp, such as the DEA and the FDA, to determine whether a substance is controlled and subject to criminal penalties. The comment presented an alternative testing methodology where testing methods must be able to determine the potential for THCA to convert into delta-9 THC, and the test result must reflect that ability as well as the aggregate computation, but the controlling factor whether a crop meets the definition of hemp and is within the ''acceptable hemp THC level'' relies only upon the delta-9 THC element. Thus, for compliance purposes, delta-9 THC is the standard, and the lab report must at least reflect THCA, delta-9 THC, and the Total THC results, but Total THC should not be determinative in whether a farmer has to destroy his crop.

Industry impacts. Commenters asserted that testing for THCA concentration, a component they argued which is not psychoactive, would vastly undermine the efficient production of hemp and the growth of the industry. Some comments supported the 0.3 percent THC standard, but said requiring testing for total THC goes beyond what is statutorily required, to the detriment of producers. Commenters argued that the difference between levels of delta-9 THC and total THC in hemp is significant, and that crops that would otherwise be compliant measuring only for delta-9 THC would not be compliant when measuring for Total THC. Comments asserted that testing for total THC with a threshold of 0.3 percent effectively lowers the allowable hemp THC level to an even lower limit.

Comments also described the correlation between total CBD and total THC production and explained that producers trying to maximize CBD production will not be able to do so successfully if total THC levels are restricted to 0.3 percent. One comment claimed that a farmer can produce hemp plants with up to 25 percent cannabinoid content while staying under 0.3 percent delta-9 THC limit, but that the farmer would have to plant twice as many acres of a less potent hemp variety to produce the same amount of CBD end product and stay compliant under the IFR's Total THC limit.

Several comments reported that some CBD hemp processors reject product with CBD amounts of less than 8 percent. According to comments, breeders have worked years to develop cultivars that meet the 0.3 percent delta-9 THC threshold, but many cultivars would not be compliant under the total THC limit. Comments predicted that with a standard of 0.3 percent total THC, growers will stop growing hemp for CBD because the risk is too high that their hemp crops will exceed the limit and be destroyed, defeating the purpose for growing crops for the potential high returns related to CBD production. Comments further lamented that the industry would lose investments they've already made.

According to comments, many States that have only been measuring delta-9 THC under 2014 Farm Bill pilot programs have developed companion

marketing programs that have been tailored to complement State hemp production programs. Comments asserted the total THC limit in the IFR would significantly impact these new and emerging markets and cripple the industry in those States, preventing them from selling their product.

Some comments claimed that common industry practice is to measure THC and THCA independently. Comments recommended USDA treat THC and THCA as two separate molecules and only be concerned with the amount of THC in a sample, rather than total available THC.

One comment recommended that if USDA wants to test for total THC, the limit should be raised to 0.694 percent, with negligence set at 1.094 percent, and that growers whose samples measure between the two limits should be allowed to retest samples with up to two certified labs of their choice at a cost of $500 each. Another comment recommended that samples be tested for THC and THCA separately, with limits of 0.3 and 1.0 percent, respectively.

AMS response: The 2018 Farm Bill requires that State and Tribal plans provide a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp. In order to use post-decarboxylation, the sample must be heated or a conversion made to account for the lack of heating process. This means that the total THC must account for THCA and delta-9 THC.

Currently, some States and Indian Tribes use gas chromatography (GC) to test hemp. In GC testing, heat is applied to the sample which THCA, producing delta-9 THC (a psychoactive compound), so that the final delta-9 THC result is actually a total THC result. GC is the more traditional technique used for THC testing and GC results are typically reported as ''delta-9 THC'' without distinguishing that the reported delta-9 THC is actually total THC.

Liquid chromatography (LC) testing typically does not involve the use of heat, so the THCA in a sample does not decarboxylate. In LC, results for THCA and delta-9 THC are obtained separately and can be reported separately. Cannabis naturally contains more THCA than delta-9 THC; if the THCA concentration is ignored while testing by LC, it is improbable to correctly distinguish hemp varietals from drug varietals. A total THC needs to be calculated post-testing in order to determine the ''post-decarboxylation'' delta-9 THC value as required by the 2018 Farm Bill. In this way, all testing methodologies report the same information.

AMS acknowledges that some States do not currently test for total THC and that switching to testing for total THC may have a negative impact on those State programs. Most laboratories that use LC obtain THCA results and delta-9 THC results in the same analysis, so the information should be readily available to incorporate a calculation for Total THC. The opposite is also true. If USDA was to ignore the statutory requirement of using post-decarboxylation or other similarly reliable methods and allow for THC levels that do not account for decarboxylation, States and Tribes that currently require testing for total THC could experience a negative impact. When States or Tribes use different methods to measure THC, it impacts commerce because producers are not all on the same playing field. Also, since total THC at 0.3 percent is harder to obtain, those States and Tribes currently using total THC have been potentially selling less or destroying more hemp. Further, many in the industry have already made the switch to total THC since the IFR was published, diminishing the impact.

AMS consulted with the Departments of Justice and Health and Human Services to develop the IFR. The Drug Enforcement Administration's Analysis of Drugs Manual cites GC methodology, initially labeling results as delta-9 THC and then defining total THC and instructing how to determine compliance using total THC.

In order to provide flexibility to States and Indian Tribes administering their own hemp production programs, alternative testing protocols will be considered by AMS if they are comparable and similarly reliable to the baseline mandated by section 297B(a)(2)(ii) of the AMA and established under the USDA plan and procedures. Updated USDA procedures for sampling and testing will be issued concurrently with this rule and will be provided on the USDA website.

This final rule covers hemp production. Hemp products are regulated under the Food and Drug Administration and its various statutes.[15]

Statutory Compliance and Congressional Intent: Several comments expressed concern about regulatory inconsistency between the 2018 Farm Bill language testing methods and the IFR requirements. Commenters urged USDA to reconsider the legislative record and Congress's intent in passing the 2014 and 2018 Farm Bills. According to numerous comments, the plain language of the 2018 Farm Bill statute does not support the IFR's requirement to test for total THC. Commenters asserted that if Congress had intended samples to be tested for total THC, they would have so specified, rather than making the specific reference to delta-9 THC in the statute. Comments concluded that concentrations of THCA in hemp should be irrelevant to its legal status under the regulations. One comment characterized ''decarboxylated value'' as a new legal term and questioned USDA's authority under the 2018 Farm Bill to create such a term. One comment went on to say that the term ''potential conversion'' as appearing in the IFR is offensive because Federal criminal law does not convert a legal substance into an illegal one simply because the substance has the ''potential'' to be converted.

Several comments cited a letter from Senators Merkley and Wyden,[16] authors of the Hemp Farming Act of 2018 that was included in the 2018 Farm Bill, as evidence that the IFR wrongly requires testing of Total THC. In that letter, Senators Merkley and Wyden asserted that requiring hemp samples to be tested using methods by which the reported THC concentration accounts for the conversion of THCA to THC ''is a complete reversal of the Congressional intent expressed in that law and requires testing that Congress specifically did not include.'' Comments also asserted that the Farm Bill definition of hemp is clear in that ''all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not'' of the hemp plant are expressly lawful so long as the pant does not contain a delta-9 THC concentration of above 0.3 percent. Thus, according to these comments, the IFR required measurement of a lawful plant-based acid when distinguishing between hemp and marijuana under the Controlled Substances Act, and such a requirement contradicts the plain language of the Farm Bill and the spirit of the law.

[15] The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act).

[16] *https://www.merkley.senate.gov/news/press-releases/wyden-merkley-to-dea-interim-rule-on-hemp-contradicts-congressional-intent-by-criminalizing-intermediate-steps-in-hemp-processing-2020#:~:text=Authors%20of%20the%20provision%20in,by%20seriously%20misunderstanding%20hemp%20processing.* See *https://beta.regulations.gov/comment/AMS-SC-19-0042-0884.*

One comment asserted that requiring test reports of THC concentration to account for conversion of THCA into THC effectively mandates that only test methods relying on post-decarboxylation be used, nullifying Congressional intent that other similarly reliable methods that don't require conversion of THCA to THC should be authorized. The comment recommended revising the rule to comply with the Congressional mandate to allow testing through other similarly reliable methods.

AMS response: AMS is not making a determination of Congressional intent when passing the 2018 Farm Bill provision for hemp. Instead, AMS is following the plain statutory language that states that a State or Tribal plan shall be required to include ''a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian Tribe''.

International Impact: Some comments asserted that the average global delta-9 THC limit is 1.0 percent. Others claimed that Europe has adopted a 0.3 percent THC limit, but that it applies only to delta-9 THC and not total THC. Comments contend that American hemp production required to comply with at 0.3 percent total THC limit will be disadvantaged in the international marketplace. Comments proposed that matching a global standard by establishing a higher delta-9 THC threshold or total THC limit would strengthen U.S. producers' market competitiveness. Other comments warned that reducing the domestic hemp supply by imposing the IFR's 0.3 percent total THC limit will incentivize importation of hemp biomass and hemp derivatives produced in countries with lower labor costs and less restrictive regulatory regimes, and that domestic hemp and hemp derivatives will be priced out of the market.

AMS response: The 2018 Farm Bill authorizes USDA to issue regulations to regulate the production of hemp and defines hemp in terms of the concentration of THC in a Cannabis sativa L. plant. A Cannabis sativa L. plant is considered hemp, and therefore not a controlled substance, if the THC concentration is not more than 0.3 percent on a dry weight basis. AMS does not have the discretion to change this threshold in the definition of hemp even if this threshold could impact the global competitiveness of U.S.-produced hemp.

Calculating Total THC

The 2018 Farm Bill and IFR identified and described the procedure for testing THC concentration using post-decarboxylation or other similarly reliable methods. The term decarboxylated was defined in the IFR as the completion of the chemical reaction that converts THC-acid (THCA) into delta-9 THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9 THC and eighty-seven and seven tenths (87.7) percent of THC-acid. The term decarboxylated is also commonly used in science and is the precursor to the term ''post-decarboxylation,'' which appears in the 2018 Farm Bill's mandate on the acceptable cannabis testing methodologies for identifying THC concentration levels. AMS adopted this definition in this final rule.

Conversion Efficiency: Many stakeholders opposed USDA's conversion formula described in the IFR. Comments claimed the IFR was based on 100 percent conversion efficiency, which is only achievable under controlled laboratory testing conditions and is not possible outside of a laboratory environment. One comment stated the IFR failed to account for the inefficiency of the decarboxylation process. Numerous other comments characterized the USDA formula as theoretical and explained that the realistic conversion efficiency is between 30 and 75 percent. For example, several commenters cited a peer reviewed study which found 72 percent to be a viable efficiency factor and provided the calculation formula: Total Potential THC = (0.72) × [(0.877 × THCA) × delta-9THC)]. Additionally, a commenter suggested USDA utilize three different conversion factor tiers (0, 30, or 70 percent) depending on the end-use varietal because the THC concentration varies by varietal. The commenter argued that the conversion factors should reflect the different end-uses.

One comment said the calculation for ''Total Potential THC'' should be defined and incorporated into the final rule because the decarboxylation percentage definition is critical for standardization and uniformity in the industry. Otherwise, according to the comment, States could adopt different decarboxylation percentages in their equations, causing confusion for growers. The comment gave the following formulas as examples: (Total potential THC = 0.877 × percent THCA + percent delta-9 THC) as compared to (Total Potential THC = 0.877 × 0.70 × percent THCA + percent delta-9 THC), assuming a 70 percent THCA decarboxylation to delta-9 THC rate.

Another comment explained the need to include delta-8 THC into any calculation for the future state delta-9 THC.

AMS response: Delta-8 THC only exists in a trace amount in marijuana which has a high Delta-9 THC concentration. The Delta-9 THC amount is already low in hemp, so the concentration of Delta-8 THC would be basically undetectable in hemp. A quote from the ''WHO Expert Committee on Drug Dependence Critical Review—Isomers of THC'' regarding the relative amount of Delta-8 THC to Delta-9 THC that can be found at *https://www.who.int/medicines/access/controlled-substances/IsomersTHC.pdf?ua=1.*

The above range means that Delta-8 THC occurs at a level that is roughly 1000 times less than Delta-9 THC. So, if Delta-9 THC was observed at 0.3 percent in hemp, then the Delta-8 THC concentration would be roughly around 0.0003 percent. This contribution is completely negligible and contributes nothing significant to the total THC content. The trace amount of Delta-8 THC is about 100 times less than the uncertainty (MU) of the test method, further demonstrating that it is insignificant and not worthy of consideration in the final assessment of THC for hemp compliance.

AMS is adopting the calculation provided in the IFR for determining total THC. However, the calculation has been clarified to explain the use of the molar conversion ratio to mathematically convert THCA to delta-9 THC. As written in the IFR, the calculation may have been misunderstood as containing a conversion efficiency factor, which is not the case. THCA cannot be added to delta-9 THC without accounting for the difference in molecular mass. Using stoichiometry, a molar conversion ratio (0.877) is used to mathematically convert THCA in terms of delta-9 THC. The molar mass of THCA is 358.47 g/mol and the molar mass of delta-9 THC is 314.45 g/mol. In other words, the mass of THCA has to be adjusted or multiplied by 0.877 to be comparable to the mass of delta-9 THC.

The 2018 Farm Bill requires that the THC content be expressed post-decarboxylation, which means that the conversion of THCA into delta-9 THC to account for the potential total THC in a sample must be taken into account. The term ''potential'' is used because it is not possible to readily, consistently, and reliably calculate the precise extent of

the conversion of THCA to THC under *any and all* circumstances. Therefore, the calculation for total THC assumes 100 percent conversion efficiency and is hereby retained in this regulation. The calculation for total THC [total THC = (0.877 × THCA) + (delta-9 THC)] assumes that 100 percent of the THCA is decarboxylated, producing to delta-9 THC, meaning that it gives the maximum (or potential, or theoretical) total THC. The final rule includes a definition for total THC to provide more specificity on this issue. This is standard procedure for how theoretical yield is calculated in chemistry. The issue is that theoretical yield does not always equal actual yield. Just because a maximum total THC can be calculated does not mean that the maximum is always obtained; however, there is potential for this maximum to be obtained. The amount of THCA that actually decarboxylates, producing delta-9 THC, is dependent on multiple variables; primarily, the amount of heat it is exposed to and the amount of time it is exposed to that heat. These variables, in turn, depend on what is being done to a cannabis sample (tested via LC, tested via GC, used for smoking, used for extraction, etc.).

Incorporating the use of a conversion efficiency factor into the calculation is problematic due to these variables. Designating different conversion efficiency factors based on intended end use is not practical as the factors can still vary. For example, if an end-use of extraction is intended, there are many different types of extraction processes and even within one specific process there are still many different variables that will affect the conversion efficiency. Ultimately, there is no way to standardize a conversion efficiency factor based on end-use, methodology, or processing. The infrastructure does not currently exist to measure and monitor conversion efficiency.

In terms of conversion during instrumental analysis, many commenters referenced a study conducted by Dussy [17] that determined a conversion efficiency factor for a specific GC setup. The author of the study recommends determining THCA and delta-9 THC separately and calculating total THC (using the equation the IFR stated to use). The author says that ''every total Δ9 THC value determined after decarboxylation [by using GC] gives a minimal content rather than an exact value''. Therefore, the author proposes that labs using GC should calculate their own method's conversion efficiency and then apply their efficiency to their result to increase their total THC value to make it comparable to LC. This is the opposite of what many commenters are proposing in that they wanted LC methods to incorporate conversion efficiency into their LC results to make total THC lower. The further complication of this ''opposite'' approach is that it is impossible without having a single conversion efficiency which, as stated previously, cannot be agreed upon and can vary widely. Furthermore, no matter how the conversion efficiency was to be applied, requiring each lab to determine their own method's efficiency would require significant effort.

Delta-8 THC is a cannabinoid that can be formed from delta-9 THC. It is typically only found in very small quantities in plants, if it is found at all, and is more often obtained by growing a plant with high delta-9 THC and then converting the delta-9 THC into delta-8 THC through an extraction and conversion process in a lab to make a distillate product. It is rarely included in total THC calculations and many labs do not test for it. Delta-8 THC is unrelated to the 0.3 percent delta-9 THC limit or the ''post-decarboxylation delta-9 THC'' that are defined and required in this final rule.

Similarly Reliable Testing Methods

The 2018 Farm Bill states that State, Tribal, or USDA plans shall include ''a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp.''

The IFR included two examples of standard industry post-decarboxylation testing methods that meet 2018 Farm Bill requirements: Gas and liquid chromatography with detection. AMS selected these standard methods of chromatography as the best options for testing but also provided flexibility for alternative sampling and testing protocols if they are comparable and similarly reliable to the baseline mandated by the 2018 Farm Bill and established under the USDA plan and procedures.

Comments: Some comments expressed support for the use of post-decarboxylation. One comment described liquid chromatography as a preferable testing method over gas chromatography because there are no published methods for gas chromatography that show 100 percent conversion of THCA to THC. Comments suggested liquid chromatography is more accurate and representative than gas chromatography. USDA received a comment that because Tribes often do not have ready access to gas chromatography and may only be able to access liquid chromatography, the rules need to allow for a more lenient formula.

Many more comments opposed the IFR requirement to use post-decarboxylation testing methods on the grounds that the IFR too strictly interpreted or unnecessarily developed regulatory requirements that are not consistent with the statutory language of the 2018 Farm Bill. Comments stated that USDA should be flexible and allow for measuring THC levels with ''similarly reliable methods,'' as provided in the statute. Comments claimed that the IFR's exclusive endorsement of gas or liquid chromatography methods ignores this statutory flexibility. Comments further asserted that these two methods may overstate THC levels in hemp samples and that USDA should approve alternative reliable methods that may produce more accurate results.

According to some comments, reliable testing methods have emerged that do not necessitate decarboxylation to accurately measure THC concentrations. For example, comments claimed that some States recognize genetic testing that measures the ratio of cannabidiol to THC in a sample or that confirms a stable cultivar's taxonomic determination in lieu of post-decarboxylation testing to verify compliance with THC limits. Comments explained that genetic testing could include testing seed or testing during early plant growth stages, instead of depending on chemical analyses to measure THC levels in mature plants, which may be inconsistent under unpredictable growing conditions or dependent upon the time of sampling or the specific part of the plant that is sampled.

Comments advocated removing the Total THC testing requirement and recommended USDA work with scientific and agricultural communities to ensure testing standards are established and similarly reliable methods are developed that will accurately identify and measure THC without the forced conversion of other cannabinoids, isomers, and/or acids.

States Operating under 2014 Farm Bill Authority: Comments said that USDA should recognize that States have been effectively regulating hemp production using approved testing methods under 2014 Farm Bill pilot

[17] Dussy F.E.; Hamberg, C.; Luginbühl, M.; Schwerzmann, T.; Briellmann, T.A. Isolation of Δ9 THCA–A from hemp and analytical aspects concerning the determination of Δ9 THC in cannabis products. *Forensic Science International, 149,* 3–10, 2005.

programs. Comments argued that by applying the IFR's new testing standard, certain hemp plants that are legally grown under one or more of the existing pilot programs are converted into plants that violate the 2018 Farm Bill. Comments contended that while USDA will argue that States and Tribes can propose a testing method other than post decarboxylation, the alternative method still has to measure potential conversion of THCA into THC.

Comments said further that the IFR must consider that hemp testing is an evolving science and that THC testing methods are likely to change over time. They stated that imposing new testing requirements is adding costs for growers, marketers, and regulators, and is limiting the number of labs that can perform these tests, for unnecessary and possibly impermissible reasons. Finally, comments questioned whether USDA has the authority to impose new testing requirements when the statute spells out the testing standards to be applied in granting approval to State and Tribal plans.

A comment cited case law that held that under the Administrative Procedure Act (APA), agency decisions must be reasonable and based on factors and evidence that support the decision, divergent views notwithstanding. It suggested the IFR is arbitrary and capricious under the APA because USDA (1) ''has relied on factors which Congress has not intended it to consider, '' (2) ''entirely failed to consider an important aspect of the problem,'' (3) ''offered an explanation for its decision that runs counter to the evidence before the agency,'' and (4) has made a decision that ''is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'' It further claimed that a court must sustain an agency's action unless it determines that the agency committed a ''clear error in judgment.'' The commenter asked that their comment be considered within the context of these legal standards, and argued that THCA is not psychoactive; but can be converted into delta-9 THC through a chemical reaction, and that such a reaction may cause otherwise lawful hemp plants to test ''hot.'' The comment projected further that such ''hot'' plants will require disposal, causing a significant and unnecessary loss of hemp production, which will in turn reduce economic development and job growth in many rural communities.

The comment said post-decarboxylation testing was not required under the 2014 Farm Bill pilot program and the same plants that are legal under 2014 Farm Bill could be illegal under the IFR. The comment recognized that the pilot program will not be authorized after 2021 but said current disparate treatment under the two laws is problematic.

AMS response: The 2014 Farm Bill included a 0.3 percent THC level but did not include the requirement for this measurement to account for decarboxylation. Thus States have the flexibility to determine testing methodologies. The 2018 Farm Bill states that procedures for testing use post-decarboxylation or other similarly reliable methods to determine delta-9 tetrahydrocannabinol concentration levels in hemp. AMS stated in the IFR and further adopts the language in this final rule that at this time two methods meet this requirement for decarboxylation. The current acceptable testing methods include gas and liquid chromatography, including LC with UV detection. As other testing methods and alternatives are developed by industry, AMS will review and evaluate their compliance with the 2018 Farm Bill. At this time, genetic testing has not been determined to be a similarly reliable testing methodology.

This final rule provides States and Indian Tribes the option to develop different sampling methodologies based on end use, including grain and fiber, to better account for differences in these plants. Biomass only needs to be tested after remediation to ensure that the sample that represented the plant that once tested above the acceptable THC level did not result in the plant being a controlled substance. This final rule does not set requirements for testing final products—but hemp plants, regardless of their end use, must still use the same testing procedures.

Although the USDA plan does not allow for sampling based on end use, AMS will study the experience of States and Tribes that adopt methodologies based on end use. If it appears that the data and experience of those States and Tribe suggest that their methodologies may be adaptable to the USDA plan, AMS may explore a sampling scheme based on end use for producers under the USDA plan in the future through notice and comment rulemaking.

License Application Period

AMS received comments on the timeframe established in the IFR for submitting applications for a USDA license. The application period extends between August 1 and October 31.

Comments: Several comments opposed the August-through-October window for USDA license applications and renewals. They explained that many outdoor hemp crops are harvested in September and October and that farmers are busy with harvest activities related to other crops as well during that time of year. Comments noted that farmers typically finalize decisions about the coming crop year during the winter, after having time to attend industry and trade conferences, enter into production contracts, and obtain crop loans and insurance. Thus, according to comments, a longer application window or a later application window would give farmers time to plan for the coming year and submit hemp production license applications as appropriate. Comments also noted that a longer application period would give producers time to complete the mandatory background check. Some comments recommended the application period be extended to December 31. Others recommended a winter application period of January 1 to March 15.

Other comments recommended even greater flexibility in application periods. Comments explained that harvest cycles for hemp growers may vary regionally and by operation type. They said a significant number of hemp operations involve year-round cultivation, maintenance of mother clones, clone propagation, indoor cultivation, and/or tissue culture. Time and resources to gather and submit paperwork would not coincide with the down-cycles in productivity and would strain these types of operations. Some recommended USDA adopt a year-round, rolling application period with different deadlines for different operation types or sizes. One comment said it was unclear in the IFR whether State and Tribal plans were required to adhere to the same window provided for under USDA's plan. Several comments urged USDA to provide greater regulatory flexibility at the State and Tribal levels to determine the appropriate application and renewal timeframes for their jurisdictions. An example was given of a State's agriculture department transitioned enrollment from a restricted to an unrestricted timeframe to better manage the logistical challenges related to the enrollment period.

AMS response: AMS agrees with the commenters opposed to a limited USDA license application window and will allow for applications to be submitted for a USDA license year-round. This will provide greater flexibility to hemp producers to determine when to apply for a license or renew their license. This decision recognizes the different regional harvest timetables and production types used by hemp producers, and how flexible timetables

may allow producers to prepare applications during lower level periods of production activity thereby reducing some of producers' burden on time and resources when the producer is planning the next planting cycle(s). States and Tribes can determine their license application window as it best meets their programs.

FSA Reporting and Information Sharing

AMS received comments on the IFR requirement that hemp producers report acreage and provide licensing information to USDA's Farm Service Agency (FSA). Hemp producers must provide FSA information about their hemp crop acreage, such as its location and size, and must provide the producer license or authorization number issued under the hemp production plan under which they operate. States, Indian Tribes, and USDA must collect the same information, as well as other producer information, under their respective plans. USDA then assembles and maintains FSA and plan information and makes it available to law enforcement agencies, as required under the 2018 Farm Bill.

Comments: Several comments expressed strong support for FSA programs generally, acknowledging that FSA programs provide farmers valuable access to Federal programs and funding, and that registering crop acreage with FSA would help mainstream hemp production within agricultural communities. Comments noted that requiring hemp growers to register with FSA is similar to registration requirements for growers of other commodities and that FSA already compiles reports about other crops. However, many commenters opposed the requirement to register with FSA when they are already required to provide the same information to their licensing authority. Comments argued that the duplicative reporting requirement is unnecessarily burdensome to farmers, could be confusing, and could discourage farmers from seeking hemp production licenses or from growing hemp. One comment speculated that confusion about the duplicative requirement could lead to unintended violations by growers who don't comply. Other comments speculated that lower program participation would inhibit industry growth and deprive States and Indian Tribes of licensing fees that enable them to fund their respective production plans.

Comments noted that the statute does not specify dual reporting of crop acreage to both FSA and the plan authorities under which they operate.

Several comments took exception with the IFR's assumption that most hemp farmers are already registered and familiar with FSA and its programs. Comments from some State agriculture departments asserted that within their jurisdictions most farmers in general do not already work with FSA.

One comment asserted that participation in FSA programs is voluntary and that hemp growers should not be precluded from participating in the commenter's State program because they forego FSA registration. Other comments suggested that farmers growing hemp for personal use and hemp farmers also growing medical marijuana may be hesitant to register crop acreage with Federal agencies.

One comment expressed concern about FSA staffing in rural areas and asked USDA to increase funding to support additional reporting obligations. Another comment suggested USDA develop and fund one standardized reporting program for all plans and growers that would decrease program reporting burdens for all entities. Some comments encouraged streamlining collection of crop acreage information by allowing the use of open-source GIS mapping instead of FSA data and reporting tools. Comments also suggested USDA could rely on States and Tribes to provide grower crop acreage and registration information since they already collect it. Several comments recommended eliminating the FSA registration requirement altogether.

AMS response: AMS acknowledges the FSA reporting requirement may present a hurdle for certain hemp producers, particularly new and beginning farmers, farmers in rural locations, and farmers located in Tribal territories. However, AMS determined that the FSA reporting requirement is essential for two key reasons: Real-time data collection and field-based resources.

First, USDA is required under the 2018 Farm Bill to provide law enforcement with certain ''real-time'' information about who is growing hemp, whether their license is in good standing with the regulatory body issuing the license, and the location(s) of where hemp is being grown. The daily collection of this information through FSA county offices enables USDA to easily transmit the required information to law enforcement. FSA maintains the technology necessary for data collection and geographical land identification. These tools will provide easy access to information needed for law enforcement and for other agricultural programs. This information is compiled in one system, using an information sharing mechanisms currently used by law enforcement and which they are familiar with, and transmitted to law enforcement in a safe manner, which otherwise would not be as readily available through State and Tribal reporting. States and Tribes must provide information to USDA in a format that is compatible with USDA's information sharing system. USDA will work with States and Tribes on system format and other information necessary to share information.

Secondly, FSA's county network is expansive with over 2,000 field office locations. FSA offices provide services both in person and virtually to accommodate the needs of producers.

Its mission runs parallel to other USDA agencies including Risk Management Agency, Natural Resources and Conservation Service, and Rural Development, each of which provide a wide range of benefits and services to local communities. AMS noted that in many cases, FSA is co-located with other Federal, State and county-level government offices which means a variety of services are provided through one central location. These services frequently include information on insurance and risk management programs, conservation and irrigation technical expertise, agricultural credit for operating or marketing, and rural housing loans. As such, the requirement is considered by AMS to be particularly important to new and beginning farmers who traditionally are not familiar with the wide range of programs and services offered by Farm Service Agency and the other USDA agencies.

Definition of ''Lot''

AMS received comments on the definition of ''lot'' for providing geographical determination of hemp production and for sampling purposes. One comment explained that nursery operators and their field operating counterparts may need to file hundreds of permits for a single greenhouse under the IFR. The comment described as an example one greenhouse at a nursery, which may have upwards of 36 benches, in which each bench could have 20 different hemp varieties growing at any one time. The comment said that the IFR would require that single greenhouse to have 720 ''lots,'' and based on most States' current rules, 720 containment plans, destruction plans, and transportation notices when any plants are moved—all possibly requiring agency approval prior to any action

being taken. It further explained that the growing cycle for nursery stock could be as short as five to six weeks, and different varieties could take their place. The comment said a nursery with five or six greenhouses on a relatively small acreage may have to register thousands of lots and submit thousands of associated plans. It recommended that such a nursery should only be required to designate the actual greenhouse or indoor growing structure itself as used for the cultivation of hemp generally, and the term ''lot'' should not be defined to include any restriction or limitation to the same hemp varietal. The comment proposed revising the definition of ''lot'' to mean a contiguous area in a field, greenhouse, or indoor growing structure used for the cultivation of hemp.

AMS response: In this final rule, AMS is clarifying that the term ''lot'' has the same meaning as other terms used by FSA, as found in 7 CFR 718.2, to mean the same production area, such as ''farm,'' ''tract,'' ''field,'' and ''subfield.'' AMS uses the term ''lot'' to help growers and oversight officials identify farm locations, field acreage, and variety (*i.e.,* cultivar). Although a hemp producer must report their ''lot'' information to FSA, when a producer visits the FSA office to report hemp crop acreage, FSA staff will determine the appropriate designation for the specific location(s) where hemp is being grown. FSA staff will not provide a ''lot number'' to producers as described in the IFR, but instead designate either a ''field'' or ''subfield'' as the unique identifying number. This number is considered equivalent to a ''lot number.''

A lot must always contain the same variety or strain of cannabis throughout the area because the final rule requires lot-based testing.

Certified Seed

The IFR explains that under the 2014 Farm Bill, various States developed seed certification programs to help producers identify hemp seed that would work well in their specific geographic areas.

Comments: Some comments concurred with USDA's decision not to introduce a hemp seed certification program with the IFR. Numerous commenters said that such a program would not be appropriate, that it would be too difficult to regulate, or that it would be premature now. Other comments said a federal hemp seed certification program is not necessary because some States and Indian Tribes had already developed such programs for their jurisdictions or are capable of doing so. Numerous comments said they recognized the difficulty of developing a hemp seed certification program but nonetheless urged USDA to pursue what they characterized as an important effort to allow for consistency among hemp producers when resources permit.

One comment asserted that seed certification is key to a regulated hemp industry and explained that certification is a common practice in the international seed industry. Several comments contended that USDA must develop a seed certification program to prevent hemp growers from purchasing and planting seed of unproven quality—or of the wrong varieties for their purposes—and risking unnecessary financial loss and regulatory violations. Comments claimed that hemp farmers already have difficulty verifying the origin, genetics, and reliability of hemp varieties currently on the market, and that a seed certification program would help farmers know whether seed they purchase is appropriate for their growing conditions or intended hemp product end-use. Numerous comments inferred that a seed certification program would identify hemp varieties that had been tested and proven to reliably produce compliant hemp plants in specific geographic areas.

Some comments argued USDA should not engage in hemp seed certification because plant genetic expression is influenced by environmental conditions and seed certifiers cannot guarantee plants will have THC concentrations within the acceptable range. Other comments countered that assertion and referenced a comment that reported on the analysis of cannabis genome trials and concluded that cannabinoid concentration is 80 percent or more controlled by genetics rather than environmental conditions.

Comments claimed that hemp varieties developed under proper breeding programs and certified in the European Union and Canada had been proven to have stable cannabinoid profiles across multiple regions. They suggest that comparable results could be achieved under a USDA seed certification program.

A comment claimed that the lists of acceptable/approved varieties provided by the processor and/or the governing authority in the State in which the hemp is grown needs to be updated soon and regularly. The policy language may be acceptable, but these lists need attention quickly so that ill-suited varieties are not planted and insured when planted outside of the area and not likely to perform as well.

Some comments asserted it is not necessary for USDA to develop a seed certification program now because the Association of Official Seed Certifying Agencies (AOSCA) has already established national standards for hemp field crop cultivars and is reviewing issues related to the development of certification standards for feminized seed and clones of CBD hemp. Other comments recommended USDA adopt AOSCA standards in the development of a Federal seed certification system, and several comments said that some States have already adopted AOSCA protocols for production of certified seed for commercial sale to farmers. For example, a comment stated that a state currently recognizes 17 hemp seed varieties that have been certified for use in that state in accordance with AOSCA standards. The comment said the state encourages farmers to use certified seed when possible and the state intends to rely on certified seed to streamline the hemp testing program in the future.

A comment clarified that there is a difference between seed that has been certified according to AOSCA standards (or an international equivalent standard) for varietal purity, and seed that has been tested for THC or other compounds. It asserted that some State programs have confused the terminology and urged USDA to clarify the difference and promote use of certified seed for varietal purity. The comment said the hemp industry has access to numerous proven varieties and that plant breeders are making strides to develop more varieties with specific characteristics.

Numerous other comments reinforced the need for seed certification programs that ensure hemp seed meets high standards for proper labeling, reliable germination rates, purity, and the ability to produce healthy plants. Some comments supported seed certification under State or Tribal programs, claiming such localized programs have proven successful in areas where they've been developed and used, and saying that such programs promote crop predictability and reduce uncertainty for farmers. One comment asserted that not only seed, but clone certification is a must, to ensure that growers are getting what they think they are when they purchase clones from nurseries. Some comments asserted confidence in certified seed could be extended to crop insurers, who could provide coverage at prices that reflect reduced risk. Some comments suggested growers using seed certified under a Federal certification program should be indemnified against legal liability or financial losses related to production of hemp that tests higher than the acceptable THC level. Some comments suggested States and Tribes that adopt seed certification programs

for cultivars reliably producing compliant plants should be authorized to exempt such cultivars from hemp sampling and testing requirements or to employ random, risk-based sampling schemes supported by data about those cultivars.

AMS Responses: AMS is not establishing a seed certification program for hemp. The IFR explained USDA's decision to not establish a seed certification program was due to a lack of accurate data and the advanced technology necessary to develop such a program. The term ''certification,'' as used here, means tested or verified and does not necessarily mean certified for seed varietal purity or genetics. AMS understands that some seed certification-related studies are already under way in different locations and that results of these studies are helpful in production risk mitigation. AMS recommends the use of hemp seed from varieties that have undergone a variety review, following the process outlined in the Federal Seed Act and associated regulations, (7 U.S.C. 1551–1611 and 7 CFR part 201), and produced according to AOSCA standards. These types of seed have been screened and tested for purity and are properly labeled. This final rule maintains flexibility for stakeholders to continue with trials of seed varietals and does not prohibit the use of any hemp varietals by industry. Updating the varieties list is a State and Tribal issue, as they developed them. This final rule does not address seed certification. However, USDA will consider such a program in the future if enough information is available. If there is sufficient data to support a program, USDA will explore adopting one through rulemaking under the APA.

Separately from this hemp production regulation, AMS administers the Plant Variety Protection Office (PVPO). This office actively accepts applications of seed-propagated hemp for plant variety protection. Under the U.S. Plant Variety Protection Act, PVPO examines new applications and grants certificates that protect varieties for 20 years (25 years for vines and trees). PVPO provides intellectual property protection to breeders of new varieties of seeds and tubers. Certificate owners have rights to exclude others from marketing and selling their varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work.

Regulations for Different Operations

The 2018 Farm Bill requires any producer growing hemp to be licensed either by their applicable State or Tribal authority or USDA. The IFR further required that an authorized sampling agent collect samples from floral material for THC concentration testing in order to determine compliance with the Federally established THC threshold. Some operations growing hemp do not grow to the stage where flower material is present and as such cannot test the floral material.

Clones and Cloning: Comments noted there are a significant number of grower operations that cultivate and produce hemp plants year-round. Some of these operations grow hemp varietals and maintain mother clones and/or grow plants for clonal propagation or tissue culture propagation purposes. Comments explained that hemp varietals grown in these types of production systems do not usually reach full maturity. According to comments, before achieving the floral stage of development, many of these hemp varietals are sold and enter the stream of commerce as starter plants that other licensed hemp growers may transplant to a field or greenhouse to be raised to full maturity and harvest. Comments questioned how immature or juvenile hemp plants with no floral material to test can demonstrate regulatory compliance under the IFR.

Microgreens: Comments raised similar concerns about hemp raised and marketed as microgreens or other types of immature plants intended for human consumption, noting that these plants cannot be tested for regulatory compliance because they have no floral material to test. Comments encouraged USDA to develop a regulatory process in which THC concentration testing may occur for immature, non-flowering hemp varietals so that operations like those producing clones or microgreens can support the development of the hemp industry.

One comment representing a hemp cultivation and distribution corporation in several states provided a pre harvest test on a microgreen variety grown in two different States. One State test reported 0.17 percent total cannabinoids and the other test reported 0.0193 percent total cannabinoids. Based on these tests, commenter indicated that hemp leaf greens/microgreens and related crops are not in danger of excess THC.

Hemp Research: Numerous comments stated the need for a separate regulatory scheme to support hemp research. Comments explained that the plant breeding process by its nature requires breeders to bring multiple varieties of plants to maturity in order to evaluate their characteristics and potential use in ongoing hybridization projects. They said, for example, that plants with desirable characteristics such as frost and drought tolerance or pest resistance must be identified and preserved, while plants with unwanted genetic traits or diseases must be separated and destroyed in order to stabilize the genetics for THC expression and other desirable traits and understand how environmental factors, disease, and insect pressure affect the expression of those traits. According to comments, the THC concentration in such plants could exceed the acceptable THC level in the IFR and plant breeders could find themselves in violation of the law. As well, they explained that the IFR's disposal requirement could force breeders to destroy valuable plant material and waste years of work, as well as funding.

Other comments asked USDA to support research into hemp pollination and drift. Comments reported industry concern that cross pollination could reduce the value of neighboring CBD flower crops. They asked USDA to focus on grain producing geographic areas and varieties to provide the science to support large acreage growers.

Comments explained that the IFR's THC threshold of 0.3 percent reduces the incentive to conduct hemp variety research because of the likelihood that many plants will exceed that threshold. For example, comments suggested the THC limit for hemp plants in licensed breeding programs could be raised to 0.6 percent or 1.0 percent or higher. They suggested breeders be allowed to raise plants to maturity, collect data and save seed for further research, and be required to destroy noncompliant plant material at the end of the growing season. Other comments suggested that breeders and researchers should not have to wait for hemp plants to flower and undergo testing before they can remove and destroy those plants with undesirable traits.

Comments asserted that hemp strains used in genetic studies authorized by the 2014 Farm Bill and compliant with other program regulations may now be in jeopardy due to the uniform application of the IFR's 0.3 percent THC threshold and plant disposal requirements. They noted how a regulation that requires the disposal of what was previously compliant hemp will undermine the efforts and millions of dollars invested by farmers and researchers. Other comments indicated that not having the ability to replicate certain genetic traits from a plant that is noncompliant can slow the development of industry.

Comments from and about university research programs suggested that USDA make land grant universities eligible for special research carve-outs or regulatory

exemptions to allow them to continue research efforts. Other comments suggested USDA define criteria under which researchers and other plant breeders could be eligible for special research program exemptions. They suggested USDA develop criteria for certification or qualification of hemp researches and breeders, and some suggested those meeting specified criteria could be exempt from the IFR's crop destruction and reporting requirements, provided they adhere to other restrictions, such as prohibiting research material from entering the chain of commerce, disposing of non-compliant plant material, and limiting plot size. Some commenters noted that without such allowances their university administrators would not allow them to continue research with any form of cannabis, including hemp, due to concerns about Federal grant disqualification.

One commenter requested an exemption for Tribal research facilities so that they will not have to destroy all non-compliant plants.

Comments noted that USDA's National Institute of Food and Agriculture had not issued requests for applications on hemp research and that hemp was not listed for funding under the Specialty Crop Research Initiative. Comments suggested more agronomic research is needed to address current gaps in knowledge related to hemp production and management and to standardize seed.

AMS response: Due to the variability in immature plants across producers, States, and Tribes, and the lack of consistency across varietals, USDA is unable to establish or standardize an approach to dealing with immature plants for USDA licensees. However, AMS acknowledges operations that grow hemp for certain purposes that do not bring plants to their flowering stage like clones and microgreens, may not need to meet the same sampling and testing requirements as operations that grow flowering hemp. The final rule provides States and Tribes the flexibility to consider performance-based sampling protocols to address these concerns. As allowed under the AMA, States and Indian Tribes can be more restrictive and may impose sampling and testing requirements on these producers.

USDA also acknowledges that research institutions face special circumstances when conducting hemp research. Accordingly, this rule provides sampling and testing flexibility to these institutions and producers working with them to conduct hemp research under the USDA plan. Producers that produce hemp for research must obtain a USDA license or a State or Tribal license. However, the hemp that is produced for research is not subject to the same sampling requirements or the requirements pertaining to non-compliant plants, provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. USDA licensees will need to submit an alternative sampling method to USDA for approval and shall ensure the disposal of all non-compliant plants. USDA licensees shall also comply with the reporting requirements including reporting disposal of non-compliant plants.

AMS views this flexibility as necessary to help support research and development as it relates to hemp production by industry, particularly in its infancy. This decision allows these types of research facilities and institutions to oversee the study of hemp plants through trialing and genetics research. Over time, the flexibility provided by this final rule will help to stabilize industry by providing greater understanding of hemp genetics and how certain varietals respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as information about more stable and consistently reliable hemp varietals becomes available. Any non-compliant plants produced by research institutions as a result of research and development will still need to be disposed and disposal will need to be verified with documentation. Research institutions that handle ''hot'' hemp must follow CSA requirements for handling marijuana.

Sampling Agents

This final rule reiterates that samples of hemp collected for purposes of testing THC must be collected by sampling agents, or by Federal, State, Tribal or local law enforcement agents authorized by USDA to collect samples. Requirements and training materials for sampling agents are provided on USDA's website.

Third-party Sampling Agents: Some comments supported the use of third-party sampling agents to help offset the cyclical demand for hemp sample collection and to ensure integrity in the sampling process. Comments noted that some State agriculture departments have relied on in-house personnel to perform sampling activities and that these States did not use or require third-party sampling agents during piloting.

One comment reported use of third-party certified samplers for the 2020 season, and as of the date of their comment, had employed 74 certified sampling agents. The commenter said the State recommends producers make appointments with sampling agents 30 days in advance prior to intended harvests, and that they had not received any feedback regarding unavailability of sampling agents based on the 15-day window. The comment went on to report that the State had received numerous anecdotes of next-day availability for sampling, which the comment suggested would not be possible without the use of third-party sampling agents.

Resources: Several commenters worried that there would be insufficient numbers of appropriately trained, USDA-approved sampling agents available during harvest periods to ensure that all crops could be sampled, tested, and harvested within the 15-day window specified in the IFR. They asserted that sampling backlogs and delayed testing and harvesting would cause crops to mature beyond the acceptable hemp THC content concentration, resulting in crop disposals and financial losses for farmers. Several comments said producers in rural and remote mountainous areas would be particularly impacted, since sampling agent travel into those areas would require extra time and expense.

Comments described how some States developed sustainable hemp oversight programs using risk-based sampling methodology to support regulatory monitoring of hemp growers. They asserted these same States would find it difficult to meet the IFR's sampling requirement because of a limited budget to hire and train additional personnel for sampling all hemp production. Comments reported having to make appointments for sample collection a week in advance under risk-based sampling plans and predicted it would be even harder to arrange for sample collection on a timely basis under the IFR's requirement that all hemp lots be sampled and tested.

Commenters presented two proposals to alleviate this strain—allowing producers to collect their own samples and reducing the volume of farms and plants from which samples are collected.

Some commenters requested that USDA compile a publicly available national list of sampling agents.

Sampling Agent Training: Comments highlighted the importance of providing robust training for sampling agents and recommended subsequent annual, documented refresher training be required. Some comments recommended USDA develop and implement a sampling agent certification scheme, while others suggested States and Tribes retain the authority to develop sampling agent training. Other comments suggested including a sampling agent training application on the USDA website.

Other Comments on Sampling Agents: Other comments objected to the IFR's provision that sampling agents be given unlimited access to all areas listed in the producer's license. Comments claimed that this provision, in addition to the fact that default sampling agents may also be law enforcement representatives, seems to associate the now legal hemp industry with potential illegal activity. Comments stated further that while State, Tribal, and USDA personnel may require such access for audits or other purposes, broad access is not necessary for sampling hemp, and that sampling access should be limited to cannabis plant material being cultivated as hemp.

Other commenters suggested that sampling agents should be agricultural specialists rather than law enforcement specialists in order to alleviate possible tension between Indian Tribes and law enforcement, and would ensure that the sampling agents have an understanding of the agricultural product they are working with.

AMS response: AMS agrees with the many commenters that sampling agent training should be enhanced. Standardized training for sampling agents will help achieve regulatory consistency. As such, AMS will provide training documents for sampling concurrently with publication of this final rule. The revised sampling agent training will establish uniform and standardized criteria, including sampling processes and procedures, to ensure the sampling agents understand regulatory provisions of this final rule and the appropriate processes associated with sampling activities. This will help ensure that sampling done by different agents will be conducted similarly. AMS anticipates this will minimize variances in sampling practices that may affect the samples and ultimately the test results.

Training documents will explain how sampling agents can meet the sampling requirements of this final rule. States and Indian Tribes with an approved plan may require the sampling agents used by their licensed producers to take the USDA training, or they may develop their own custom training. This decision does not change the requirement that designated agents collect samples. We are retaining the requirement from the IFR that the use of third-party agents is acceptable. Requiring sample collection by trained agents ensures that samples are collected consistently throughout the industry and no conflict of interest exists between the sampler and grower.

Further, AMS has addressed commenters' concerns about adequate resources by allowing for States and Indian Tribes to design a sampling plan in accordance with the AMA and this final rule that suits their needs and resources. Additional discussion of sampling methodologies and flexibilities is included elsewhere in this final rule.

AMS agrees with the concerns that sampling agents be given unlimited access to all areas listed in the producer's license and is clarifying that sampling agents need access only to areas where the hemp is grown and stored so they can perform their sampling work.

AMS agrees with comments that allowing third-party individuals to become certified hemp sampling agents creates jobs, gives producers greater flexibility during the harvest season, and allows the States and Tribes to reallocate resources. The final rule does not limit sampling agents to law enforcement officers and does not prevent agricultural specialists operating as sampling agents. Because States and Indian Tribes with approved plans may approve their own sampling agents, USDA encourages States and Tribes to maintain their own lists of sampling agents.

Sampling Methodology

AMS posted supplemental Sampling Guidelines for Hemp Growing Facilities on its website. The guidelines describe sampling procedures, including the number of cuttings to take for sampling each lot and how to pace a hemp field when sampling. A few comments addressed the Sampling Guidelines and recommended alternative sample volumes and field sampling patterns.

End-use/risk-based sampling: Comments asserted that hemp sampling requirements should differ based on the crop's end-use, primarily whether the crop is used for grain and fiber production or for cannabinoid extraction. They contended that the IFR requirement to sample every hemp lot, regardless of the crop's end-use, is expensive and burdensome for States, Indian Tribes, and individual growers. Comments generally discouraged requiring sampling and testing every lot for THC since THC concentration is significantly lower in male plants and grain/fiber varietals. Comments from State agriculture departments that administer pilot programs under the 2014 Farm Bill also explained how risk-based sampling requirements under their programs function. Comments emphasized that a ''one-size-fits-all'' regulation is inappropriate and discourages innovation as there are different risk-profiles for hemp based on its end-use.

Comments maintained that grain and fiber varietals are less likely than cannabinoid crops to exceed the THC threshold and argued that assessing all hemp by the same standard may result in strained oversight resources and inefficiencies. One comment asserted that THC concentration in varietals grown for grain is reduced dramatically by the production of seeds in the flower and, therefore, hemp grown for grain is at lower risk of exceeding the THC limit. Comments also noted that the flower parts, where a majority of the THC is concentrated, do not fairly represent the THC content of the entire plant, which is used in biomass and fiber production.

One State agriculture department noted that many of the seed and fiber varietals being grown in their State were originally bred in Canada and have been selected for low THC content as part of Canada's hemp program for many years. Several trade association comments noted that hemp grain/seed is not a source of cannabinoids, and that grain and fiber varietals are largely developed from certified, pedigreed seed that meets all THC testing standards. Commenters contrasted that with hemp crops grown for cannabinoids, and that the latter show higher phenotypic variability and lack of uniformity in the field because they have received less focus in breeding programs. One comment stated that hemp varietals grown for cannabinoid production often have questionable origins and are at a greater risk of producing higher THC than varieties grown for grain or fiber. Another comment claimed there are currently no certified varieties of hemp for CBD production.

Many comments agreed that hemp grown for cannabinoid production is more likely to exceed acceptable THC limits. Data from 2019 submitted with a comment showed that 13 percent of hemp samples tested exceeded 0.3 percent THC, and all were CBD varietals. The comment further recommends that certified seed varieties should be sampled and tested from a random selection of hemp grain and

fiber fields 30 days prior to harvest. For uncertified varieties, it recommends requiring a post-harvest test, as well as a pre-harvest test of a random selection of fields within 30 days of harvest. According to comments, those hemp crops being grown for cannabinoids should be subject to higher scrutiny and more frequent testing.

Another commenter cited data from the Midwestern Hemp Database [18] showing that many publicly available varieties are exhibiting a linear (or curvilinear) relationship between Total CBD (%) and Total THC (%). Given this presumed relationship, Total CBD percentages are often not able to exceed 8 percent without exceeding the regulatory threshold of 0.3 percent THC. The commenter said these moderate levels of CBD production can have significant impacts on profitability as growers and therefore a whole plant testing methodology would help to mitigate this linear relationship.

Comments identified States and other institutions where they think risk-based oversight modeling works to ensure hemp is at 0.3% acceptable hemp THC level. For example, the Kentucky Department of Agriculture publishes a ''Varieties List'' to track THC content across hemp varieties. Comments characterized this as a useful tool for hemp farmers when planning production cycles and selecting hemp varietals. Several comments also described how, at the State level, other measures support risk-based oversight, like randomized sampling crops of a percentage of the total grower population or the use of risk criteria to identify ''high risk'' growers. Commenters credited these types of practices and activities with allowing states to efficiently oversee hemp production under pilot programs. Other comments described how financial institutions routinely incorporate risk-based modeling into the risk assessment of lending decisions, and that similar modeling should be adopted by USDA for sampling and testing.

Comments argued that subjecting all varietals to the same regulatory requirements under the final rule will compound logistical challenges to oversight bodies, strain resources, and increase costs for low-risk farmers. They said testing based on hemp's end-use created a more flexible approach to oversight while benefiting the farmer.

Two state department of agriculture comments supported end use or risk-based sampling methods in order to account for producers using certified seed, producing hemp for industrial use purposes, fiber, grain, seed, extraction of biomass, and indoor producers growing plants only in vegetative state for research or resale that pose a low risk for detectable THC content.

Several other comments suggested ways USDA could incorporate risk-based sampling into the domestic hemp production program. Comments recommended USDA evaluate and consider allowing greater regulatory flexibility for States and Tribes to develop and use risk-based modeling to guide their sampling and testing activities. According to comments, this approach would help offset the anticipated strain on resources during peak sampling that would otherwise result under the IFR requirements.

Two State agriculture departments recommended that crops produced from AOSCA-certified seed, which they said currently only include grain and fiber varietals, be considered low-risk for testing and compliance purposes. Comments said that as more CBD hemp varietals are developed and certified, they could also be subject to less stringent testing protocols.

A few comments suggested the adoption of a random risk-based sampling and testing scheme to reduce grower costs and relieve pressure on approved labs by reducing the number and volume of required tests. One comment indicated State hemp regulators have successfully developed sampling requirements for end-use that ensure adherence to State and Federal regulations, while allowing for flexibilities around State resources. Other comments sought requirements establishing a minimum number of cuttings per lot (*e.g.,* ''5'' cuttings per lot regardless of size.) For example, one comment suggested that when sampling lots of less than 1 acre, taking cuttings of one plant will not allow for a representative sample, so a minimum of 5 plants be identified for cuttings. Another comment said that the sampling requirements in the IFR, as applied to a 170-acre field, could require the sampling of as many as 110 plants from that field which would be impossible for a state department of agriculture to meet. As an alternative, USDA might provide a fixed sliding scale (for example, a lot of less than 10 acres requires 5 plants; a lot between 10 acres and 20 acres requires 6 plants; and so on) rather than leaving those calculations to each state. Alternatively, another comment explained how their state sampling protocol currently utilizes the parameters of a minimum of 6 cuttings per lot or acre, whichever is smaller, with the option for producers to increase the quantity of cuttings collected as they see fit (up to 150 cuttings per lot). Another comment described how contracted labs for their state have requested at least 40 grams of wet material and up to 60 grams if the licensee is also needing additional testing such as heavy metals, pesticides and mycotoxins.

One comment reported the results of a 2019 controlled study where the top 12 inches of the plant and the top 2 inches of flowering material were collected from each of 83 plants, for a total of 166 samples. The samples were tested using gas chromatography with flame ionization detection. Test results showing total delta-9 THC of the 2-inch cuttings were, on average, 0.0273 percent higher than results for the 12-inch cuttings. The comment interpreted the results to suggest that including vegetation from the entire plant yields lower THC results, and that all parts of hemp plants should be sampled because producers generally harvest the entire plant.

One comment reported that their State requires samples for any size lot to include 30 buds (subsamples) to insure there is large enough volume of material to provide for adequate sample testing. Another comment reported that State staff are directed to look at a cultivar and evaluate it for uniformity with respect to maturation, height, color, and basic plant architecture. According to the comment, uniformity within a cultivar results in fewer plants sampled than a cultivar exhibiting greater phenotypic diversity for the same acreage. The comment supported providing States with authority to establish sampling protocols, given the significant variation in plant counts between fields (on a per acre basis) and phenotypic diversity within and between cultivars. The comment also recommended that AMS provide guidance on a recommended number of plants to be sampled per unit area, including the plant density for each sample number recommendation.

One comment advocated revisions to USDA's sampling guidelines. The commenter said the State has had to deviate from USDA's sampling table, specifically for smaller lots. According to the comment, taking a sample from one plant does not provide enough material for lab testing, and the State has had to bear the cost of taking a second sample. The comment mentioned that some of the State-contracted labs have requested at least 40 grams of wet material and up to 60 grams, if the licensee is also requesting additional testing, such as for heavy

[18] *https://farmdoc.illinois.edu/field-crop-production/hemp/midwestern-hemp-database-a-new-tool-for-hemp-growers.html.*

metals, pesticides, and mycotoxins. The comment also explained that to keep from delivering excess material from large lots to labs, inspectors take the required number of cuttings, then homogenize the sample, keep the required 40 to 60 grams, and leave the remaining sample material in the field. The comment supported a sampling protocol that would provide adequate testing material without unnecessarily overcutting plants material.

One comment reported results of a poll they conducted among States after the end of the 2018 growing season. According to the comment, three States—New York, Pennsylvania, and Minnesota—reported they had analyzed the THC content in microgreens, and none were found to be above 0.3 percent total THC.

One comment reported that their State has tested every hemp lot produced in Minnesota in the past five years, and that hemp grown for grain and fiber has never tested above the 0.3 percent total THC limit. According to the comment, varieties grown in Minnesota are certified varieties found either on the Health Canada List of Approved Cultivars or the European Union's Organization for Economic Co-operation and Development List of Varieties Eligible for Seed Certification.

One comment reported their State has implemented a risk-based sampling frequency schedule, under authorities provided for in the 2014 Farm Bill, using end-use and certified seed as guidance. According to the comment, official total THC results collected from regulatory samples and formal research samples showed that hemp grown from certified seed have a low risk of testing above 0.3 percent. Additionally, the grain or stalk components of hemp have zero to negligible levels of total THC. The comment recognizes that more research is needed in this area but is confident that the utilization of hemp variety categories to determine the department's sampling frequency has been successful to date.

AMS response: AMS agrees that States and Indian Tribes need more flexibility in developing sampling methodologies. For States and Indian Tribes with primary regulatory authority, USDA is altering the sampling requirements in this final rule to allow performance-based sampling methodologies. Information submitted by States that participated in the 2014 pilot program show various ways these States are already using performance-based sampling. Some States are using a list of varieties that work in their geographical area while others rely on evaluation on what they consider high risk producers. USDA finds the data submitted by commenters to be reliable because these States have been growing hemp since the 2014 pilot program started and they have sufficient data to develop their sampling plans. AMS agrees with commenters that the performance-based concept is the same method that financial institutions use. Further, performance-based programs are also used by other scientific and Federal agencies such as USDA's Food Safety and Inspection Service and FDA.

AMS finds that it makes sense to encourage States and Indian Tribes to consider performance-based alternatives when developing sampling plans. The final rule provides the standard; however, States and Indian Tribes have the flexibility to determine how to achieve that standard tailored to their specific needs.

The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp licensees under their jurisdiction. State and Tribal plans must include a procedure for accurate and effective sampling of hemp that meets the requirements of the final rule. The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level. Alternatively, States and Indian Tribes may design a sampling method that is performance-based that ensures, at a confidence level of 95 percent, that plants will not test above the acceptable hemp THC level. This plan must be part of the State or Tribal plan. A performance-based method may consider: (1) A seed certification process or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe; (*2*) whether a producer is conducting research at an institution of higher learning or that is funded by a Federal, State, or Tribal government; (*3*) whether a producer has consistently produced compliant hemp plants over several years or several seasons; and other similar factors. USDA believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. Sampling protocols submitted by States and Indian Tribes must comply with the thresholds established by the 2018 Farm Bill and this final rule. If performance-based sampling requirements are not included in a State or Tribal plan, every lot, and thereby every producer must be sampled and tested.

When evaluating sampling protocols submitted by States and Indian Tribes, USDA will take into consideration whether the performance-based factors the State or Indian Tribe used have the potential to ensure compliance at a 95 percent confidence level. USDA licensed producers are required to comply with the sampling requirements in this final rule. Additional guidance on sampling for USDA licensees or States and Indian Tribes that decide to use these guidelines is available on the USDA website at *https://www.ams.usda.gov/rules-regulations/hemp/information-sampling.* USDA may develop a performance-based sampling in the future if data is available and if it deems appropriate. Separate rulemaking and comment process will be necessary to establish a performance-based sampling plan by USDA.

USDA plans to audit State and Tribal activities to assess program compliance with all Federal requirements, which includes review of the performance-based sampling implemented by States and Indian Tribes.

Sampling Guidance: A comment noted that although the sampling protocol was issued as a guideline, it appears to be binding with regard to how hemp must be sampled. The comment said AMS should clarify that there may be other acceptable sampling procedures that would meet the IFR's sampling requirement. The comment explained further that some States operating hemp programs under the 2014 Farm Bill have established detailed hemp sampling protocols that producers are used to and should be allowed to continue.

Another comment appreciated the IFR's provision that the AMS Sampling Guidelines may need continual updating and refinement as industry, academia, and government discover new evidence, science, products, and innovations.

A comment described the hemp field sampling plan they adopted from Florida's nematode sampling plan. The plan recognizes that nematodes are unlikely to be evenly distributed throughout an orchard or field, which would also allow for accurate detection of THC fluctuation within a hemp field. The comment said Florida's sampling plan is accepted by every State and country to whom they send citrus plant material that has been screened for nematodes and recommended AMS

revise the hemp Sampling Guidelines to incorporate Florida's sampling plan.

A comment said Kentucky requires cuttings from five plants per lot, believing this standard provides a reasonably representative sampling of the plants in each lot. It opposed the sliding scale in AMS's Sampling Guidelines, saying the sliding-scale calculation relies upon a decades-old pesticide residue sampling regime that may or may not be appropriate for calculating confidence levels in a hemp plant's THC levels. The comment asserted the sliding scale formula, which depends on a variable factor based on historical data, is likely to create state-to-state variations in the number of samples that must be collected, and would require States with historically lower rates of non-compliant THC test results to take more samples per lot than those States with historically higher rates of non-compliance, which the comment found to be illogical. The comment explained that applying the Sampling Guidelines' sliding scale calculation to a 170-acre field could require the sampling of as many as 110 plants from that field. It went on to say that sampling a single field under that scenario would overburden available sampling and laboratory staff, make transporting sample material difficult, and make grinding sample material an impossible workload. The comment recommended AMS specify a single number of plants to be sampled from every lot, regardless of the lot's size, or publish a fixed sliding scale for industry-wide use, rather than leaving those calculations to each State. This comment was supported by several state departments of agriculture.

A comment noted the importance of moisture content consistency in compliance sampling and recommends 8–12 percent moisture content standardization. They also noted the need for best practices to be identified for drying sample material.

Several comments said USDA's sliding scale sampling protocol results in too little a sample for small acreages and too large a sample for large acreages. Comments asserted, for example, that one cutting for four acres or less would not be suitable to collect a representative sample and could put small acreage farmers at a higher risk of being violative or not might be sufficient to capture uncertainty related to population variability in a newly established crop. Another comment said that a true representative sample needs to entail multiple subsamples collected spatially across a field and pooled into an average sample. Further, according to the comment, since cannabinoids tend to increase along the height of the plant, floral material should be sampled at random heights from plants rather than all from the tops of plants to be representative.

Another comment recommended revisions to the Sampling Guidelines to provide that sampling agents should sample fields in a zig-zag pattern. The comment further recommended that AMS revise the Sampling Guidelines to provide that three cuttings should be taken from every plant sampled, and that the three cuttings should be taken of floral, stem, leaf and stalk material at three different points on the plant. It argued that floral material makes up only 25 to 30 percent of hemp plants and that, to be truly representative of the sampled plant, the sample should consist of cuttings of all plant materials from throughout the plant.

One comment recommended requiring that samples consist of a minimum of 4 ounces of material to provide an adequate amount for testing. Another comment suggested USDA research and review multiple sampling protocols and select the best among them.

AMS response: AMS agrees that establishing clear and standardized Sampling Guidelines is important for all hemp producers and States and Indian Tribes with primary regulatory authority over hemp. AMS issued Sampling Guidelines and is updating that guidance to reflect the changes from the IFR to this final rule. States and Indian Tribes with USDA-approved hemp production plans may develop their own sampling procedures that take into account regional and other differences and are performance-based, so long as those procedures meet the requirements in the regulations at § 990.3. The entirety of the State or Tribal sampling plan, including any guidelines, must be included in the State or Tribal plan submitted to USDA for approval. When developing such plans the State or Indian Tribe must follow the requirements of this final rule that relate to where the cutting takes place including only flower material, and the number of inches necessary for sampling. Specific to sample size or weight of a cutting, AMS does not agree that establishing a specific volume is prudent given the variances in flower size and densities, and different scales of hemp production. It would be difficult to consistently sample at an exact weight of plant material across the spectrum of producers and therefore is not included in this final rule. Rather, AMS specifies a length (approximately five to eight inches) from the ''main stem'' (that includes the leaves and flowers), ''terminal bud'' (that occurs at the end of a stem), or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant.

This is considered appropriate and fair to balance the collection of sufficient plant material necessary for compliance laboratory testing while avoiding the need to cut excessive and unreasonable amounts of plant material.

Further, AMS determined this final rule must provide some additional degree of flexibility for States and Indian Tribes in the development of their sampling plans, which is why as an alternative, this final rule allows for performance-based sampling methodologies in State and Tribal plans.

Flexibilities afforded to States and Indian Tribes developing their own hemp production plans will allow them to incorporate best practices, as those change and develop over time. For example, States and Indian Tribes can adapt field-walking patterns to various sized and shaped hemp grower operations. AMS believes that a national standard would be difficult to consistently apply given the various grower operations and that standard ''zig-zag,'' or letters ''M'' or ''Z'' walk patterns may not be feasible for sample collection of micro-acreage producers, very large scale producers or those with polygonal hemp lots.

As an alternative option, AMS has updated the Sampling Guidelines and Protocols in conjunction with the publication of this final rule. This resource document is available online and offers guidance States or Indian Tribes can adopt and incorporate into their own USDA-approved sampling procedures.

Flower Versus Whole Plant Sampling

The IFR requires the collection of samples from the flower material of hemp plants for laboratory testing.

Comments: Several comments expressed support for sampling only hemp flowers, as provided in the IFR, although many recommended changes to the overall flower material sampling requirements. Those recommendations and commenters' explanations for them are addressed in another section of the comment analysis. Numerous comments opposed the IFR's floral material sampling requirement, preferring instead composite sampling of the flowers, stems, stalks, and seeds, and asserting such samples would be more truly representative of the entire plant and lot. Numerous comments agreed that cannabinoid concentrations are higher in the flower than in other parts of the plant, and many comments

argued that sampling only floral material would cause more samples to inappropriately and unfairly test ''hot'' and lead to unwarranted and costly crop disposals.

Several comments said that sampling only the flowering material of the hemp plant is inconsistent with the definition of industrial hemp, as amended by the 2018 Farm Bill, which refers to the whole hemp plant. Comments asserted that the statute did not limit sampling to floral material and challenged USDA's interpretation of the statutory sampling requirement. As well, comments argued that requiring sampling of only flowering material could lead to legal challenges from producers who would be forced to destroy hemp that may be statutorily compliant, but not compliant with the IFR. They recommended that the regulations provide for sampling the whole plant and that USDA define the term ''whole plant'' to include the flower, stalk, and leaves.

Some comments stated that sampling only flower material ignores the hemp grown for seed and stalk end-uses, and not for cannabinoids. Comments claimed that sampling and testing only flowering material would limit industry diversification in terms of producing hemp for biomass intended for uses other than THC production. To address this, several recommendations for revisions to the IFR's sampling requirements were offered. Some comments recommended taking larger samples from prescribed parts of hemp plants that would include other than flowering material. For example, both State departments of agriculture and Indian Tribes recommended taking branch samples from two or more specified parts of plants that would include flowers, stems, stalks, and seeds, and proposed a range of sample lengths they considered appropriate, from 4 to 18 inches. Some recommended taking samples of the lower part of branches as well as flowering tips from the same plant. Several comments urged USDA to adopt risk-based sampling requirements that would better align with the intended end-use of hemp crops, like grain and fiber. Other comments recommended revising the IFR to allow States and Indian Tribes to design sampling requirements to meet the particular needs of producers in their jurisdictions, like producers who are well experienced with growing hemp and understand the potential to grow a non-compliant crop.

Commenters expressed the widely shared view that cuttings for hemp samples must come from various locations on the plant, not just the top third as indicated by the Sampling Guidelines. They explained that marketable hemp product comes from a composite of the entire plant, not just the top, and asserted that flower material samples should likewise come from the entire plant to ensure the sample accurately reflects the lot from which it is taken. Comments also voiced the need for greater regulatory clarity on the size of the floral cuttings due to concerns that no regulatory requirements address floral collection by authorized sampling agents, and variances in types of materials collected may affect test results.

Cannabinoid Concentrations: Comments described phytochemical characteristics of *Cannabis sativa* L and argued that samples taken from only one part of the plant are not representative of the whole plant. Some comments contended that flowers at the top of the plant have higher concentrations of THC and other cannabinoids—by as much as 30 percent, according to some—than flowers elsewhere on the plant. One comment cited a study [19] that found that top-only sampling, as prescribed in many State testing programs, leads to an overestimation of THC content by nearly 37 percent. The study stated that to better represent total crop THC levels, samples should be taken from the top, middle, and bottom of plants in equal quantities. Commenters asserted that sampling flowers from only the top of the plant could lead to incorrect conclusions about the lot's compliance and lead to inappropriate and costly lot disposals.

Other comments contended that THC concentrations are not necessarily higher at the top of the hemp plant. One comment used data to show that the distribution of THC concentrations throughout hemp plants is not consistent between varieties. It cited a 2019 comparison study in which 4-inch cuttings of floral material from two hemp varieties were taken from the top, middle, and bottom sections of plants. In one variety, total THC was highest in samples taken at the top, and lowest in samples taken from the bottom of plants. In the other variety, total THC varied little between samples from plant top, middle, and bottom positions. The comment said the data refutes the belief that THC levels are highest at the top of the plant and supports sampling from all parts of the plant to obtain an accurate representation of each lot's composite marketable hemp product.

Sampling technique: Some comments cautioned that inconsistent potency measurements may be the result of divergent sampling approaches and recommended that USDA provide regulatory clarity as to the proper sampling process.

A comment encouraged USDA to establish clear numeric designations of how much floral material is taken from each plant. Comments varied in their suggestions on sample cut including: 12 inches per plant; cuts from the top and bottom 18 inches of a terminal branch of the plant to achieve a more representative sample; cutting from the top twenty centimeters from the main stem of the female plant; eight to ten inches of the plant's primary stem; whole plant sampling whereby the top 1/3rd, middle 1/3rd and bottom 1/3rd are each sampled; and to ground the whole plant—not only the top 1/3rd—as that is not representative of the delta-9 THC level of the plant.

AMS response: The IFR required the collection of samples from the flower material of hemp plants for laboratory testing. Following the publication of the IFR, AMS made available at *www.ams.usda.gov/rules-regulations/hemp* a supplemental document addressing Sample Guidelines as a reference resource to industry. This resource document indicates that hemp samples are comprised of cuttings from just underneath a flower material located at the top one-third of the plant. Following review of public comment from various stakeholders, AMS determined this final rule will allow for additional sampling methodologies for determining the sample size from the lot as described previously under the ''Sample Size'' discussion. However, since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. The final rule specified pre-harvest samples shall be approximately five to eight inches from the ''main stem'' (that includes the leaves and flowers), ''terminal bud'' (that occurs at the end of a stem), or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant. This aligns provisions of this final rule with the common practices of several States that significantly participated in the 2014 Farm Bill hemp pilot programs. This decision further balances the need to collect a sufficiently large portion of the plant's flower, where THC and other cannabinoids are at their most concentrated, and the need to avoid cutting a portion of the hemp plant that

[19] ''THC Distribution in Field Grown Hemp Prior to Harvest,'' J. Scott Lowman, Jack He, Mike Clark, and Mark Gignac; The Institute for Advanced Learning and Research (IALR), Danville, Virginia.

poses logistical challenges to shipment, drying and preparing for laboratory tests. AMS believes this provision will help standardize sampling across the nation.

AMS considered the differences of pre-harvest vs. post-harvest sampling and determined the most practicable way to identify THC concentrations of the plant is through pre-harvest sampling since the floral material is still intact. Floral material must be intact to assure the material submitted for testing is in fact the flower part of a hemp plant and it has not been compromised or mixed with other plant parts. AMS also considered the many commenters who endorsed ''whole plant'' sampling. AMS concluded that measuring THC concentration through floral material testing is more appropriate and practicable than testing the entire plant because testing the entire plant will dilute the THC concentration in the sample, except as allowable under remediation, as discussed elsewhere in this final rule. Further, the study cited by a commenter that shows THC concentrations throughout hemp plants are not consistent between varieties does not support the use of whole plant sampling because it compares different plant varieties, not the THC level on different parts of the same plant variety where the sample is taken. Accordingly, sampling the top part of the plant will provide the most accurate results.

Since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. AMS will modify the sampling requirement to state that the sample shall be approximately five to eight inches from the ''main stem'' that includes the leaves and flowers, ''terminal bud'' that occurs at the end of a stem, ''or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant. AMS believes this consistency will help establish a level playing field for all U.S. hemp producers. The Sampling Guidelines issued concurrently with this rule includes additional details.

AMS also includes additional flexibilities for disposal and remediation of ''hot'' hemp that would reduce the costs to producers. These are discussed later in this final rule and in separate guidelines published concurrently.

Measurement of Uncertainty (MU)—Field Sampling

The IFR did not address the subject of uncertainty when conducting field samples and only speaks to the measurement of uncertainty in performing laboratory tests for regulatory compliance.

Comments: Several comments noted that not accounting for MU in sampling is a potential oversight that should be addressed in the final rule. Several comments note that field sampling is the largest source of variability in any testing process, due to the choices individual sampling agents make and field condition variability. Comments argued that there is a wide degree of variability among individual plants in a hemp crop and that this contributes to further uncertainty in field sampling. Due to this uncertainty in the field during sample collection, commenters suggested that an MU for field sampling be included in the final rule.

Several State agriculture departments argued that the MU value should account for variability in the steps that occur before a sample reaches the laboratory. Comments noted the various steps in the field sampling process, such as cutting, bagging, sealing, transporting, and handling, and explained that each increases uncertainty in the THC testing results before the sample even arrives at the laboratory for compliance testing. Commenters asserted that uncertainty related to each step in the field sampling collection process should be accounted for in the MU.

Several comments argued that, without a standardized MU for field sampling, some hemp crops with specific end-uses would be disproportionately impacted. According to comments, hemp crops grown for cannabinoids show the most phenotypic variability and lack of uniformity in the field. Comments said this variability should be accounted for before the sample reaches the laboratory.

One comment suggested following the ISO 15189 standards that take into account uncertainty sources during the analytical phase where the measurement actually occurs. Several comments requested that USDA establish a standardized method of calculating uncertainty resulting from sample collection procedures and for uncertainty in laboratory testing methods. One comment noted that USDA's Sampling Guidelines do not require the USDA-approved sampling agent to communicate to the laboratory anything related to crop variations or the agent's sampling methodologies that may contribute to uncertainty in testing the hemp crop for compliance.

A comment suggested a method for calculating MU that would include pre- and post-laboratory activities: MU would be calculated as the square root of the sum of squared values for pre- and post-laboratory activities, or, (a) squared plus (b) squared = (c) squared, where (a) is field sampling activities and (b) is laboratory MU. The comment offered this example: *If the in-laboratory measurement of uncertainty (b) is calculated as 0.0300 percent, and the field sampling measurement of uncertainty (a) is estimated to be 0.0400 percent, then the total measurement of uncertainty (c) would be 0.0500 percent.*

An institute that commented discussed research which found that sampling from the whole plant more accurately reflected what was observed in a field. The comment explained how the current USDA method, which analyzes only the top ⅓ of the plant, generates data that is error-prone and results that likely do not represent the actual THC levels that are present in the hemp plants in the field as a whole. It said, for example, in one research field, THC levels ranged from 0.06 percent to 2.46 percent in the top ⅓ plant samples when individual plants were evaluated separately.

The research also found significant variation in THC concentration across plants, which the commenter attributed to the lack of ability of the sampling procedure to generate a consistent, reproducible sample from any given hemp field. The research found if the field contains plants that are not completely uniform in their THC levels relative to each other, it is possible that this small subsample in any given analysis could over-represent plants that have higher levels of THC, thereby leading to failure of the field. On the other hand, equally possible, that analysis could over-represent plants that have lower levels of THC, leading to passing the field. The research stated that the most likely result of a sampling test is an inaccurate assessment of the total THC levels based on the method used to sample the plants in the field and then prepare them for extraction.

A comment from a private laboratory noted that when field sampling and pre-analysis handling and processing is done properly and uniformly, the pre-analysis measurement uncertainty can be reduced to 5–10 percent. The comment suggested that test results might be more consistent and uniform when collecting samples in a ''W'' pattern with a minimum of 10–15 individual cuttings taken from the top and middle third of the plant.

Some comments recommended USDA conduct or fund a study to determine appropriate requirements for calculating sampling uncertainty.

AMS response: AMS appreciates the different suggestions submitted by commenters on ways to handle potential

variability and uncertainty associated with sampling. AMS recognizes that a variability in sampling may contribute to the overall uncertainty of the final result. For reasons explained below, AMS in unable to adopt a national standard for calculating the MU for sampling. However, States and Indian Tribes, may include one in their State or Tribal plan as part of their performance-based alternative method for sampling under § 990.3(a)(2)(iii).

In order to develop a standardized approach to sampling MU, a sampling plan must first be well-established, standardized, and studied to accurately account for uncertainty differences in sampling methodologies. To measure uncertainty of the complete process, from primary sampling through analytical determination, all steps in the process must be included. There are many intermediary steps that must be measured, such as sampling conditions, sample preparation, sample preservation, and transportation, all of which are not always present and/or completed the same each time sampling occurs. States producing hemp under the 2014 Farm Bill have developed sampling plans that vary widely; sampling MU is not something that can be easily studied, calculated, or broadly standardized. Due to the variability in sampling across producers, States, and Indian Tribes, and the lack of available data, USDA is unable to establish or standardize a specific MU value or boundaries (upper or lower) for general use.

In the future, standards organizations, such as ASTM International through their Committee (D37) on Cannabis, will be establishing sampling standards that States, Indian Tribes, and producers could use to improve or help control sampling uncertainty. USDA also recognizes that States and Indian Tribes may have or will conduct their own study of the sampling uncertainty within their States or territories taking into account the conditions that may affect sampling. Those States and Indian Tribes may be able to calculate or standardize the MU for sampling within their States and territories. For those reasons, States and Indian Tribes may incorporate a sampling MU as part of an alternative method for sampling under § 990.3(a)(2)(iii).

Post-Sample Harvest Window

The IFR required testing for total delta-9 tetrahydrocannabinol concentration levels and sampling for such testing was required to occur within 15 days prior to the anticipated harvest of cannabis plants. The IFR required sampling to be conducted by a Federal, State, local, or Tribal law enforcement agency or their designee.

Comments: Numerous comments expressed opposition to the 15-day post-sample harvest window. Comments argued that a 15-day window is too short and urged AMS to make it longer, providing several examples of anticipated difficulties with the 15-day window.

According to comments, the 15-day sampling window in the IFR did not allow enough flexibility to reckon with adverse weather conditions that could delay or preempt field sampling and harvest activities. Comments said that isolated producers and others with limited access to harvest machinery might not be able to complete harvests within 15 days of sampling if weather prevents them from getting into the fields. Comments also noted that in some hemp production areas, climate changes are trending toward wetter harvest seasons, with frequent and catastrophic flooding in recent years. Other comments provided examples of climate variations across the U.S. and explained that the 15-day window is not uniformly suitable for all regions, some of which may be more prone to early freezes and other conditions that could forestall a timely harvest or force producers to harvest before receiving test results in order to save their crops.

Comments also pointed out that a 15-day window does not adequately accommodate a commonly employed two-phase harvest technique, wherein farmers first harvest the seeds and flowers and then the plant's stalks.

Comments additionally stated logistical challenges related to sampling on larger hemp farms or farms with several varietals. They asserted that the number of required samples greatly increased under the IFR from what was required under most State administered pilot programs, and that collecting, drying, and submitting samples for those additional lots will be very difficult within the 15-day window. A commenter stated that, in 2019, Colorado sampled only 23 percent of all registered hemp lots within a 30-day sampling window under the pilot program, while under the IFR requirements, they would need to collect more than four times as many samples in half the time.

Many commenters—from producers, state departments of agriculture, and Tribal governments—anticipated bottlenecking delays at laboratory testing facilities due to the limited number of DEA-registered laboratories available to provide testing. Comments from laboratories agreed that the increased demand for hemp testing would strain existing resources and make it difficult to return results to farmers in time to complete harvesting within the 15-day window. One commenter from a private laboratory also noted the strain on human resources this would create to oversight activities because laboratory employees are required to accompany sampling agents through the sampling process within the window. Other comments noted a possible shortage of available farm workers during a tight harvest window.

Comments from Indian Tribes stated that the requirement to test within 15 days prior to harvest by DEA registered laboratories is not practical for Indian Tribes, explaining that many Indian Tribes were moved to desolate lands where growing crops is hampered by location, quality of the land, available water and infrastructure, and access to ready transportation. Further, Indian Tribes said growers are hampered by the economies of size. Comments suggested that in much of the Indian Tribe territories, Tribes will not be able to develop large farms that reduce risk.

Many comments recommended increasing the sampling window to 30 days. Some suggested that producers be allowed to harvest before the return of laboratory results, but not be allowed to release product until test results are obtained. One comment added that allowing post-harvest testing would incentivize farmers to monitor their crops prior to harvest in order to minimize the need to destroy crops. Another comment recommended that all hemp testing labs be required to return results to growers within 15 days of receiving samples. Other comments proposed revising the regulations to require only that harvest commence, rather than be completed, within the specified period following sampling.

Data on compliance testing from North Carolina [20] cited a recent study showed an average of 12.65 days taken to receive test results, with a range of between 2 days and 41 days. It estimates that 50 percent of growers would begin to harvest before receiving the results of their THC compliance test and 22.5 percent would complete their harvest without receiving their results.

Another State department of agriculture said it has been operating their pilot program utilizing a 25-day harvest window but noted that 25 days has proved an insufficient amount of time in their experience managing their pilot program. They recommend the

[20] *https://beta.regulations.gov/comment/AMS-SC-19-0042-5294.*

final rule utilize, at minimum, a 30-day sampling window.

A State extension service cited data from the Midwestern Hemp Database and reports from Rock River Laboratory which shows that 68 percent of the requests for THC compliance testing were submitted during the period of September 8th–October 1st and note this will create a tight peak window during which samples will be submitted. Due to this peak timeframe of compliance testing needs, several State departments of agriculture note that during these peak times there will be staffing shortages, delays in sampling, delays in analyzing material, delays in the reporting of results and delays due to unsuitable harvest conditions.

Another State department of agriculture recommends that certified seed varieties should be sampled and tested from a random selection of hemp grain and fiber fields 30 days prior to harvest. For uncertified varieties, it recommends requiring a post-harvest test, as well as a pre-harvest test of a random selection of fields within 30 days of harvest.

One commenter discussed data showing that different cultivars accumulate cannabinoids at different rates and at different times. Given the rapid changes in cannabinoid levels, the comment said its data highlights the challenges of scheduling pre-harvest regulatory samples and harvest dates.

Finally, a few comments asked for clarification about the 15-day window. Some said it was unclear whether harvest must commence or be completed within the window. Others asked whether a producer is prohibited from harvesting before testing is completed. One comment stated that the 2018 Farm Bill does not contain a timing requirement.

One comment reported that their current sample-to-harvest window is 25 days, and that it does not appear to be long enough to sample all the State's outdoor hemp crops maturing concurrently.

One comment reported that the IFR's 15-day harvest window is not feasible to implement and puts incredible stress on the developing State's hemp industry. According to the comment, the State applied a 30-day sample-to-harvest window during the four years it participated under the 2014 pilot program. During the 2020 growing season, the State reported it has struggled to sample and test the 5,809 acres and 1.46 million indoor square feet that comprise the fields and facilities of the State's 700 licensed growers within 20 days. The comment claims that the State does not have the financial capability or staff resources to ensure sampling can be achieved at every field within the optimal and correct time.

Data analysis provided by North Carolina State University [21] evaluated the 2018–2020 turnaround times for labs reporting THC test results to growers on 3,317 lots. The analysis found that in 22.5 percent of cases, growers would have had to commence harvest with no knowledge of their test results to meet the 15-day harvest window requirement in the IFR. The comment asserted that in reality, growers would need lab results in 10 days or less in order to make informed harvest decisions, in which case they assumed approximately 50 percent of the state growers would have had to start harvesting without knowing their test results. The comment referenced NCSU farm cost studies that showed farmers with some equipment at their disposal will spend approximately $14,000 per acre on hemp cultivation. Noting that of those costs, seed/plant acquisition and labor are the greatest expenses, the comment asserted that harvest is the most labor-intensive activity, and that requiring farmers to harvest without knowing whether their hemp crop is compliant or marketable puts them at great financial risk. The comment recommended extending the post sampling harvest window to 30 days to reduce financial risk for farmers.

A comment from another state noted that given the State's size and geography, distances between hemp production sites could be greater than 2000 miles, making the 15-day sample-to-harvest window impractical for them. The comment recommended allowing States and Tribes, who are better aware of their geographies and resources, to determine their own windows, up to 30 days.

One comment reported the State has three inspectors geographically dispersed throughout the State, servicing approximately 200 farms harvesting within the same 8-week time period. The comment advocated extending the harvest window to 30 days to cope with unforeseen weather events, extended travel, lab turnaround, resampling and testing, and other delays.

One comment contained preliminary findings from an ongoing 2020 study [22] conducted by a state and a state university that showed different cultivars of hemp accumulate cannabinoids at different rates and at different times in plant maturity. Study data showed that some cultivars can rapidly accumulate THC and CBD, with weekly changes of as much as 0.1 percent THC and 1.5 percent CBD in some cases. The study found that the rates of THC and CBD accumulation were parallel in the four cultivars studied, with the CBD:THC ratio staying consistent around 24:1. The study concluded that given the rapid rate of change in cannabinoid levels, samples taken 2, 3, or 4 weeks prior to harvest may not accurately reflect the cannabinoid profile of the harvested material. The study further concluded that a larger harvest window increases the likelihood that non-compliant plant material will be harvested and potentially rejected at market, costing the grower the additional expense of harvesting.

AMS response: AMS recognizes weather and climate-related factors affect all cycles of agricultural production including pre-planting, planting, management, and harvest. AMS also understands these factors may vary by region from year to year, and that certain conditions might cause some farmers to alter their normal harvest timeframe as a result of factors beyond their control as mentioned in several comments. It is common agricultural practice to harvest crops taking into consideration weather patterns such as rain, wind or freezes. Producers also harvest crops based on the availability of labor and transportation, crop rotation and market demand among many factors. A 15-day harvest window may not allow producers the flexibility needed to take all these factors into consideration.

AMS considered the impact of the 15-day window on resources needed for sampling and testing activities. We acknowledge that sample collection may require an authorized sampling agent to visit multiple farms of varying sizes over a very short period of time. AMS further understands that in some places, the sampling agent may visit a farm on multiple occasions due to the size and harvest cycle of the farm. AMS also considered the turnround time for producers to receive results from laboratory testing.

This final rule allows farmers to commence harvests before receiving test results, as did the IFR. However, crops may not be released in commerce or further processed until tests confirm that the lots in question are compliant with the regulations. Harvests must be completed within the 30-day timeframe

[21] Ibid.

[22] Pearce, Bob et al. Sequential Sampling of Four Hemp Cultivars for Cannabinoids—2020; University of Kentucky, College of Agriculture, Food, and Environment and Kentucky Department of Agriculture. *https://beta.regulations.gov/comment/AMS-SC-19-0042-5762.*

provided by the final rule. AMS does not believe harvests should occur after that time because, generally, total THC levels continue to increase with time and there is too great a risk that the levels would increase after 30 days and thus the sample that was tested would not be an accurate reflection of the total THC of the harvested crop.

Regarding comments on laboratory resources, AMS considered input from our Science and Technology Program, which conducts laboratory testing for numerous agricultural commodities and oversees our third-party laboratory approval program. AMS assessed testing activities, which include the receiving, selection, drying, processing (through liquid or gas chromatography), analysis, storage, and reporting of hemp test results. AMS considered the time necessary to ship samples to the laboratory and to issue test results back to the grower, recognizing that not all farms have readily available internet to expedite receipt of electronic laboratory notifications. Standard mail may be the primary means of communication for rural populations in certain regions and Tribal lands. AMS also considered the level of routine work at testing facilities across the nation and their capacity to efficiently process hemp samples while continuing unrelated, non-hemp laboratory activities. AMS agrees that it may be difficult at the peak of the season for high-volume laboratories to consistently issue timely results to growers, as producers experienced and DEA acknowledged, impacting growers' ability to make harvest decisions.

Based on comments received and knowledge of agricultural practices, AMS determined that the post-sampling harvest window should be extended to allow hemp harvests to be completed within 30 days after sampling. AMS believes allowing the additional time will provide flexibility for dealing with unforeseen weather events and other agricultural factors, and better accommodate complicated harvest processes. AMS also believes this will reduce strain on testing resources and ensure test results can be returned to growers on a timely basis.

Laboratory Accreditation—Laboratory Approval Program (LAP) and International Standards Organization (ISO)

The IFR required hemp growers to obtain testing from DEA-registered laboratories to ensure proper handling, disposal, and reporting of samples that exceed allowable THC limits for hemp and may therefore be controlled substances. As part of the IFR, AMS asked stakeholders whether laboratory accreditation should also be required for hemp testing labs. Specifically, AMS asked about accreditation through AMS's LAP, through the ISO standards (ISO 17025), or through both, and if so, which would be preferable.

Comment: Comments reflected a range of views across the industry, both in support of and opposition to additional laboratory certification requirements. In general, commenters preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory certification/registration/accreditation requirements imposed by USDA regulation.

Supportive of LAP and ISO: Some comments supported requiring additional accreditation through both LAP and ISO. Comments explained that LAP accreditation imposes analytical standards and limits that ensure reliable and consistent results across hemp labs, while ISO 17025 accreditation ensures that labs adhere to their own established protocols. Comments asserted that additional accreditation is essential to ensure that laboratories, government entities, and farmers comply with regulations. One comment that supported requiring both accreditations said the scope of the ISO 17025 standards should include hemp testing methods.

One comment said requiring LAP and/or ISO accreditation in conjunction with DEA registration is a step in the right direction because current standards are subpar and do the industry a disservice, while adding LAP and/or ISO accreditation would provide a baseline standard that benefits all stakeholders, including consumers.

Either LAP or ISO: Other comments advocated requiring additional accreditation through either LAP or ISO, but not both. Comments said that requiring one or the other would be adequate to provide testing integrity, but that requiring both would unnecessarily overburden labs and create a testing bottleneck as labs worked toward accreditation. One comment said that since hemp products are consumable, public health and safety should be of paramount concern when choosing a lab accreditation program.

Comments supporting LAP accreditation specifically said such accreditation would improve grower access to qualified labs and would improve the efficiencies and protect the competitive interests of non-DEA labs. Comments favoring LAP accreditation pointed out that LAP already incorporates ISO 17025 standards and includes regular audits and records management requirements. Comments added that incorporating ISO standards into LAP accreditation lends confidence in testing procedures and results, which in turn creates a fair marketplace for hemp. They asserted that the benefits of LAP accreditation outweigh the costs because they emphasize quality controls and accurate analytical performance by knowledgeable and trained staff. One comment suggested that using LAP-approved labs would facilitate USDA's hemp program oversight and the development of an evidence-based data tracking system. Another comment pointed out that LAP offers growers a complete online listing of qualified labs from which to choose.

Some comments argued against adopting LAP accreditation, saying the accreditation process is expensive and burdensome for laboratories, and that the user-fee program benefits only USDA. One comment said that it is unclear from the IFR how LAP differs from ISO and whether LAP accreditation offers more confidence in test results than ISO accreditation. Another comment said that LAP accreditation would be redundant to ISO accreditation and is not necessary.

Some comments favored the use of laboratories with ISO 17025 accreditation in addition to or instead of DEA-registration. Comments noted that hemp laboratories in many States already have ISO accreditation, although some are not DEA-registered. They suggested use of those labs should be grandfathered into approved hemp production plans. Some comments asserted that between LAP- and ISO-accreditation, ISO is the best alternative for the hemp industry because it meets the needs of the hemp industry, and at a reported cost of $25,000, it reduces unnecessary expense and regulatory burden for labs and growers. One comment recommended that USDA specify that the most current ISO 17025 standard be required for accreditation—the 2017 version.

Neither LAP nor ISO: Several comments opposed requiring additional laboratory accreditation on top of DEA-registration. Some comments called it ''overkill,'' and said requiring additional accreditation would put an undue strain on laboratories and delay testing and reporting results for growers.

None of the Above: Several comments opposed specifying any particular laboratory registration or accreditation and recommended instead that States and Indian Tribes be authorized to determine appropriate standards for hemp testing laboratories under their respective production plans. Comments said that allowing States and Indian Tribes to determine their own lab

certification schemes would allow them to maintain appropriate testing capability while finding the best fit for the economic profile of their regulated jurisdictions. One comment suggested USDA encourage laboratories to participate in the Hemp Proficiency Testing Program established by the University of Kentucky, rather than building an accreditation program from scratch through LAP.

Other Alternatives: One comment asked USDA to clarify why any additional accreditation should be required. Another comment suggested that if laboratory accreditation is necessary, AMS should explore the most cost-effective choice from among LAP, ISO, or other commercial accreditations to minimize costs for growers. A comment suggested that DEA-registered labs not be required by the rule but be allowed as backups for labs with other accreditations. Another comment speculated that if only LAP or ISO accreditation were required, and DEA registration was not, growers would test their crops more frequently. Some comments recommended that no specific accreditation be required because the process is too costly and time consuming and would discourage labs from participating in the program. One comment suggested that USDA encourage labs to adhere to ISO 17025 standards, but not require accreditation.

Some comments suggested that LAP accreditation would be beneficial to the industry, but that such a program should be developed incorporating the expertise of former DEA or other chemists with experience testing cannabis. Other comments supported using ISO-accredited labs until LAP accreditation can be fully developed and used on a trial basis to gather adequate experience and data. One comment suggested allowing States, Tribes, and USDA to contract with commercial labs or use private labs that adhere to ISO standards.

AMS response: AMS noted that commenters generally preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory registration requirements outlined in DEA regulations. Adding ISO 17025 or other accreditation requirement to laboratories would decrease the number of laboratories available to perform hemp tests. AMS also noted some commenters opposed accreditation requirements due to cost implications and additional burden. While we strongly encourage laboratories to be accredited to ISO/IEC 17025 (by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) signatory accreditation body), because it will help ensure lab results are more accurate, ISO 17025 accreditation requires significant time and financial commitment to pursue and maintain. This it is most challenging for smaller and start-up labs. The initial accreditation can cost $5,000–$10,000 (and in some case more) and yearly ongoing costs are $3,000–$8,000. Smaller labs may not have the resources to pursue accreditation in a timely manner or they may have to spend more time and money for consultants to assist them in setting up a quality management system and to navigate the application and audit processes.

Based on this input, AMS will not require USDA administered lab approval program or require ISO 17025 accreditation because doing so would increase the financial burden on producers and reduce the availability of laboratories that can test for THC level in hemp. AMS is committed to continue looking into this option.

DEA Laboratory Registration Requirement

The IFR required that laboratory testing of hemp for the purpose of determining compliance under the program be conducted by laboratories appropriately registered with DEA. However, on February 27, 2020, USDA announced guidance delaying the requirement to use laboratories registered with DEA for testing. Under this guidance, testing can be conducted by labs that are not yet DEA-registered until the final rule is published, or Oct. 31, 2021, whichever comes first. This deadline was later extended to December 31, 2022. This change was intended to allow additional time to increase DEA-registered analytical lab capacity.

Comments: A few comments supported the DEA-registration requirement. Some comments favored dual laboratory accreditation (*e.g.,* DEA and ISO 17025 accreditation or DEA and AMS LAP accreditation) saying that such combinations would assure technically competent, unbiased testing and results reporting. One comment agreed with DEA lab registration but said that labs that have applied for DEA registration by Nov 1, 2020, should be allowed to continue testing (as under pilot programs) as the certification process takes so long. It further observed that while the IFR seemed settled on HPCL as the testing method, the rule does not specify the detection method as it should. The comment recommended mass spectrometry as the most accurate.

Another comment agreed with DEA lab registration, saying that otherwise, any lab could be handling controlled substances without observing stringent DEA requirements. The comment argued that allowing any lab to test hemp creates an unfair business advantage for non-DEA labs that do not have to pay high costs of maintaining DEA registrations. Further, those non-DEA labs would be handling controlled substances inconsistent with Federal law.

More commonly, comments opposed the DEA-registration requirement for hemp testing laboratories. Commenter concerns were as follows:

Logistics: Numerous comments stated there are not enough DEA-registered labs to handle the volume of samples required under the IFR's sampling and testing regulations. Comments predicted that such limited capacity would exacerbate existing bottlenecks, greatly increasing the likelihood that THC levels in sampled crops would continue to rise while farmers wait for test results. Several comments noted that the IFR allowed farmers to harvest sampled crops before receiving test results, however many prefer not to expend time and money harvesting a crop that might not be marketable. Comments also anticipated growers' testing fees would increase to cover the addition of testing resources at existing DEA-registered labs.

Some comments noted that not all States or Tribal lands have DEA-registered labs within or near their boundaries. According to comments, where DEA labs do exist, they are generally located in urban areas at some distance from rural farms. They explained that the scarcity of DEA-registered labs in reasonable proximity to farms will increase costs for transporting samples and increase the turnaround time for obtaining test results. Some comments submitted by Indian Tribes also asserted that the DEA had failed to consult with Tribes about its accreditation process and that it failed to timely respond to Tribes' requests for lab results.

Accreditation: Comments said that DEA-registration is costly and time consuming for laboratories and that such expenses would discourage existing labs from seeking DEA registration. One comment said that DEA accreditation is too expensive to be required for ''low-level THC testing.'' Comments suggested alternatives, including:

- Allow testing by labs accredited under ISO 17025
- Allow testing by labs approved under AMS's LAP

- Allow testing by labs accredited by States or Tribes
- Allow testing by labs accredited under other accreditation programs
- Allow testing by labs with dual accreditation (*e.g.* DEA and ISO, or DEA and LAP)
- Allow continued testing by labs approved to do so under the 2014 Farm Bill
- Allow for a transition period to allow labs time to work toward registration

One comment suggested that allowing for alternative laboratory accreditation would increase competition between labs, reduce costs for growers, and reduce the potential bottleneck created by allowing for only DEA-registered lab testing.

Another comment argued that although accreditation is costly, relying on it could help enforce strict standards and ensure less variability between testing labs. Some comments suggested USDA fund accreditation of private labs to help offset the cost of expensive accreditations and encourage more labs to seek necessary accreditation.

Other comments suggested DEA expedite its lab approval process and make it easier for existing labs to obtain DEA registration.

Other commenters stated that the DEA lab accreditation process requires State approval and not Tribe approval and that this is unworkable because of occasionally difficult relationships between some Tribes and States and because hemp is prohibited in a couple of States.

Finally, several comments recommended AMS provide a phase-in period of as much as two years to allow existing labs to continue hemp testing while they work toward DEA registration so the industry will have access to adequate testing options during its development.

DEA and Controlled Substances: Comments expressed concern about many aspects of DEA's involvement with the hemp program. Comments argued that hemp is a legal agricultural commodity under the 2018 Farm Bill and requiring testing by DEA labs insinuates hemp is a controlled substance regulated under the Controlled Substance Act. Commenters asserted that treating hemp as a controlled substance exceeds the intent of the 2018 Farm Bill. Comments also suggested USDA's IFR impeded Congressional intent to foster the development of a new agricultural sector.

One commenter representing a processor of hemp, specifically for CBD products, said they were concerned about an IFR published by DEA and that the rule by DEA could inadvertently criminalize hemp at various stages of its production process. They encouraged USDA to eliminate DEA's involvement.

Comments also said DEA involvement in USDA's program discourages participation by laboratories and by growers, neither of whom may care to risk prosecution for inadvertent criminal acts if a test result indicates they raised or possess a controlled substance. Some comments said private labs with ISO or other accreditation don't want to obtain DEA accreditation, fearing the tension it will cause between themselves and their grower customers because of the requirement to report potential criminal activity. Other comments said growers fear repercussions related to possible felony prosecution for growing crops considered illegal, including loss of chemical application permits that allow them to manage other crops. One comment argued that it isn't necessary to involve DEA in hemp testing, that it distracts that agency from other vital Federal work.

According to some comments, most DEA-registered laboratories are crime labs that do not offer commercial testing services. As reported by a State, the DEA may be reluctant to even visit—let alone approve—certain laboratories because of the handling and testing of marijuana, although considered legal by the State. Other States with legal medical and/or recreational marijuana provisions commented that their labs may not want to seek DEA registration because they choose to focus on marijuana testing. Some comments said labs that handle marijuana may not in fact obtain DEA registration, thus laboratory capacity to process hemp samples at the volume and speed required by the IFR may not materialize.

One comment assumed DEA-registered labs might test only for cannabinoids, while other commercial labs would be able to perform additional testing, for instance for microbes, heavy metals, and pesticide residues, saving growers the additional expense of multiple tests.

Some comments recommended USDA waive the requirement to use DEA-registered labs in States where recreational marijuana is legal, thus increasing the number of labs available for hemp testing. Other comments recommended DEA change its standards to allow labs that handle legal marijuana to also handle hemp.

Cost Management: A few comments suggested that restricting hemp testing to DEA-registered labs creates a monopoly among labs that already have such accreditation or have the financial backing of large, vertically integrated companies to enable them to do so. Comments recommended that existing State, Indian Tribe, university, or other Federal labs with demonstrated ability to perform testing according to USDA standards be allowed to do so, thus providing opportunities for more interested participants and keeping testing costs down for growers. Some comments suggested USDA contract with State, Tribe, or Federal labs to provide required testing. Other comments recommended capping costs for DEA-registered lab testing at $25–$50 per test.

Alternatives: One comment asked USDA to clarify whether all independent labs must be DEA-registered to test hemp or whether only State labs needed to obtain that accreditation.

AMS response: In consultation with the Department of Justice, AMS determined it must retain the provisional requirement that laboratories testing hemp for the purposes of regulatory compliance be registered with DEA. This requirement further extends to any laboratory testing hemp throughout the growing season to informally monitor THC concentration. The basis for this determination is rooted to the statutory requirements of the Controlled Substances Act (CSA), which requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process. The CSA states that it is unlawful to possess a controlled substance (21 U.S.C 844) and requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process (21 U.S.C. 822) with a few specific exemptions. Further, 21 CFR 1301.13 includes categories that require registration with DEA, including chemical analysis where laboratories fall.

AMS is aware through stakeholder comment that many stakeholders oppose the DEA registration requirement. AMS is also aware of widely held concern among stakeholders, especially Indian Tribes, that an insufficient number of DEA-registered laboratories exist and have limited accessibility to those in rural or regional locations away from metropolitan areas. AMS understands how this combination of variables leads to delays in sample processing by DEA-registered laboratories and how this affects producers' harvest timetables. AMS also knows that since the IFR was published, numerous laboratories have applied for registration and DEA is

working diligently to process these requests. For this reason, DEA is delaying enforcement of this requirement until December 31, 2022. AMS anticipates this delay will provide adequate time for testing facilities to obtain DEA registration.

While we understand the commenters' concern about DEA involvement, the 2018 Farm Bill distinguishes hemp from marijuana, a controlled substance under DEA's regulatory authority, based on the THC concentration level in the cannabis plant. Although a producer may have intended to cultivate hemp, it is possible that the plant is marijuana because of the THC concentration level. If that is the case, the producer would then be subject to DEA regulations and jurisdiction. USDA coordinated with DEA so that producers that inadvertently produce marijuana may be able to take remediation steps consistent with DEA's regulations to avoid potential criminal liability. Additionally, the 2018 Farm Bill makes clear that negligent production of hemp will not subject the producer to criminal enforcement activity. *See* 7 U.S.C. 1639p(e)(2)(C).

AMS also acknowledges that some laboratories believe the DEA-registered laboratories are crime labs that do not offer commercial testing services and DEA may be reluctant to approve laboratories because of the handling and testing of marijuana, although considered legal by the State. However, AMS does not have any information that would support this belief. AMS is aware that DEA continues to add laboratories to their approved list.

Accordingly, any laboratory testing hemp for purposes of regulatory compliance must be registered by DEA to conduct chemical analysis of controlled substances (in accordance with 21 CFR 1301.13). Registration is necessary because laboratories could potentially handle cannabis that tests above the 0.3 percent concentration of THC on a dry weight basis, which is, by definition, marijuana and a Schedule 1 controlled substance. Instructions for laboratories to obtain DEA registration, along with a list of approved laboratories, are available on the USDA Domestic Hemp Production Program website.

Laboratory accreditation options are discussed earlier in this rule. USDA does not have any authority over the DEA's laboratory accreditation process.

DEA's IFR published August 21, 2020, (85 FR 51639) is out of the scope of this final rule.

Measurement of Uncertainty (MU)—Laboratory Testing

The IFR required that laboratories calculate and include the measurement of uncertainty (MU) when they report THC test results.

Comments: Several comments expressed support for requiring that the MU be accounted for when testing the THC concentration of hemp due to the variability in laboratory testing equipment and complex mathematical principles involved. Comments generally emphasized that the inclusion of a standardized MU was needed for the industry to develop, as hemp farmers should not be exposed to risks of economic loss that are created by mathematical inconsistencies within an individual laboratory's computations. Several comments emphasized the importance of USDA clarifying the method for MU calculation in the rule because it is part of what determines whether hemp must be disposed.

One commenter cited a study [23] that found that test results on samples from each field sent to five different labs deviated significantly, ranging from a low of 22 percent deviation to a high of 41 percent depending on the field.

Some comments expressed the need for a standard, specific MU in the final rule to prevent licensees from ''shopping around'' for laboratories with the most lenient testing. Comments noted there is no universally accepted way to calculate MU, so differences in MU values used by various laboratories are just as likely to result from differences in calculation method as they are from differences in instrument quality or use. Several comments explained that the lack of a standardized MU in the rule incentivizes inaccuracy by potentially driving customers to laboratories willing to use MUs with greater ranges.

Many comments advocated specifying an MU to create uniformity in testing across the nation. One comment noted that variation in MU values could be problematic for interstate commerce and result in a hemp crop that is compliant in one state being shipped to another state where it would be considered noncompliant. Other comments argued that it may be too soon in the scientific process for USDA to include a standard MU because laboratories, particularly in States that didn't previously have cannabis programs, haven't had time to do the research necessary to determine an appropriate MU.

Comments from States that administered pilot programs under the 2014 Farm Bill offered several suggestions on approaches to MU calculations. A comment recommended using laboratories participating in the University of Kentucky—Division of Regulatory Services' Hemp Proficiency Testing Program to establish an MU through a set of guidelines rather than in the rule. The commenter concluded that the Hemp Proficiency Testing Program could be tasked with calculating and announcing an MU that would be used for compliance testing purposes on a nationwide basis. The comment added that including the MU in the guidelines rather in the rule would allow it to be refined over time as instrumentation and calculations develop, rather than having to modify the hemp regulation.

Some comments advocated having multiple testing methodologies to choose from and including requirements for calculating MU for each method. Other comments recommended that instead of requiring a specific MU, USDA should determine a maximum threshold for allowable MU value. Comments argued that a maximum threshold would prevent forum shopping by consumers looking for laboratories with the most lenient MU ranges, but still allow laboratories to use their own calculations. One comment recommended revising the MU provision of the IFR to include a maximum uncertainty level that laboratories cannot exceed and suggested the maximum uncertainty value should be one-third or less of the target uncertainty. Another comment suggested USDA use guidelines from the United States Pharmacopeia for determining THC concentration, which include calculations for significant figures such as MU.

A comment asked USDA to clarify the role of significant figures in using MU to determine total THC concentration because, they argued, in both of the IFR's examples for determining compliance, the lower end of the range can be written as 0.3 percent, if rounding to match significant figures. It suggested requiring the lower value of the THC calculation distribution range, which accounts for uncertainty, to be less than or equal to 0.30 percent rather than 0.3 percent.

One commenter stated that for the cannabis plants exceeding the acceptable THC levels, USDA should incorporate a MU for laboratory deviation of .0500 percent for the many different variable ways that a sample arriving at a laboratory could result in an inaccurate test. This includes cutting,

[23] Evaluation of methods used to sample hemp for regulatory compliance testing;'' Gang, David R. and Anna Berim; Washington State University, Pullman, WA; 2020.

bagging, sealings, transporting, handling, and other pre-laboratory activities.

One comment cited guidance from the National Institute of Standards and Technology providing that assigned uncertainty should be small relative to the total uncertainty targeted for test samples. The comment asserted that, as a rule of thumb, assigned uncertainties should be about one-third or less of the target uncertainty to ensure that uncertainty in the certified value will have negligible influence on the results of measurements. According to the comment, laboratories with well-developed processes will provide the most accurate and precise results and their uncertainty will be very small. The comment advocated that USDA provide an uncertainty range that cannot be exceeded by participating laboratories, thereby reducing the risk that producers will shop for laboratories with the widest uncertainty. The comment asserted that such a provision would also improve data comparability across the hemp industry.

AMS response: AMS appreciates the different suggestions submitted by commenters on ways to improve the calculation of MU and also acknowledges the variability in laboratory testing equipment that may exist. However, based on the input received and limited data available at the time of its review, AMS will only require that hemp testing laboratories complete a MU calculation as part of the mathematical test result for THC concentration. This final rule does not establish or standardize an upper or lower boundary for general use by laboratories to calculate a measurement of uncertainty. MU is typically not standardized, but rather is controlled using test methods controlled by performance standards (*e.g.,* AOAC Standard Method Performance Requirements 2019.003 that can be found at *https://www.aoac.org/resources/smpr-2019003/*).

USDA does not recommend establishing a MU upper limit (maximum) because (1) MU is typically not standardized, but is controlled using standard test methods, and (2) USDA does not have the data to set an upper limit, so setting it would be arbitrary, not scientific. The hemp and scientific industries are just beginning to discuss standard test methods, and the final rule does not establish an explicit test method. Setting an upper limit or maximum MU does not resolve the core issue and would not encourage or drive labs to improve accuracy and precision.

Setting an upper limit would in effect be setting a maximum or absolute MU. This may encourage labs to adopt the maximum MU as their MU, rather than drive for a smaller uncertainty. USDA may allow for establishing limits in the future, if needed, once methods are established and USDA has access to Proficiency Testing results and the reported MUs.

Additionally, this rule retains the flexibility for State and Tribal Departments of Agriculture to include specific requirements regarding MU for laboratories conducting hemp regulatory testing under their specific state or Tribal hemp programs if they meet the minimum standard set in this final rule. AMS encourages State and Tribal regulatory agencies to coordinate in developing proficiency and testing methods, similar to the program administered by the University of Kentucky, but participation in these types of programs is not required by this regulation.

Disposal

The IFR stipulated that cannabis exceeding an acceptable THC level must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under the CSA, rather than hemp.

Destruction vs. *Disposal:* Several comments noted that the 2018 Farm Bill specifies only ''disposal,'' of hemp testing above the acceptable THC level, yet the IFR required ''destruction'' of such material. Comments argued that the IFR's destruction requirement is an overreach. Comments asked USDA to revise the regulations to require only disposal of non-compliant plants or plant parts, and to provide either general parameters or specific provisions regarding acceptable methods of disposal. Several comments asked AMS to provide or expand the requirements for disposal of non-compliant material.

Although a few comments supported destroying non-compliant hemp crops, most comments that addressed the topic argued against total crop destruction if alternative disposal methods are available and practical. Comments explained that crop loss is financially devastating to growers—and doubly punitive if the grower must pay to destroy the crop—as well as a waste of valuable resources that could be repurposed and provide at least some return to growers. Comments explained that crop destruction can be a drain on limited official resources, depending on the availability of law enforcement personnel and equipment for the potential need to collect, transport, and oversee the destruction of non-compliant plant material. Further, a comment from an Indian Tribe noted that requiring crop destruction is culturally offensive to indigenous people that traditionally use every part of every animal and plant that can be utilized.

Disposal Methods: Several comments asserted that the only disposal methods available under DEA regulations are incineration or chemical digestion and argued that the current rules under the CSA are designed for disposal of pharmaceuticals and chemical-based illegal drugs, not for the disposal of agricultural crops. Comments asserted that incineration by DEA is not efficient or environmentally sound, and in some places may not be allowed. They noted that burning crops releases harmful carbon dioxide and other pollutants into the air, contributes to the risk of wildfires, and wastes valuable plant nutrients that could be used elsewhere.

Numerous comments stated that the rule should provide alternative methods of disposal for non-complaint hemp plants to protect growers against total crop loss and preserve valuable resources. Several comments recommended USDA adopt disposal rules established under their various State and Tribal regulations. Comments suggested growers be allowed to mulch or disc the non-compliant crop into the soil at the farm, which would build up soil nutrients, improve soil water holding capacity, and improve soil tilth. Other comments suggested growers could recuperate some of their investment by marketing non-compliant crops for other non-ingestible or non-consumable products like fiber, building materials, biofuel, biochar, bioplastics, and animal bedding. A few comments suggested growers should be permitted to export or ship non-compliant hemp to countries or States that have legalized recreational or medical marijuana. Numerous comments recommended a surgical approach to disposing of non-compliant plants by allowing for the removal and disposal of only the plant parts testing over the acceptable THC level, while allowing growers to market the remaining parts. One comment suggested the Federal Government could buy non-compliant crops for no less than 50 percent of the market value and use them to manufacture paper, plastics, and fuel for government and military uses. Other comments proposed remediation as an alternative to crop destruction; comments on remediation are discussed in another section of this comment analysis. One comment suggested further research be conducted to identify appropriate alternatives for crop disposal, and one comment

suggested that industry stakeholders, governments, regulators, and law enforcement officials work together to develop disposal options under the program.

Disposal Oversight: Several comments recommended that States, Indian Tribes, or local authorities be allowed to determine appropriate crop disposal methods for their jurisdictions. Comments further recommended that State, Tribal, or local regulatory officials be authorized to oversee disposal of non-compliant hemp, as several have done prior to the establishment of the Domestic Hemp Production Program. One comment recommended further that hemp disposals handled by the State should not imply criminal intent on the part of growers. Comments said that allowing for local oversight would reduce strain on DEA and other law enforcement resources and ensure disposals can be handled on a timely basis. One comment from a State agriculture department said that when law enforcement officers have been invited to attend crop disposals in their jurisdiction, officers are typically unavailable. Other comments argued that growers should automatically become DEA-registered reverse distributors if their test results exceed acceptable hemp THC levels so they can dispose of the non-compliant crops themselves and provide acceptable evidence (*e.g.,* photo or video) that they have done so, or so they can do so in the presence of regulatory officials. Some said USDA should pay for official oversight of crop disposal or there should be no charge for that service.

Comments noted that AMS had not yet posted disposal guidelines on its website at the time those comments were submitted, although the IFR had committed AMS to doing so. Some comments said interested entities were unable to complete applications for program participation because AMS had not yet provided disposal requirements.

Several comments asserted that DEA regulations do not mandate specific disposal methods, so long as the ''desired result'' is achieved. Comments asked for more specifics on DEA disposal procedures, including what disposal methods or processes were allowed under the IFR, what the timeline is for disposal, and what results are desired.

One comment asked whether all of a grower's crops would be disposed if one of the lots tested above the acceptable hemp THC level. Others asked whether marketing non-compliant crops for non-ingestible and non-consumable products would be considered a form of disposal. One comment asked whether USDA would consider providing crop insurance for losses due to disposal of ''hot'' crops. One comment asked whether stored hemp product produced under previous programs that allowed for higher THC levels would be disposed under the new program, or could be ''grandfathered'' in.

One comment contended that certain language in the IFR was inconsistent, and as a result, the IFR could be interpreted to require disposal of hemp that does not meet the IFR's definition of hemp, rather than the disposal of hemp that does not meet the acceptable hemp THC level.

AMS response: AMS received significant comments on this requirement from State and Tribal regulatory agencies, producers, and other hemp industry stakeholders and based on this input, AMS determined it necessary to include specific on-farm hemp disposal activities and to provide oversight flexibilities.

As explained in the IFR, State and Tribal plans are required to include procedures for ensuring effective disposal of plants produced in violation of this Part. As part of its review, AMS noted the cultural implication of the use of the term 'destruction' and accordingly amended the regulatory provision to clarify the disposal activities required of growers in cases when a sample tests above the acceptable total THC level.

AMS also determined that producers benefit from greater regulatory flexibility to control on-farm disposal activities according to production schedules that are not dictated by the availability of reverse distributors to physically witness disposal activity. State and Tribal plans must still include procedures to verify disposal. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements the direct growers to provide pictures, videos, or other proof that disposal occurred successfully. State and Tribal plans must also include requirements to submit to AMS the monthly disposal report documenting any on-farm disposals that occurred during the prior month. Additional information on specific disposal methods is available to producers, State, and Tribal oversight agencies is available on the AMS website.

Disposal through the agricultural practices appearing in this final rule reflected those allowable under the IFR, and previously published to the AMS web page in February 2020. These included plowing under, mulching/composting, disking, bush mower/chopper, deep burial, and burning. These activities align with normal and routine production actions by farmers. AMS believes specifying these activities help hemp growers determine which activity best supports their operation to transition non-compliant crop into a non-retrievable or non-ingestible form. These methods also allow recycling non-compliant plant materials back into the earth, a viewpoint AMS learned through public comment to be especially relevant for producers practicing cultural conservation practices. AMS recognized that controlled burning is the closest farm practice to incineration but controlled burns may not be a viable option for producers in some places due to wildfire risk or state prohibition against using controlled burns.

Remediation

The IFR stipulated that cannabis exceeding the acceptable THC level must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under CSA, rather than hemp. In addition, the IFR stated that noncompliant plants may not be further handled, processed, or enter the stream of commerce, and that the licensee shall ensure the lot is disposed. The IFR did not stipulate any provisions to allow for remediation activities that reduce the THC concentration to levels within the acceptable limit.

Remediation of non-compliant crops into compliant plant biomass: Numerous comments expressed support for remediation of non-compliant plants to help farmers mitigate against financial loss. Comments claimed that not having remediation options would be a barrier to industry growth because farmers would be unable to bear the financial risk of losing crops. One commenter used 2019 production and economic data to project that applying the IFR to 2019 statewide non-compliant test rates (17 percent), farmgate losses due to crop destruction could have totaled $842.6 million in Colorado.[24] According to the comment, adding losses related to lost processing and manufacturing due to the same crop destruction could have brought the economic cost to approximately $1.2 billion. It suggested that allowing for remediation of non-compliant crops testing between 0.3 and 1.0 percent THC in the same scenario would preserve

[24] Polis, Jared; Phillip J. Weiser; and Kate Greenwood: State of Colorado Comments in Response to USDA Establishment of a Domestic Hemp Production Program; *https://beta.regulations.gov/comment/AMS-SC-19-0042-3358.*

about $798 million in direct farmgate value, or $1.1 billion of total economic value for the State.

Numerous comments explained that non-compliant plants can be remediated by chemical processes that either remove and destroy THC or dilute THC concentrations, thereby transitioning the remaining material into biomass blends which then test at or below the Federally allowable THC threshold of 0.3 percent. Thus, according to comments, crop remediation through one of these processes is a viable alternative to total crop loss. Some comments suggested processors could be registered with DEA to handle such remediation processes to ensure THC is extracted, handled, and disposed or marketed legally. Other comments suggested that USDA could issue processor permits to allow them to handle hot crops to bridge the perceived legal gap between farmer and consumer. Some comments further suggested growers could bear processing costs then retake possession of the remaining biomass for use or sale elsewhere. Several comments suggested growers themselves could be allowed to merge ''hot'' lots with lots testing below allowable hemp THC limits to create a compliant, homogenized blend.

Some comments suggested non-compliant crops could be remediated by removing the only flowers and retaining the seeds and stalks for other use. Other comments argued that the IFR testing provisions conflict with CSA provisions that exempt seeds and stalks of plant material from the definition of marijuana, and several comments urged USDA to modify the IFR to require only that the parts of the plant exceeding the THC limit be destroyed.

One comment advocated that States be allowed to remediate non-compliant crops through milling and blending the harvest lot to include the entire plant to a homogenized state, then retesting the lot. The comment included the results of a comparative analysis based on crops that initially tested over the legal threshold of 0.3 percent total THC during Arizona's 2019–2020 growing season.[25] According to the comment, producers opted to attempt remediation as described for a total of 25 lots representing 568.6 acres of hemp. Of the 25, 19 lots representing 507 acres successfully reduced the total THC amount to be compliant, for an 89.71 percent recovery of acres that would otherwise have required disposal. The comment reported that the average amount of THC was reduced by 31.61 percent, and suggested that while this remediation process might not be successful for crops that are significantly over the legal threshold, and while the market value of the resulting biomass may be reduced, the process may allow growers to recover some of their losses.

One comment[26] reported on a survey of all Minnesota hemp growers who had experienced lot failures since the beginning of their pilot program in 2016. According to the comment, reported losses varied greatly, ranging between $22,000 and $70,000 per year. The comment further described the State's analysis of 1,492 hemp lot samples from 2016 through September 2020, which showed that 10.3 percent tested at or above 4.0 percent total delta-9 THC, although there was no indication of non-compliance with program rules or of illegal drug activity on the part of growers. The comment recommended that States and Tribes be allowed to develop remediation plans to salvage non-compliant crops.

Post-harvest sampling and retesting: Several comments suggested retesting post-harvest samples to confirm THC levels. Comments provided examples of some State agriculture departments that implemented post-harvest sampling and testing processes under the 2014 Pilot Programs. For instance, one comment cited results from the 2018 season in which they allowed post-harvest retesting of hemp plots that originally tested between 0.4 and 1.0 percent THC. The comment said under Kentucky rules, farmers were allowed to choose between immediate destruction of the leaf and floral material of the crop, without additional testing, or paying the $250 fee for a post-harvest retest of harvested and ground up hemp material, in which the THC concentration was diluted. It stated that of 29 growers whose lots tested between 0.4 and 1.0 percent THC, 22 chose retesting and none of those returned a second measurement above 0.3999 percent THC. Thus, those growers were able to realize a return on their investment. The remaining seven cases did not elect to retest—five elected to destroy the entire plant and 2 destroyed only floral and leaf materials, salvaging the stalks. The data showed the acreage destroyed represented approximately one percent of total acreage. The comment concluded that post-harvest grinding and retesting offers a viable economic solution for farmers seeking to recuperate their investment on crops that initially test non-compliant. Other comments urged USDA to provide for retesting provisions, including remediation activities, that more favorably support farmers who seek to salvage crop value. Some of these comments requested that USDA clarify retesting procedures if a harvest has already occurred.

Statutory implications: Comments from Tribes and other stakeholders expressed concern that the 2018 Farm Bill only requires ''procedure for effective disposal,'' and urged USDA to allow producers greater regulatory leniency as they become familiar with growing a new crop by permitting alternative remediation methods that do not require crop destruction.

AMS Response: This final rule covers testing of the hemp plant to determine acceptable THC levels as required by the 2018 Farm Bill. This final rule does not cover testing for seeds and stalks individually nor does it cover processing or the licensing of processors.

As described in the IFR, hemp exceeding the acceptable THC level may not be further handled, processed, or enter the stream of commerce. The licensee shall ensure the disposal of the noncompliant crop. Before such disposal occurs, AMS believes it important and necessary that hemp growers be provided the opportunity to remediate THC from non-compliant crops in order to stave off financial risk associated with the loss of investment in their hemp crop.

AMS agrees with comments that consider remediation as a viable activity for farmers to minimize crop loss and to salvage the value of remaining compliant plant material. For this reason, the final rule provides regulatory flexibility that allows remediation activities—either disposing of flower materials and salvaging the remainder of the plant or blending the entire plant into biomass plant material. Through both forms of remediation, the farmer may be able to minimize losses and, in some case, produce a return on investment. A guidance document will be published with this rule to illustrate approved remediation techniques. USDA will also finalize the guidance document on disposal techniques.

Additionally, AMS determined that pre-harvest sampling and testing yield the truest measurement of THC concentration at the point of harvest. AMS further maintains this position in this final rule. AMS notes that if the test results show the original THC

[25] Caravetta, John: Arizona Department of Agriculture Additional Comments on USDA Interim Final Rules on Domestic Hemp Production; *https://beta.regulations.gov/comment/AMS-SC-19-0042-5645.*

[26] Petersen, Thom: Minnesota Department of Agriculture Comments on USDA Interim Rule: Establishment of a Domestic Hemp Production Program; *https://beta.regulations.gov/comment/AMS-SC-19-0042-5548.*

concentration exceeded the Federally allowable limit, the licensee may request the laboratory retest the pre-harvest sample. This retest would not entail the use of post-harvest plant material. However, if the farmer elects to perform remediation activities under a USDA, State or Tribal plan, an additional sampling and testing of the remediated crop must occur to determine THC concentration levels. Only those crops testing below the acceptable hemp THC level limit will be considered successfully remediated and thus allowed to enter the stream of commerce. All other remaining non-compliant crops must then be properly disposed.

AMS believes the inclusion in the final rule of remediation and post-harvest sampling after remediation provides the additional flexibility requested by commenters that expressed the need for farmers to have greater opportunity of success entering the hemp production industry.

Reverse Distributors

The IFR requires the collection and destruction of noncompliant material by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer or their designee.

Comments: Comments largely opposed the use of DEA-registered reverse distributors to dispose of noncompliant material. Comments asserted that many States and producers operating under the 2014 Farm Bill have implemented policies related to disposal of non-compliant material that do not require DEA involvement. Comments argued there are relatively few registered reverse distributors on DEA's 2019 list and pointed out that some of the major hemp production States have very few or no registered reverse distributors. Comments claimed existing DEA-registered reverse distributors haven't the resources or training to oversee destruction of large plots of agricultural crops in remote areas, and that such limitations would create a compliance bottleneck. Comments asked USDA to clarify who would be responsible for paying DEA reverse distributors for crop disposal services.

One comment asserted that DEA regulations prohibit reverse distributors from accepting controlled substances from other than DEA registrants, making it impossible for hemp farmers to release non-compliant hemp directly to DEA reverse distributors. One comment suggested that hemp growers could automatically become reverse distributors if their hemp samples test above acceptable THC levels so growers could legally manage crop destruction on their own. Another comment asked whether DEA would allow for a waiver from the current limitation on reverse distributors to allow reverse distributors to accept cannabis material for disposal from individuals or entities who cultivate hemp in accordance with their state's approved plan, but who do not hold a Schedule I DEA registration.

Numerous other comments expressed concern that alternative law enforcement agencies (non-DEA) will face the same resource constraints as the DEA. Comments described how State law enforcement officials are typically unwilling or unavailable to participate in the disposal of noncompliant crops and suggested this is due to the lower prioritization of hemp compliance oversight in light of more pressing public safety and crime intervention responsibilities. For example, a comment representing rural counties said this conflict in priorities is particularly acute in rural areas where resources are already stretched too thin. The comment asserted that while preventing serious violations of controlled substances laws is a priority for law enforcement agencies, hemp with slightly elevated THC levels is unlikely to be sold as marijuana. The comment advocated formulating hemp disposal procedures entirely outside the scope of law enforcement. One comment worried about the stress and stigma on growers having law enforcement personnel descend upon their farms in connection with hemp disposals. Other comments supported allowing State regulatory authorities to oversee or authorize disposal of non-compliant material, asserting that States can safely and efficiently complete the process at a much lower cost to producers and States.

Some comments supported disposal of non-compliant material by law enforcement. Some suggested that States, rather than Federal agencies, work with State and local law enforcement to handle disposals. One comment suggested that the definition of ''duly authorized Federal, State, or local law enforcement officer'' be modified to include disposal under the authority of State or local law enforcement in order to address the anticipated increase in required disposals. Finally, comments from Indian Tribes urged USDA to expand the definition of law enforcement in the final rule to include Tribal law enforcement.

AMS response: AMS acknowledges the many stakeholders who expressed through comment concerns about the collection of non-compliant plants by DEA-registered reverse distributors, or duly authorized Federal, State, or local law enforcement. AMS notes that law enforcement policies and priorities are not set by USDA and the 2018 Farm Bill does not provide this authority. To address public comment, this final rule will retain disposal requirements stated in the IFR but will further clarify what ''disposal'' means relative to the role of reverse distributors.

AMS relaxed the disposal requirements enacted under the IFR in February 2020. This decision followed consultation with DEA. This provided growers the added flexibility to conduct on-farm disposal activities themselves, without required onsite law-enforcement supervision. Based on positive feedback received from State and Tribal oversight agencies and producers following the relaxation of disposal requirements, AMS is permanently allowing for on-farm disposal flexibility in the final rule.

Under this final rule producers do not need to use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants (7 CFR 990.3(a)(3)(iii)(E) and 990.27) if the producer disposes of the plants using one or more of the means described by USDA at *https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities.* It is the agency's intent that these methods allow producers to apply common on-farm practices as a means of disposal while rendering the controlled substance non-retrievable or non-ingestible. Producers must document the disposal of all non-compliant plants in accordance with § 990.27. Reporting can be accomplished by providing USDA with a completed: ''USDA Hemp Plan Producer Disposal Form.''

Cannabis with a THC level of over 0.3 percent on a dry weight basis is a controlled substance, that must be disposed of onsite according to the disposal methods approved by USDA. The State, Indian Tribe or the state's department of agriculture wishing to have primary regulatory responsibility have the responsibility for establishing protocols and procedures to ensure non-compliant plants are appropriately disposed of in compliance with applicable State, Tribal, and Federal law. States and Indian Tribes operating under approved hemp production plans must notify USDA of any occurrence of non-conforming plants or plant material and provide the disposal record of those plants and materials monthly. There is a similar requirement for producers operating under the USDA plan. Additionally, USDA will conduct

random audits of licensees to verify hemp is being produced in accordance with the provisions of the rule.

State and Tribal plans must still include procedures to verify disposal but would have the additional flexibility to use in-person verification where deemed necessary or, when practicable, require producers provide pictures, videos, or other proof of disposal. AMS believes this decision will further alleviate the strain to oversight resources and allow State and Tribal authorities to more efficiently and autonomously monitor hemp production in their jurisdictions.

Additionally, the final rule expands the definition of ''law enforcement'' to include Tribal law enforcement.

Negligent Violation Threshold

The IFR specified that a producer commits a negligent violation when a reasonable effort to grow hemp is made and the total THC dry weight concentration exceeds 0.5 percent.

Supporting an increase of negligent violation threshold: Most comments that addressed negligent violations opposed the 0.5 percent total THC threshold in the IFR, and many advocated raising the threshold to 1.0 percent or higher, offering suggestions ranging between 0.99 and 5.0 percent total THC. Comments said the 0.5 percent threshold can be too easily breached by prudent farmers for any number of environmental or genetic factors that are beyond grower control. One comment supported the 0.5 percent negligence threshold, and others noted it but signaled neither support for nor opposition to the threshold particularly.

Some comments suggested that a 1.0 percent threshold would provide a safe environment in which both new and veteran farmers can operate comfortably. Comments in favor of a 1.0 percent negligence threshold noted that several States and other countries have established a 1.0 percent threshold for their jurisdictions that seems reasonable and achievable in most situations. A few comments pointed out that a 1.0 percent threshold is relatively low compared to the THC levels in marijuana, which commenters said typically range from 10 to 15 percent. Other comments advocated higher thresholds that they claim would give farmers the peace of mind to continue building an industry that is just taking off. Finally, one comment asked whether an MU was figured into the IFR's negligent violation threshold and advocated setting the threshold at 1.5 percent THC and specifying that that threshold includes the MU.

A state department of agriculture estimates that 42 licenses would need to be revoked at 0.5 percent stated in the IFR. They further estimate that this number would shrink to only about 12 licenses were the threshold increased to 1.0 percent under the final rule.

A state hemp steering committee commented that a 0.5 percent threshold will deter the experimentation of different varietals and that this research is essential to discovering which varietals work best in different climate zones and soil types as well as for the development of better genetics.

Another state department of agriculture explained that 13 percent of the hemp samples taken in 2019 tested over the THC limit. The average THC level in those failures was 1.07 percent Delta-9 THC post-decarboxylation. A hemp association within the state agreed with the commenter's recommendation that the level defined for negligence should be increased to 1 percent THC.

One comment reported that more than 5.5 percent of the pre-harvest samples collected under the State's plan in 2019 were found to have a THC concentration of greater than 0.5 percent. Another comment reported that 13 percent of hemp samples taken in 2019 tested over the THC limit. According to the comment, data for all years through September 2020 show that most hemp lot failures occur between 0.4 percent and 1.0 percent THC.

Data submitted with a comment from a State University researcher showed that 8.5 percent of 3,508 samples tested during 2018–2020 exceeded the IFR's negligent violation threshold of 0.5 percent THC. The comment said that 65 percent of those would not be considered negligent violations if the threshold were raised to 1.0 percent. Framing study results another way, the comment explained that at a negligence threshold of 0.5 percent, the State would have revoked 42 producer licenses, whereas at a 1.0 percent threshold, the State would have revoked only 12 licenses, given three negligent violations in a five-year period, a reduction of 72 percent in revocations by changing the threshold to 1.0 percent.

One comment reported that based on test results they'd seen this year, 1.0 or 1.5 percent would be a more appropriate threshold for negligence, due to the heterogeneity of the plant and the awareness of the industry.

Implementation timeframe: Some comments suggested that it is too early in the industry's development to determine a realistic numeric threshold, and they recommended USDA delay fixing a uniform standard until the industry has more experience and better understanding of the relationship between all the hemp production factors. Still other comments asserted that negligence should not be determined numerically at all, but by a determination about the farmer's intent. Several comments said that ''negligence is a state of mind, not a number.''

General comments on 0.5 percent threshold: Several comments argued USDA arbitrarily determined the 0.5 percent negligence threshold. One comment asked USDA to provide the research reports used to inform the selection of the 0.5 percent negligence threshold. Another questioned whether USDA used test results based on the total THC standard established in the IFR to set the negligence threshold, since it was the commenter's experience that producers routinely report difficulty meeting that standard. One comment reported anecdotally that its farm sends three samples from the same composite lot sample to three testing laboratories and gets three different results, which the comment ascribes to the variation in lab procedures. Another comment said that there are no established uniform standards for cannabinoid testing, such that even from reputable labs it will not be entirely clear what the results mean.

The impact of the 0.5 percent threshold on production: Several comments said the 0.5 percent negligence threshold in the IFR provided very little buffer (at 0.2 percent) between the 0.3 percent THC allowed under the program and the 0.5 percent threshold for determining a negligible violation. What several comments called a ''safe harbor'' for growers was nevertheless considered too narrow by many, saying that it left virtually no room for error. Comments argued that requiring growers to both exercise reasonable care *and* produce crops with only 0.5 percent THC or less is too stringent a standard and does not really offer the ''safe harbor'' intended. One comment argued that USDA cannot provide a ''safe harbor'' for violations of the 0.3 percent THC cap because that cap is enforced by other Federal and State agencies. A few comments said that the THC levels in 2014 DEA confiscations averaged 11.84 percent THC and argued that the negligence level under USDA hemp program rules should be closer to the average DEA culpability level.

A comment from a state department of agriculture used 2019 production and testing data to demonstrate that raising the IFR's threshold from 0.5 percent to 1.0 percent could theoretically reduce

the number of its farmers exceeding the negligent violation threshold by more than 75 percent. Several comments advocated a 2.0 percent threshold, while others suggested the elimination of the negligence threshold altogether.

Comments highlighted uncertainty in the genetic variation of hemp varietals and other factors like weather conditions, soil type, plant disease, and pest pressures that may further exacerbate the risk of exceeding the 0.5 percent threshold. As well, comments explained that hemp plants mature rapidly just before harvest. One commenter described seeing plants go from 0.18 to 0.62 percent total THC in one week. Comments suggested that enforcing the 0.5 percent negligence threshold on growers who truly do not intend to grow marijuana is excessive penalization when THC levels can change that rapidly. Comments argued that it is not appropriate to add further penalties to hot crop destruction. Other comments suggested that administrative and logistical factors beyond the grower's control, such as bottlenecks in sampling and testing, can likewise create compliance risks for growers under the 0.5 percent threshold.

AMS response: Based on these comments, AMS is increasing the negligent violation to a 1.0 percent threshold. AMS acknowledges that a lower total THC threshold will result in a higher number of negligent violations. AMS also understands that factors beyond the control of farmers may cause an increase in total THC-levels, such as seed genetic, weather and climate, and may contribute to crops exceeding the negligent violation threshold. AMS believes that the data provided in the comments clearly showed that increasing the negligent violation threshold to 1.0 percent would diminish the risk that producers would incur negligent violations without adding a greater risk of non-compliant material reaching channels of commerce.

AMS also reviewed the test results of certified hemp varieties planted in Kentucky in 2017 and 2018 under its 2014 Farm Bill program. Kentucky has a certified seed program that it believes will yield hemp. The plants from the certified varieties tested below 0.8 percent THC concentration level. Additionally, AMS reviewed the test results of varieties that were eligible to be cultivated under the Nevada 2014 Farm Bill program in 2018. The plants from those varieties tested below 0.9 percent THC concentration level. Given those test results based on varieties that those two states believed would yield hemp, AMS determined that a 1 percent THC concentration level for negligence would account for the fact that a reasonable reliance on certified or eligible varieties may still yield a plant that tests above the acceptable hemp THC level.

The impact of the 0.5 percent threshold on crop research: Comments described the IFR's 0.5 percent negligent violation threshold as a rate limiting factor to industry innovation and hemp research. One comment said that hemp farmers, growing under pilot authorization of the 2014 Farm Bill, routinely planted multiple varieties of hemp to see which performed best. According to the comment, the low negligence threshold in the IFR discourages such hemp trialing and innovation because farmers face greater risk of receiving three negligent violations in one or two seasons and losing eligibility to grow hemp for another five years. Comments from research universities found the IFR's negligent violation provisions unworkable for institutions testing numerous varieties and production variables each season for the same reason. Comments suggested a higher threshold for negligent violation would give industry the regulatory flexibility to conduct research with reduced risk of violating regulatory requirements.

AMS response: AMS recognizes the violation threshold may incentivize (or disincentivize) innovation by research institutions and producers. AMS acknowledges more innovation and research across industry will bring more stability to stakeholders. The 1.0 percent negligent violation threshold provides new and existing producers across States and Indian Tribes additional flexibility to innovate and research with reduced risk for noncompliance. AMS believes the 1.0 percent threshold incentivizes innovation across industry more so than a 0.5 percent violation threshold.

Statutory implications: Some comments argued that establishment of the 0.5 percent negligence threshold in the IFR was arbitrary and capricious under the APA and asked USDA to provide more information about how the threshold for negligence was determined. Some comments asserted that *negligence* is a well-established legal doctrine, and they argued that USDA cannot artificially and arbitrarily declare a threshold for negligence. A couple of comments suggested that putting farmers on probation, suspending them from program participation, and requiring them to destroy their crops based on an arbitrary number rather than on court findings is a violation of due process under the U.S. Constitution's Fifth Amendment.

AMS response: Congress established the definition of hemp and defined the threshold of THC concentration at 0.3 percent dry weight. The statute did not define negligent violation. USDA derived the definition of negligence from the definition of negligence in Black's Law Dictionary (10th ed. 2014). USDA set the level of total THC concentration at 0.5 percent for a negligent violation to establish a clear buffer so that any crop testing out of compliance would not automatically trigger a violation. The 0.5 percent was based on data from three states participating in the 2014 Farm Bill pilot program. AMS believes raising the negligent violation threshold from 0.5 percent to 1.0 percent in the final rule provides a greater buffer and reduces farmers' exposure to risk of violation accrual and license suspension.

Oversight Authority: Several comments suggested the government should have the ability to determine negligence and culpability based on facts and circumstances surrounding violations and not solely on a numeric threshold. Other comments asserted that the 2018 Farm Bill's language leaves room for an Indian Tribe to apply its own negligence standard. Similarly, other comments from the industry said that States should be allowed to evaluate potentially negligent violations of State plans.

AMS response: With regard to violations and culpability determination, AMS seeks to establish a regulatory framework that ensures consistency in oversight activities of hemp production. Variations of criteria or the use of subjectivity in oversight could result in bias against or leniency to some hemp farmers simply based on location. Leaving the decision of what constitutes a negligent violation to abstract factors rather than objective metrics may result in differences between States and Indian Tribes. Because farmers may grow hemp in different locations, and in some cases are subject to multiple oversight authorities, it is important the thresholds for violations are consistent across oversight authority jurisdictions to which the grower is responsible. Having a threshold that is well established and transparent provides a minimum framework to producers.

In developing the compliance requirements for State and Tribal plans, USDA recognizes that there may be significant differences across States and Indian Tribes in how they will administer their respective hemp programs. Accordingly, if, at a minimum, the requirements of the 2018 Farm Bill and applicable parts of this

regulation are met, States and Indian Tribes are free to determine whether or not a licensee under their applicable plan has taken reasonable steps to comply with plan requirements. As previously stated, this final rule provides that a producer shall not be subject to more than one negligent violation per calendar year. State and Tribal plans may tailor the timing around this requirement to align with their growing season or other applicable dates.

Financial and business risk: Several comments linked the 0.5 percent THC threshold with a greater likelihood of producers committing negligent violations, receiving corrective action plans, and even committing culpable negligent violations. Comments stressed that a low negligence threshold puts farmers at higher risk of accumulating negligent violations, even when growers take reasonably prudent steps to mitigate against the production of noncompliant plants. According to comments, this, in addition to the loss of the crop, jeopardizes farmers' access to crop insurance and business loans.

Comments addressed the negative impact of the accrual of negligent violations on the financial stability of the individual business. They described how a hemp grower's access to credit and insurance is jeopardized when negligent violations accumulate and lead to a determination of culpable negligence. Comments explained that lending institutions and insurance providers look for risk factors. They also raised questions about how the accrual of negligent violations may be interpreted by lender or providers. Comments said that many insurers will not cover crop losses if losses are due to the growers' negligence. Commenters implored USDA to explain how violations can lead to determinations of culpable negligence and to provide guidance about how a reasonable farmer can avoid growing noncompliant hemp.

AMS response: AMS acknowledges institutional lenders view violations as risk factors in decision making. AMS also notes that not all culpable violations are derived from the accrual of negligent violations. Culpable violations may be the result of producers violating other parts of the 2018 Farm Bill. However, the 2018 Farm Bill explicitly considers certain actions as constituting negligent violations. AMS's intention is to provide a threshold between 0.3 percent THC level and what would be considered a negligent violation so not all hemp that tests over the 0.3 percent be considered a negligent violation. Because a producer will not have committed a negligent violation every time he or she grows hemp with a concentration of hemp above the 0.3 percent level, this will assist producers when requesting loans or other financial assistance. AMS will provide risk mitigation activities such as remediation and disposal provisions as well as increasing the negligent violation threshold to 1.0 percent to diminish the number of violations that are considered negligent.

Some producers have more than one field or farm in a state or across state boundaries. Assigning more than one negligent violation might be detrimental to these producers. For example, if a producer uses the same seed in multiple locations, and that seed results in a THC level over 0.3 percent, all of that production must be disposed or remediated. All of these locations could be determined a separate violation. However, AMS wants to clarify that a producer may not be found to have committed more than one negligent violation per year.

Barriers to entry: Several comments suggested that a 0.5 percent negligence threshold threatens the survival of farmers in an emerging industry. Comments suggested that the low threshold is a barrier to entry for new farmers or farmers with no experience growing hemp, who risk high initial capital investments to establish operations. Comments argued that the low threshold favors larger farms using industrialized hemp varieties and production practices, and that the low negligence threshold in the IFR would unnecessarily criminalize farmers working with a legal agricultural commodity.

AMS response: All persons interested in growing hemp must meet the eligibility criteria established in the 2018 Farm Bill and this final rule. Negligent violations document instances when the statue or rule are violated such as when a grower fails to report a legal description of land on which hemp is grown or fails to dispose of a noncompliant crop. All farmers, regardless of the size of their operations, face the same set of requirements. Even though the 2018 Farm Bill sets the THC concentration level at 0.3 percent, it does not define what THC level in cannabis will give rise to a negligent violation. Left undefined, this lack of definition is troublesome as it could make enforcement uneven among States and Indian Tribes. The IFR provided that hemp producers do not commit a negligent violation if they make reasonable efforts to grow hemp and the marijuana does not have a THC concentration of more than 0.5 percent. Increasing this threshold to 1.0 percent benefits producers, including small and new farmers, that intended to grow hemp but whose crops tested ''hot'' even though they made reasonable efforts to grow hemp.

Resources and enforcement: One State commented that it currently enforces a 1.0 percent negligence threshold. According to the comment, lowering the threshold to 0.5 percent would significantly increase the rate of negligent violations in that State, require more State and Federal resources to enforce the regulation, and be financially burdensome to novice farmers. It stated that the 0.5 percent negligence threshold is lower than the threshold DEA designates as the upper THC limit for ''inconclusive marijuana/hemp.'' The comment found the IFR's 0.5 percent threshold inconsistent with some laboratories' testing capabilities and suggests raising the rule's threshold to 1.0 percent.

AMS response: AMS anticipates that the closer the negligent violation threshold is to 0.3 percent total THC, the greater the likelihood that oversight authorities issue more negligent violations. Moreover, whenever a producer commits a negligent violation, the oversight authorities must also establish a corrective action plan as required by regulation. AMS believes that increasing the negligent violation threshold to 1.0 percent would therefore reduce some burden to oversight authorities by reducing the number of negligent violations and corrective action plans that oversight authorities must issue and administer. AMS notes that regardless of the negligent violation threshold, any crop exceeding the Federal allowable total THC concentration must be disposed of according to regulatory requirements. AMS disagrees that the DEA's enforcement program for marijuana should affect how AMS manages its compliance program for hemp.

State and Tribal Resources

The IFR required States and Tribal governments to certify they have the resources and personnel to carry out the practices and procedures of their respective plans. Further, the IFR provided for audits of State and Tribal plans to include review of the resources and personnel employed to administer and oversee its approved plan. Finally, the IFR specified audit reporting requirements and remediation steps for States and Tribal governments found to be non-compliant with USDA requirements.

Comments: Comments from many States expressed enthusiasm for partnering with USDA in the regulation

of domestic hemp production. The comments were supportive of establishing a national regulatory framework that would bring clarity and consistency to the regulation of hemp production across the U.S. They emphasized that many States have enacted legislation to facilitate the regulation of hemp production. No comments received from the States demonstrated a reluctance to work with USDA in establishing regulations.

The requirement for States and Indian Tribes to certify to USDA that they have the capacity to administer a domestic hemp program was not addressed explicitly in any of States' comments. However, many of the comments from the States and Indian Tribes registered concerns with some aspects of the IFR. Most of the comments from States and Indian Tribes delineated areas where the burden of regulatory oversight might be reduced, or efficiencies realized, by revisions to the regulations.

Several comments expressed concern that State and Tribal governments would not be able to perform their responsibilities under the program as currently established. One comment said the lack of appropriate personnel, training, and protocol would lead to an untenable backlog in the collection and testing of samples. Many comments focused on the sheer number of samples that must be collected, processed, and tested under the program. The shortage of DEA-registered labs in the States and the new sample collection protocols were also areas of concern, although that was addressed shortly after the IFR went into effect with the announcement of enforcement discretion.[27] Points of potential weakness in the States' and Tribal governments' implementation of the IFR were raised by many commenters, both explicitly and in implied remarks. Many of the comments referenced State and Tribal government infrastructures being strained under the new regulatory requirements, especially during peak harvest intervals, and that those factors could contribute to the failure of the States and Indian Tribes to fulfill their oversight obligations. A number of comments alluded to the burden of any breakdown in the regulatory scheme being borne by hemp producers directly, as with samples that are not timely collected by State inspectors and the samples then testing ''hot'' without any remediation options, or labs that are not able to process samples due to capacity issues.

Numerous comments made recommendations to address the increased regulatory burden on States and Tribal governments. Many recommended changing the 15-day post-sample harvest period to 30 days to allow more time for States and Tribal governments to collect and process samples, balance workloads, and alleviate potential backlogs. In addition, several comments contended that the increased sampling requirements in the proposal (*i.e.* requiring sampling of every lot) would burden the process and contribute to delays in growers receiving results. Those comments recommended revising the sampling protocol (reducing number of samples required per producer) to help relieve the strain on government resources. Lastly, comments suggested that allowing labs that are ISO 17025 accredited to process samples, as opposed to only allowing labs with DEA registration, would enhance the State's ability to provide validated, accurate, and timely testing.

One commenter said they had talked with a number of States that expressed strong concerns over the additional burdens as a result of the IFR. The commenter further stated that some states they are considering whether to ''opt-out'' of administering a hemp production plan themselves in favor of USDA administering a plan.

Lastly, one comment stated that if there was a bureaucratic slow down or insufficient resources on the part of USDA, a farm should be allowed to have some recourse to be able to harvest. That comment, and others that were similar in spirit, effectively questioned what mitigation efforts would be undertaken for producers in the short run if a State or Indian Tribe ultimately lacks the necessary resources and personnel to administer its plan and fails to perform the obligations it certified it could undertake.

AMS Response: The issues raised in these comments are mostly addressed under other sections in this rule (*e.g.,* 15-day harvest window, laboratory accreditation). AMS agrees that there are regulatory burdens of this program, which are discussed in this rule. States and Indian Tribes have multiple options that would allow producers in their States or territories to grow hemp. States and Indian Tribes can develop their own plan, send their producers to grow under the USDA plan, or States can continue under the 2014 Farm Bill pilot program. Many States and Indian Tribes assess fees on producers to cover their expenses for sampling, oversight and other costs of this program. These options provide producers different alternatives to grow hemp under different regulatory schemes. Additionally, USDA has decreased the risk of the regulatory burden on States and Indian Tribes being borne by hemp producers by addressing various issues commenters identified that could cause States and Indian Tribes to be unable to timely fulfill their responsibilities such as by modifying the sampling protocol and changing the 15-day post-sample harvest period to 30 days. Other burdens associated with this final rule that the producer must cover should be considered by producers, as in any agricultural business, before a decision to grow hemp is made.

Appeals—Denial of Application and Appeal of Test Results

The IFR addressed the denial of applications to grow hemp in Part V. APPEALS. The IFR also provided an option to appeal test results in which producers can request that a second test be performed if they disagree with the first test results.

Comments: A comment recommended that USDA establish a clear deadline for applicants who wish to appeal the denial of their grower applications. The comment noted that the IFR already required a State or Indian Tribe appealing the suspension or revocation of a hemp production plan to file an appeal ''within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later.'' The commenter noted that no such similar deadline is identified for applicants who have been denied USDA hemp grower licenses.

One comment asserted that denials of ''licensure'' may occur for ''whatever reason.'' Two other commenters submitted examples of State regulatory language from California and Ohio, each of which include provisions for the denial of applications for license.

Several comments suggested USDA establish an appeals process through which someone with a felony conviction may demonstrate completion of appropriate steps to become eligible hemp producers.

AMS response: This rule retains the IFR provision that an applicant for a USDA hemp production program license may appeal a license denial to the AMS Administrator. USDA licensees may appeal denials of a license, renewals, license suspensions, or license revocations to the AMS Administrator must be submitted in writing and received within 30 days of the receipt of notification of the denial or within the time-period provided in the letter of notification, whichever occurs later. State and Tribal plans reviewed and approved by USDA are

[27] *https://www.ams.usda.gov/rules-regulations/hemp/enforcement.*

required to include an appeal process for producers to appeal licensure decisions. In response to the comment that USDA should establish an appeals process through which someone with a relevant felony conviction may demonstrate completion of appropriate steps to become eligible hemp producers, it is important to note that limitations as a result of relevant felonies are set in the 2018 Farm Bill.

Appeals—Technical

The IFR stated that producers can request a second test be performed if they disagree or have doubts about the original test results.

Comments: One comment indicated that if there is a discrepancy between compliance testing for THC concentration, there needs to be a process for farmers to appeal. Another comment noted that no administrative appeal process exists for producers who wish to challenge a decision they believe adversely affects them, such as test result. Another commenter cited personal experience with one State agriculture department and described as ''unfair'' a regulatory system that does not allow for an appeal process through which a farmer may contest test results.

AMS response: USDA is maintaining its position that producers *under a USDA plan* are able to request a second test be conducted when they do not agree or have questions about a test result. This rule provides flexibility to allow States and Indian Tribes to provide for retesting if the State or Indian Tribe chooses to do so.

Transportation and Shipping Documents

Under the 2018 Farm Bill and the IFR, neither States nor Indian Tribes may interfere with the transportation of lawfully produced hemp through States or Tribal territories, even if hemp production is prohibited within a particular State or Tribal territory. Public comments related to transporting hemp focused primarily on facilitating the interstate transportation of hemp.

Interstate commerce: Many comments applauded the IFR's reiteration of the statutory provision that allows for interstate shipments of lawfully produced hemp and hemp products without interference by State or Tribal law enforcement. Some asked USDA to clarify that prohibited interference includes that from State, Tribal, or Federal law enforcement, including DEA. Other comments wanted confirmation that interstate commerce includes entry into and egress from Tribal territories and that Tribal hemp production licenses be honored for purposes of interstate commerce transport and commerce.

Commenters stated they had already encountered situations where States passed temporary regulations conflicting with the 2018 Farm Bill and impeding interstate commerce. For example, comments noted an Idaho Executive Order—Transportation of Hemp—issued in 2019, that they claimed would ''excessively frustrate interstate hemp transportation and growth of the hemp industry.'' One airline carrier comment explained that under this Order, ''transporters may have to stop, get inspected, and be subject to detention each time they cross jurisdictional boundaries'' and that airlines would avoid carrying hemp if this issue is not remedied.

Comments from Indian Tribes expressed concern that despite the 2018 Farm Bill, Tribes transporting hemp through States have a bias against Tribal hemp production. There were suggestions of the use of a USDA form or stamp authorizing transportation to address these obstacles. One commenter also requested that USDA provide for recourse for Indian Tribes that are prohibited from moving hemp through neighboring States.

AMS Response: At this time, USDA recommends that transporters carry a copy of the producer's license or authorization, as well as any other information the governing State or Indian Tribe recommends or requires that will validate that the transporter is transporting legally-grown hemp. As allowed under the 2018 Farm Bill, States and Indian Tribes can be more restrictive, which includes possible transportation paperwork requirements by States or Indian Tribes. USDA is not adding transportation paperwork requirements to this rule because it does not have jurisdiction over common carriers or other types of transporters.

Comment: A comment asserted that intrastate commerce of hemp that does not meet all the requirements of the IFR should remain under the State's authority, and farmers producing hemp compliant with the 2018 Farm Bill but not the IFR should be allowed to do so, as long as that hemp is not transported across State lines. The comment advocated for no Federal preemption, citing to section 297B(a) of the 2018 Farm Bill, which provides that ''nothing in this subsection preempts or limits any law of a State or Indian Tribe that (i) regulates the production of hemp; and (ii) is more stringent than this subtitle.''

AMS Response: The 2018 Farm Bill does not preempt State law provided that the State adopts a plan that is approved by USDA and the plan may provide for more stringent requirements. A State has the responsibility for enforcing the requirements of its plan. Thus, hemp that is produced under a State's plan should meet the requirements of the final rule.

Shipping Documentation: Several comments encouraged USDA to facilitate the unimpeded flow of hemp in interstate commerce by implementing identity preservation or tracking systems or requiring the use of standardized shipping labels, packaging, or other documentation to certify to stakeholders and law enforcement authorities that the cargo in transport is Federally legal hemp. Comments suggested the use of USDA-issued stamps or forms that are recognizable, understood, and accepted by all law enforcement authorities. Several Indian Tribes made this suggestion because they are concerned about law enforcement transportation issues, particularly in Idaho, South Dakota, Maine, New York and Wisconsin. According to comments, such forms could verify that cargo hemp is compliant with USDA-approved production plans. Other comments suggested the use of a standardized bill of lading across the industry that sets out essential information about the shipment for easy reference by transporters, regulators, processors, and law enforcement officials to ensure all loads have been lawfully produced in accordance with Federal, State, or Tribal law. A comment from an association of county agriculture commissioners and sealers suggested USDA require the officially certified lab report to accompany shipments of hemp product during interstate shipment.

Comments suggested various commercial systems for recognizing legally produced hemp in transport. Other comments asked USDA to devise a standard documentation system for hemp carriers that would more easily absolve them of legal liability related to transporting hemp. Comments recommended that USDA coordinate with the hemp industry; Federal agencies such as DEA, the Department of Transportation, and the Department of Justice; and State agencies, including law enforcement and transportation departments, to develop such documentation.

Some comments additionally recommended adopting specific hemp packaging and labeling requirements on the basis that they would support compliance and enforcement tasks. Some comments advised USDA to provide specific regulations for testing hemp in transit so that such testing, if

necessary, be conducted in a standard manner, consistent with the requirement that all pre-harvest Total THC testing be conducted by DEA-registered laboratories. Other comments recommended that hemp loads be sealed to ensure their integrity and mitigate the interference of illicit products.

Comments advocated that USDA host a central hemp database for reporting data applicable to all phases of hemp production that would be ''read only'' to law enforcement, saying such a system would be particularly beneficial in resolving questions related to interstate commerce. One comment advocated for the use of a centralized hemp clearinghouse to capture hemp flower transfer to processors or manufacturers for CBD extraction, including information on the licensed producers and receivers of raw materials, the total weight of materials being transferred, testing certificates indicating THC levels of the materials being transferred, and other State-mandated criteria, as well as information on the vehicles being used to transport the materials. It further recommended USDA evaluate methods to physically identify and segregate products containing hemp-derived CBD to differentiate legitimate from potentially illicit products.

AMS response: AMS understands the importance of ensuring safe passage of hemp across states and Tribal jurisdictions. Section 10114 of the 2018 Farm Bill specifically states that ''Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp.'' USDA issued a memorandum addressing this issue.[28] Several States already identified documents to facilitate transportation of hemp across states. AMS strongly encourages producers of hemp and carriers providing transportation services to provide the following documentation accompanying the hemp cargo: Copies of the laboratory testing report(s), hemp grower license, invoice/bill of lading, and contact information of buyer and seller. The 2018 Farm Bill does not provide specific authority to USDA to This final rule does not adopt any requirement for interstate transportation of hemp. As required by the 2018 Farm Bill, USDA is developing a database that will share information about hemp production with law enforcement. The database will identify the contact information for the producer, a legal description of the land on which hemp is produced, and status of the producer's license or other required authorization from the State or Indian Tribe.

''In-Process'' Material

Comments: Several comments mentioned ''in-process material,'' described as material made from otherwise qualifying hemp plant material, such as crude CBD oil and distillate, or as any hemp material that is compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any way for use in the manufacture of hemp products. Commenters asked USDA to clarify that once hemp has been tested and allowed to enter commerce, it should be considered legal material thereafter. One comment suggested the establishment of specifications or guidance for any part in the ''in-process material'' manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the hemp product.

One comment explained the perception that in-process materials are not allowed to transfer freely between processors, causing bottlenecks in product processing. According to the comment, some hemp processors may be limited to performing only one step of a multi-step process to derive hemp products, such as distilling CBD oil and isolating the CBD molecule. It said processor-to-processor transfers of in-process hemp materials should be authorized between U.S. States with valid hemp programs, which would open a processing bottleneck and allow both hemp materials and cash to flow more freely. The comment asserted such authorization would improve prices for CBD end-products, which would trickle down to hemp growers.

Some commenters stated that it is commonly known that THC levels in initially compliant hemp may rise above the 0.3 percent delta-9 THC limit during subsequent processing. Commenters expressed concern that some jurisdictions believe the ''in-process material'' should be diluted to always maintain the level below 0.3 percent delta-9 THC, even during transportation to another processor. However, several comments argued that ''in-process material'' is neither consumer ready nor a ''finished'' product and that dry-weight measurements related to hemp THC levels are calculated on the initial plant material and not the finished product to ensure compliance with the threshold.

AMS response: The 2018 Farm Bill directed USDA to establish a national regulatory framework for hemp production in the U.S., and the final rule outlines provisions for this mandate. The IFR and this final rule do not cover hemp or its products beyond production. Further, DEA has issued regulations covering some of these products or ''in-process materials''.[29] Accordingly, this final rule does not address ''in-process materials,'' processors, end-products, processing of CBD or other cannabinoids or anything that may contain hemp or hemp byproducts.

Equal Treatment for Tribes

Comments: Some commenters said that final rule should provide Indian Tribes at least as many opportunities regarding hemp production and regulation as those granted to States and that the final rule should allow Indian Tribes to catch up quickly with States that have been allowed to develop production methods and markets under the 2014 Farm Bill provisions.

AMS Response: This final rule does not distinguish between States and Indian Tribes. USDA recognizes that both State and Tribal governments have the ability to authorize and to regulate the production of hemp within their States or territories consistent with the 2018 Farm Bill and the final rule.

Psychoactive Effects of Cannabinoids

Delta 9 THC or THC is the primary psychoactive component of cannabis. As mandated by the 2018 Farm Bill, hemp must be verified as having THC concentration levels of 0.3 percent or below on a dry weight basis.

Comments: Several comments referenced different studies to support conflicting positions regarding the psychoactive effects of THC and used study findings to argue that the IFR's THC limit should be revised. Many comments cited the ''Defining Hemp: A Fact Sheet'' from the Congressional Research Service, updated March 22, 2019, that said a level of about 1 percent THC is considered the threshold for cannabis to have a psychotropic effect or an intoxicating potential. Other commenters argued THC levels of 5 percent or more are necessary for marijuana to have a psychoactive impact or commercial value. Comments noted that hemp is generally characterized as plants that are low in delta-9 THC and high in levels of CBD,

[28] Memorandum from Stephen Vaden, Office of General Counsel to Sonny Perdue, Secretary of Agriculture, Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp (May 29, 2019).

[29] *https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17356.pdf.*

the primary non-psychotropic compound. Many comments stated that research shows that CBD affects the ability of THC to bind to CB1 receptor in cells, thus blocking the psychoactive effects of THC.

Other comments representing health organizations stated that research is challenging the widely accepted premise that CBD is not intoxicating. They further stated that the THC found in CBD products can be intoxicating and has caused significant and serious consequences in terms of job loss, health, and exposure to pediatric populations. Some comments provided personal testimony that while using CBD for health benefits they had not experienced psychoactive or intoxicating effects.

Other comments reported that the United Nations standard STR/NAR/40 uses a ratio of ([THC] + [CBN])/[CBD] to determine whether a plant is likely to have a psychoactive effect.

AMS response: AMS appreciates understanding different views on the psychoactive effects of THC. However, this topic is outside the scope of the final rule, and AMS made no revisions to the program based on these comments. The 2018 Farm Bill defined hemp as having a THC concentration of 0.3 percent or less. Medicinal use of hemp or CBD is covered under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9, sec. 301, *et seq.* and under the FDA's jurisdiction.

Miscellaneous Comments

Comments: One comment pointed out that the IFR's hemp definition did not include the application of an MU, but that the definition of acceptable hemp THC level does. The comment said references to the definition of hemp should be changed to refer to acceptable hemp THC level so there is uniformity across the final rule.

AMS Response: USDA has made references to acceptable hemp levels when appropriate. The acceptable hemp levels include the MU to account for differences in laboratory conditions or environments. There is no intention to change the definition of hemp that is stated by the 2018 Farm Bill.

Comments: Another comment recommended improving the clarity of the final rule by deleting the words ''or THC'' from the definition of delta-9 THC, as well as deleting the sentence ''For the purposes of this part, delta-9 THC and THC are interchangeable.'' The comment further recommended that the definition of Total delta-9 THC be expanded to clarify that it includes delta-9 THC combined with delta-9 THCA to account for the conversion of delta-9 THCA into delta-9 THC when the plant material is dried. Finally, the comment recommended that in all cases where ''THC'' is referenced throughout the final rule document with no further clarification, ''THC'' should be changed to ''delta-9 THC.'' The comment said these clarifications will be helpful in administration of the rule.

AMS Response: AMS is adding a definition of ''Total THC'' to clarify the use of the term in this rule. Total THC accounts for the conversion of THCA into THC. We believe using THC and delta-9 THC interchangeably is appropriate.

Comment: One comment claimed that making the IFR effective immediately gave farmers preparing for imminent harvest no time to comply with the new testing and threshold requirements, increasing their risk of producing plants that were legal under the 2014 and 2018 Farm Bill statutes but potentially illegal under the IFR.

AMS response: USDA's decision to make the IFR effective immediately was to provide a framework for the 2020 growing season. However, States had the option to continue operating under the 2014 Farm Bill. States and Indian Tribes were provided time to develop plans on time for their planting and harvest season.

Comment: USDA should work with other agencies, including DEA and DOJ, to develop cohesive information and guidance regarding enforcement related to hemp.

AMS response: AMS has worked with DEA and other agencies in developing these regulations to assure that the intent of the 2018 Farm Bill provisions for hemp are met. USDA is responsible for the regulatory oversight of hemp production and DEA and other law enforcement agencies are responsible for enforcing the law regarding marijuana.

Miscellaneous Comments—Out of Scope

In addition to addressing specific provisions of the IFR, comments also addressed other topics related to the hemp industry.

Comments: One comment advocated the creation of a USDA commodity checkoff program for one or more categories of hemp (*e.g.* grain, fiber, CBD) and recommended that USDA work with hemp industry trade organizations and stakeholders to administer checkoff funds to support hemp agronomic and market development. Another comment included a newsletter item quoting USDA as saying that such a program could be developed.

One comment asked USDA to support the hemp industry by adding hemp seed foods to those offered through school lunch and other government feeding programs.

One comment said that hemp extracts and concentrates and byproducts from hemp should be afforded the same legal status and protections as the hemp from which they originated.

One comment suggested that the IFR did not consider compliant hemp topical products that make up a large portion of the market or other applications that cannot be inhaled or ingested.

One comment advocated that hemp and CBD should be covered and protected under the Perishable Agricultural Commodities Act (7 U.S.C. 499 *et seq.*).

Some comments said farmers should only be allowed to sell hemp to licensed brokers, handlers, and processors, and not directly to the public. They further advocated requiring license information to be part of the documentation that accompanies hemp shipments.

A couple of comments urged USDA to establish good manufacturing practices for CBD manufacture.

One comment claimed that chemical and seed providers have developed aggressive tactics which may be used to hamper hemp producers.

One comment requested updating banking regulations to allow banks to do business with entities whose income is derived from hemp and/or legal cannabis. Another comment requested an examination on how bonding could protect hemp farmers against companies and contracts that have not been honored, causing financial harm to the grower.

One commenter suggested to discontinue the program totally or at least discontinue the CBD portion because there is too much potential for abuse and waste of taxpayer dollars. The commenter stated that it could be okay to continue the coverage for the seed and fiber. They also stated that USDA should not be in the marijuana business.

AMS received comments on the impact of the current statutory and regulatory structure on banking and insurance related to hemp production. Commenters expressed concern that the 0.3 percent THC ceiling and the required disposal of cannabis testing above 0.3 percent THC would hinder the ability of hemp producers to obtain insurance, loans, or other financial services. One commenter also urged AMS to clarify if the preemption language in section 10114(a) of the 2018 Farm Bill encompasses interstate banking, financial services, and

insurance transactions and if USDA intends to supersede, coordinate, or adopt guidance issued by other Federal agencies related to hemp production.

A comment suggested banks could offer insurance for crop losses if the hemp had a THC concentration that was greater than 0.3 percent but less than or equal to 0.5 percent, similar to offering coverage for losses due to factors beyond the grower's control, depending on various USDA culpability findings. Another comment advocated that crop insurance be available for hot hemp.

A comment stated that Non-Irrigated (NI) acreage should be uninsurable because good producers who are serious about growing the crop would not bother with NI acreage. Another comment discussed establishment of ''Earliest Plant Dates'' (EPD), Late Plant Period (LPP), and Final Plant Date (FPD), and references sections of what may be a State or Tribe plan and the difficulty of finding farmers growing hemp in comparable environments for determining such dates and insurance coverage. It also recommended developing a Replant Endorsement (with premium associated) to insure 50 to 75 percent of seed costs for replant. Finally, a commenter stated that germination tests should be required before the crop is planted and set a minimum standard of 85 percent germination—and those under that standard would be uninsurable. Several commenters argued that USDA should (1) ban hemp and hemp related products imported into the United States; (2) establish import limits on the number of clone material; (3) eliminate all imported hemp and concentrates into the U.S. for the next 2 years, except for trades to the Canadian marketplace, but exportation must still be open for our country and product markets outside the United States; and (4) establish clear rules on how imported hemp and hemp products will be regulated.

One commenter expressed concern about the current regulation of CBD as a prescription drug arguing that the prescription-only status for CBD is unwarranted and will facilitate the illegal market that continues to exist for these products. One commenter noted that the regulatory ambiguity resulting from the FDA's lack of guidance on CBD negatively impacts hemp producers and requires greater clarity.

One commenter raised concerns about the ability of farm workers seeing U.S. naturalization to be able to participate in hemp production based on a fear that U.S. Immigration and Customs Enforcement will view work in hemp production as an ''exclusionary activity'' that would be a barrier to naturalization.

Several commenters expressed concern regarding hemp production in close proximity to other agricultural crops. Commenters also expressed concern regarding drying and processing of hemp near other crops and residential areas. One commenter suggested that AMS support research on pollination and drift related to hemp production.

One comment asked USDA to clarify whether section 10114(a) of the 2018 Farm Bill extends to interstate banking, insurance, or financial services involving hemp and hemp products. According to the comment, it is not clear whether interstate commerce in hemp and hemp products necessarily includes the payment for any hemp and hemp products through various methods, such as wires, checks, automated clearinghouse transactions, credit card or other financial transactions, including loan proceeds.

One comment advocated the use of their company's blockchain technology to address industry and law enforcement concerns about chain-of-custody in sampling, transporting, and testing hemp.

One comment requested that a clear statement be included in the final rule that USDA concurs that the exportation of hemp and hemp products is legal. It noted that the 2018 Farm Bill does not prohibit exports, and stated, without providing any empirical evidence, that there is sufficient interest in exporting hemp and hemp products from the U.S. It also suggested that a dedicated tariff code for hemp and hemp-derived products be established to facilitate export trade.

AMS Response: These comments all address issues that are beyond the scope of the rule. This rule only covers the production of hemp. Issues such as promotion of hemp under a research and promotion program; adding this product to other programs including feeding programs or PACA; importing or exporting of hemp; who can produce hemp in the U.S.; processing the commodity; insurance and banking; research or setting production boundaries; requirements on further products such as CBD; or other subjects mentioned above, are not the subject of this rulemaking or within other USDA or federal, State, Tribal, or private industry responsibilities and authorities.

Comments on the IFR's Regulatory Analyses

Civil Rights Review

The IFR included a Civil Rights review that found the rule would not have adverse effects on protected persons or groups, deny them program benefits, or subject them to discrimination.

Comments: One comment indicated that small farmers face challenges related to costs of seed. Another commenter associated the destruction of non-compliant hemp as posing a great risk of economic hardship on hemp farmers, especially the small minority farmers.

Several comments from Indian Tribes explained that certain provisions of the IFR, for example laboratory DEA-registration requirements, the definition of key participants, and Tribal law enforcement availability, did not sufficiently account for the specific circumstances and challenges facing Indian Tribes across the nation such as the remote location of many Indian Tribes, the limited economic resources of Indian Tribes, and Tribal decision-making structures. Comments pointed out that this final rule must ensure Tribal civil regulatory authority to help Tribal nations build and implement successful plans. Other Tribal comments identified the requirements for the complete destruction of the plant as, ''disproportionately economically disastrous for our small Native American farmers,'' explaining that Native American farmers tend to be significantly smaller and operate on very small margins.

One commenter suggested that AMS reconsider the potential civil rights implications of this rule on the convicted felons because the IFR, if unchanged, will have a disproportionate negative impact on both Black and Latino Americans, who according to DOJ data, represent 38.8 percent and 37.2 percent (respectively) of the total population of Federally sentenced drug offenders. The commenter compares this data to the data from U.S. Department of Health and Human Services' rates of illicit drug use among White Americans (9.5%), Black Americans (10.5%,) and Latino American (8.8%).

Another commenter claimed that using ''flawed/inaccurate science with lower standards is a direct example of failing to preserve the protection of the public at large,'' and ''USDA cannot legally implement their proposed rules without violating the mission statement of the agency.''

AMS response: AMS considered the potential civil rights implications of this rule on minorities, women, and persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. Additionally, this rule would not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination. This rule is neutral and of general applicability.

We also note that some of the burdens or hardship described in the comments are required by the 2018 Farm Bill. First, the 10-year ineligibility restriction applicable to persons convicted of a State or Federal felony is a requirement of the 2018 Farm Bill. Also, as stated previously the basis for the DEA lab registration is rooted to the statutory requirements of the Controlled Substances Act, that requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process and thus cannot be eliminated. Additionally, the 2018 Farm requires effective disposal of non-compliant plants.

Moreover, AMS conducted a Civil Rights Impact Analysis in accordance with USDA's Departmental Regulation 4300–004: Civil Rights Impact Analysis.[30] AMS's analysis did not find any evidence that the final rule would adversely or disproportionality impact hemp producers in protected groups, regions or Tribes as compared to the general population of hemp producers or State Departments of Agriculture.

Regulatory Impact Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives when an action is deemed to have significant impacts. If regulation is necessary, then agencies must select the action that maximizes net benefits, including potential economic, environmental, public health and safety effects, and equity. Executive Order 13771 mandates that agencies provide the best approximation of total costs associated with a new or repealed regulation. AMS prepared a Regulatory Impact Analysis (RIA) with the purpose of accomplishing these objectives.

Comments: Very few comments addressed the RIA specifically, but we received many comments with information related to assumptions that fed into the RIA such as percent of hot hemp, testing burdens, lab registration burdens. AMS addressed these comments in the general comment section and took into consideration information provided for the RIA.

One comment acknowledged that USDA's economic analysis was based on sound and reasonable methodology but said that its expectations were not confirmed by actual market events in 2019. The commenter compiled production data provided in other comments in an effort to present a more current analysis of the hemp market. The comment pointed out that the RIA underestimated the number of hemp production licenses that would be issued and hemp acres that would be planted in the 2019 growing season. According to the comment, while the RIA called only for a doubling of licenses beyond the 2018 benchmark, the actual rate of licenses increased by 476 percent in 2019. Similarly, the comment reported actual planted hemp acreage in 2019 to be close to 230,000 acres, well over the 155,000 acres assumed by the RIA. The comment went on to say that the rate of growth for new licenses outpaced the rate of growth for consumer sales by 3:1, while the RIA had assumed a 1:1 rate over the next four years. The comment explained that supply growth has outstripped demand and created significant market imbalance and, as a result, market prices have dropped and driven down revenues to hemp producers.

The comment cited the gross revenue for floral material estimated in Table 1 of the RIA, which ranges from $2,333 to $24,000 per acre under the assumption that two-thirds of an acre is planted for floral material. Based on market data published in November 2019, after the IFR's publication, the comment suggested that the actual range of gross revenue for floral material per two-thirds of an acre was $2,728 to $17,261. The comment then applied the variable cost of planting one full acre of floral material estimated in the RIA, $28,638 per acre, to this range of gross revenue. This calculation resulted in a loss of $11,377 to $25,910 per acre, which the comment said is incorrect given that the variable cost per acre of floral material was deducted from the gross revenue per two-thirds of an acre. For an accurate estimate of net revenue, it stated that gross revenue and costs must be represented in terms of the same unit of measurement.

The comment suggested that the downstream effects of an unbalanced economic supply equation would further disrupt the profitability of sectors that are intended to support the transportation, processing, and retail sales of the product. It cited sales data reporting a 50 percent decline in the price of CBD extracts and concentrates from April 2019, stating that the oversupply of hemp has affected the entire commercial supply chain.

The commenter disagreed with the methodology used to project the net social benefit of hemp per acre in the IFR, saying that methodology assumed social benefit is a static figure. The commenter asserted instead that social benefit is ''a fluid figure that is heavily influenced by time and supply and demand economics'' and that it will likely fall over time.[31]

Further, it argued that the estimated 2019 societal willingness to pay of $2,650 per acre, which was calculated in the RIA using Kentucky grower sales and planted acreage, is not representative of the rest of the United States. Based on the hemp product sales in Chart 1 of the RIA, the estimated return to producers of processor sales of 31 percent, which was calculated in the RIA by comparing Kentucky grower and processor sales, and total U.S. planted acres estimated in Table 3 of the RIA, the comment calculates a 2019 national societal willingness to pay of $2,325 per acre. This result indicates that the societal willingness to pay based on Kentucky data is 14 percent higher than the estimate for the United States as a whole. The comment also calculates a national societal willingness to pay for 2018 of $4,047, which illustrates that a decline in societal willingness to pay of 42.5 percent occurred in 2019.

The comment cautioned that the net social benefit calculated in the IFR was over inflated because it represents a point in time during the industry's infancy. The comment argued that the industry faces a market depression and recommended a quota system for licensing classified by intended use. In this recommendation, the comment offered a detailed approach to estimating acreage required to meet demand for hemp grown for use in the CBD market. The analysis resulted in an estimated 44,509 acres required to meet demand in 2020, 83,336 acres for 2021, 188,558 acres for 2022, 255,899 acres for 2023, and 309,773 acres for 2024. The comment expanded upon its recommendation of a quota licensing system, suggesting that a number of licenses be granted by range of acreage, thereby ensuring that a share of licenses is reserved for small farmers.

Another comment asserted that unless the IFR definition of hemp is revised to include cannabis with a total THC level

[30] *https://www.ocio.usda.gov/sites/default/files/docs/2012/CRIA%20DR%204300-004-final.pdf.*

[31] *https://beta.regulations.gov/comment/AMS-SC-19-0042-1490.*

of not more than 1.0 percent on a dry weight basis, it will not be economically viable to grow hemp for flower in the U.S. According to the comment, if the THC limits of the IFR are maintained in the final rule, the RIA should be revised to reflect the impact of the rule on total yield and CBD concentration of harvestable flowers, reduced value of CBD hemp seed, and the unknowable market value of CBD. The comment predicted that although the value of hemp seed for flower might be reduced marginally, other input costs would remain very high.

One comment recommended differentiation between hemp biomass and hemp flowers in the IFR's analysis of market prices for floral material. The comment said that hemp biomass refers to full plant material, including stems, leaves, and flowers, while hemp flower refers to the part of the plant that contains trichomes which houses richly and densely populated cannabinoid content. The comment said the prices in the RIA are consistent with prices for hemp biomass, and suggested prices for hemp flowers ranging from $25 to $800 per pound, depending on the percentage of CBD present.

Two comments asserted that USDA grossly underestimated the sampling time and cost in the IFR. Comments were concerned that readers might assume hemp sampling and testing costs fees are preset. The comments suggested that hemp sampling is a more complex logistical problem than contemplated in the IFR because of the geography and scope of sampling on farms. The comments encouraged USDA to calculate anticipated sampling costs to include a minimum number of hours for each step in the sampling process, and to consider factors such as travel time and coordination of supplies and personnel for the sampling effort.

One comment disagreed with the IFR statement that the new hemp production program would expand production and sales of domestic hemp, benefitting U.S. growers and consumers. The commenter said that production costs for his CBD hemp farm were approximately $16,000 per acre, but because of the IFR's restrictiveness and his resulting inability to bring the crop to full maturity, the crop would likely only return $9,000 per acre. The commenter said they were unwilling to make that kind of risky investment and was unwilling to decide whether to plan for future crops until USDA finalizes its rule.

AMS response: AMS is aware that the number of licenses and amount of acreage that were estimated in the RIA of the IFR were underestimated. Entrance of producers into the market spiked at an unexpected rate in 2019, driving up acreage along with licenses. AMS utilized the most current data available to it in its analysis of the hemp market in the IFR and the final rule.

Regarding the estimate in one comment of net loss ranging from $11,377 to $25,910 per acre, it is important for gross revenue and costs to be represented in the same unit of measure for an accurate net revenue calculation, which, in this case, they are not. The variable cost per one acre of floral material was deducted from the gross revenue per two-thirds of one acre of floral material, resulting in a larger loss than if calculated using the same unit of measurement. AMS has adjusted the calculation of net revenue in the table below using the market price data cited by the comment. AMS appreciates the comment's citation of its sources and utilized similar sources in the RIA of this final rule.

Planted acres	Yield	Price	Gross revenue	Variable cost	Net revenue
Low estimate					
2/3	1,000	$4.09	$2,727	$19,092	$(16,365)
1	1,000	4.09	4,090	28,638	(24,548)
High estimate					
2/3	1,200	21.58	17,264	19,092	(1,828)
1	1,200	21.58	25,896	28,638	(2,742)

Furthermore, AMS understands and appreciates the commenter's argument that net social benefit andsocietal willingness to pay are over inflated in the IFR. Due to the relative scarcity of industry data, AMS made many assumptions in its analysis in the IFR, some of which were not realized. In order to caution industry stakeholders of the volatility of the hemp market, however, AMS used variable cost estimates to calculate net returns to producers, which ranged from a loss of nearly $17,000 to a gain of $6,240. In the single year since publication of the IFR, a greater amount of data has become available to AMS, which allows the analysis in the final rule to rely less on assumptions that may not be actualized.

AMS only has the authority regarding hemp regulation granted to it by the 2018 Farm Bill. The recommendations to establish a quota system for issuing licenses based on intended use and to revise the definition of hemp such that it includes cannabis with up to 1.0 percent total THC on a dry weight basis are outside of the authority of USDA. The 2018 Farm Bill provided USDA no authority to regulate production volume. Additionally, USDA cannot adjust the statutory definition of hemp.

AMS has also reviewed the sampling procedures and costs characterized in approved state and Tribal plans to better estimate the time and resultant fees that will be charged to producers for sampling in the hemp program.

Small Business Impacts

AMS performed a Regulatory Flexibility Analysis (RFA) in conjunction with the IFR that considered the effects of the rule on small businesses particularly.

Comments: One organization that represents the views of small entities stated that small hemp producers have significant startup costs that affect their ability to be competitive in the hemp industry. The comment notes that hemp production is labor-intensive and has licensing and regulatory costs that are not typically incurred by producers of other agricultural crops. Small entities indicated that only those businesses with adequate capital and large-scale operations would be able to survive and comply with the requirements of this rule. Further, comments conveyed that this rule will raise real barriers to entry for small and disadvantaged producers and could prevent these critically important producer groups from even entering the hemp industry.

Other comments stated that the negative effects of the regulatory incongruence in the IFR

disproportionately affect farmers, in particular new and small farmers—and small or already disadvantaged hemp farmers will face additional risks if the IFR is not changed.

One comment claimed the 2014 and 2018 Farm Bills presented an innate prejudice for institutional research, including State departments of agriculture and institutions of higher education and this prejudice continued in the IFR. The commenter says this is similar to the bias of California's draft State plan, where individuals permitted to be grower or breeders, but the program's compliance burdens are effectively beyond the reach of most individuals.

Commenters stated that this rule will disrupt small producers who were successfully producing hemp under prior pilot programs. One organization reported that hemp producers have stopped growing hemp altogether until they can be certain about what the requirements for producing hemp. Comments also reported that some hemp buyers have not renewed their contracts. Comments stated that several of the provisions of this rule impose unnecessary burdens on small entities. Comments suggested that many of the sampling and testing requirements should be revisited and alternatives should be considered and analyzed to minimize the burden to small producers. In addition, comments said that small business are very concerned about the risk of losing their economic investment due to mandatory disposal, the lack of control over growing conditions, genetics of neighboring crops, and timing and precision of the testing.

Comments from State departments of agriculture expressed strong concern as to the additional burdens they would incur as a result of the rule. These burdens may be directly passed to small producers in the form of delayed responses to license applications, renewals, and appeals; testing backlogs; duplicative reporting requirements; new license fees; and other programmatic issues.

One comment claimed that, based on six years of administering their hemp program, many of the most rigid requirements of the IFR are not only unnecessary, but also likely to have a disproportionately adverse impact on new farmers and farmers with smaller operations. According to the comment, these farmers already face great risk in the current marketplace, and need regulatory help, rather than impediments, in order to grow and thrive. The comment urged AMS to provide a more sensible, flexible, and practical regulatory scheme to encourage industry growth.

*AMS response: A*MS understands that there is a great deal of uncertainty in the hemp industry currently and has made efforts to minimize any burden which may befall producers as a result of this rule. To that end, USDA is not charging producers any fees for licensing or collecting any fees from producers to support AMS' administration of the hemp program. The fee structure developed by States and Indian Tribes to administer their hemp programs lies outside of the purview of USDA. On average, AMS anticipates total fees paid by producers under a State or Tribal Plan to amount to $800 per grower. This amount includes licensing and other fees intended to generally fund the operations of States or Tribal Programs. Fees for sampling and testing, on average, amount to about $300 per lot. The cost for an annual background check for three key participants is $54. AMS estimates an annual reporting and recordkeeping burden of $129 per grower. Altogether, these costs total $1,283 per grower, assuming one lot requires sampling and testing. This total cost is 0.1 percent of $1 million, which is the largest amount in annual receipts that a grower may receive to be considered to be a ''small business'' under the Small Business Size Standards of the U.S. Small Business Administration (SBA).

In response to comments, AMS has revised its sampling and testing methodology to allow for performance-based sampling, which should reduce the burden on all producers, large and small. Section 990.3 details this revised methodology. In addition, AMS has modified its disposal requirements, and allows for remediation of noncompliant crops. These remediation options are described in § 990.27.

AMS understands the concerns raised by state departments of agriculture regarding the requirements of administering a commercial hemp program. For this reason, AMS has made every effort to provide States and Indian Tribes flexibility to administer their hemp programs, including whether they charge for fees or other costs or cover those expenses from other State or Tribal resources. If the burden for a State or Indian Tribe to administer its own hemp program remains too great, however, the State or Indian Tribe may elect to participate in the Federal plan and allow AMS to administer the program. By providing this flexibility, USDA believes it is less likely that the burdens on State and Tribal resources will be passed on to small businesses.

Tribal Matters

The IFR provided that States and Indian Tribes may submit hemp production plans to USDA for approval. Individual producers from States or Tribal territories that do not have USDA-approved plans may file separate applications for hemp production licenses under the general USDA hemp production plan. Below are several comments and AMS's responses regarding matters of particular concern to Indian Tribes and Tribal members.

Comments: Comments said the regulations fail to treat Indian Tribes on an equal basis with States by repeatedly failing to include the term ''Tribe'' when referring to the State and local jurisdictions. According to comments, by doing so, the regulations fail to respect Tribal sovereignty and self-government.

AMS response: USDA agrees that Indian Tribes must be treated the same as States under the regulations. There were a few occasions where USDA mistakenly left out ''Tribe'' from the language in the regulation. USDA is correcting these mistakes in the IFR by revising the language of the final rule to insert ''Tribe'' after ''State'' in the definition of *Law Enforcement Agency* in § 990.1; insert ''Tribe'' after ''State'' in § 990.24(a); and revise § 990.40(d), which incorrectly referred to ''States and territories of Indian Tribes,'' to refer to ''States and Indian Tribes''.

Comments: Several comments asserted that USDA should not define ''territory of an Indian Tribe'' and claimed that by doing so, USDA violates Tribal treaty rights to farm on Tribal territories. Comments argued that such a definition should be left up to each Indian Tribe. Further, comments contended that the definition of ''territory of an Indian Tribe'' at § 990.1 inappropriately refers to a criminal statute, 18 U.S.C. 1151, to define an Indian Tribe's territory and regulatory jurisdiction. Other comments supported the use of the Indian country definition, but asked for the removal of the requirement that the lands must be within the Indian Tribe's jurisdiction, primarily because it causes uncertainty as to whether Indian Tribes may regulate hemp production on non-Indian owned fee lands within a Tribe's territorial boundaries. Comments also asked that AMS clarify that States cannot interfere with hemp production within the territory of an Indian Tribe.

AMS Response: If an Indian Tribe does not assume primary jurisdiction over the Tribe's Indian territory, USDA has jurisdiction over the hemp production on an Indian Tribe's

territory pursuant to the 2018 Farm Bill. USDA, therefore, must know the limits of its jurisdiction over such Indian territory, just as it must know its jurisdiction over lands ordinarily within State jurisdiction.

The IFR defined ''territory of the Indian Tribe'' at 7 CFR 990.1 as having the same meaning as ''Indian Country'' in 18 U.S.C. 1151. Upon consideration of comments submitted by Indian Tribes, USDA concurs that reference to the criminal law definition of Indian country could be confusing.

Therefore, in the final rule USDA revised the definition of ''territory of the Indian Tribe'' to incorporate language from other Federal statutes, but without explicitly cross-referencing such statutes. Specifically, the final rule defines ''territory of the Indian Tribe'' to mean (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

In the 2018 Farm Bill, Congress provided authority for any Indian Tribe to seek USDA approval to become the primary regulator of hemp production within the ''territory of the Indian Tribe.'' The 2018 Farm Bill did not provide a definition of the term territory of the Indian Tribe, and there is no universally accepted definition of that term, or similar terms, within the field of Federal Indian law. In describing jurisdictional boundaries associated with Indian Tribes, various Federal statutes use several terms, including Indian country, Indian lands, Federal Indian reservations, and areas within the Indian Tribe's jurisdiction, among others.

Thus, by its very nature and history, the statutory term ''territory of the Indian Tribe'' is ambiguous. According to the Indian canon of construction, ''statutes are to be construed liberally in favor of the Indians, with ambiguous provisions interpreted to their benefit. . . .'' *Montana* v. *Blackfeet Tribe of Indians,* 471 U.S. 759, 766 (1985) (citations omitted). In addition, USDA may address ambiguities in a statute that it administers, with any reasonable interpretation of the ambiguous term entitled to judicial deference. *Chevron U.S.A. Inc.* v. *Nat. Res. Defense Council, Inc.,* 467 U.S. 837, 842–43 (1984). In this case, Congress provided no indication that the term ''territory of the Indian Tribe'' should apply more narrowly than similar terms that have been defined and interpreted in other Federal statutes and programs. Moreover, a narrow interpretation that excluded nontribal fee lands within reservations would perpetuate the problem of checkerboard jurisdiction over lands within Indian reservations, adding unnecessary confusion and uncertainty to the challenges of implementing the hemp program in Indian country. Therefore, the USDA includes a regulatory definition of the term ''territory of the Indian Tribe'' that is based on the definition of Indian country in 18 U.S.C. 1151 and the definition of Indian lands in the Indian Gaming Regulatory Act, 25 U.S.C. 2703(4).

The definition includes all lands within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, which encompasses on-reservation parcels held in fee simple by non-members of the Indian Tribe. Similar provisions are found in the criminal jurisdiction definition of Indian country, 18 U.S.C. 1151; in the Clean Water Act, 33 U.S.C. 1377(h); the Clean Air Act, 42 U.S.C. 7601(d)(2)(B).

The U.S. Environmental Protection Agency (''EPA'') interpreted the statutes that it administers as providing authority to Indian Tribes over non-Tribal fee lands within Indian reservations. EPA Final Rule: Indian Tribes—Air Quality Planning and Management, 63 FR 7254 (Feb. 12, 1998); EPA Interpretive Rule: Revised Interpretation of Clean Water Act Tribal Provision, 81 FR 30,183 (May 16, 2016). EPA found that the Clean Water Act and Clean Air Act provided a delegation of authority to Indian Tribes over non-Tribal fee land within reservations. *See Arizona Public Serv. Co.* v. *EPA,* 211 F.3d 1280 (D.C. Cir. 2000). The agency found legislative intent and a common-sense reasoning to treat Indian reservations holistically for purposes of environmental regulation.

Similarly, USDA interprets the 2018 Farm Bill as authorizing Indian Tribes to become—with USDA's approval of a hemp plan—the primary regulators of hemp production within their territories, including on nontribal fee lands within reservations. This authority applies without regard to the Indian Tribe's ability to demonstrate inherent regulatory authority over non-Indians under the factors set forth in *Montana* v. *United States,* 450 U.S. 544 (1981). Additionally, this definition will make clear the area over which USDA will have regulatory authority including licensing if the Indian Tribe does not have an approved plan or a plan submitted to USDA for approval.

Comment: Some comments said Indian Tribes did not have the benefit of operating under the 2014 Farm Bill and, consequently, have not developed the farming techniques and regulatory systems that States have. Therefore, according to comments, Indian Tribes should be given a grace period while they develop best practices.

AMS response: Not all States operated under the 2014 Farm Bill, and some Indian Tribes did enter into Tribal—State agreements under the 2014 Farm Bill. Therefore, establishing a regulatory grace period for Indian Tribes only is not workable. Indian Tribes may take advantage of training and technical assistance offered by the USDA and other entities to ensure that they implement the best systems possible.

Comments: Some comments claimed that negligent violations by Indian Tribes under § 990.6 may cause Indian Tribes to be ineligible for other programs.

AMS response: The 2018 Farm Bill describes three types of negligent violations under State and Tribal plans. The negligent violations detailed in § 990.6 are required to be included in State and Tribal plans pursuant to the 2018 Farm Bill.

Comment: A comment contended that the requirement for a geospatial site identification at § 990.3(a)(1)(ii) is too expensive for Indian Tribes, unnecessary, and not readily available. Comments said the Department of the Interior has land records that could be used to obtain necessary information.

AMS response: A legal description of the land where hemp is grown is required by the 2018 Farm Bill. Geospatial location is one form of meeting such requirement. Producers are required to provide information to FSA on the geographical location of hemp production. FSA offices will provide assistance in identifying such location at no cost to producers.

Comments: Some comments said USDA should conduct more Tribal consultations and provide USDA and DEA training for hemp producers. One Indian Tribe requested more time to

allow Indian Tribes to organize a Tribal Advisory Council of Tribal Leaders to continue with the development and implementation of federal hemp policy.

AMS Response: In addition to previous Tribal consultations and extending and reopening the IFR's comment period, USDA added a September 2020 Tribal consultation to receive additional information, particularly from 2020 growing season producers. See the section on *E.O. 13175 Consultation and Coordination with Indian Tribal Governments* in this document for further discussion about the consultations. If Indian Tribes organize a Tribal Advisory Council of Tribal Leaders, USDA would appreciate any future feedback. Additionally, USDA is available to provide technical assistance when requested, including training. USDA is adding training for sampling to its website.

Comments: Comments said that Indian Tribes and individuals within the territory of the Indian Tribe should not have to be regulated by States, but should be able to go directly to USDA for licensing if the Indian Tribe opts out of developing its own Tribal plan and the Indian Tribe does not otherwise prohibit hemp production.

AMS Response: Subpart C, the USDA Hemp Production Plan, governs hemp producers in the absence of a Tribal plan. Therefore, any Indian Tribes or individuals wishing to produce hemp must comply with those regulations if not covered under a State or Tribal plan. If an Indian Tribe decides not to develop its own hemp plan, a producer may directly apply for a USDA license. States were not delegated authority under the 2018 Farm Bill to regulate hemp production within the territory of an Indian Tribe.

Comment: Indian Tribes should be allowed to implement their Tribal preference laws.

AMS Response: Nothing in the IFR or the final rule prevents Indian Tribes from implementing their Tribal preference laws.

Comment: A comment said that Tribal ordinances and interstate commerce regulations need to address price gouging in seeds and input.

AMS Response: This comment is outside the scope of this rule.

Comment: A comment said the Bureau of Indian Affairs and USDA should review 25 CFR part 162 governing agriculture and business leases to ensure that the hemp regulations here do not conflict with that part or cause additional regulatory hurdles.

AMS response: 25 CFR part 162 establishes certain requirements for leasing trust or restricted Indian lands. USDA conferred with the Department of the Interior, the agency regulating Indian land, and did not identify any conflicts between the two sets of regulations.

Comment: A comment suggested USDA hire an Indian law expert to assist with development of the final rule.

AMS response: USDA agreed and hired a consultant with 40 years-experience as an Indian law attorney to assist with the development of the final regulations and the review of Tribal plans.

Comment: Comments said the criminal history checks required by the IFR should be expanded to include the Department of Justice Tribal Access Program (TAP). According to comments, those using TAP would then be able to directly access criminal history checks. Comments also said the regulations need to clarify whether the criminal history check can be a name check or a finger-print check.

AMS Response: USDA conferred with the DOJ Office of Tribal Justice and was informed that Indian Tribes can use the TAP program to access the FBI Identity History Summaries. The FBI Identity History Summaries may be based on name check or a finger-print check.

Comment: Comments noted that the term ''key participant'' is defined at § 990.1 in a manner that is not necessarily consistent with an Indian Tribe's unique organization and methods of doing business. Comments explained, for example, that an Indian Tribe may be the owner of a hemp farm. Comments asserted that although the Indian Tribe's governing council may be the ultimate decision-maker as the owner, it would not be appropriate to include them in the felony and background investigations. Therefore, comments said Indian Tribes should be permitted to identify their own ''key participants'' if they are operating under a USDA plan and the requirements of § 990.22.

AMS Response: USDA understands the concerns raised by Indian Tribes regarding the application of the criminal history report requirement and the felony conviction restriction on Tribal leaders. However, USDA must ensure that entities operating under a USDA plan comply with the felony conviction restriction in the AMA. For reasons explained in the IFR, USDA believes that the appropriate approach in determining who participates in the program, and therefore subject to the felony conviction restriction, is to focus on those who exercise executive managerial control over hemp production. USDA also believes that this focus should be consistent across the USDA plan regardless of the person who is applying for a license. For the foregoing reasons, USDA has clarified the definition of key participants in the final rule to provide that the definition ''does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.'' AMS notes that an Indian Tribe may adopt its own hemp plans subject to USDA approval. When adopting a hemp plan, the Indian Tribe can determine who participates in its plan and will be subject to a criminal history check.

Comment: USDA received a comment that it should affirm Tribal sovereignty by not allowing other federal agencies, such as the DEA, to interfere with Tribal hemp remediation.

AMS Response: USDA does not have the authority to control the actions of other federal agencies acting properly within their authority.

Comment: USDA received comments that USDA owes a trust responsibility to Indian Tribes. According to commenters, that trust responsibility requires acknowledging the unique challenges that Indian Tribes face including that (1) most tillable land was taken from Indian Tribes during homesteading; (2) Tribes' participation in the farm program results in only a 60 percent yield of their non-Indian counterparts; (3) the finance system is usurious as financiers discount the value of Tribal assets or refuse to consider them at all; and (4) American Indian producers will be disproportionately disadvantaged because their farms are significantly smaller and are generally run with only one crop by families with small margins.

AMS Response: USDA acknowledges that it has a special government-to-government relationship with Indian Tribes, and believes that, in preparing and issuing this final rule it has acted in accordance with that relationship. In response to concerns regarding the unique challenges Indian Tribes face, as explained in the Civil Rights Review of this final rule, AMS conducted a ''Civil Rights Impact Analysis'' and did not find any evidence that the final rule would adversely or disproportionality impact Indian Tribes or Tribal members producing hemp as compared to the general population of hemp producers or State Departments of Agriculture. Indian Tribes may take advantage of training and technical assistance offered by the USDA to ensure that they

implement the best systems possible. Additionally, USDA is available to provide technical assistance when requested.

State and Tribal vs. Federal Regulation

The preamble of the IFR stated that ''[n]othing preempts or limits any law of a State or Indian Tribe that regulates the production of hemp and is more stringent than the provisions in the 2018 Farm Bill.'' Further, Section 297B of the AMA expressly states that it does not preempt a State or Indian Tribe's ability to adopt more stringent requirements or to prohibit the production of hemp. This was codified in the IFR in § 990.3(b)(1), which provides that nothing in the part preempts or limits any law of a State or Indian Tribe that regulates the production of hemp and is more stringent than this part or Subtitle G of the Act.

Comments: Many of the comments received stated that the provisions of the IFR were more stringent than the regulations of pilot programs established by States under the authority of the 2014 Farm Bill. In fact, the majority of all comments received either took exception to the perceived increase in regulatory requirements for hemp production under the IFR, or presented recommendations for alternative requirements under the final rule that would not be as restrictive or burdensome as the provisions in the IFR.

No comments were received that either affirmed or opposed the rights of States and Indian Tribes to promulgate more stringent regulations for their jurisdictions. However, one comment said rather than using the flexibility allowed in the law to let states develop sensitive state plans, the IFR had rigid controls not required by law or correlated to the relatively low-level risk of non-compliant hemp. The comment further said USDA should establish baseline requirements but provide States flexibility to consider the dynamics of agricultural production that depend on farm and field conditions, weather, and the timing appropriate for planting, harvesting, the varieties being cultivated and the marketing of crops. Other comments agreed with recommendations to allow States and Indian Tribes to determine certain provisions that are not central to the minimum regulatory requirements of the IFR, such as application windows and reporting.

AMS response: The 2018 Farm Bill expressly preserved the ability for State and Tribal hemp production plans to establish additional provisions stricter than the baseline regulations required by the 2018 Farm Bill. These baseline regulations require all State and Tribal plans to include certain minimum requirements for licensing, sampling, testing, disposal, and information collection. These requirements could certainly be considered ''more burdensome'' than certain State hemp production plans operated under 2014 Farm Bill pilot program provisions, but they are intended to provide consistency and transparency among the U.S. hemp industry as it matures. Prior to the passage of the 2018 Farm Bill, States operating hemp pilot programs could administer these programs with minimal Federal oversight, and without baseline requirements around sampling, testing, and other program requirements because the 2014 Farm Bill programs are for research. The 2018 Farm Bill established baseline requirements for hemp production for hemp production across the U.S. regardless of the purpose of the production.

Preemption

Comment: AMS received comments asserting that the IFR did not abide by the mandate of the 2018 Farm Bill that there be no preemption of state or Tribal laws that regulate the production of hemp and are more stringent than the hemp provisions in the federal statute.

AMS response: Section 297B(a)(3) of the AMA provides that for States and Indian Tribes with primary regulatory jurisdiction over the production of hemp, there is no preemption if that State or Indian Tribe both regulates the production of hemp and that regulation is more stringent than the 2018 Farm Bill or the implementing regulations. Thus, the no preemption provision of the 2018 Farm Bill is to make clear that more stringent requirements are not preempted. AMS finds that the 2018 Farm Bill requires the implementation of federally mandated minimum standards, which all jurisdictions must follow, allowing for certain further restrictions by States and Indian Tribes.

Recordkeeping Requirement

Comment: One commenter argued that the recordkeeping requirements of the IFR violated the 4th Amendment's prohibition against unreasonable search and seizure and was ''arbitrary and capricious'' and a violation of the APA.

AMS Response: The 2018 Farm Bill established a hemp production program in the U.S. subject to oversight from the Secretary of Agriculture. Part of that congressional mandate is for the Department of Agriculture to establish a plan by which it collects information from producers to ensure compliance. While hemp is no longer a Schedule 1 drug, USDA can only make the determination of whether the crop is legal hemp (which it regulates) or illegal marihuana (which it does not regulate) through the mechanisms Congress has authorized. Recordkeeping requirements are paramount to that determination, which is required by Congress. AMS is retaining the recordkeeping requirements of the IFR.

APA Notice and Comment Concerns

Comment: Some commenters claimed that in issuing an IFR, AMS acted arbitrarily and capriciously in violation of the APA. Commenters argued that the good cause statement included in the IFR was not adequate to support its issuance rather than going through notice and comment rulemaking.

AMS Response: AMS does not agree with these comments and believes that there was good cause to issue the IFR. AMS has encouraged public input on the IFR since its issuance and has provided many opportunities for public comment.

Criminal Background Checks and Definition of Key Participants

Comment: Several commenters argued that the restrictions on participation in hemp production for people with criminal convictions related to a violation of a state or Federal controlled substance law are not necessary and that hemp should be treated the same as all other commodities, which do not have similar restrictions. Commenters argued that there should be an exception for people with disqualifying criminal convictions who could demonstrate rehabilitation and that this restriction conflicts with state statutory requirements in some states. One commenter argued that USDA should conduct all criminal background checks rather than States or Indian Tribes.

AMS Response: AMS acknowledges various stakeholders' advocacy for reduced restrictions to entry in hemp production. However, the restriction on participation-based on a criminal conviction for violation of a state or Federal law related to controlled substances is a requirement established by statute and AMS does not have the authority to change to waive this restriction.

Definition of Key Participants

Comment: Some commenters requested that AMS change the definition of key participants to more clearly state which individuals within a business entity would be required to submit a criminal history report. One commenter requested that AMS align the definition of key participant with

the definitions of ''legal entities'' and ''beneficial owners'' in Department of Treasury regulations. Another commenter suggested that AMS define who must submit a criminal history report in States and Indian Tribes that have an approved plan for primary regulatory authority over hemp in their jurisdiction.

AMS Response: AMS acknowledges various stakeholders' advocacy for a single definition of ''key participants'' for all hemp producers. However, AMS will not require that States or Indian Tribes with an approved plan for primary regulatory authority over the production of hemp in their jurisdiction adopt the USDA definition of ''key participants.'' States and Indian Tribes are free to incorporate the AMS definition of key participants into their plan but they are not required to do so. They must, however, define who participates in their plan and, for each license or authorization they issue, must identify at least one individual who will be subject to a criminal history check. The Department of Treasury definitions of ''legal entities'' and ''beneficial owners,'' while similar to the definition of ''key participants'' adopted herein apply broadly to the corporate structure of a business entity. USDA finds the ''key participant'' definition to best describe those individuals responsible for compliance with this program or ''leadership structure of a business entity.''

X. Regulatory Analyses

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Domestic Hemp Production Program's information collection requirements have been previously approved by Office of Management and Budget (OMB) and assigned OMB No. 0581–0318. The 60-day public comment period was imbedded in the interim final rule (IFR) which was published on October 31, 2019, and ended on December 30, 2019. Because of the very tight timeline for publishing the IFR, OMB granted conditional emergency approval of these seven forms on December 3, 2019. The USDA Office of Chief Information Officer (OCIO) published the 30-day Notice for the three-year renewal at 85 FR 36828 on Thursday, June 18, 2020.

While writing the IFR there was very limited data available to make the initial burden calculations under the Paperwork Reduction Act (PRA). Since the IFR was published, USDA has been able to gather much more accurate data on the number of producers, disposal rates, and time burdens for completing the forms. Because of this new information, AMS is updating the burden calculations currently approved by OMB. AMS will submit an updated Information Collection to align the new calculations in the FR with the 0581–0318 package.

AMS received over 4,600 comments in the first public comment period and 1,100 during the second comment period on the overall regulation. A specific analysis of each topic area in the comment analysis section of the final rule. AMS did not receive public comments specifically on the PRA nor on the time burden hour calculations to complete any of the forms. One comment from the Alabama Department of Agriculture wrote that 10 minutes for a State or Tribal producer license application was too low, so that has been increased to 20 minutes.

AMS used an initial estimate of 9,000 total producers for the IFR. This was based on the limited data from State Departments of Agriculture and the hemp advocacy group, Vote Hemp. Based on a review of hemp production data from State Departments of Agriculture, and the data reporting services from Hemp Benchmarks and Vote Hemp, AMS now estimates 20,000 producers as a yearly average to use for the purposes of reporting calculations. These numbers will be updated every three years. While the current percent of hemp growers licensed under USDA is drastically smaller than this, AMS assumes approximately 20 percent or 4,000 producers will be licensed under the USDA plan, and the other 80 percent or 16,000 producers licensed under State and Tribal USDA-approved programs.

The description and function of the seven reporting forms remains the same from the IFR and initial OMB approval. These forms require specific information be submitted by States and Tribes operating their own domestic hemp plans, from producers participating in the USDA Plan, and from laboratories testing for THC content. Reporting and recordkeeping burdens reflecting revised reporting hours and the projected additional producers are described in the following sections. All time and cost figures have been approximated to the nearest whole number. The table below explains these changes numerically.

Costs of Reporting and Recordkeeping

The initial estimate of 100 State and Tribal plans remains accurate since the majority of States and Indian Tribes will have their own programs. As of the Fall of 2020, USDA has already approved 65 individual State and Tribal programs, with more to come. The amount of State approved programs will also increase once the 2014 Farm Bill pilot authority expires and those additional States submit plans. States and Indian Tribes with approved plans are required to report certain information to USDA through three Forms: The ''State and Tribal Hemp Producer Report'', the ''State and Tribal Hemp Disposal Report'', and the ''State and Tribal Hemp Annual Report''. USDA collects information from all hemp producers under a State, Tribal or USDA program through the FSA report form ''Report of Acreage''. USDA collects information from USDA producers through the ''USDA Producer Application'', the ''USDA Annual Report'' and the ''USDA Disposal Report''. Laboratories provide information on the ''Laboratory Test Report''.

AMS has updated PRA calculations using the Occupational Employment Statistics Survey of the Bureau of Labor and Statistics [32] using the 2019 data. The mean hourly wage of a compliance officer, as reported in May 2019, was $35 per hour. This is the same numerical value as the May 2018 report. Assuming 39 percent of total compensation accounts for benefits, the total compensation of a compliance officer is $57 per hour. This $57 per hour will be used throughout the PRA section.

Respondents: States or Tribes With Approved Plans

AMS initially estimated that the time required for States and Indian Tribes to fill in the information for each of these forms will be 20 minutes or 0.33 hours with a 5 minute or 0.08 hours record keeping burden. This estimate has been updated from 20 minutes to 60 minutes or one hour. The ''State and Tribal Hemp Producer Report'' and the ''State and Tribal Hemp Disposal Report'' are due to USDA every month. The ''State and Tribal Hemp Annual Report'' form must be submitted to USDA once per year. Similar to the other two State and Tribal forms, the annual time burden was initially 20 minutes but has been updated to 60 minutes. The time burden for each State and Indian Tribe to complete and maintain these three forms is now 12 hours for each monthly form and 1 hour for the annual report, for a total of 25 hours per State and Tribe with an approved plan. Given the estimated number of approved State and Tribal plans is 100, the total cost is 250 hours and $14,250.

[32] *https://www.bls.gov/oes/home.htm.*

Respondents: Producers Under State or Tribal Plans (Information Only, Not Completing the Forms)

The time required of producers to supply the information for the ''State and Tribal Hemp Disposal Report'' and the ''State and Tribal Hemp Annual Report'' will stay the same at 10 minutes for reporting and 5 minutes for recordkeeping burden for each producer for these two forms. The ''State and Tribal Hemp Producer Report'' time estimate is now increased to 20 minutes with a 5 minute record keeping burden for each producer, per the suggestion from the Alabama Department of Agriculture.

In the IFR, AMS originally estimated that the majority of States and Indian Tribes would have three-year producer licenses, and producers would only submit this information once every three years. Since approving 60 State and Tribal plans, the majority of State and Tribal licenses are issued on a yearly basis instead. AMS estimates that the 16,000 State and Tribal producers will submit license information each year for State and Tribal programs. In addition to obtaining a license, all hemp producers are required to prove that they do not have prior drug related convictions that would disqualify them from participation in the program. States have some flexibility in what they require of applicants to make this demonstration. However, for purposes of this analysis, AMS will use the cost of the FBI Identify Summary, $18, as a proxy cost for all background reports, and 3 key participants for each license each year, although if we were to take into account comments, it is likely there will be more than 3 key participants each year. In the chart below is a cost breakdown of the application and background check for producers under a State or Tribal program.

FBI Identity Summary	Number of respondents	Number of responses	Total annual resposes	*3 Key participants	Cost of background check ($18)	Plus burden cost of application	Total cost
Cost for State and Tribal producers (3 key participants every year)	16,000	1.0000	16,000.00	48,000.00	$864,000.00	$379,666.00	$1,243,666.00

In the IFR, AMS estimated that 20 percent of lots will need to be disposed even though the current rate of disposal is closer to 12%. This assumption is based on the increased number of new entrants to the market who may not be successful in their first year or two. AMS is introducing a new performance-based method to sampling, which will decrease the amount of testing and noncompliant tests. Therefore, AMS estimates that 1,600 lots will be disposed under State and Tribal programs. The producers under a State or Tribal program will provide their disposal information to their individual regulatory body. The States and Indian Tribes will then use that information to complete the monthly ''State and Tribal Hemp Disposal Report''.

These are just the costs and burden of collecting and maintain the information associated with the disposal, not the actual disposal. The actual cost of disposing of the non-compliant ''hot'' hemp is discussed in the RIA.

In total, producers under a State or Tribal program provide information and hold records for three forms. The total time burden for these producers providing and maintaining this information is estimated at 11,061 total hours and $630,466.

Respondents: Producers Participating in the USDA Plan

To produce hemp under the USDA Plan, a producer, which may be an individual producer or a business, completes the ''USDA Hemp Plan Producer Licensing Application'' and an FBI Identity Summary. If all parts of the application and summary are valid, AMS issues a license. The total burden per respondent of this form will maintain the same as in the IFR; 10 minutes for the time and 5 minutes for record keeping for a total of 15 minutes, or .25 hours. Licenses under the USDA Plan must be renewed every three years, so each producer only submits this information once every three years. In the IFR, AMS initially estimated that there will be 1,000 participants in the USDA Plan. AMS has now updated this estimate to be 20 percent of the total hemp producers, or 4,000 producers each year. Because the USDA license is valid for three years, approximately 1,332 producers will complete this form each year. The total annual burden for this form is 544 hours and $31,603.

In addition to the ''USDA Hemp Plan Producer Licensing Application'' submitted once every three years, producers must submit criminal history reports for each of their key participants. AMS estimates each producer to have three key participants submit criminal history reports to USDA. The cost of a criminal history report is $18 apiece, so three key participates would cost $54 per participant. As stated previously, AMS estimates that it will receive 1,332 license renewals in each year. Each of these 1,332 renewals will include a background summary for three key participates. Adding the cost of 1,332 renewals at $71,928 with the cost of the background check is $31,603 for the renewals and means there is an annual cost of $103,531.

FBI Identity Summary	Number of respondents	Number of responses per respondents	Total annual resposes	*3 Key participants	Cost of background check ($18)	Plus burden cost of application	Total cost
Cost for USDA producers (3 key participants every three years)	4,000	0.3330	1,332.00	3,996.00	$71,928.00	$31,603.00	$103,531.00

Similar to the required annual report submitted by States and Indian Tribes to USDA, producers operating under the USDA Plan must submit the ''USDA Hemp Plan Producer Annual Report'' to USDA each year. AMS estimates the time burden of submitting this form will maintain the same, at 25 minutes, or 0.42 hours, per respondent. AMS has updated the initial estimate of 1,000 participants in the USDA Plan, to 4,000 producers. Therefore, the total burden of this form has increased from 416 hours to 1,665 hours, costing $94,916 annually.

When a hemp sample tests above the acceptable hemp THC level, the material from the specific lot must be disposed. The producer and disposal agent must complete the ''USDA Hemp Plan Producer Disposal Form''. The burden for this form will stay at 25 minutes, or 0.42 hours, per respondent.

Using the same assumptions regarding the prevalence of non-compliant crops and the costs of disposal that were used in generating the estimates of hemp disposal reporting (and disposal) for State and Tribal programs, the 4,000 producers that will participate in the USDA Plan will generate 400 samples that test high for THC content. The total reporting burden of this form will amount to 167 hours and cost $9,492 annually.

Altogether, the annual burden for the USDA producers completing and maintain the three USDA forms ''USDA Hemp Plan Producer Licensing Application'', the ''USDA Hemp Plan Producer Disposal Form'', and the ''USDA Hemp Plan Producer Annual Report'' amounts to an annual total of 2,386 hours and a cost of $136,011.

Respondents: Laboratories

The 2018 Farm Bill requires that all domestically produced hemp be tested for total THC content on a dry-weight basis, whether produced under a State or Tribal Plan or the USDA Plan. Using data from FSA the initial estimate of two lots of hemp per producer remains accurate. However, the new performance-based sampling process will decrease the number of total samples that are collected and tested.

AMS requires all laboratories testing hemp for THC to submit all test results, whether passing or failing, via the ''Laboratory Test Results Report''. AMS maintains the estimated reporting and recordkeeping burden for this form at 35 minutes, or .58 hours. AMS originally estimated that 7,700 total hemp producers would submit 15,400 samples to test. AMS has updated this estimate to 8,000 total tests annually. Therefore, the total annual burden of these tests and the accompanying ''Laboratory Test Results Report'' form decreased from 8,399 hours to 4,664 hours, and costs $265,848.

Respondents: All Producers

The FSA collects information on crop acreage through the ''Report of Acreage'' form. Hemp producers under all plans are required to fill in the information for this form once they receive their license or authorization from USDA, a State, or Indian Tribe and have planted the crop. AMS will keep the initial reporting burden and record keeping burden at 35 minutes, or 0.58 hours. AMS has added 60 minutes or one hour for the travel time to and from the FSA office, for a total of 90 minutes. With the increased number of producers and the addition of travel time, AMS estimates the burden for the 20,000 producers will be 31,660 hours and cost $1,804,620.

Total Reporting and Recordkeeping Costs for All Respondents

Altogether, the annual burden for reporting and recordkeeping for all respondents is 52,296 hours, costing a total of $2,980,864 per year. This is the sum of the annual burden of reporting and recordkeeping to States and Indian Tribes operating their own plans, to producers participating in the State and Tribal Plans, to producers participating in the USDA Plan, including the cost of a criminal history report for three key participants, and to laboratories testing samples for THC content.

TABLE

Name	Form	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total reporting hours	Number of record keepers	Annual hours per record keeper	Total record keeping hours	Total hours	× $57
State and tribal forms											
State and Tribal Hemp Producer Report (Old).	AMS–23	100	12.0000	1,200.00	0.3333	399.96	100	0.083	8.30	408.26	$23,270.82
State and Tribal Hemp Producer Report (Update).	AMS–23	100	12.0000	1,200.00	1.0000	1,200.00	100	0.083	8.30	1,208.30	68,873.10
State and Tribal Producer Responses (Old).	information only	8,000	0.3330	2,664.00	0.1670	444.89	2,664.00	0.083	221.11	666.00	37,962.00
State and Tribal Producer Responses (Update).	information only	16,000	1.0000	16,000.00	0.3333	5,332.80	16,000	0.083	1,328.00	6,660.80	379,665.60
State and Tribal Hemp Disposal Report (Old).	AMS–24	100	12.0000	1,200.00	0.3333	399.96	100	0.083	8.30	408.26	23,270.82
State and Tribal Hemp Disposal Report (Update).	AMS–24	100	12.0000	1,200.00	1.0000	1,200.00	100	0.083	8.30	1,208.30	68,873.10
State and Tribal Producer Disposal Responses (20% then x 2 for 2 lots/producer) (Old).	information only	2,680	1.0000	2,680.00	0.1670	447.56	2,680	0.083	222.44	670.00	38,190.00
State and Tribal Producer Disposal Responses (25% of lot from 80% of producers) (Update).	information only	1,600	1.0000	1,600.00	0.1670	267.20	1,600	0.083	132.80	400.00	22,800.00
State and Tribal Hemp Annual Report (Old).	AMS–25	100	1.0000	100.00	0.3333	33.33	100	0.083	8.30	41.63	2,372.91
State and Tribal Hemp Annual Report (Update).	AMS–25	100	1.0000	100.00	1.0000	100.00	100	0.083	8.30	108.30	6,173.10
State and Tribal Hemp Annual Report Response (Old).	information only	6,700	1.0000	6,700.00	0.1670	1,118.90	6,700	0.083	556.10	1,675.00	95,475.00
State and Tribal Hemp Annual Report Response (Update).	information only	16,000	1.0000	16,000.00	0.1670	2,672.00	16,000	0.083	1,328.00	4,000.00	228,000.00
USDA Producer Forms											
USDA Hemp Plan Producer Licensing Application (Old).	AMS–26	1,000	0.3330	333.00	0.1670	55.61	333	0.083	27.64	83.25	4,745.25
USDA Hemp Plan Producer Licensing Application (Update).	AMS–26	4,000	0.3330	1,332.00	0.1670	222.44	4,000.00	0.083	332.00	554.44	31,603.31
USDA Hemp Plan Producer Disposal Form (20% x 2 lots for 2 lots/producer) (Old).	AMS–27	400	1.0000	400.00	0.3333	133.32	400	0.083	33.20	166.52	9,491.64
USDA Hemp Plan Producer Disposal Form (25% x lots from 20% of all producers) (Update).	AMS–27	400	1.0000	400.00	0.3333	133.32	400	0.083	33.20	166.52	9,491.64

TABLE—Continued

Name	Form	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total reporting hours	Number of record keepers	Annual hours per record keeper	Total record keeping hours	Total hours	× $57
USDA Hemp Plan Producer Annual Report (Old).	AMS–28	1,000	1.0000	1,000.00	0.3333	333.30	1,000	0.083	83.00	416.30	23,729.10
USDA Hemp Plan Producer Annual Report (Update).	AMS–28	4,000	1.0000	4,000.00	0.3333	1,333.20	4,000	0.083	332.00	1,665.20	94,916.40
All Producer Forms											
Report of Acreage (Old).	FSA–578	7,700	1.0000	7,700.00	0.5000	3,850.00	7,700	0.083	639.10	4,489.10	255,878.70
Report of Acreage (Update + 60 min travel time).	FSA–578	20,000	1.0000	20,000.00	1.5000	30,000.00	20,000	0.083	1,660.00	31,660.00	1,804,620.00
Laboratory Test Results Report (2 lots/all producers) (Old).	AMS–22	7,700	2.0000	15,400.00	0.5000	7,700.00	7,700	0.083	639.10	8,339.10	475,328.70
Laboratory Test Results Report (100% of CBD; 50% of fiber; 50% of grain) (Update).	AMS–22	8,000	1.0000	8,000.00	0.5000	4,000.00	8,000	0.083	664.00	4,664.00	265,848.00
Total for Updates										52,295.86	2,980,864.25

Each column is a section of the burden estimate, with the cost of $57 per hour calculated in the last column. Each row represents the old or the new reporting calculations.

E-Government Act

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. We recognize using an electronic system will promote efficiencies in developing and implementing the new USDA Domestic Hemp Production Program. Since this is a new program, AMS is working to make this process as effective and user-friendly as possible.

Civil Rights Review

AMS has considered the potential civil rights implications of this rule on minorities, women, and persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities who are subject to these regulations. This final rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this rule does not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

This final rule reflects AMS's response to public comment and input provided by stakeholders. The final rule provides States and Indian Tribes the regulatory authority over hemp production in their jurisdictions. It also establishes a Federal plan for hemp producers located in States or territories of Indian Tribes that do not have their own USDA-approved hemp oversight plan. There is no evidence that the final rule will potentially adversely or disproportionality impact hemp producers in protected groups, regions or Indian Tribes differently than the general population of hemp producers or State Departments of Agriculture.

Executive Order 13132—Federalism

AMS has examined the effects of provisions in this final rule on the relationship between the Federal Government and the States, as required by Executive Order 13132 on ''Federalism.'' Our conclusion is that this rule does have federalism implications because the rule has substantial and direct effects on States, on the relationship between the National Government and States, and on the distribution of power and responsibilities among the various levels of government. The federalism implications of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve State plans that meet statutory requirements and to audit a State's compliance with its State plans. Overall, the final rule attempts to balance both the autonomy of the States with the necessity to create a Federal framework for the regulation of hemp production.

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of States will be imposed ''. . . only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.'' Section 297B of the AMA is the statutory authority underlying the rules for USDA to review, approve, disapprove, or revoke State plans for hemp production. Until the passage of the 2018 Farm Bill, hemp was a Schedule I controlled substance as it fell within the CSA definition of marijuana. When hemp was exempted from the definition of marijuana as part of the 2018 Farm Bill, in connection with removing it from that list, Congress established a national regulatory framework for the production of hemp. Because cannabis plants with a THC level higher than 0.3 are marijuana and on the Federal controlled substances list, ensuring that hemp produced under this program is not marijuana is of national significance.

In addition to establishing a national regulatory framework for hemp production, Congress expressly preempted State law with regard to the interstate transportation of hemp. Section 10114 of the 2018 Farm Bill States that ''[n]o State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.'' Thus, States and Indian Tribes may not prevent the movement of hemp through their States or territories even if they prohibit its production. Congress also expressly preempted a State's ability to prosecute negligent violations of its plan as a criminal act in section 297B(e)(2)(c). That preemption is incorporated into this rule.

Section 3(d)(2) of the E.O. 13132 requires the Federal Government to defer to the States to establish standards where possible. Section 4(a), however, expressly contemplates preemption when there is a conflict between exercising State and Federal authority under Federal statute. Section 297B of the AMA requires State plans to include six practice and procedures and a certification. It also expressly states that it does not preempt a State's ability to adopt more stringent requirements or to prohibit the production of hemp. Section 297D of the AMA requires USDA to promulgate regulations to implement subtitle G of the AMA, which includes section 297B. Subpart B of the final rule repeats those requirements, providing more detail where necessary. States have wide latitude to develop the required practice and procedures. Subpart B includes more details on the testing and sampling of hemp plants to establish a national standard to determine whether the plants meet the statutory definition of hemp. Likewise, the final rule requires States to follow DEA requirements for disposal of marijuana for cannabis plants exceeding the acceptable hemp THC level. Finally, the final rule also reaffirms that States may adopt more stringent standards and prohibit hemp production within their jurisdiction.

Section 6 of E.O. 13132 requires consultation with State officials in development of the regulations. AMS conducted significant outreach with State officials including individual meetings, participation in conferences with State officials, and listening sessions where State officials from all States were invited. During our consultation with the States, representatives from various State agencies and offices expressed the following concerns about sampling and testing procedures. Most requested that USDA adopt uniform, national requirements to facilitate the marketing of hemp. Some States advocated that USDA defer to each State to determine the appropriate procedures for its plan. USDA recognizes the value of a national standard to promote consistency while allowing States the flexibility to adopt procedures that fit their circumstances. As explained above, USDA is adopting performance standards for sampling and testing. As long as the procedures in the State plans meet those standards, AMS will find those procedures acceptable.

As AMS implements this new program, we will continue to consult with State officials to obtain their feedback on implementation.

Finally, we have considered the cost burden that this rule would impose on States as discussed in the Regulatory Impact Analysis of this document.

AMS has assessed this final rule in light of the principles, criteria, and

requirements in Executive Order 13132. We conclude that this final rule: Is not inconsistent with that E.O.; will not impose significant additional costs and burdens on the States; and will not affect the ability of the States to discharge traditional State governmental functions.

Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

AMS examined the effects of provisions in the final rule on the relationship between the Federal Government and Tribal governments, as required by E.O. 13175 on ''Consultation and Coordination with Indian Tribal Governments.'' We concluded that the final rule does have substantial direct effects on Tribal governments, on the relationship between the National Government and Tribal governments, and on the distribution of power and responsibilities among the various levels of government. The effects of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve Tribal plans that meet statutory requirements and to audit a Tribal government's compliance with its Tribal plans. Overall, the final rule attempts to balance both the autonomy of the Tribal governments with the necessity to create a Federal framework for the regulation of hemp production.

As with States, Tribal governments will have wide latitude in adopting procedures including adopting requirements that are more stringent than the statutory ones. For reasons stated in the federalism analysis, AMS is adopting national standards for sampling, testing, and disposal of non-compliant plants that Tribal plans must also incorporate.

AMS conducted extensive outreach to Tribal governments through individual discussions with Tribal representatives, by extending the regulatory comment periods and through the following more formal consultations.

Tribal Consultation May 2019: On May 1 and 2, 2019, USDA held a formal Tribal consultation on the 2018 Farm Bill including a session on hemp production. This consultation occurred at the National Museum of the American Indian located in Washington DC. In addition to listening sessions for the general public, USDA hosted a listening session for Tribal governments following the formal Tribal consultation on May 2, 2019. USDA officials attended meetings with representatives of Tribal governments. On December 11, 2019, roughly 41 days after the publication of the domestic hemp production program interim final rule, USDA held a second formal Tribal consultation. This consultation provided information on the interim final rule. This consultation occurred in Las Vegas, Nevada, and attendees included USDA officials, Tribal leaders, Tribal proxies, non-consulting Tribal members, non-profit representatives, businesses, law firms, private individuals, and other government employees. On September 24, 2020, USDA held a third formal Tribal consultation and provided information on the interim final rule. This consultation occurred virtually and attendees included USDA officials, Tribal leaders, Tribal proxies, non-consulting Tribal members, non-profits representatives, Businesses, law firms, private individuals, and other government employees.

During the May 2019 consultation, Tribal representatives from several Tribal Governments expressed their opinions that the 2018 Farm Bill permitted the USDA Secretary to allow AMS to approve Tribal plans ahead of issuing regulations of the USDA plan. Indian Tribes stated that approving hemp plans immediately would allow those Indian Tribes (and States) with a plan to begin planting for the commercial production of hemp in 2019. The USDA Secretary released a Notice to Trade (NTT) on February 27, 2019, to explain that Tribal and State plans would not be reviewed or approved until AMS finalized regulations ahead of the 2020 planting season. Additionally, the NTT stated that until regulations were in place, States, Indian Tribes, and institutions of higher education could continue operating under authorities of the 2014 Farm Bill. The 2018 Farm Bill extension of the 2014 authority expired 12 months after USDA had established the plan and regulations required under the 2018 Farm Bill. Congress extended this expiration until January 1, 2022. After the May Tribal consultation, USDA issued a second NTT on May 27, 2019, to clarify that Tribal governments through the authorities in the 2014 Farm Bill are permitted to grow industrial hemp for research purposes during the 2019 growing season. USDA appreciates the urgency in which the Indian Tribes wish to engage in this new economic opportunity. We worked expeditiously to develop and promulgate the IFR so that States and Indian Tribes could submit their plans in time for the 2020 season.

Tribal Consultation December 2019: During this consultation Indian Tribes expressed how some provisions of the interim final rule are too rigid and that USDA did not consider practical problems and potential economic harm faced by Indian Tribes under the program.

Indian Tribes requested more extensive Tribal consultation and the inclusion of other agencies involved in hemp production and enforcement. In response, USDA extended the public comment date by thirty additional days to January 29, 2020 and agreed to conduct an additional consultation after the first growing season. AMS also reopened the public comment period for thirty days in the Fall of 2020.

Tribal Consultation September 2020: Consultation also occurred on September 24, 2020.

Based on the comments and consultations received, we made changes to the final regulations. Although Indian Tribes will still incur costs in complying with final rule, those costs should be outweighed by the benefits that the Indian Tribes realize in commercial hemp production occurring within their territories.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined, in agreement with AMS, that this rule has substantial direct tribal implications that require continued outreach efforts to determine if tribal consultation under E.O. 13175 is required. Based on AMS outreach efforts to date, OTR does not believe that tribal consultation is necessary at this time. If a tribe requests consultation AMS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives when an action is deemed to have significant impacts. If regulation is necessary, then agencies must select the action that maximizes net benefits, including potential economic, environmental, public health and safety effects, and equity. This rule meets the definition of an economically significant regulatory action under Executive Order 12866, as it is likely to result in an annual effect on the economy of $100 million or more. USDA considers this to be a deregulatory action as it allows the development of a niche market that cannot exist under the state pilot programs authorized under the Agricultural Act of 2014 (2014 Farm Bill). This action finalizes the interim final rule published on October 31, 2019, that expanded production options and enabled interested farmers to grow hemp.

Executive Order 13771 mandates that agencies provide the best approximation of total costs associated with a new or repealed regulation. AMS has prepared this Regulatory Impact Analysis with the purpose of accomplishing these objectives. USDA considers this to be a deregulatory action under Executive Order 13771 as it allows for the development of a niche market that cannot exist under current regulation. This rule removes barriers to entry and enables domestic farmers to grow hemp.

Regulatory Impact Analysis

Regulations must be designed in the most cost-effective manner possible to obtain the regulatory objective while imposing the least burden on society. This rule finalizes and updates the interim final rule that established a national regulatory oversight program for the production of hemp. This program is necessary to effectuate the mandate in the Agriculture Improvement Act of 2018, known as the 2018 Farm Bill, to coordinate State and Tribal government hemp production regulations with the newly established federal regulations for hemp production in States and Indian Tribes not regulated by State or Tribal plans. This program is intended to provide consistency in production, sampling and testing of hemp product to ensure compliance with the acceptable hemp THC level.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform, and is not intended to have retroactive effect. The discussions on Executive Orders 13132 (Federalism) and 13179 (Consultation and Coordination with Tribal Governments), above, address the extent to which the rule preempts State law, and the impacts of the rule to Tribal governments. The discussion above regarding appeals under new part 990, subpart D, describes the administrative procedures that must be exhausted prior to a judicial challenge.

Introduction

On October 31, 2019, USDA promulgated an interim final rule establishing a national program for the production of industrial hemp. A regulatory analysis was performed in support of that regulation and published as part of the preamble to that rule. This analysis is intended to update the previous analysis to reflect additional information gained through the first year of operation of that program and to assess whether any of the modifications to the program made in response to public comment have significant impacts on the estimated costs or benefits of the final program.

In the IFR, AMS estimated lower and upper bounds to calculate the total net benefits of the rule to society at large. These net benefits were calculated for 2020 through 2022 only due to lack of data for future years. In the IFR, 2020 estimated net benefits ranged from a loss of nearly $4 million to a gain of $17.6 million; for 2021, a net benefit of $23 million to $46 million; and, for 2022, a net benefit of nearly $49 million to $74 million. In this final rule, the estimated net benefits, as shown in Table 12, are $46 million in 2020; $87 million in 2021; $135 million in 2022; $190 million in 2023; $226 million in 2024; and, $351 million in 2025.

The estimates of net benefits resulting from this final rule differ from those in the IFR due to a variety of factors. First of these is the large increase in planted acreage and market entrants in 2019, the scale of which was unexpected. (There may be other unexpected changes due to the pandemic, but we cannot estimate those at this time.) Changes in other variables, as well, contributed to the increase in net benefits in the final rule over the IFR. A comparison of the variables that are assumed constant (across years 2020 through 2025) in the IFR and the final rule is shown in Table 1 below. In the year between publication of the IFR and this final rule, additional information regarding the hemp industry has emerged to the benefit of this analysis. AMS believes that the modifications to the analysis from the IFR to the final rule represent the state of the hemp industry to the greatest extent practicable. The modifications in this final rule are intended to further support the hemp marketplace and provide the greatest flexibility possible while still ensuring the program complies with the 2018 Farm Bill.

AMS suspects that this rule, compared to the IFR, will incentivize participation in the market and allow for more farmers to be successful. In particular, AMS attributes this to two policies. First, AMS anticipates that the flexibilities in disposal and remediation of non-compliant hemp will help minimize the risk to farmers, therefore increasing participation in the industry. Second, AMS anticipates that the increased threshold for negligent hemp (from 0.5 percent to 1.0 percent) will also reduce risk to farmers and allow for more innovation.

AMS received numerous comments providing data on the different aspects of the hemp industry, that while informative, could not be incorporated in the RIA due to such factors as they were too regionally focused, small in sample size, or lacked the depth of data points to be representative of the national hemp market. An example of this is the portion of retests performed on hemp samples that initially tested higher than 0.3 percent THC.

Table 1. Comparison of variables assumed constant in IFR and Final Rule

Variables	Intended Use	IFR Low	IFR High	Final Rule	Final Rule Data Sources
Price per lb	Cannabinoids	$ 3.50	$ 30.00	$ 3.90	The Jacobsen. Estimates based on 2019 and 2020 prices.
	Fiber	$ 0.07	$ 0.67	$ 0.09	
	Grain	$ 0.65	$ 1.70	$ 0.53	
Yield per acre	Cannabinoids	1,000	1,200	1,500	Hemp enterprise budgets from seven universities.
	Fiber	2,000	11,000	8,000	
	Grain	800	1,600	1,200	
Portions of planted acreage by intended use	Cannabinoids	67%		80%	The Jacobsen. Hemp Daily Bulletin, September 8, 2020.
	Fiber	17%		3%	
	Grain	17%		17%	
Variables	**Plans**	**IFR Low**	**IFR High**	**Final Rule**	**Final Rule Data Sources**
Portions of lots sampled & tested	USDA	100%		Based on 95% CI and 1% margin of error	Standard statistical performance objective.
	State/Tribal	100%			
Sampling & testing cost	USDA (per lot)	$ 599	$ 830	$ 565	State departments of agriculture.
	State/Tribal (per license)	Included in program administration cost			
Variables		**IFR**		**Final Rule**	**Final Rule Data Sources**
Portion of sales attributable to the rule		50% of growth		20% of total	State depts. of ag.
Opportunity cost per acre		$ 591		$ 630	NASS.
Program administration cost		$ 1,000		$ 800	State depts. of ag.
Portion of lots testing > 0.3% THC		40%		25%	National Industrial Hemp Regulators.
Disposal cost per acre		$ 200		$ 14.25	State depts. of ag.

The 2014 Farm Bill defined hemp as the plant *Cannabis sativa* L. and any part of that plant with concentrations of THC no greater than 0.3 percent on a dry weight basis. While belonging to the same species as the plant that produces marijuana, hemp is distinctive from marijuana in its chemical makeup. The marijuana plant contains high levels of the cannabinoid delta-9 tetrahydrocannabinol (THC), which is the chemical that produces psychoactive effects. Hemp may contain no greater than 0.3 percent THC on a dry weight basis.

Prior to the 2014 Farm Bill, hemp had never been designated in a Federal law as different from cannabis generally. The first regulation of hemp occurred in 1937 with the Marihuana Tax Act, which required all producers of the species *Cannabis sativa* to register with and apply for a license from the Federal government. The ''Hemp for Victory'' Campaign during World War II promoted production of hemp for rope to be used by U.S. military forces. At the end of the war, however, the requirements in the Marihuana Tax Act resumed. In 1970, Congress passed the Controlled Substances Act, granting the Attorney General the authority to regulate production of cannabis, including hemp.

The 2014 Farm Bill authorized pilot programs, as permitted by State law, for hemp cultivation for research purposes to be administered by academic institutions and State departments of agriculture. By 2019 approximately half of the states had developed such a pilot program. The research under these pilot programs included market research, which allowed cultivated hemp to enter the stream of commerce as inputs into various consumer products. For example, in Kentucky, one of the first states to enact a pilot program, producer sales to processors totaled $1.6 million in 2016, $7.5 million in 2017, $17.7 million in 2018, and $51.3 million in 2019.[33] Hemp biomass contains concentrations of the cannabinoid cannabidiol, known as CBD. High prices for hemp harvested for cannabinoids, relative to those of other agricultural commodities, have fueled producer interest in hemp production since 2014.

2018 Farm Bill

The 2018 Farm Bill allowed the production and sale of industrial hemp either under a State or Tribal program approved by the USDA or under a Federal license for producers in areas with no approved plan and no explicit State or Tribal statute prohibiting the production of hemp. The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). Accordingly, products containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as FDA-regulated products containing any other substance. The 2018 Farm Bill removed hemp from the list of controlled substances, decontrolling hemp production in all U.S. States, territories, and lands belonging to Indian Tribes, unless prohibited by State or Tribal

[33] Kentucky Department of Agriculture.

Law. This action eliminates the uncertain legal status at the Federal level of hemp production and allows the U.S. Department of Agriculture (USDA) to provide hemp producers with crop insurance programs, potentially reducing risk to producers and providing easier access to capital. The statute also prohibits interference in the interstate transport of hemp by States, including those States that prohibit hemp production and sales. As a result, hemp producers will have access to nationwide markets.

Need for Regulation

The rule is necessary to facilitate the domestic cultivation of hemp for sale into the market for hemp products by creating a set of minimum standards to ensure that hemp being produced under this program meets all statutory requirements. The rule establishes minimum requirements for States and Indian Tribes to obtain program approval and, for producers operating under the Federal program to obtain a license and meet operating requirements under that license. Without these provisions, it would not be possible to grow hemp legally.

Both the declassification of hemp, and the prohibition on interference with interstate transportation apply to hemp that is grown under an approved State or Tribal plan, or under a Federal license. As a result, this regulation facilitates provisions of the 2018 Farm Bill that would otherwise be self-implementing.

Overview of the Action

The 2018 Farm Bill granted regulatory authority of domestic hemp production to the State departments of agriculture, Tribal governments, and USDA. States and Indian Tribes wishing to operate their own programs must submit to USDA plans that include provisions for maintaining information regarding the land on which hemp is produced, for testing the levels of THC, for disposal of plants that do not meet necessary requirements, and for procedures to ensure compliance with the requirements of the new part, including background checks of all key participants. State and Tribal Plans must be approved by USDA. This rule outlines requirements by which the USDA would approve plans submitted by States and Tribal governments for oversight of hemp production. The 2018 Farm Bill also directs USDA to develop a plan for use by hemp producers in States or Indian Tribes where no State or Tribal Plan has been approved and that do not prohibit the cultivation of hemp. These actions will promote consistency in regulations governing the legal production of hemp across the country.

Baseline Definition

The 2014 Farm Bill authorized hemp research pilot programs to be administered by states and universities. The 2018 Farm Bill repealed these pilot programs beginning one year from the publication of a USDA rule; however, the 2021 Continuing Appropriations Act extended the authorization of the 2014 pilot programs until January 1, 2022. From 2014 to 2018, planted acreage tripled in every year, reaching nearly 63,500 acres in 2018. In the year following the signing of the 2018 Farm Bill, planted acreage increased by more than 400 percent to 327,600 acres in 2019.[34] The surge of entrants into the hemp market in 2019 left many producers with unsold inventory. In Kentucky alone, more than $100 million of hemp material went unsold due to lack of buyers in 2019. The large number of entrants into the market in 2019 caused a surplus of hemp production, which in turn caused prices to fall and revenue losses to producers.

Despite the producer excitement that ensued in 2019 following the signing of the 2018 Farm Bill, only 17 states opted to participate in the new hemp programs in time for the 2020 growing season. These 17 states accounted for about 20 percent of the total estimated planted acreage in 2020. Given the apparent affinity by states for the 2014 pilot programs, AMS assumes that in the absence of the 2018 Farm Bill, the 2014 Farm Bill pilot programs would have continued indefinitely. Indeed, the 2014 Farm Bill offered no sunset date for these programs. In order to capture the impacts of this rule on affected entities, AMS attributes 20 percent of the estimated planted acreage from 2020 through 2025 to the 2018 Farm Bill and this rule which enables its prescriptions. This 20 percent reflects the amount of planted acreage in the 17 states that opted to participate in the 2018 Farm Bill hemp programs for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the 2014 pilot programs until the 2021 Continuing Appropriations Act extended the authorization of the 2014 pilot programs to January 1, 2022. By enrolling in the new hemp programs, these 17 states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs. The remaining 80 percent of planted acreage estimated from 2020 through 2025 will be treated as attributable to the 2014 pilot programs under the assumption that they would have continued in the absence of the 2018 Farm Bill which terminated them.

In the interim final rule (IFR), AMS attributed 50 percent of the growth in producer sales from 2020 through 2022 to the 2018 Farm Bill and this enabling rule. In deriving this assumption, AMS considered the rate at which hemp acreage had increased in recent years, the number of States whose hemp pilot programs produced a crop in recent years, and the number of States that passed legislation following the signing of the 2018 Farm Bill in anticipation of this rule's enactment in time for the 2020 growing season. In the time between publication of the IFR on October 31, 2019, and the beginning of the 2020 growing season, 17 states representing 20 percent of planted acreage opted to participate in the hemp programs mandated by the 2018 Farm Bill. This portion of enrollment is less than AMS anticipated in the IFR.

Affected Entities

As of July 2020, States, Indian Tribes, and USDA had issued 19,121 producer licenses. This figure represents licenses issued in 44 States and one Tribe. About 70 percent of states reported at the time that they were still accepting applications, which indicates that the number of 2020 producer licenses issued is likely to grow. For this reason, AMS estimates that up to 20,000 producer licenses will be issued in 2020. Based on the slowed pace in growth of producer licenses from 2019 to 2020, AMS assumes an annual growth rate in producer licenses of 10 percent from 2020 through 2025, for the purposes of this analysis. The result is shown in Table 2. AMS is unaware of any estimates that exist regarding the number of producer licenses that will be issued in the coming years; however, the novelty of hemp as a commercial agricultural commodity, the resolutions of uncertainty surrounding regulations, the expected growth in demand for existing and new hemp products, and the effective establishments of State, Tribal, and Federal hemp programs may

[34] Sources include the following: State Departments of Agriculture; Vote Hemp. 2016–2019 Crop Reports; and, Mark, Tyler, Jonathan Shepherd, David Olson, William Snell, Susan Proper, and Suzanne Thornsbury. February 2020. Economic Viability of Industrial Hemp in the United States: A Review of State Pilot Programs, EIB–217, U.S. Department of Agriculture, Economic Research Service.

continue to draw producers into the market.

TABLE 2—ESTIMATED PROJECTION OF NUMBER OF PRODUCER LICENSES ISSUED

Year	2020	2021	2022	2023	2024	2025
Growers	20,000	22,000	24,200	26,620	29,282	32,210

Sources and notes:
2020 figure based on July 2020 National Industrial Hemp Regulators conference call.
2021–2025 figures based on assumed annual growth rate of 10% in producer licenses.

As of the writing of this analysis, three states had opted to participate in the USDA Federal Plan authorizing producers to cultivate hemp. These states are Hawaii, Mississippi, and New Hampshire. Together, they represent more than 300 producers in 2020. The number of licensed producers participating in the Federal Plan is likely to grow over time due to both greater entrance of producers into the market in these three states and additional states, Indian Tribes, and territories opting to participate in the USDA Plan. At the end of 2020, less than 2 percent of the total number of producers were licensed by USDA. The extension of the 2014 pilot programs to 2022, which was included in the 2021 Continuing Appropriations Act published October 1, 2020, resulted in fewer producers participating in the USDA Plan. Prior to the extension of the 2014 pilot programs, the portion of participants under the USDA Plan was about 10 percent of the total number of 2020 producers, with the expectation for further enrollment. For the purposes of this analysis, therefore, AMS assumes that 20 percent of the total number of licensed producers will be participants of the USDA Plan, and the remaining 80 percent will be participants of a State or Tribal Plan.

In addition to hemp producers, this rule will impact state departments of agriculture, Tribal governments, and USDA as these entities will bear the responsibility to ensure that hemp producers abide by the State and Tribal Plans and the USDA Plan for regulating hemp. At the time this document was written, more than 40 Indian Tribes, at least 40 states, and two U.S. territories had plans approved by USDA or were in the process of submitting plans for USDA approval. At least three states have opted to participate in the USDA plan, and one state and one territory await legislation authorizing hemp production. AMS anticipates receiving further interest in both the Federal Plan and the plans administered by states, Indian Tribes, and territories in the coming months when the provisions of the 2014 Farm Bill expire and States and Tribes start implementing their programs. For the purposes of this analysis, AMS assumes that 100 states, Indian Tribes, and territories will administer their own plans in every year from 2020 through 2025. AMS acknowledges that this number is likely to change from year to year, depending on market conditions, which affect the ability of a state, tribe, or territory to manage its own hemp program. Because AMS has no way to predict future market or state political conditions, for simplicity, it assumes a constant of 100 states, Indian Tribes, and territories administering their own plans from 2020 through 2025.

Finally, this rule will impact laboratories that will provide testing services to producers and program administrators. As of the writing of this analysis, there were 67 laboratories that test hemp that are registered with the DEA. USDA is requiring that all samples tested for THC concentration levels be conducted in DEA-registered laboratories; however, enforcement of this requirement has been delayed until December 31, 2022.

Expected Costs and Benefits of the Rule

The 2018 Farm Bill grants authorization for production of hemp to all states and Indian Tribes, unless prohibited by State or Tribal Law. This rule enables states, Indian Tribes, and USDA to regulate this authorization. This rule is expected to generate benefits and costs to hemp producers, state departments of agriculture, Tribal governments, USDA, and laboratories. The benefits of this rule are expected to outweigh the costs, however, and the burden on the impacted entities is anticipated to be minimal.

Producers

Using figures from Hemp Industry Daily and the Brightfield Group, AMS estimates retailer sales of hemp products to range from $2.5 billion in 2020 to nearly $17 billion in 2025. Based on price spreads from farm to consumer, published by the Economic Research Service (ERS), AMS assumes a pass-through rate of 20 percent from retailer to producer.[35] AMS also assumes that import values account for 15 percent of the producer share of retail sales. This estimate was derived using 2019 and 2020 import data from the Foreign Agricultural Service (FAS) of USDA. At the time of this analysis, import data for 2020 was only available for the months of January through August. In order to gauge what total 2020 imports might be, AMS applied to the figure of total imports for January through August 2020 ($55 million) the average percentage change that occurred in the four months from August through December of recent years (40 percent). Applying the assumptions of 20 percent price pass-through from retailer to producer and import values of 15 percent of the producer share of retail sales to the estimates of retailer sales results in estimated total producer sales of $432 million in 2020 to $2.9 billion in 2025, shown in Table 3.

TABLE 3—ESTIMATED RETAILER AND PRODUCER HEMP PRODUCT SALES

[Millions]

Year	2020	2021	2022	2023	2024	2025
Total retailer sales [1]	$2,540	$4,485	$6,740	$9,310	$10,995	$16,800

[35] ERS. Price Spreads from Farm to Consumer. September 2020.

TABLE 3—ESTIMATED RETAILER AND PRODUCER HEMP PRODUCT SALES—Continued

[Millions]

Year	2020	2021	2022	2023	2024	2025
Producer share of retail sales [2]	508	897	1,348	1,862	2,199	3,360
Imports [3]	76	135	202	279	330	504
Total producer sales [4]	432	762	1,146	1,583	1,869	2,856

[1] Retailer sales estimates based on the following stores: 2020–2024 estimates from Hemp & CBD Industry Facebook 2019, Hemp Industry Daily, ''Annual U.S. Hemp-Derived CBD Retail Sales Estimates.'' Published October 16, 2019. 2025 estimate from Brightfield Group. ''US CBD Market Forecast Reduced Due to Health Consolidation.'' Published July 31, 2020.

[2] Product of total retailer sales and 20% share of retail sales passed to producers; estimate of 20% share of retailer prices based on Economic Research Service publications of ''Price Spreads from Farm to Consumer''.

[3] Assumes imports account for 15% sales at the producer level; source for assumption is FAS 2015–2019 import data, HTS codes 1207990320 and 5302100000.

[4] Difference of producer share of retail sales and imports.

The estimates in Table 3 reflect total producer sales in aggregate. AMS is unaware of any data that currently exists that would indicate sales by individual producer. Given the varied nature of the hemp industry, producer sizes are anything but uniform; therefore, AMS has not attempted to project sales by individual producer as it would likely result in false conclusions and misleading information. Similarly, data comparing sales by producers under the 2018 Farm Bill and what sales under the 2014 Farm Bill may have been in the absence of the 2018 Farm Bill does not currently exist. Further, AMS believes that this estimate would not differ greatly given the greater access to nationwide markets and flexibilities provided to producers under the 2018 Farm Bill.

In addition, AMS acknowledges that raw harvested hemp product may take years to enter the retail market after it passes through the supply chain. For instance, product sold at the retail level in 2021 may include hemp that was harvested in 2019. In acknowledging this, AMS understands that the estimated producer sales for a given year in Table 3 may not represent actual producer sales for that year, but rather, sales from prior years. AMS is unaware of any data that exists that would identify when a harvested hemp crop is sold into the retail market. For the purposes of this analysis, therefore, and for simplicity, AMS assumes that the producer sales estimated in Table 2 represent sales at the producer level for the same year as the retail sales from which they are derived.

As discussed in the ''Baseline Definition'' section of this analysis, AMS estimates that 20 percent of the producer planted acreage from 2020 through 2025 will be attributable to the 2018 Farm Bill and this rule which enables its prescriptions. This 20 percent reflects the amount of planted acreage in the 17 states that opted to participate in the 2018 Farm Bill hemp programs in time for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the 2014 pilot programs. By enrolling in the new hemp programs, these 17 states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs. The remaining 80 percent of producer planted acreage estimated from 2020 through 2025 will be treated as attributable to the 2014 pilot programs under the assumption that they would have continued in the absence of the 2018 Farm Bill which terminated them. In Table 4, AMS has calculated total planted acreage inclusive of all domestic producers, using the estimates of total producer sales in Table 3 and assumptions that are stated and cited in the table. From the estimates of total planted acreage in Table 4, AMS calculated the planted acreage due to the rule in Table 5, along with the estimate of sales attributable to the rule. These estimates of sales due to the rule will be referenced as the benefits of the rule to producers in the calculation of net benefits in Table 10.

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Table 4. Calculation of planted acreage required to meet estimated total producer sales

Assumed constant in each year

Intended use	Portion of total sales[1]	Yield (lbs/acre)[2]	Price per lb[3]	Price per acre[4]	Portion of harvested volume sold[5]	Portion of planted acreage harvested[6]
Cannabinoids	99%	1,500	$ 3.90	$ 5,850	65%	75%
Fiber	0.5%	8,000	$ 0.09	$ 720	90%	
Grain	0.5%	1,200	$ 0.53	$ 636	95%	

Year	Total producer sales (millions)[7]	Intended use	Sales by use (millions)[8]	Acres-worth sold[9]	Volume sold (lbs)[10]	Volume harvested (lbs)[11]	Harvested acreage[12]	Planted acreage[13]
2020	$ 432	Cannabinoids	$ 427	73,074	109,610,769	168,631,953	112,421	159,102
		Fiber	$ 2	2,999	23,988,889	26,654,321	3,332	
		Grain	$ 2	3,395	4,073,585	4,287,984	3,573	
2021	$ 762	Cannabinoids	$ 755	129,030	193,545,000	297,761,538	198,508	280,934
		Fiber	$ 4	5,295	42,358,333	47,064,815	5,883	
		Grain	$ 4	5,994	7,192,925	7,571,500	6,310	
2022	$ 1,146	Cannabinoids	$ 1,134	193,905	290,856,923	447,472,189	298,315	422,184
		Fiber	$ 6	7,957	63,655,556	70,728,395	8,841	
		Grain	$ 6	9,008	10,809,434	11,378,352	9,482	
2023	$ 1,583	Cannabinoids	$ 1,567	267,842	401,762,308	618,095,858	412,064	583,165
		Fiber	$ 8	10,991	87,927,778	97,697,531	12,212	
		Grain	$ 8	12,443	14,931,132	15,716,981	13,097	
2024	$ 1,869	Cannabinoids	$ 1,850	316,318	474,476,538	729,963,905	486,643	688,711
		Fiber	$ 9	12,980	103,841,667	115,379,630	14,422	
		Grain	$ 9	14,695	17,633,491	18,561,569	15,468	
2025	$ 2,856	Cannabinoids	$ 2,827	483,323	724,984,615	1,115,360,947	743,574	1,052,327
		Fiber	$ 14	19,833	158,666,667	176,296,296	22,037	
		Grain	$ 14	22,453	26,943,396	28,361,470	23,635	

Sources and notes:

[1] Kentucky Department of Agriculture 2019 producer data.

[2] Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.

[3] The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.

[4] Product of yield and price per lb.

[5] Kentucky Department of Agriculture 2019 producer data.

[6] State departments of agriculture.

[7] See Table 3.

[8] Product of total producer sales and portions of total sales.

[9] Quotient of sales by use and price per acre.

[10] Product of yield and acres-worth sold.

[11] Quotient of volume sold and portion of harvested volume sold.

[12] Quotient of harvested volume and yield.

[13] Quotient of the sum of harvested acreage and portion of planted acreage harvested.

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To calculate total planted acreage nationwide in Table 4, from which planted acreage due to this rule will be estimated in Table 5, AMS assumed the following to remain constant in each year from 2020 through 2025: Portion of total sales by intended use; yields by intended use; prices per pound by intended use; portions of harvested volume sold by intended use; and the portion of planted acreage that is typically harvested. Using 2019 producer data from the Kentucky Department of Agriculture, AMS estimates that of total sales of hemp products, cannabinoids accounts for 99 percent, and fiber and grain each account for 0.5 percent. Also based on data from the Kentucky Department of Agriculture, AMS estimates that 65 percent of the harvested volume of hemp for cannabinoids is sold, 90 percent of hemp harvested for fiber is sold, and 95 percent of hemp harvested for grain is sold.[36] This assumption is also referenced in Table 5. AMS compared the hemp enterprise budgets published by seven different academic institutions for yield estimates which

[36] The Kentucky Department of Agriculture is widely recognized as a reliable source for hemp market data as it has collected data from its producers since the inception of its hemp program in 2014. Much of this data is publicly available and was cited by many commenters.

represent the growing conditions across the country. Aside from these seven, AMS is unaware of any other hemp enterprise budgets published by an academic institution.

Based on 2019 and 2020 prices published by the Jacobsen, AMS assumes constant per-pound prices for cannabinoids, fiber, and grain of $3.90, $0.09, and $0.53, respectively.[37] AMS acknowledges that prices are unlikely to remain constant from year to year, particularly for cannabinoids; however, AMS has considered 68 weeks of cannabinoids prices in determining its estimate of $3.90 per pound. This price assumes 6 percent CBD at $0.65 per CBD percentage per pound. Using these prices and yield estimates, AMS calculated a price per acre for each intended use of hemp. Finally, the assumption that 75 percent of planted acreage is harvested was estimated using data from multiple state departments of agriculture. The assumed constants of the portion of planted acreage that is harvested, yield by intended use, portion of harvested volume that is sold, and prices by intended use are also utilized in Table 5.

Table 5. Calculation of producer sales attributable to the rule

Assumed constant in each year

Intended use	Portion of planted acreage due to the rule[1]	Portion of planted acreage[2]	Portion of planted acreage harvested[3]	Yield (lbs/acre)[4]	Portion of harvested volume sold[5]	Price per lb[6]
Cannabinoids	20%	80%	75%	1,500	65%	$ 3.90
Fiber		3%		8,000	90%	$ 0.09
Grain		17%		1,200	95%	$ 0.53

Year	Total planted acreage[7]	Planted acreage due to rule[8]	Intended use	Planted acreage due to rule by use[9]	Harvested acreage due to rule[10]	Volume harvested due to rule[11]	Volume sold due to rule[12]	Sales by use due to rule (millions)[13]	Total sales due to rule (millions)[14]
2020	159,102	31,820	Cannabinoids	25,456	19,092	28,638,339	18,614,920	$ 72.6	$ 76
			Fiber	955	716	5,727,668	5,154,901	$ 0.5	
			Grain	5,409	4,057	4,868,518	4,625,092	$ 2.5	
2021	280,934	56,187	Cannabinoids	44,949	33,712	50,568,090	32,869,259	$ 128.2	$ 133
			Fiber	1,686	1,264	10,113,618	9,102,256	$ 0.8	
			Grain	9,552	7,164	8,596,575	8,166,747	$ 4.3	
2022	422,184	84,437	Cannabinoids	67,549	50,662	75,993,072	49,395,497	$ 192.6	$ 200
			Fiber	2,533	1,900	15,198,614	13,678,753	$ 1.2	
			Grain	14,354	10,766	12,918,822	12,272,881	$ 6.5	
2023	583,165	116,633	Cannabinoids	93,306	69,980	104,969,659	68,230,279	$ 266.1	$ 277
			Fiber	3,499	2,624	20,993,932	18,894,539	$ 1.7	
			Grain	19,828	14,871	17,844,842	16,952,600	$ 9.0	
2024	688,711	137,742	Cannabinoids	110,194	82,645	123,967,928	80,579,153	$ 314.3	$ 327
			Fiber	4,132	3,099	24,793,586	22,314,227	$ 2.0	
			Grain	23,416	17,562	21,074,548	20,020,820	$ 10.6	
2025	1,052,327	210,465	Cannabinoids	168,372	126,279	189,418,934	123,122,307	$ 480.2	$ 499
			Fiber	6,314	4,735	37,883,787	34,095,408	$ 3.1	
			Grain	35,779	26,834	32,201,219	30,591,158	$ 16.2	

Sources and notes:

[1] Portion of planted acreage in states which had plans approved by USDA for a hemp production program to begin in time for the 2020 growing season; planted acreage data from state departments of agriculture.

[2] The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.

[3] State departments of agriculture.

[4] Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.

[5] Kentucky Department of Agriculture 2019 producer data.

[6] The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.

[7] See Table 4.

[8] Product of total planted acreage and portion of planted acreage due to rule.

[9] Product of planted acreage due to rule and portion of planted acreage by use.

[10] Product of planted acreage due to rule by use and portion of planted acreage harvested.

[11] Product of harvested acreage due to rule and yield.

[12] Product of volume harvested due to rule and portion of harvested volume sold.

[13] Product of volume sold due to rule and price per lb.

[14] Sum of sales by use due to rule.

[37] The Jacobsen Publishing Company. Weekly hemp prices from July 2019 through August 2020.

In addition to the assumptions already identified in reference to Table 4, AMS assumes constant the portion of planted acreage due to the rule and portions of planted acreage by intended use. As described in the ''Baseline Definition'' section, AMS assumes that 20 percent of total planted acreage can be considered as attributable to the rule. This proportion represents the amount of planted acreage of the states that had plans approved by USDA for a hemp production program, as authorized by the 2018 Farm Bill, in time for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the 2014 pilot programs. By enrolling in the new hemp programs, these states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs.

The Jacobsen estimated that of total planted acreage in 2020, 80 percent was for cannabinoids, 3 percent was for fiber, and 17 percent was for grain. AMS acknowledges that planted acreage by intended use is likely to change from year to year as a result of market conditions. The portion of acreage intended for cannabinoids has, indeed, decreased from its levels in 2019, with grain and fiber gaining greater consumer attention. AMS is unaware of any data that forecasts planted acreage by intended use in years beyond 2020. For the purposes of this analysis, and for simplicity, therefore, AMS assumes constant the portions of planted acreage by intended use as reported for 2020.

To reiterate, AMS is aware that raw hemp product at the producer level may take years to enter the retail market. The analysis in Tables 4 and 5 is meant to show potential consumer demand for hemp products at the producer level in years 2020 through 2025, and not necessarily the producer sales of hemp cultivated in these specific years. These estimates are sensitive to changes in price. Because planted acreage is derived from total sales, a change in price causes an inverse change in the estimate of planted acreage; however, the relationship between price and sales is, of course, positive.

Many states reported to AMS that the land on which hemp is currently grown was previously utilized for cultivation of corn. Using data from the National Agricultural Statistics Service (NASS) on the production value of corn for grain and acres harvested, AMS determines a value per harvested acre of corn of $630. This value is a national average of the three-year period of 2017 through 2019, which are the most recent years for which data is available.[38] For the purposes of this analysis, this value of $630 per acre will serve as the opportunity cost to hemp producers. The opportunity cost is the potential returns that are foregone in pursuit of an alternative. The potential foregone returns, in this case, are $630 per acre for corn cultivation; and, the alternative is hemp cultivation. Applying this value to the estimates of acreage required to meet estimated producer sales as calculated in Table 5 results in the total opportunity cost to producers in years 2020 through 2025 as shown in Table 6.

TABLE 6—CALCULATION OF OPPORTUNITY COST OF HEMP CULTIVATION UNDER RULE

2017–2019 average returns per acre of corn for grain [1]						$630
Year	2020	2021	2022	2023	2024	2025
Planted acres due to rule [2]	31,820	56,187	84,437	116,633	137,742	210,465
Opportunity cost (millions) [3]	$20	$35	$53	$73	$87	$133

Sources and notes:
[1] National Agriculural Statistics Service (NASS).
[2] See Table 5 estimate calculation.
[3] Product of 2017–2019 average retunns per acre of corn for grain and acres worth of hemp sold.

In the IFR, AMS calculated an opportunity cost of $591 per acre, using an average of returns per acre for all cropland, weighted by area planted or bearing. This estimate utilized NASS crop totals for fruits, vegetables, and traditional field crops. At the time of the writing of the IFR, AMS had little information as to the prior uses of land currently being cultivated for hemp. To address this in the final rule, AMS sought input from state departments of agriculture, most of which reported that the land on which hemp is currently grown was previously utilized for cultivation of corn.

AMS has modified its sampling and testing requirements, which are described in the section in this rule titled ''Sampling for total THC'', to allow for ''performance-based sampling''. A performance-based protocol must have the potential to ensure at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level. Performance-based sampling achieves defined objectives and focuses on results. It differs significantly from a prescriptive action in which licensees are provided detailed direction on how those results are to be obtained. A performance-based approach would simply set a performance objective (*e.g.,* reliability of 95 percent) and allow the States and Indian Tribes considerable freedom in how to achieve that reliability objective with their sampling methodology.

To estimate the number of lots to be sampled in each year, AMS employs the Cochran Formula:

$$n_0 = \frac{Z^2 p(1-p)}{e^2},$$

where n_0 is the sample size, Z is the z-value associated with a confidence interval, p is the estimated proportion of the population that has the attribute in question, and e is the margin of error or the desired level of precision.

Inserting the z-value that corresponds to a 95 percent confidence interval, assuming maximum variability for p at 50 percent, and applying the margin of error of one percent results in the following sample size:

[38] NASS. Quick Stats. Variable ''Corn, grain—production, measured in $'' divided by variable ''Corn, grain—acres harvested''.

$$n_0 = \frac{1.96^2(0.5(1-0.5))}{0.01^2} = 9{,}604\ samples.$$

The Cochran Formula assumes an unlimited population size; however, the formula can be modified to return a smaller sample size for a finite population:

$$n = \frac{n_0}{1+\frac{(n_0-1)}{N}},$$

where n is the modified sample size, n_0 is the Cochran Formula sample size, and N is the population size.

Table 7 shows the number of sampled lots, *n,* required for a 95 percent confidence interval and one percent margin of error for each year's total number of lots, *N.* The total annual cost of sampling and testing borne by producers is calculated using a cost per lot of $565, which was estimated using hourly rates for inspectors and for laboratory services of $75 and $98, respectively; two hours, apiece, spent sampling, driving, and testing; 120 miles driven; and, $0.58 per mile compensation. In its calculation of total number of lots from total planted acreage, AMS utilized the portions of planted acreage by intended use, introduced in Table 5, and data from the Farm Service Agency (FSA) from which average lot sizes for hemp by intended use were derived.

Table 7. Calculation of sampling and testing costs to producers

Assumed constant in each year

Intended use	Portions of planted acreage by use[1]	Average number of acres per lot[2]	Cochran Formula[3]	Modification for small sample size[4]	Sampling & testing cost per lot[5]
Cannabinoids	80%	10	$n_0 = \frac{Z^2 p(1-p)}{e^2}$	$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$	$ 565
Fiber	3%	15			
Grain	17%	37			

Year	Total planted acreage[6]	Intended use	Total planted acreage by use[7]	Total number of lots[8]	n_0	n	Sampling & testing costs (millions)[9]
2020	159,102	Cannabinoids	127,282	12,728	9,604	5,659	$ 3.20
		Fiber	4,773	318			
		Grain	27,047	731			
2021	280,934	Cannabinoids	224,747	22,475	9,604	6,886	$ 3.89
		Fiber	8,428	562			
		Grain	47,759	1,291			
2022	422,184	Cannabinoids	337,747	33,775	9,604	7,606	$ 4.30
		Fiber	12,666	844			
		Grain	71,771	1,940			
2023	583,165	Cannabinoids	466,532	46,653	9,604	8,069	$ 4.56
		Fiber	17,495	1,166			
		Grain	99,138	2,679			
2024	688,711	Cannabinoids	550,969	55,097	9,604	8,272	$ 4.67
		Fiber	20,661	1,377			
		Grain	117,081	3,164			
2025	1,052,327	Cannabinoids	841,862	84,186	9,604	8,688	$ 4.91
		Fiber	31,570	2,105			
		Grain	178,896	4,835			

Sources and notes:

[1] The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.

[2] Farm Service Agency producer data.

[3] Where n_0 is the sample size, Z is the z-value associated with a confidence interval, p is the estimated proportion of the population that has the attribute in question, and e is the margin of error or the desired level of precision.

[4] Where n is the modified sample size, n_0 is the Cochran Formula sample size, and N is the population size.

[5] Assumes hourly rates for inspector of $75 and for laboratory services of $98; also assumes time spent sampling, time spent driving, and time spent testing of 2 hours each; assumes 120 miles driven and mileage compensation rate of $0.58 per mile.

[6] See Table 4.

[7] Product of total planted acreage and portions of planted acreage by use.

[8] Quotient of total planted acreage and average number of acres per lot.

[9] Product of sample size n and sampling & testing cost per lot.

Some portion of tested lots are likely to return results with THC concentrations greater than 0.3 percent. To estimate this percentage, AMS utilized data, specific to this very question, collected by the National Industrial Hemp Regulators during a November 2019 meeting. The average portion of tests that would return results of THC concentrations greater than 0.3 percent, weighted by the number of tests administered in each state, was 25 percent. In Table 8, AMS applies this percentage to estimate total noncompliant lots in each year and the cost to dispose of noncompliant acreage. AMS is aware of other estimates of THC concentration failure rates. As of November 2020, States and Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, approximately 12 percent were destroyed due to THC levels exceeding 0.3 percent. This data, however, is limited because many approved plans have not all been fully

implemented. USDA expects more data will be available as the 2021 season begins and States and Tribes implement their programs.

Table 8. Calculation of disposal costs to producers

Assumed constant in each year

Intended use	Portion of tests with results of noncompliant THC levels[1]	Portions of planted acreage by use[2]	Average number of acres per lot[3]	Disposal time per acre of hemp (hours)[4]	Compliance officer hourly salary[5]	Cost per acre of noncompliant hemp disposal[6]
Cannabinoids	25%	80%	10	0.25	$ 57	$ 14.25
Fiber		3%	15			
Grain		17%	37			

Year	Intended use	Sampled & tested lots[7]	Noncompliant lots[8]	Noncompliant acres[9]	Total noncompliant acreage disposal costs (millions)[10]
2020	Cannabinoids	5,659	1,415	11,319	$ 0.30
	Fiber			637	
	Grain			8,899	
2021	Cannabinoids	6,886	1,721	13,772	$ 0.36
	Fiber			775	
	Grain			10,828	
2022	Cannabinoids	7,606	1,902	15,212	$ 0.40
	Fiber			856	
	Grain			11,961	
2023	Cannabinoids	8,069	2,017	16,139	$ 0.42
	Fiber			908	
	Grain			12,689	
2024	Cannabinoids	8,272	2,068	16,544	$ 0.43
	Fiber			931	
	Grain			13,008	
2025	Cannabinoids	8,688	2,172	17,377	$ 0.46
	Fiber			977	
	Grain			13,663	

Sources and notes:

[1] National Industrial Hemp Regulators' conference call. November 2019.

[2] The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.

[3] Farm Service Agency producer data.

[4] AMS estimate based on state and producer feedback.

[5] Bureau of Labor and Statistics. Occupational Employment Statistics Survey. May 2019; see PRA section.

[6] Product of disposal time per acre of hemp and compliance officer hourly salary.

[7] See Table 7 sample size n.

[8] Product of sampled & tested lots and portion of tests with results of noncompliant THC levels.

[9] Product of noncompliant lots, portions of planted acreage by use, and average number of acres per lot.

[10] Product of the sum of noncompliant acres and cost per acre of noncompliant hemp disposal.

AMS has issued guidance on approved methods for disposal of noncompliant hemp material, including plowing under, mulching or composting, disking, bush mowing or chopping, deep burial, and burning. AMS requires disposal of noncompliant hemp using one of these methods. Discussion with state departments of agriculture and producers led AMS to estimate an average of 15 minutes per acre required to dispose of noncompliant material. This 15-minute estimate is an average across all disposal methods. According to the May 2019 Occupational Employment Statistics Survey of the Bureau of Labor and Statistics, the mean hourly wage of a compliance officer is $35. Assuming 39 percent of total compensation accounts for benefits, then total compensation of a compliance officer is $57 per hour. This is described in the Paperwork Reduction Act (PRA) section of this

rule. Applying the total hourly salary of a compliance officer to the disposal time per acre of hemp results in a per acre cost of $14.25 for disposal of noncompliant hemp acreage.

The PRA section details the burdens of reporting and recordkeeping and their associated costs. Table 9 shows the calculations of the reporting and recordkeeping costs to producers that will be imposed by this rule. All assumptions in this table have been previously introduced. The PRA section describes how each estimate of time was calculated per required form.

Table 9. Calculation of total reporting and recordkeeping costs to producers

Assumed constant in each year

Portions of producer licenses issued by Plan[1]		Portion of total planted acreage or lots under USDA Plan[2]	Reporting & recordkeeping hours per producer (required of all)[3]		Reporting & recordkeeping hours per disposed lot[4]		Hourly salary of a compliance officer[5]
USDA Plan	State/Tribal Plans	15%	USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	$ 57
20%	80%		2.14	2.25	0.42	0.25	

Year	Producers[6]			Noncompliant lots for disposal[7]		Total reporting & recordkeeping hours[8]		Total producer reporting & recordkeeping cost (millions)[9]
	Total	USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	
2020	20,000	4,000	16,000	212	1,203	8,640	36,289	$ 2.56
2021	22,000	4,400	17,600	258	1,463	9,514	39,953	$ 2.82
2022	24,200	4,840	19,360	285	1,616	10,466	43,951	$ 3.10
2023	26,620	5,324	21,296	303	1,715	11,508	48,330	$ 3.41
2024	29,282	5,856	23,426	310	1,758	12,650	53,131	$ 3.75
2025	32,210	6,442	25,768	326	1,846	13,908	58,422	$ 4.12

Sources and notes:

[1] Portions of the number of producers under the USDA Plan and the State and Tribal Plans in 2020; data from state departments of agriculture.

[2] Portion of planted acreage in states operating under USDA Plan; planted acreage data from state departments of agriculture.

[3] See PRA section.

[4] See PRA section.

[5] Bureau of Labor and Statistics. Occupational Employment Statistics Survey. May 2019; see PRA section.

[6] See Table 2 for total producers; product of total producers and portions of producer licenses issued by Plan.

[7] Product of noncompliant lots in Table 8 and portions of total planted acreage or lots under USDA Plan versus State/Tribal Plans.

[8] Sum of the product of reporting & recordkeeping hours per producer and producers and the product of reporting & recordkeeping hours per disposed lot and noncompliant lots for disposal.

[9] Product of hourly salary of a compliance officer and the sum of total reporting & recordkeeping hours.

In order to obtain a producer license, AMS requires that each producer, or key participant of a business entity, submit to a background check, or criminal history report, at least every three years. A key participant is a person with a direct or indirect financial interest in the hemp-producing entity, including a chief executive officer, a chief operating officer, and a chief financial officer. The cost of a criminal history report conducted by the Federal Bureau of Investigation (FBI) is $18 per record. For the purposes of this analysis, AMS assumes each producer license to represent three key participants. The total annual cost of a background check for three key participants every three years at minimum is $18 per producer.

The producer net benefits of this rule to society are shown in Table 10. Subtracted from producer sales due to the rule are the opportunity costs of the land on which hemp is currently grown; sampling and testing costs; disposal of noncompliant acreage; reporting and recordkeeping burdens; and, annual background checks. The producer net benefits of this rule to society range from $49 million in 2020 to $357 million in 2025.

TABLE 10—PRODUCER NET BENEFITS TO SOCIETY

[Millions]

	2020	2021	2022	2023	2024	2025
Grower sales due to rule	$75.51	$133.34	$200.38	$276.78	$326.88	$499.46
Opportunity cost	(20.05)	(35.40)	(53.20)	(73.48)	(86.78)	(132.59)
Sampling & testing	(3.20)	(3.89)	(4.30)	(4.56)	(4.67)	(4.91)
Disposal of noncompliant material	(0.30)	(0.36)	(0.40)	(0.42)	(0.43)	(0.46)
Reporting & recordkeeping	(2.56)	(2.82)	(3.10)	(3.41)	(3.75)	(4.12)
Background checks	(0.36)	(0.40)	(0.44)	(0.48)	(0.53)	(0.58)
Net benefits	49.05	90.47	138.95	194.43	230.72	356.80

States, Indian Tribes, and USDA

States and Indian Tribes have the authority to establish fee structures to fund their hemp programs. As of the writing of this analysis, about half of the states with plans approved by USDA reported their programs as being full funded through user-fees. To estimate the cost of administering a hemp program, AMS calculated an average of the total fees charged to producers by these states, which reported as fully user-fee funded, to use as a proxy for the per producer cost of hemp program administration. The fees used to calculate this average included those with such designations as application fee, site registration fee, licensing fee, and others. The average did not include fees associated with sampling and testing as these were calculated separately in Table 7. AMS estimates an average cost per producer of hemp program administration of $800 annually. AMS has no reason to believe that Indian Tribes or USDA will be any more or any less efficient than states in program administration. AMS believes, therefore, that this figure is a suitable proxy for the cost of program administration to states, Indian Tribes, and USDA per producer who cultivates hemp as a result of this rule.

As discussed in the ''Baseline Definition'' section, 17 states opted to participate in the new hemp programs authorized by the 2018 Farm Bill in time for the 2020 growing season. These states represented 20 percent of both planted acreage nationwide and the number of producers nationwide. By applying this percentage to the total number of producers in each year, as shown in Table 2, AMS estimates the number of producers that will cultivate hemp due to this rule. The product of the number of producers due to this rule and the $800 per grower proxy for administration costs results in program administration costs to States, Indian Tribes, and USDA of $3 million in 2020 to $5 million in 2025.

This rule places a reporting and recordkeeping burden on states and Indian Tribes as detailed in the PRA section of this rule. The total time required per state or tribe for reporting and recordkeeping is 25.25 hours annually. AMS assumes constant the number of states and Indian Tribes that will operate their own hemp programs at 100 in total from 2020 through 2025. In total, the time required of 100 states and Indian Tribes for 25.25 hours of reporting and recordkeeping is 2,525 hours. Applying the hourly salary of a compliance officer of $57 to this total results in an annual cost to all states and Indian Tribes of reporting and recordkeeping of $143,919, or $1,439 per state or tribe.

The total administration costs to states, Indian Tribes, and USDA are calculated in Table 11. They include the costs to all three entities of program administration, and the costs of reporting and recordkeeping to states and Indian Tribes. Total administration costs to states, Indian Tribes, and USDA range from $3 million in 2020 to $5 million in 2025.

TABLE 11—TOTAL COSTS TO STATES, INDIAN TRIBES, AND USDA

[Millions]

	2020	2021	2022	2023	2024	2025
Program administration	$(3.20)	$(3.52)	$(3.87)	$(4.26)	$(4.69)	$(5.15)
Reporting & recordkeeping	(0.14)	(0.14)	(0.14)	(0.14)	(0.14)	(0.14)
Total costs	(3.34)	(3.66)	(4.02)	(4.40)	(4.83)	(5.30)

Laboratories

This rule also places a reporting and recordkeeping burden on laboratories as they will be required to report on the results of samples tested for THC content to the entities administering the hemp programs. The PRA section of this rule estimates an annual reporting and recordkeeping requirement for laboratories of 0.58 hours per sampled and tested lot. As calculated in Table 7, the total number of lots to be sampled and tested in each year is 5,659 in 2020; 6,886 in 2021; 7,606 in 2022; 8,069 in 2023; 8,272 in 2024; and, 8,688 in 2025. Multiplying the total number of lots to be sampled and tested in each year by the annual reporting and recordkeeping requirement of 0.58 hours per sampled and tested lot and by the hourly salary of a compliance officer of $57 results in the total annual costs to laboratories as shown in Table 12.

TABLE 12—TOTAL COSTS TO LABORATORIES

[Millions]

	2020	2021	2022	2023	2024	2025
Reporting & recordkeeping	$(0.19)	$(0.23)	$(0.25)	$(0.27)	$0.27)	$(0.29)

Total Net Benefit

Producers, states, Indian Tribes, and USDA, and laboratories are the entities most likely to be impacted by this rule. For this reason, the net benefits or costs of this rule to these entities have been evaluated in this analysis. The total net benefits to society as a whole and their present values by year are shown in Table 13. The rule has a positive net benefit in every year, ranging from $46 million in 2020 to $351 million in 2025.

TABLE 13—TOTAL NET BENEFITS TO SOCIETY

[Millions]

Entity	2020	2021	2022	2023	2024	2025
Producers	$49.05	$90.47	$138.95	$194.43	$230.72	$356.80
States, Tribes & USDA	(3.34)	(3.66)	(4.02)	(4.40)	(4.83)	(5.30)

TABLE 13—TOTAL NET BENEFITS TO SOCIETY—Continued

[Millions]

Entity	2020	2021	2022	2023	2024	2025
Laboratories	(0.19)	(0.23)	(0.25)	(0.27)	(0.27)	(0.29)
Total	45.52	86.58	134.68	189.76	225.61	351.21

Present values of net benefits annualized at the given discount rates

Discount rates	2020	2021	2022	2023	2024	2024
3%	$45.52	$84.06	$126.95	$173.66	$200.45	$302.96
7%	45.52	80.92	117.63	154.90	172.12	250.41

Alternatives

In developing this final rule, AMS considered several alternatives to the policies that were adopted. The first of these was related to methodologies for sampling. The methodologies considered include sampling and testing of all lots, as mandated in the IFR, sampling and testing based on risk, and sampling and testing based on performance. The latter of these was the sampling methodology that was chosen for the final rule as it results in the lowest total cost to producers. Performance-based sampling also grants flexibility to States and Indian Tribes in the development of sampling methodologies. In the IFR, AMS required sampling of every hemp lot, regardless of intended use; however, AMS has determined that compliance to this method would too greatly burden producers as well as program administrators, whose responsibility it would be to enforce it. AMS also considered requiring risk-based sampling, which would mandate minimum portions of sampling of lots by intended use. The portions of lots to be sampled by intended use that were considered were 50 percent of lots for cannabinoids, 10 percent of lots for fiber, and 10 percent of lots for grain. AMS currently lacks sufficient data to successfully carry out a risk-based sampling methodology that would be applicable to the varying growing regions nationwide; therefore, the risk-based sampling methodology was not chosen for this final rule. An analysis of these sampling methodologies is illustrated in Table 14.

Table 14. Analysis of alternative sampling methodologies

Intended use	Portions to be sampled & tested based on methodology			Cost per lot of sampling & testing
	All lots (IFR)	Risk-based	Performance-based (FR)	
Cannabinoids	100%	50%	USDA Plan acreage only	$ 565
Fiber		10%		
Grain		10%		

Year	Intended use	Total number of lots	Lots sampled & tested			Total cost of sampling & testing		
			IFR	Risk-based	Performance-based	IFR	Risk-based	Performance-based
2020	Cannabinoids	12,728	13,777	6,469	5,659	$ 7,784,210	$ 3,654,983	$ 3,197,536
	Fiber	318						
	Grain	731						
2021	Cannabinoids	22,475	24,327	11,423	6,886	$ 13,744,954	$ 6,453,779	$ 3,890,515
	Fiber	562						
	Grain	1,291						
2022	Cannabinoids	33,775	36,559	17,166	7,606	$ 20,655,739	$ 9,698,656	$ 4,297,440
	Fiber	844						
	Grain	1,940						
2023	Cannabinoids	46,653	50,499	23,711	8,069	$ 28,531,888	$ 13,396,808	$ 4,559,260
	Fiber	1,166						
	Grain	2,679						
2024	Cannabinoids	55,097	59,639	28,003	8,272	$ 33,695,823	$ 15,821,472	$ 4,673,701
	Fiber	1,377						
	Grain	3,164						
2025	Cannabinoids	84,186	91,126	42,787	8,688	$ 51,486,114	$ 24,174,691	$ 4,908,947
	Fiber	2,105						
	Grain	4,835						

Sources and notes:
See Table 7 for calculations and references.

Secondly, AMS considered retaining at 0.5 percent the limit for total THC content that would result in a negligent violation, as required in the IFR. Based on comments, however, AMS has determined this requirement to too greatly burden producers as factors beyond the control of the producer, such as seed genetics, weather and climate, may cause an increase in total THC-levels. By increasing the negligent violation threshold to 1.0 percent, AMS diminishes the risk to producers of incurring a negligent violation, which results in time and cost savings to producers and to program-administering entities.

Finally, AMS considered mandating a post-sample harvest window of 15 days, as required in the IFR. Based on comments and in consideration of the time required to complete sampling and testing activities, AMS has determined that requiring a 15-day post-sample harvest window would place undue strain on resources. AMS believes that the extension of the post-sample harvest window to 30 days will provide producers with a beneficial flexibility to adjust to unforeseen weather events and will accommodate complicated harvest processes.

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities. AMS prepared an initial regulatory flexibility act analysis presented with the interim final rule, and has now prepared this Final Regulatory Flexibility Act Analysis. AMS has determined that this rule will have a significant economic impact on a substantial number of small businesses because many small businesses will not be able to participate in the hemp market without this rule.

Need for Regulation

The rule is necessary to facilitate the domestic cultivation of hemp for sale into the market for hemp products by creating a set of minimum standards to ensure that hemp being produced under this program meets all statutory requirements. The rule establishes minimum requirements for States and Indian Tribes to obtain program approval and, for producers operating under the Federal program to obtain a license and meet operating requirements under that license. Without these provisions, it would not be possible to grow hemp legally.

Both the declassification of hemp, and the prohibition on interference with interstate transportation apply to hemp that is grown under an approved State or Tribal plan, or under a Federal license. As a result, this regulation facilitates provisions of the 2018 Farm Bill that would otherwise be self-implementing.

Overview of the Action

The 2018 Farm Bill granted regulatory authority of domestic hemp production to the State departments of agriculture, Tribal governments, and USDA. States and Indian Tribes wishing to operate their own programs must submit to USDA plans that include provisions for maintaining information regarding the land on which hemp is produced, for testing the levels of THC, for disposal of plants that do not meet necessary requirements, and for procedures to ensure compliance with the requirements of the new part, including background checks of all key participants. State and Tribal Plans must be approved by USDA. This rule outlines requirements by which the USDA would approve plans submitted by States and Tribal governments for oversight of hemp production. The 2018 Farm Bill also directs USDA to develop a plan for use by hemp producers in States or Indian Tribes where no State or Tribal Plan has been approved and that do not prohibit the cultivation of hemp. These actions will promote consistency in regulations governing the legal production of hemp across the country.

Potentially Affected Small Entities

The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $1 million. Unfortunately, very little data exists on hemp grower sales receipts. To conduct this analysis, however, AMS estimated prices per acre by intended use of hemp to find the acreage equivalent of $1 million per intended use. AMS encountered data limitations due to the lack of reporting by States and Tribes that have not started implementing the 2018 Farm Bill provisions and the extension of the 2014 Farm Bill provisions which do not require reporting from States.

To this end, AMS utilized data on acreage by intended use from the Kentucky Department of Agriculture and the Montana Department of Agriculture. Together, Kentucky and Montana make up a large amount of domestic acreage and represent diversity in hemp planted by intended use. For the purpose of this analysis, therefore, AMS assumes that the combined planted acreage by intended use in Kentucky and Montana adequately represent the planted acreage by intended use across the United States.

For yield estimates, AMS compared the hemp enterprise budgets published by seven different academic institutions that represent the growing conditions across the country. Aside from these seven, AMS is unaware of any other hemp enterprise budgets published by an academic institution. AMS sourced 2019 and 2020 prices from the Jacobsen to estimate per-pound prices for cannabinoids, fiber, and grain of $3.90, $0.09, and $0.53, respectively. The price for cannabinoids assumes 6 percent CBD content at $0.65 per CBD percentage per pound.

Using these prices and yield estimates, AMS calculated a price per acre for each intended use of hemp, as shown in Table 15. From the estimates of price per acre by intended use, AMS calculated the equivalent of $1 million in acres of hemp product per intended use. Of the 922 unique producers in the combined data from the Kentucky and Montana Departments of Agriculture, 97 percent reported acreage no greater than the amounts necessary to reach $1 million, based on the estimated prices per acre. Assuming that these data are representative of the U.S. as a whole, then 97 percent of domestic producers of hemp would meet the SBA size standard of a small business of annual receipts of no greater than $1 million.

Table 15. Calculation of the portion of producers considered to be small per SBA standards

Intended use	Yield (lbs/acre)[1]	Price per lb[2]	Price per acre[3]
Cannabinoids	1,500	$ 3.90	$ 5,850
Fiber	8,000	$ 0.09	$ 720
Grain	1,200	$ 0.53	$ 636

Intended use	Acreage equivalent of $1 million[4]	Small producers
Cannabinoids	171	97%
Fiber	1,389	
Grain	1,572	

Sources and notes:

[1] Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.

[2] The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.

[3] Product of yield and price per lb.

[4] Quotient of $1 million and price per acre by intended use.

Alternatives Considered To Minimize Impacts of the Rule

In developing this final rule, due to comments received and experiences from the 2020 season, AMS considered several alternatives to the policies that were adopted. The first of these was related to methodologies for sampling. The methodologies considered include sampling and testing of all lots, as mandated in the IFR, sampling and testing based on risk, and sampling and testing based on performance. The latter of these was the sampling methodology that was chosen for the final rule as it results in the lowest total cost to producers. Performance-based sampling also grants flexibility to States and Indian Tribes in the development of sampling methodologies. Some States currently have considered performance-based sampling under the 2014 Farm Bill. However, this information is not available and will need to be evaluated and approved by USDA as part of State and Tribal plans before it can be implemented under the 2018 Farm Bill program if States and Tribes decide to utilize this option. In the IFR, AMS required sampling of every hemp lot, regardless of intended use; however, AMS has determined that compliance to this method would too greatly burden producers as well as program administrators, whose responsibility it would be to enforce it. AMS also considered requiring risk-based sampling, which would mandate minimum portions of sampling of lots by intended use. The portions of lots to be sampled by intended use that were considered were 50 percent of lots for cannabinoids, 10 percent of lots for fiber, and 10 percent of lots for grain. AMS currently lacks sufficient data to successfully carry out a risk-based sampling methodology that would be applicable to the varying growing regions nationwide; therefore, the risk-based sampling methodology was not chosen for this final rule.

Secondly, AMS considered retaining at 0.5 percent the limit for total THC content that would result in a negligent violation, as required in the IFR. Based on comments, however, AMS has determined this requirement to too greatly burden producers as factors beyond the control of the producer, such as seed genetics, weather and climate, may cause an increase in total THC-levels. By increasing the negligent violation threshold to 1.0 percent, AMS diminishes the risk to producers of incurring a negligent violation, which results in time and cost savings to producers and to program-administering entities.

Finally, AMS considered mandating a post-sample harvest window of 15 days, as required in the IFR. Based on comments and in consideration of the time required to complete sampling and testing activities, AMS has determined that requiring a 15-day post-sample harvest window would place undue strain on resources. AMS believes that the extension of the post-sample harvest window to 30 days will provide producers with a beneficial flexibility to adjust to unforeseen weather events and will accommodate complicated harvest processes.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as ''major,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 7 CFR Part 990

Acceptable hemp THC level, Agricultural commodities, Cannabis, Corrective action plan, Delta-9 tetrahydrocannabinol, Drugs, Dry weight basis, Hemp, Liquid chromatography, Laboratories, Marijuana.

■ For the reasons stated in the preamble, AMS revises 7 CFR part 990 to read as follows:

PART 990—DOMESTIC HEMP PRODUCTION PROGRAM

Subpart A—Definitions

Sec.
990.1 Meaning of terms.

Subpart B—State and Tribal Hemp Production Plans

990.2 State and Tribal plans; General authority.
990.3 State and Tribal plans; Plan requirements.
990.4 USDA approval of State and Tribal plans.
990.5 Audit of State or Tribal plan compliance.
990.6 Violations of State and Tribal plans.
990.7 Establishing records with USDA Farm Service Agency.
990.8 Production under Federal law.

Subpart C—USDA Hemp Production Plan

990.20 USDA requirements for the production of hemp.
990.21 USDA hemp producer license.
990.22 USDA hemp producer license approval.
990.23 Reporting hemp crop acreage with USDA Farm Service Agency.
990.24 Responsibility of a USDA licensee prior to harvest.
990.25 Standards of performance for detecting total delta-9 tetrahydrocannabinol (THC) concentration levels.
990.26 Responsibility of a USDA producer after laboratory testing is performed.
990.27 Non-compliant cannabis plants.
990.28 Compliance.
990.29 Violations.
990.30 USDA producers; License suspension.
990.31 USDA licensees; Revocation.
990.32 Recordkeeping requirements.

Subpart D—Appeals

990.40 General adverse action appeal process.
990.41 Appeals under the USDA hemp production plan.
990.42 Appeals under a State or Tribal hemp production plan.

Subpart E—Administrative Provisions

990.60 Agents.
990.61 Severability.
990.62 [Reserved]
990.63 Interstate transportation of hemp.

Subpart F—Reporting Requirements

990.70 State and Tribal hemp reporting requirements.
990.71 USDA plan reporting requirements.

Authority: 7 U.S.C. 1639o note, 1639p, 1639q, 1639r.

Subpart A—Definitions

§ 990.1 Meaning of terms.

Words used in this subpart in the singular form shall be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of provisions and regulations of this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

Acceptable hemp THC level. When a laboratory tests a sample, it must report the total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis and the measurement of uncertainty. The acceptable hemp THC level for the purpose of compliance with the requirements of State or Tribal hemp plans or the USDA hemp plan is when the application of the measurement of uncertainty to the reported total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3 percent or less. For example, if the reported total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35 percent and the measurement of uncertainty is ±0.06 percent, the measured total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29 percent to 0.41 percent. Because 0.3 percent is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of plan compliance. This definition of ''acceptable hemp THC level'' affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of ''marihuana,'' 21 U.S.C. 802(16), in the CSA.

Act. Agricultural Marketing Act of 1946.

Agricultural Marketing Service or *AMS.* The Agricultural Marketing Service of the U.S. Department of Agriculture.

Applicant. (1) A State or Indian Tribe that has submitted a State or Tribal hemp production plan to USDA for approval under this part; or

(2) A producer in a State or territory of an Indian Tribe that is not subject to a State or Tribal hemp production plan and who has submitted an application to USDA for a license under the USDA hemp production plan under this part.

Audit. An official inspection of an individual's or organization's accounts and paperwork or documentation by an independent body. An audit also refers to a compliance audit of States and Indian Tribes with approved hemp production plans by USDA to determine compliance with their approved plan, the regulations in this part, and the Act. For this part, audit relates to documentation related to authorities under the 2018 Farm Bill to produce hemp.

Cannabis. A genus of flowering plants in the family Cannabaceae of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. Cannabis refers to any form of the plant in which the total delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined.

Controlled Substances Act (CSA). The Controlled Substances Act as codified in 21 U.S.C. 801 *et seq.*

Conviction. Means any plea of guilty or nolo contendere, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. For purposes of this part, a conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or nolo contendere and enter a plea of not guilty and the case is subsequently dismissed, the individual is no longer considered to have a conviction for purposes of this part.

Corrective action plan. A plan proposed by a licensed hemp producer and approved by the governing entity for correcting a negligent violation or non-compliance with the applicable State, Tribal, or USDA hemp production plan, its terms, the applicable law(s), and/or this part. Also, a plan proposed by a State or Tribal government for correcting violations or non-compliances with USDA-approved State or Tribal hemp programs.

Criminal history report. The Federal Bureau of Investigation's Identity History Summary.

Culpable mental state greater than negligence. To act intentionally, knowingly, willfully, or recklessly.

Decarboxylated. The completion of the chemical reaction that converts THC-acid (THCA) into delta-9 THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a molecular mass conversion ratio that sums delta-9 THC and eighty-seven and seven tenths (87.7) percent of THC-acid ((delta-9 THC) + (0.877 * THCA)).

Decarboxylation. The removal or elimination of carboxyl group from a molecule or organic compound.

Disposal. An activity that transitions the non-compliant product into a non-retrievable or non-ingestible form. Such activities include plowing, tilling, or disking plant material into the soil; mulching, composting, chopping, or bush mowing plant material into green

manure; burning plant material; burying plant material into the earth and covering with soil.

Delta-9 tetrahydrocannabinol or *THC.* Delta-9 THC is the primary psychoactive component of cannabis. For the purposes of this part, delta-9 THC and THC are interchangeable.

Drug Enforcement Administration or DEA. The United States Drug Enforcement Administration.

Dry weight basis. The ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

Entity. A corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in the hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.

Farm Service Agency or *FSA.* An agency of the United States Department of Agriculture.

Gas chromatography or *GC.* A type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.

Geospatial location. A location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

Handle. To harvest or store hemp plants or hemp plant parts prior to the delivery of such plants or plant parts for further processing. ''Handle'' also includes the disposal of cannabis plants that are not hemp for purposes of chemical analysis and disposal of such plants.

Hemp. The plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Immature plants. A cannabis plant that is not flowering.

Indian Tribe or *Tribe.* As defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Information sharing system. The database that allows USDA to share information collected under State, Tribal, and USDA plans with Federal, State, Tribal, and local law enforcement.

Key participants. A sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer, and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers. This definition also does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.

Law enforcement agency. Any Federal, State, Tribal, or local law enforcement agency.

Liquid chromatography or *LC.* A type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. LC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid absorbent material to separate and analyze compounds.

Lot. A contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout the area. The term lot also means the terms ''farm,'' ''tract,'' ''field,'' and ''subfield'' as these are terms used by FSA in 7 CFR 718.2 to define lot.

Marijuana. Or ''marihuana'', as defined in the CSA, means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The term ''marihuana'' does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (7 U.S.C. 1639o). ''Marihuana'' means all cannabis that tests as having a THC concentration level of higher than 0.3 percent on a dry weight basis.

Measurement of Uncertainty (MU). The parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

Negligence. Failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part.

Phytocannabinoid. Cannabinoid chemical compounds found in the cannabis plant, two of which are delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD).

Plan. A set of criteria or regulations under which a State or Tribal government, or USDA, monitors and regulates the production of hemp.

Post-decarboxylation. In the context of testing methodologies for THC concentration levels in hemp, means a value determined after the process of decarboxylation that determines the potential total delta-9 tetrahydrocannabinol content derived from the sum of the THC and THCA content and reported on a dry weight basis. The post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The post-decarboxylation value of THC can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact. This technique requires the use of the following conversion: [Total THC = (0.877 x THCA) + THC] which calculates the potential total THC in a given sample. See the definition for decarboxylation.

Produce. To grow hemp plants for market, or for cultivation for market, in the United States.

Producer. A producer as defined in 7 CFR 718.2 specifically of hemp.

Remediation. Remediation refers to the process of rendering non-compliant cannabis, compliant. Remediation can occur by removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds. Remediation can also occur by shredding the entire plant into a biomass like material, then re-testing the shredded biomass material for compliance.

Reverse distributor. A person who is registered with the DEA in accordance with 21 CFR 1317.15 to dispose of

marijuana under the Controlled Substances Act.

Secretary. The Secretary of Agriculture of the United States Department of Agriculture.

State. Any one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

State department of agriculture. The agency, commission, or department of a State government responsible for agriculture in the State.

Territory of the Indian Tribe. (1) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation;

(2) All dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State;

(3) All Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and

(4) Any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

Total THC. Total THC is the value determined after the process of decarboxylation, or the application of a conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total delta-9 tetrahydrocannabinol content derived from the sum of the THC and THCA content and reported on a dry weight basis. This post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, such as gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The total THC can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact. This technique requires the use of the following conversion: [Total THC = (0.877 x THCA) + THC] which calculates the potential total THC in a given sample.

Tribal government. The governing body of an Indian Tribe.

USDA licensee. A person, partnership, or corporation licensed under the USDA planto grow hemp under the terms established in this part and who produces hemp.

Subpart B—State and Tribal Hemp Production Plans

§ 990.2 State and Tribal plans; General authority.

States or Indian Tribes desiring to have primary regulatory authority over the production of hemp in the State or territory of the Indian Tribe shall submit to the Secretary for approval, through the State department of agriculture (in consultation with the Governor and chief law enforcement officer of the State) or the Tribal government, as applicable, a plan under which the State or Indian Tribe monitors and regulates that production.

§ 990.3 State and Tribal plans; Plan requirements.

(a) *General requirements.* A State or Tribal plan submitted to the Secretary for approval must include the practice and procedures described in this paragraph (a).

(1) A State or Tribal plan must include a practice to collect, maintain, and report to the Secretary relevant, real-time information for each producer licensed or authorized to produce hemp under the State or Tribal plan regarding:

(i) Contact information as described in § 990.70(a)(1);

(ii) A legal description of the land on which the producer will produce hemp in the State or territory of the Indian Tribe including, to the extent practicable, its geospatial location; and

(iii) The status and number of the producer's license or authorization in a format prescribed by USDA.

(2) A State or Tribal plan must include a procedure for accurate and effective sampling of hemp that includes the requirements in this paragraph (a)(2).

(i) Samples from cannabis plants must be collected within 30 days prior to the anticipated harvest, for total delta-9 tetrahydrocannabinol concentration level testing. Samples must be collected by a sampling agent. Producers may not collect samples from their own growing facilities.

(ii) Samples shall be obtained from the flowering tops of plants when flowering tops are present, and shall be approximately five to eight inches in length from the ''main stem'' (that includes the leaves and flowers), ''terminal bud'' (that occurs at the end of a stem), or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant.

(iii) The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, States and Tribes may adopt a performance-based method that meets the requirements in paragraphs (a)(2)(iii)(A) and (B) of this section.

(A) The alternative method must be part of the State or Tribe's hemp plan and is subject to USDA approval.

(B) The alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabisplant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level. The alternative method may consider one or more of the following factors:

(*1*) Seed certification process or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe;

(*2*) Whether the producer is conducting research on hemp;

(*3*) Whether a producer has consistently produced compliant hemp plants over an extended period of time; and

(*4*) Factors similar to those in this paragraph (a)(2)(iii)(B).

(iv) During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site if possible.

(v) Sampling agents shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants (whether growing or harvested), to areas where hemp is grown and stored, and to all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(vi) A producer shall not harvest the cannabis crop prior to samples being taken.

(vii) Sampling agents must be trained using USDA, State, or Tribal training procedures. States and Indian Tribes must maintain information, available to producers, about trained sampling agents.

(3) A State or Tribal plan must include a procedure for testing that is able to accurately identify whether the sample contains a total delta-9 tetrahydrocannabinol content concentration level that exceeds the acceptable hemp THC level. The procedure must include a validated testing methodology that uses post-

decarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result must report the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting the requirements of this paragraph (a)(3) include, but are not limited to, gas or liquid chromatography with detection. The total THC concentration level shall be determined and reported on a dry weight basis.

(i) Any test of a representative sample resulting in higher than the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part and shall be disposed of or remediated in accordance with § 990.27.

(ii) Samples of hemp plant material from one lot shall not be commingled with hemp plant material from other lots.

(iii) Laboratories conducting analytical testing for purposes of detecting the concentration levels of Total THC shall meet the following requirements:

(A) Laboratory quality assurance must ensure the validity and reliability of test results;

(B) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing;

(C) The demonstration of testing validity must ensure consistent, accurate analytical performance;

(D) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part; and

(E) Effective disposal procedures for non-compliant samples that do not meet the requirements of this part.

(F) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(G) Sample preparation of pre- or post-harvest samples shall require grinding of sample to ensure homogeneity of plant material prior to testing. Sample preparation may follow a procedure described by USDA.

(H) After December 31, 2022, States and Indian Tribes shall require that only laboratories registered with the DEA may conduct testing under this section.

(4) A State or Indian Tribe shall require testing laboratories to comply with USDA reporting requirements in subpart F of this part. Laboratories shall only submit test results used to determine compliance with this part. Test results from informal testing conducted throughout the growing season shall not be reported to USDA.

(5) A State or Tribal plan must include a procedure to comply with the enforcement procedures in § 990.6.

(6) A State or Tribal plan must include a procedure for the disposal or remediation of cannabis plants if the sample representing that plant tests above the acceptable hemp THC level.

(i) The disposal must be conducted either by using a DEA-registered reverse distributor or law enforcement; or on site at the farm or hemp production facility.

(ii) The State or Tribal plan must include procedures to verify the disposal or remediation of the cannabis plant. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements that direct growers to provide pictures, videos, or other proof that disposal or remediation occurred successfully. Disposal and remediation means are described at AMS's website.

(iii) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels.

(7) A State or Tribal plan must include a procedure for conducting annual inspections of, at a minimum, a random group of producers to verify that hemp is not produced in violation of this part.

(8) A State or Tribal plan must include a procedure for submitting the report described in § 990.70 to the Secretary by the first of each month. If the first of the month falls on a weekend or holiday, the report is due by the first business day following the due date. All such information must be submitted to the USDA in a format that is compatible with USDA's information sharing system.

(9) The State or Tribal government must certify that the State or Indian Tribe has the resources and personnel to carry out the practices and procedures described in paragraphs (a)(1) through (9) of this section.

(10) The State or Tribal plan must include a procedure to collect and share information with USDA to support the information sharing requirements in 7 U.S.C. 1639q(d). The State or Tribal government is responsible for reporting the information identified in paragraphs (a)(10)(i) through (iii) of this section with AMS. The State or Tribal hemp production plan must include the following:

(i) A requirement that producers report their hemp crop acreage to the FSA, consistent with the requirement in § 990.7.

(ii) Assignment of a license or authorization identifier for each producer in a format prescribed by USDA.

(iii) A requirement that producers report the total acreage of hemp planted, harvested, and, if applicable, disposed or remediated. The State or Tribal government shall collect this information and report it to AMS.

(b) *Relation to State and Tribal law.* A State or Tribal plan may include any other practice or procedure established by a State or Indian Tribe, as applicable; *Provided,* That the practice or procedure is consistent with this part and Subtitle G of the Act.

(1) *No preemption.* Nothing in this part preempts or limits any law of a State or Indian Tribe that:

(i) Regulates the production of hemp; and

(ii) Is more stringent than this part or Subtitle G of the Act.

(2) *References in plans.* A State or Tribal plan may include a reference to a law of the State or Indian Tribe regulating the production of hemp, to the extent that the law is consistent with this part.

§ 990.4 USDA approval of State and Tribal plans.

(a) *General authority.* No later than 60 calendar days after the receipt of a State or Tribal plan for a State or Tribal territory in which production of hemp is legal, the Secretary shall:

(1) Approve the State or Tribal plan only if the State or Tribal plan complies with this part; or

(2) Disapprove the State or Tribal plan if the plan does not comply with this part. USDA shall provide the State or Tribe with written notification of the disapproval and the cause for the disapproval.

(b) *Amended plans.* A State or Tribal government, as applicable, must submit to the Secretary an amended plan if:

(1) The Secretary disapproves a State or Tribal plan and the State or Indian Tribe wishes to have primary regulatory authority over hemp production within its State or territory of the Indian Tribe; or

(2) The State or Indian Tribe makes substantive revisions to its plan or its laws which alter the way the plan meets the requirements of this part. If this occurs, the State or Tribal government must re-submit the revised plan for USDA approval. Such re-submissions should be provided to USDA within 60 days from the date that the State or

Tribal laws and regulations are effective. Producers shall continue to comply with the requirements of the existing plan while such modifications are under consideration by USDA. If State or Tribal government laws or regulations in effect under the USDA-approved plan change but the State or Tribal government does not submit a revised plan within 60 days from the effective date of the new law or regulation, the existing plan is revoked.

(3) USDA approval of State or Tribal government plan shall remain in effect unless an amended plan must be submitted to USDA because of a substantive revision to a State's or Tribe's plan, a relevant change in State or Tribal laws or regulations, or approval of the plan is revoked by USDA.

(4) Upon USDA approval of a Tribal plan, an Indian Tribe may exercise jurisdiction and therefore primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent regulatory authority.

(c) *Technical assistance.* The Secretary may provide technical assistance to help a State or Indian Tribe develop or amend a plan. This may include the review of draft plans or other informal consultation as necessary.

(d) *Approved State or Tribal plans.* If the Secretary approves a State or Tribal plan, the Secretary shall notify the State or Indian Tribe by letter or email.

(1) In addition to the approval letter, the State or Indian Tribe shall receive their plan approval certificate either as an attachment or via website link.

(2) The USDA shall post information regarding approved plans on its website.

(3) USDA approval of State or Tribal government plans shall remain in effect unless:

(i) The State or Tribal government's laws and regulations in effect under the USDA-approved plan change, thus requiring such plan to be revised and re-submitted for USDA approval.

(ii) A State or Tribal plan must be amended in order to comply with future amendments to Subtitle G the Act and this part.

(e) *Producer rights upon revocation of State or Tribal plan.* If USDA revokes approval of a State or Tribal plan due to noncompliance as defined in paragraph (b)(2) of this section and § 990.5, producers licensed or authorized to produce hemp under the revoked State or Tribal plan may continue to produce for the remainder of the calendar year in which the revocation became effective. Producers operating in a State or Tribal territory with a revoked plan would have to apply to USDA for a license to continue producing.

§ 990.5 Audit of State or Tribal plan compliance.

The Secretary may conduct an audit to determine a State or Indian Tribe's compliance with their approved plan.

(a) *Frequency of audits.* Compliance audits may be scheduled, no more frequently than every three years, based on available resources. Audits may include an onsite-visit, a desk-audit, or both. The USDA may adjust the frequency of audits if deemed appropriate based on program performance, compliance issues, or other relevant factors identified and provided to the State or Tribal governments by USDA.

(b) *Scope of audit review.* The audit may include, but is not limited to, a review of the following:

(1) The resources and personnel employed to administer and oversee its approved plan;

(2) The process for licensing and systematic compliance review of hemp producers;

(3) Sampling methods and laboratory testing requirements and components;

(4) Disposal and/or remediation of non-compliant hemp plants or hemp plant material practices, to ensure that correct reporting to the USDA has occurred;

(5) Results of and methodology used for the annual inspections of producers; and

(6) Information collection procedures and information accuracy (*i.e.,* geospatial location, contact information reported to the USDA, legal description of land).

(c) *Audit reports.* (1) Audit reports will be issued to the State or Tribal government no later than 60 days after the audit concludes. If the audit reveals that the State or Tribal government is not in compliance with its USDA approved plan, USDA will advise the State or Indian Tribe of non-compliances and the corrective measures that must be completed to come into compliance with the Act and regulations in this part. The USDA will require the State or Indian Tribe to develop a corrective action plan, which must be reviewed and approved by the USDA. The corrective action plan must include a reasonable date by which the State or Indian Tribe will correct make corrections. USDA will approve or deny the corrective action plan within 60 days of its receipt. USDA will conduct a second audit to determine if the State or Indian Tribe is in compliance with the corrective action plan and has corrected the non-compliances.

(2) If the USDA determines that the State or Indian Tribe is not in compliance after the second audit, the USDA may revoke its approval of the State or Tribal plan for one year or until the State or Indian Tribe becomes compliant whichever occurs later. USDA will not approve a State or Indian Tribe's plan until the State or Indian Tribe demonstrates upon inspection that it is in compliance with all regulations in this part.

§ 990.6 Violations of State and Tribal plans.

(a) *Producer violations.* Producer violations of USDA-approved State and Tribal hemp production plans shall be subject to enforcement in accordance with the terms of this section.

(b) *Negligent violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to negligent producer violations as defined under this part. Producers shall not receive more than one negligent violation per growing season. Negligent violations shall include:

(1) Failure to provide a legal description of land on which the producer produces hemp;

(2) Failure to obtain a license or other required authorization from the State department of agriculture or Tribal government, as applicable; or

(3) Production of cannabis with a total delta-9 tetrahydrocannabinol concentration exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (b)(3) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a total delta-9 tetrahydrocannabinol concentration of more than 1.0 percent on a dry weight basis.

(c) *Corrective action for negligent violations.* Each USDA-approved State or Tribal plan shall provide for the correction of negligent violations. Each corrective action plan shall include, at a minimum, the following terms:

(1) A reasonable date by which the producer shall correct the negligent violation.

(2) A requirement that the producer periodically report to the State department of agriculture or Tribal government, as applicable, on its compliance with the State or Tribal plan and corrective action plan for a period of not less than the next 2 years from the date of the negligent violation.

(3) A producer that negligently violates a State or Tribal plan approved under this part shall not as a result of that violation be subject to any criminal

enforcement action by the Federal, State, Tribal, or local government.

(4) A producer that negligently violates a State or Tribal plan three times during a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(5) The State or Indian Tribe shall conduct an inspection to determine if the corrective action plan has been implemented as submitted.

(d) *Culpable violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to producer violations made with a culpable mental state greater than negligence, including that:

(1) If the State or Tribal government determines that a producer has violated the plan with a culpable mental state greater than negligence, the State or Tribal government, as applicable, shall immediately report the producer to:

(i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian Tribe, as applicable.

(2) Paragraphs (b) and (c) of this section shall not apply to culpable violations.

(e) *Felonies.* Each USDA-approved State or Tribal plan shall contain provisions relating to felonies. Such provisions shall state that:

(1) A person with a State or Federal felony conviction relating to a controlled substance may not participate in the plan and may not produce hemp under the State or Tribal plan for 10 years from the date of the conviction. An exception applies to a person who was lawfully growing hemp under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before December 20, 2018, and whose conviction also occurred before that date.

(2) The State or Tribal plan shall define who is participating in the plan or program and is subject to the felony conviction restriction for purposes of paragraph (e)(1) of this section. To determine whether a person is subject to the felony conviction restriction, the State or Tribe much obtain a criminal history report for that person. The State or Indian Tribe may require additional reports or checks as it deems necessary.

(3) For each license or authorization that the State or Indian Tribe issues, its plan must identify at least one individual as participating in the plan and for whom it will obtain a criminal history report to determine eligibility under paragraph (e)(1) of this section.

(f) *False statement.* Each USDA-approved State or Tribal plan shall state that any person who materially falsifies any information contained in an application to participate in such program shall be ineligible to participate in that program.

(g) *Appeals.* For States and Indian Tribes who wish to appeal an adverse action, subpart D of this part will apply.

§ 990.7 Establishing records with USDA Farm Service Agency.

All producers licensed to produce hemp under an USDA-approved State or Tribal plan shall report hemp crop acreage to FSA and shall provide, at minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location for each lot or greenhouse where hemp will be produced. If an applicant operates in more than one location, or is producing under multiple licenses, production information shall be provided for each location.

(b) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(c) License or authorization identifier in a format prescribed by USDA.

§ 990.8 Production under Federal law.

Nothing in this subpart prohibits the production of hemp in a State or the territory of an Indian Tribe for which a State or Tribal plan is not approved under this subpart if produced in accordance with subpart C of this part, and if the production of hemp is not otherwise prohibited by the State or Indian Tribe.

Subpart C—USDA Hemp Production Plan

§ 990.20 USDA requirements for the production of hemp.

(a) *General hemp production requirements.* The production of hemp in a State or territory of an Indian Tribe where there is no USDA approved State or Tribal plan must be conducted in accordance with this subpart, provided that the production of hemp is not prohibited by the State or territory of an Indian Tribe where production will occur.

(b) *Convicted felon ban.* A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on participating in and producing hemp under the USDA plan from the date of the conviction. An exception applies to a person who was lawfully growing hemp under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before December 20, 2018, and whose conviction also occurred before that date.

(c) *Falsifying material information on application.* Any person who materially falsifies any information contained in an application for a license under the USDA plan shall be ineligible to participate in the USDA plan.

§ 990.21 USDA hemp producer license.

(a) *General application requirements*—(1) *Requirements and license application.* Any person producing or intending to produce hemp must have a valid license prior to producing hemp. A valid license means the license is unexpired, unsuspended, and unrevoked.

(2) *Application dates.* Applicants may submit an application for a license at any time.

(3) *Required information on application.* The applicant shall provide the information requested on the application form, including:

(i) *Contact information.* Full name, residential address, telephone number, and email address. If the applicant is a business entity, the full name of the business, the principal business location address, full name and title of the key participants, title, email address (if available), and employer identification number (EIN) of the business; and

(ii) *Criminal history report.* A current criminal history report for an individual, or if the applicant is a business entity, all key participants, dated within 60 days of the application submission date. A license application will not be considered complete without all required criminal history reports.

(4) *Submission of completed application forms.* Completed application forms shall be submitted to USDA.

(5) *Incomplete application procedures.* Applications missing required information shall be returned to the applicant as incomplete. The applicant may resubmit a completed application.

(6) *License expiration.* USDA-issued hemp producer licenses shall be valid until December 31 of the year three years after the year in which license was issued.

(b) *License renewals.* USDA hemp producer licenses must be renewed prior to license expiration. Licenses are not automatically renewed. Applications for renewal shall be subject to the same terms, information collection requirements, and approval criteria as provided in this subpart for initial applications unless there has been an amendment to the regulations in this part or the law since approval of the initial or last application.

(c) *License modification.* A license modification is required if there is any

change to the information submitted in the application including, but not limited to, sale of a business, the production of hemp in a new location, or a change in the key participants under a license.

(d) *Licensing for research.* (1) Producers that produce hemp for research must obtain a USDA license. However, the hemp that is produced for research and does not enter the stream of commerce is not subject to the sampling requirements in §§ 990.24 and 990.26; provided that the producer adopts and carries out a USDA approved alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level.

(2) USDA licensees shall ensure the disposal of all non-compliant plants in accordance with § 990.27. Only research institutions registered with DEA to handle marijuana can keep hemp that tests over the 0.3 acceptable hemp THC level until the end of the study.

(3) USDA licensees shall comply with the reporting requirements in § 990.71 including reporting disposal of non-compliant plants.

§ 990.22 USDA hemp producer license approval.

(a) A license shall not be issued unless:

(1) The application submitted for USDA review and approval is complete and accurate.

(2) The criminal history report(s) submitted with the license application confirms that all key participants to be covered by the license have not been convicted of a felony, under State or Federal law, relating to a controlled substance within the past ten (10) years unless the exception in § 990.20(b) applies.

(3) The applicant, if the applicant was previously or is currently licensed, submitted all reports required as a participant in the hemp production program by this part.

(4) The application contains no materially false statements or misrepresentations and the applicant has not previously submitted an application with any materially false statements or misrepresentations.

(5) The applicant's license is not currently suspended, if the applicant is currently licensed.

(6) The applicant is not applying for a license as a stand-in for someone whose license has been suspended, revoked, or is otherwise ineligible to participate.

(7) The State or territory of the Indian Tribe where the person produces or intends to produce hemp does not have a USDA-approved plan or has not submitted a plan to USDA for approval and is awaiting USDA's decision.

(8) The State or territory of the Indian Tribe where the person produces or intends to produce hemp does not prohibit the production of hemp.

(b) USDA shall provide written notification to applicants whether the application has been approved or denied. USDA shall provide written notification to applicants in a State or territory of an Indian Tribe that has submitted a plan to USDA and is awaiting USDA approval that their application is being returned.

(1) If an application is approved, a license will be issued.

(2) Licenses will be valid until December 31 of the year three after the year in which the license was issued.

(3) Licenses may not be sold, assigned, transferred, pledged, or otherwise disposed of, alienated or encumbered.

(4) If a license application is denied, the notification from USDA will explain the reason for denial. Applicants may appeal the denial in accordance with subpart D of this part.

(c) If the applicant is producing in more than one State or territory of an Indian Tribe, the applicant may have more than one license to grow hemp. If the applicant has operations in a location covered under a State or Tribal plan, that operation must be licensed under the State or Tribal plan, not the USDA plan.

§ 990.23 Reporting hemp crop acreage with USDA Farm Service Agency.

All USDA licensees shall report hemp crop acreage to FSA within 30 days of hemp been planted and shall provide, at a minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location of the lot, greenhouse, building, or site where hemp will be produced. All locations where hemp is produced must be reported to FSA.

(b) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(c) The hemp license number.

§ 990.24 Responsibility of a USDA licensee prior to harvest.

USDA licensees must:

(a) No more than 30 days prior to the anticipated harvest of cannabis plants, have a sampling agent collect samples from the cannabis plant for total delta-9 tetrahydrocannabinol concentration level testing.

(b) Have samples collected from the flowering tops of the plant by cutting the top five to eight inches from the ''main stem'' (that includes the leaves and flowers), ''terminal bud'' (that occurs at the end of a stem), ''or ''central cola'' (cut stem that could develop into a bud) of the flowering top of the plant. Sampling guidelines and training requirements for sampling agents are available from USDA. The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.

(c) Have an authorized representative of the USDA licensee present at the growing site during a scheduled sample collection, if possible.

(d) Ensure that sampling agents are provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, (whether growing or harvested), all hemp production and storage areas, all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(e) Not harvest the cannabis crop prior to samples being taken.

(f) Use post-harvest samples only for remediated biomass.

§ 990.25 Standards of performance for detecting total delta-9 tetrahydrocannabinol (THC) concentration levels.

Analytical testing for purposes of determining total THC in cannabis plants shall meet the standards in this section.

(a) Laboratory quality assurance must ensure the validity and reliability of test results.

(b) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing.

(c) The demonstration of testing validity must ensure consistent, accurate analytical performance.

(d) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

(e) Laboratory must have an effective disposal procedure for non-compliant samples that do not meet the requirements of this part.

(f) Measurement of uncertainty (MU) must be estimated and reported with

test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(g) At a minimum, analytical testing of samples for total THC must use post-decarboxylation or other similarly reliable methods approved by the Secretary. The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result must reflect the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting the requirements of this paragraph (g) include, but are not limited to, gas or liquid chromatography with detection.

(1) The total THC shall be determined and reported on a dry weight basis. Additionally, measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(2) Any sample test result exceeding the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part.

(3) After December 31, 2022, USDA licensees may only use laboratories registered with the DEA to conduct testing under this section.

§ 990.26 Responsibility of a USDA producer after laboratory testing is performed.

(a) The producer shall harvest the crop no later than thirty (30) days after the date of sample collection.

(b) If the producer fails to complete harvest within thirty (30) days of sample collection, a second pre-harvest sample of the lot shall be required to be submitted for testing.

(c) Harvested lots of hemp plants shall not be commingled with other harvested lots or other material.

(d) Lots that meet the acceptable hemp THC level may enter the stream of commerce.

(e) Lots that do not meet the acceptable hemp THC level are subject to § 990.27.

(f) Any producer may request additional pre-harvest testing if it is believed that the original total delta-9 tetrahydrocannabinol concentration level test results were in error. Additional testing may be conducted by the laboratory that conducted the initial test, or another laboratory.

§ 990.27 Non-compliant cannabis plants.

(a) Cannabis plants exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance under the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.,* and producers must either use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants or ensure the disposal of such cannabis plant on site at the farm or hemp production facility.

(b) Producers must notify USDA of their intent to dispose of or remediate non-conforming plants and verify disposal or remediation by submitting required documentation.

(c) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels.

§ 990.28 Compliance.

(a) *Audits.* USDA licensees may be audited by the USDA. The audit may include a review of records and documentation, and may include site visits to farms, fields, greenhouses, storage facilities, or other locations affiliated with the producer's hemp operation. The audit may include the current crop year, as well as any previous crop year(s). The audit may be performed remotely or in person.

(b) *Frequency of audit verifications.* Audit verifications may be performed once every three (3) years unless otherwise determined by USDA. If the results of the audit find negligent violations, a corrective action plan may be established.

(c) *Assessment of producer's hemp operations for conformance.* The producer's operational procedures, documentation, recordkeeping, and other practices may be verified during the audit verification. The auditor may also visit the production, cultivation, or storage areas for hemp listed on the producer's license.

(1) *Records and documentation.* The auditor shall assess whether required reports, records, and documentation are properly maintained for accuracy and completeness.

(2) [Reserved]

(d) *Audit reports.* Audit reports will be issued to the producer no later than 60 days after the audit is concluded. If USDA determines through an audit that the producer is not compliant with the Act or this part, USDA shall require a corrective action plan. The corrective action plan must include a reasonable date by which the producer will correct the negligent violation. USDA will approve or deny the corrective action plan within 60 days of its receipt. Producers operating under a corrective action plan must also periodically report to USDA on their compliance with the plan for a period of not less than two calendar years following the violation. The producer's implementation of a corrective action plan may be reviewed by USDA during a future site visit or audit. If additional instances of noncompliance occur, USDA may revoke the producer's USDA license for one year or until the producer becomes compliant whichever occurs later.

§ 990.29 Violations.

Violations of this part shall be subject to enforcement in accordance with the terms of this section.

(a) *Negligent violations.* Hemp producers are not subject to more than one negligent violation per calendar year. A hemp producer shall be subject to enforcement for negligently:

(1) Failing to provide an accurate legal description of land where hemp is produced;

(2) Producing hemp without a license; and

(3) Producing cannabis exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (a) if they make reasonable efforts to grow hemp and the cannabis does not have a total THC concentration of more than 1.0 percent on a dry weight basis.

(b) *Corrective action for negligent violations.* For each negligent violation, USDA will issue a Notice of Violation and require a corrective action plan from the producer. The producer shall comply with the corrective action plan to cure the negligent violation. Corrective action plans will be in place for a minimum of two (2) years from the date of their approval. Corrective action plans will, at a minimum, include:

(1) The date by which the producer shall correct each negligent violation;

(2) Steps that will be taken to correct each negligent violation; and

(3) A description of the procedures that will demonstrate compliance must be submitted to USDA.

(c) *Negligent violations and criminal enforcement.* A producer who negligently violates this part shall not, as a result of that violation, be subject to any criminal enforcement action by any Federal, State, Tribal, or local government.

(d) *Subsequent negligent violations.* If a subsequent negligent violation occurs while a corrective action plan is in place, a new corrective action plan must be submitted with a heightened level of quality control, staff training, and quantifiable action measures.

(e) *Negligent violations and license revocation.* A producer that negligently violates the license 3 times in a 5-year

period shall have their license revoked and be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(f) *Culpable mental state greater than negligence.* If USDA determines that a licensee has violated the terms of the license or of this part with a culpable mental state greater than negligence:

(1) USDA shall immediately report the licensee to:

(i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian territory, as applicable, where the production is located; and

(2) Paragraphs (a) and (b) of this section shall not apply to culpable violations.

§ 990.30 USDA producers; License suspension.

(a) USDA may issue a notice of suspension to a producer if USDA or its representative receives some credible evidence establishing that a producer has:

(1) Engaged in conduct violating a provision of this part; or

(2) Failed to comply with a written order from the USDA–AMS Administrator related to negligence as defined in this part.

(b) Any producer whose license has been suspended shall not handle or remove hemp or cannabis from the location where hemp or cannabis was located at the time when USDA issued its notice of suspension, without prior written authorization from USDA.

(c) Any person whose license has been suspended shall not produce hemp during the period of suspension.

(d) A producer whose license has been suspended may appeal that decision in accordance with subpart D of this part.

(e) A producer whose license has been suspended and not restored on appeal may have their license restored after a waiting period of one year from the date of the suspension. If the license was issued more than three years prior to the date of restoration, the producer shall submit a new application and criminal history report to USDA.

(f) A producer whose license has been suspended may be required to provide, and operate under, a corrective action plan to fully restore their license.

§ 990.31 USDA licensees; Revocation.

USDA shall immediately revoke the license of a USDA licensee if such licensee:

(a) Pleads guilty to, or is convicted of, any felony related to a controlled substance; or

(b) Made any materially false statement with regard to this part to USDA or its representatives with a culpable mental state greater than negligence; or

(c) Is found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence or negligently violated this part three times in five years.

§ 990.32 Recordkeeping requirements.

(a) USDA licensees shall maintain records of all hemp plants acquired, produced, handled, disposed of, or remediated as will substantiate the required reports.

(b) All records and reports shall be maintained for at least three years.

(c) All records shall be made available for inspection by USDA inspectors, auditors, or their representatives during reasonable business hours. The following records must be made available:

(1) Records regarding acquisition of hemp plants;

(2) Records regarding production and handling of hemp plants;

(3) Records regarding storage of hemp plants; and

(4) Records regarding disposal and remediation of all cannabis plants that do not meet the definition of hemp.

(d) USDA inspectors, auditors, or their representatives shall have access to any premises where hemp plants may be held during reasonable business hours.

(e) All reports and records required to be submitted to USDA as part of participation in the program in this part which include confidential data or business information, including but not limited to information constituting a trade secret or disclosing a trade position, financial condition, or business operations of the particular licensee or their customers, shall be received by, and at all times kept in the custody and control of, one or more employees of USDA or their representatives. Confidential data or business information may be shared with applicable Federal, State, Tribal, or local law enforcement or their designee in compliance with the Act.

Subpart D—Appeals

§ 990.40 General adverse action appeal process.

(a) Persons who believe they are adversely affected by the denial of a license application under the USDA hemp production program may appeal such decision to the AMS Administrator.

(b) Persons who believe they are adversely affected by the denial of a license renewal under the USDA hemp production program may appeal such decision to the AMS Administrator.

(c) Persons who believe they are adversely affected by the revocation or suspension of a USDA hemp production license may appeal such decision to the AMS Administrator.

(d) States and Indian Tribes that believe they are adversely affected by the denial of a proposed State or Tribal hemp plan may appeal such decision to the AMS Administrator.

§ 990.41 Appeals under the USDA hemp production plan.

(a) *Appealing a denied USDA-plan license application.* A license applicant may appeal the denial of a license application.

(1) If the AMS Administrator grants an applicant's appeal of a licensing denial, the applicant will be issued a USDA hemp production license.

(2) If the AMS Administrator denies an appeal, the applicant's license application will be denied. The applicant may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing a denied USDA-plan license renewal.* A producer may appeal the denial of a license renewal.

(1) If the AMS Administrator grants a producer's appeal of a licensing renewal denial, the applicant's USDA hemp production license will be renewed.

(2) If the AMS Administrator denies the appeal, the applicant's license will not be renewed. The denied producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Appealing a USDA-plan license termination or suspension.* A USDA hemp plan producer may appeal the revocation or suspension of a license.

(1) If the AMS Administrator grants the appeal of a license termination or suspension, the producer will retain their license.

(2) If the AMS Administrator denies the appeal, the producer's license will be terminated or suspended. The producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(d) *Filing period.* The appeal of a denied license application, denied license renewal, suspension, or revocation must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered ''filed'' on the date received by the AMS Administrator. The decision to deny an appeal of a license application or renewal, or suspend or terminate a license, is final unless a formal adjudicatory proceeding is requested within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(e) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(f) *What to include.* All appeals must include a copy of the adverse decision and a statement of the appellant's reasons supporting why the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

§ 990.42 Appeals under a State or Tribal hemp production plan.

(a) *Appealing a State or Tribal hemp production plan application.* A State or Indian Tribe may appeal the denial of a proposed State or Tribal hemp production plan by the USDA to the AMS Administrator.

(1) If the AMS Administrator grants a State or Indian Tribe's appeal of a denied hemp plan application, the proposed State or Tribal hemp production plan shall be established as proposed.

(2) If the AMS Administrator denies an appeal, the proposed State or Tribal hemp production plan shall not be approved. Prospective producers located in the State or territory of the Indian Tribe may apply for hemp licenses under the terms of the USDA plan. The State or Indian Tribe may request a formal adjudicatory proceeding be initiated within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing the suspension or termination of a State or Tribal hemp production plan.* A State or Tribe may appeal the revocation by USDA of an approved State or Tribal hemp production plan.

(1) If the AMS Administrator grants a State or Indian Tribe's appeal of a State or Tribal hemp production plan suspension or revocation, the associated hemp production plan will remain in place and effective.

(2) If the AMS Administrator denies an appeal, the State or Tribal hemp production plan will be suspended or revoked as applicable. Producers located in that State or territory of the Indian Tribe may continue to produce hemp under their State or Tribal license until the end the calendar year in which the State or Tribal plan's disapproval was effective or when the State or Tribal license expires, whichever is earlier. Producers may apply for a USDA license under subpart C of this part unless hemp production is otherwise prohibited by the State or Indian Tribe. The State or Indian Tribe may request a formal adjudicatory proceeding be initiated to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Filing period.* The appeal of a State or Tribal hemp production plan suspension or revocation must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered ''filed'' on the date received by the AMS Administrator. The decision to deny a State or Tribal plan application or suspend or revoke approval of a plan, is final unless the decision is appealed in a timely manner.

(d) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(e) *What to include in appeal.* All appeals must include a copy of the adverse decision and a statement of the appellant's reasons supporting why the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

Subpart E—Administrative Provisions

§ 990.60 Agents.

As provided under 7 CFR part 2, the Secretary may name any officer or employee of the United States or name any agency or division in the United States Department of Agriculture, to act as their agent or representative in connection with any of the provisions of this part.

§ 990.61 Severability.

If any provision of this part is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this part or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 990.62 [Reserved]

§ 990.63 Interstate transportation of hemp.

No State or Indian Tribe may prohibit the transportation or shipment of hemp lawfully produced under a State or Tribal plan approved under subpart B of this part, under a license issued under subpart C of this part, or under 7 U.S.C. 5940 through the State or territory of the Indian Tribe, as applicable.

Subpart F—Reporting Requirements

§ 990.70 State and Tribal hemp reporting requirements.

(a) *State and Tribal hemp producer report.* Each State and Indian Tribe with a plan approved under this part shall submit to USDA, by the first of each month, a report providing the contact information and the status of the license or other authorization issued for each producer covered under the applicable State and Tribal plans. If the first of the month falls on a weekend or holiday, the report is due by the first business day following the due date. The report shall be submitted using a digital format compatible with USDA's information sharing systems, whenever possible. The report shall contain the information described in this paragraph (a).

(1)(i) For each new producer who is an individual and is licensed or authorized under the State or Tribal plan, the report shall include the full name of the individual, license or authorization identifier, Employee Identification Number (''EIN'') of the business entity, business address, telephone number, and email address (if available).

(ii) For each new producer that is an entity and is licensed or authorized under the State or Tribal plan, the report shall include full name of the entity, the principal business location address, license or authorization identifier, and the full name, title, and email address (if available) of each employee for whom the entity is required to submit a criminal history report.

(iii) For each producer that was included in a previous report and whose reported information has changed, the report shall include the previously reported information and the new information.

(2) The status of each producer's license or authorization.

(3) The period covered by the report.

(4) Indication that there were no changes during the current reporting cycle, if applicable.

(b) *State and Tribal hemp disposal or remediation report.* If a producer has produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of or remediated. States and Tribes with plans approved under this part shall submit to USDA, by the first of each month, a report notifying USDA of any occurrence of non-conforming plants or plant material and providing a disposal or remediation record of those plants and materials. This report would include information regarding name and contact information for each producer subject to a disposal or remediation during the reporting period, and date disposal or remediation was completed. If the first of the month fall on a weekend or holiday, reports are due by the first business day following the due date. The report shall contain the information described in this paragraph (b).

(1) Name and address of the producer.

(2) Producer license or authorization identifier.

(3) Location information, such as lot number, location type, and geospatial location or other location descriptor for the production area subject to disposal or remediation.

(4) Disposal or remediation completion date.

(5) Total acreage.

(c) *Annual report.* Each State or Indian Tribe with a plan approved under this part shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

(1) Total planted acreage.

(2) Total harvested acreage.

(3) Total acreage disposed and remediated.

(d) *Test results report.* Each producer must ensure that the laboratory that conducts the test of the sample(s) from its lots reports the test results to USDA. Informal testing conducted throughout the growing season for purposes of monitoring THC concentration do not need to be reported to USDA. The test results report shall contain:

(1) Producer's license or authorization identifier.

(2) Name of producer.

(3) Business address of producer.

(4) Lot identification number for the sample.

(5) Name of laboratory and, no later than December 31, 2022, the DEA registration number of laboratory for testing.

(6) Date of test and report.

(7) Identification of a pre-harvest or post-harvest retest.

(8) Test result.

§ 990.71 USDA plan reporting requirements.

(a) *USDA licensing application.* USDA will accept applications on a rolling basis. Licenses will be valid until December 31 of the year three years after the license is issued. The license application will be used for both new and renewal applicants. The application shall include:

(1) *Contact information.* (i) For an applicant who is an individual, the application shall include full name of the individual, Employee Identification Number (''EIN'') of the business entity, business address, telephone number, and email address (if available).

(ii) For an applicant that is an entity, the application shall include full name of the entity, the principal business location address, and the full name, title, and email address (if available) of each key participant of the entity.

(2) *Criminal history report.* As part of a complete application, each applicant shall provide a current Federal Bureau of Investigation's Identity History Summary. If the applicant is a business entity, a criminal history report shall be provided for each key participant.

(i) The applicant shall ensure the criminal history report accompanies the application.

(ii) The criminal history report must be dated within 60 days of submission of the application submittal.

(3) *Consent to comply with program requirements.* All applicants submitting a completed license application, in doing so, consent to comply with the requirements of this part.

(b) *USDA licensee disposal and remediation form.* USDA licensee conducts a disposal or remediation activity, that licensee must report the activity on the appropriate form to USDA no later than 30 days after the date of completion of disposal or remediation activity. The report shall contain the information described in this paragraph (b).

(1) Name and address of the producer.

(2) The USDA licensee's USDA license number.

(3) Geospatial location, or other valid land descriptor, for the production area subject to disposal or remediation.

(4) Date of completion of disposal or remediation.

(5) Signature of the USDA licensee or authorized representative.

(c) *USDA licensee annual report.* Each USDA licensee shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

(1) USDA licensee 's license number.

(2) USDA licensee 's name.

(3) USDA licensee's address.

(4) Lot, location type, geospatial location, total planted acreage, total acreage disposed and remediated, and total harvested acreage.

(d) *Test results report.* Each USDA licensee must ensure that the laboratory that conducts the test of the sample(s) from its lots reports the test results for all samples tested to USDA. Informal testing conducted throughout the growing season for purposes of monitoring THC concentration do not need to be reported to USDA. The test results report shall contain the information described in this paragraph (d) for each sample tested.

(1) USDA licensee 's license number.

(2) Name of the USDA licensee.

(3) Business address of the USDA licensee.

(4) Lot identification number for the sample.

(5) Name of testing laboratory.

(6) Date of test and report.

(7) Identification of a pre-harvest or post-harvest retest.

(8) Test result.

Bruce Summers,

Administrator, Agricultural Marketing Service.

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Part VII

Department of Health and Human Services

21 CFR Part 6

42 CFR Parts 1, 404, et al.

45 CFR Parts 8, 200, et al.

Securing Updated and Necessary Statutory Evaluations Timely; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 6

Public Health Service

42 CFR Part 1

Centers for Medicare and Medicaid Services

42 CFR Part 404

Office of the Inspector General

42 CFR Part 1000

Office of the Secretary

45 CFR Part 8

Administration for Children and Families

45 CFR Parts 200, 300, 403, 1010, and 1390

[Docket No. HHS–OS–2020–0012]

RIN 0991–AC24

Securing Updated and Necessary Statutory Evaluations Timely

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Regulatory Flexibility Act (RFA) requires agencies to publish plans to conduct periodic reviews of certain of their regulations. Multiple Executive Orders also require agencies to submit plans for periodic reviews of certain regulations. To further comply with the RFA and Executive Orders, and to ensure the Department's regulations have appropriate impacts, the U.S. Department of Health and Human Services (HHS or the Department) issues this final rule amending its regulations to set expiration dates for the Department's regulations (subject to certain exceptions), unless the Department periodically assesses the regulations to determine if they are subject to the RFA, and if they are, performs a review that satisfies the criteria in the RFA.

DATES: This final rule is effective on March 22, 2021.

FOR FURTHER INFORMATION CONTACT: James Lawrence, 200 Independence Avenue SW, Washington, DC 20201; or by email at *reviewnprm@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

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I. Summary
II. Background
III. Statutory Authority and Legal Basis for This Final Rule
IV. Provisions of Proposed Rule and Response to Public Comments
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I. Summary

On November 4, 2020, HHS published in the **Federal Register** a notice of proposed rulemaking titled ''Department of Health and Human Services Securing Updated and Necessary Statutory Evaluations Timely'' (hereinafter, ''proposed rule'').[1] On November 23, 2020, the Department held a public hearing on the proposed rule.[2] For the reasons described herein, after considering public comments on the proposed rule, HHS now finalizes the proposed rule as amended. This final rule will enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 610, and various executive orders, and improve accountability and the performance of its regulations.[3] The RFA requires federal agencies to publish in the **Federal Register** ''a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities'' in order ''to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant impact of the rules upon a substantial number of small entities.'' 5 U.S.C. 610(a). In conducting this retrospective review, agencies must consider a variety of factors, including the continued need for the rule, legal issues, public input, overlap and duplication with other federal or State and local governmental rules, and technological, economic, or other changes. 5 U.S.C. 610(b). Agency compliance with 5 U.S.C. 610 may be subject to judicial review. *See* 5 U.S.C. 611(a).

Several Executive Orders have also directed agencies to submit plans for the periodic review of certain of their regulations.[4]

The Department has tried to carry out the evidence-based approach to regulation prescribed by Congress and the executive orders, but HHS' efforts have met varying levels of success. Several States, as well as jurisdictions outside the United States, have experimented with different ways of ensuring agencies engage in retrospective regulatory reviews so that legal requirements are updated in view of emerging evidence and changed circumstances. Among the lessons that have emerged is that while statutory mandates are helpful, one of the most important factors for ensuring agencies conduct retrospective reviews of their regulations is to provide for the sunset or automatic expiration of certain regulatory requirements after a period of time unless a retrospective review determines that the regulations should be maintained.

Therefore, in order to ensure evidence-based regulation that does not become outdated as conditions change, HHS finalizes this rule to provide that, subject to certain exceptions, all regulations issued by the Secretary or his delegates or sub-delegates in Titles 21, 42, and 45 of the CFR shall expire at the end of (1) five calendar years after the year that this final rule first becomes effective, (2) ten calendar years after the year of the Section's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed[5] the Section, whichever is latest. The RFA and executive orders have only resulted in limited retrospective review by the Department. The Department believes this final rule will effectuate the desire for periodic retrospective reviews expressed in the RFA and Executive Orders, as well as ensure the Department's regulations are having appropriate impacts and have not become outdated. The literature and the Department's experience suggest that many regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated. This final rule will enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire

[1] 85 FR 70096 (Nov. 4, 2020).

[2] The transcript of the public hearing is available on the docket for the proposed rule. *See https://beta.regulations.gov/docket/HHS-OS-2020-0012/document.*

[3] Unless otherwise indicated, all references to HHS in this proposed rule include HHS' constituent agencies and other components.

[4] *See, e.g.,* Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993), Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011).

[5] ''Section,'' ''Assess,'' and ''Review'' are capitalized in this preamble where those terms have the definitions ascribed to them in the text of this final rule.

to comply with the RFA and periodically review its regulations.

II. Background

A. The Regulatory Flexibility Act

In 1980, Congress enacted the Regulatory Flexibility Act (RFA), Public Law 96–354, 94 Stat. 1164 (1980) (codified as amended at 5 U.S.C. 601–612). Congress stated that ''the purpose of this Act [is] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' 94 Stat. at 1165. Consistent with this purpose, section 3(a) of the RFA requires agencies to publish in the **Federal Register** a ''plan for the periodic review of rules which have or will have a significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610(a). The ''purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of small entities.'' *Id.* In conducting this review, Congress provided that agencies ''shall consider the following factors'':

(a) The continued need for the rule;

(b) The nature of complaints or comments received concerning the rule from the public;

(c) The complexity of the rule;

(d) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(e) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

5 U.S.C. 610(b)(1)–(5). Congress required agencies to conduct an initial review within ten years of the effective date of the RFA, as well as subsequent reviews ''within ten years of the publication of'' future final rules. 5 U.S.C. 610(a).

The retrospective review provided for in 5 U.S.C. 610 is a congressional mandate. Under the plain terms of the Act, having a plan for such reviews is not optional. Congress fashioned a private right of action for small entities to ensure agencies satisfy 5 U.S.C. 610. *See* 5 U.S.C. 611(a)(1) (''For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7.''). Originally, as one commentator explained, the RFA ''contain[ed] an extremely qualified and ambiguous provision for judicial review.'' [6] In 1996, Congress amended the RFA to more clearly provide for judicial review of violations of 5 U.S.C. 610.[7] As one House Committee report explained, the lack of judicial review made ''agencies completely unaccountable for their failure to comply with its requirements,'' a problem the amendment attempted to solve.[8]

B. Executive Orders Directing Agencies To Review Existing Regulations

Other efforts to conduct retrospective regulatory review both predate and have continued after passage of the RFA. In 1978, President Carter issued an executive order on improving federal regulations.[9] The order directed agencies to ''periodically review their existing regulations.'' [10] In determining which existing regulations to review, the order required agencies to consider, among other things, whether ''technology, economic conditions or other factors have changed in the area affected by the regulation.'' [11] The Executive Order considered suggestions from the public that all regulations be reviewed, usually 3–5 years after issuance. But the Carter Administration instead instructed that, due to agency resource limitations, agencies should concentrate their reviews on those regulations which no longer serve their intended purpose, that have caused administrative difficulties, or that have been affected by new developments.[12] The executive order also considered, but rejected, the idea of including a sunset provision in regulations on the ground that agencies cannot entirely eliminate regulations unless the law that authorized the regulations allows it.[13] However, the Department believes that executive order did not consider that the authorizing statutes for many regulations permit those regulations to be rescinded. Moreover, as discussed below, experience since 1978 has shown it is difficult to adequately conduct retrospective regulatory review if regulations do not contain sunset provisions.

Like the Carter Administration, every subsequent administration has directed agencies to engage in retrospective review of existing regulations. In 1981, President Reagan ordered agencies to ''review[ ] existing regulations'' in view of cost-benefit principles and potential alternatives.[14] In 1992, President George H.W. Bush issued a memorandum instructing agencies to conduct a 90-day review ''to evaluate existing regulations and programs and to identify and accelerate action on initiatives that will eliminate any unnecessary regulatory burden or otherwise promote economic growth.'' [15] President Clinton similarly called for review of existing regulations to determine whether they have become ''unjustified or unnecessary as a result of changed circumstances,'' and ''to confirm that regulations are both compatible with each other and [are] not duplicative or inappropriately burdensome in the aggregate.'' [16] Specifically, that Executive Order required agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a program under which the agency ''will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive Order.'' [17] The George W. Bush Administration's Acting OIRA Administrator noted that the Bush Administration was ''in the

[6] Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act,* 1982 Duke L.J. 213, 259 (1982).

[7] Contract with America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847, 865–66 (1996).

[8] H.R. Rep. No. 104–500, at 3 (1996).

[9] Exec. Order No. 12044 of Mar. 23, 1978, 43 FR 12661 (Mar. 24, 1978) (revoked by Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193 (Feb. 19, 1981)).

[10] 43 FR at 12663.

[11] *Id.*

[12] *Id.* at 12669. As discussed below, the Department is reviewing a different subset of its regulations than was directed by Exec. Order No. 12044, in part because the RFA's directive to review regulations that have a significant economic impact upon a substantial number of small entities had not yet been enacted at the time of Exec. Order No. 12044. Moreover, Exec. Order No. 12044 was responding to suggestions that the review be performed every three to five years. The Department's reviews will be performed every ten years (except for regulations that have already been in effect for ten years), which should lessen the burden on the Department's resources.

[13] *Id.* at 12669.

[14] Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193, 13193 (Feb. 19, 1981) (revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993)); *see also* Exec. Order 12498 of Jan. 4, 1985, 50 FR 1036 (Jan. 8, 1985) (creating annual regulatory planning program), revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993).

[15] Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992).

[16] Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993).

[17] *Id.*

process of reviewing a variety of existing regulations and regulatory programs in an effort to identify areas where sensible changes will yield greater benefits for the public at lower costs.'' [18]

President Obama also instructed agencies to engage in retrospective regulatory review. In 2011, President Obama issued an executive order ordering agencies ''[t]o facilitate the periodic review of existing significant regulations . . . to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' [19] Similarly, in 2012, President Obama noted that retrospective review has particular relevance ''[d]uring challenging economic times,'' and that agencies should consider whether regulations ''should be modified or streamlined in light of changed circumstances, including the rise of new technologies.'' [20]

President Trump has attempted to identify existing undue regulatory burdens and facilitate retrospective review of regulations. For example, in January 2017, President Trump issued an executive order requiring agencies to identify at least two regulations to be repealed for every one regulation proposed or otherwise promulgated.[21] Similarly, a 2017 OIRA report to Congress explained, ''Rules should be written and designed to facilitate retrospective analysis of their effects, including consideration of the data that will be needed for future evaluation of the rules' ex post costs and benefits.'' [22] In May 2020, in response to the COVID–19 pandemic, President Trump ordered agencies to ''identify regulatory standards that may inhibit economic recovery'' and to ''consider taking appropriate action, consistent with applicable law,'' including modifying, waiving, or rescinding those regulatory requirements.[23]

In addition to the executive orders, other executive branch actions have sought to spur agencies to conduct the reviews called for by 5 U.S.C. 610. One example was the Regulatory Review and Reform (r3) initiative, which the Small Business Administration launched in part to improve compliance with 5 U.S.C. 610 and further the goals of periodic reviews. The r3 initiative was a long-term project to help agencies pinpoint existing federal rules that warrant review—and to revise those rules if they are found to be ineffective, duplicative, out of date, or otherwise deficient.[24]

Consistent with these actions, HHS has conducted retrospective reviews of some of its regulations. For example, pursuant to Executive Order 13563, HHS published a list of regulations the Department identified as candidates for retrospective review.[25] The Department also took action. For example, HHS, citing Executive Order 13563, eliminated certain restrictions on the use of telemedicine in rural areas.[26]

Nonetheless, the Department has only conducted retrospective review of regulations to a very limited extent. One academic analysis determined that, in response to Executive Order 13563, the Department planned 83 retrospective analyses in 2012 and completed 33 analyses with final action by August 31, 2013.[27] By contrast, the Department issued 247 rules between the date Executive Order 13563 was issued and August 31, 2013.[28] As of July 2016, the Department had 40 planned retrospective analyses and by April 2017 had completed analyses with final action on 19 of them.[29] These findings are consistent with government assessments that the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking.[30]

Commenters on the proposed rule listed the following as examples of regulations that they and/or Congress have requested the Department to review, but that the commenters claimed were not reviewed:

- Regulations mandated for review by the 21st Century Cures Act, Public Law 114–255, sec. 2034, 130 Stat. 1033 (2016). Section 2034 of that Act, according to the commenters, requires the Secretary to lead a review by research funding agencies of all regulations and policies related to the disclosure and reporting of financial conflicts of interest to reduce administrative burden on federally funded researchers. It also calls for the Secretary to harmonize the differences between the Basic HHS Policy for the Protection of Human Research Subjects (45 CFR part 46, subpart A) and the FDA regulations for the protection of human subjects (21 CFR parts 50 and 56). Commenters stated that these regulations are well overdue for assessment and review.
- Regulations covering access to skilled therapy services, which commenters say must be updated to reflect the national settlement in the *Jimmo* v. *Sebelius* litigation to codify the fact that skilled services are covered for Medicare beneficiaries not just to improve function, but to maintain or prevent deterioration in function.
- The dockets established by FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine on Sept. 8, 2017,[31] in which the Centers requested comments and

[18] Draft Report to Congress on the Costs and Benefits of Federal Regulations Introduction, 66 FR 22041, 22054 (May 2, 2001).

[19] Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821, 3822 (Jan. 21, 2011); *see also* Exec. Order No. 13579 of July 11, 2011, 76 FR 41587, 41587 (July 14, 2011) (applying the same requirement to independent regulatory agencies).

[20] Exec. Order No. 13610 of May 10, 2012, 77 FR 28469, 28469 (May 14, 2012).

[21] Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339, 9339 (Feb. 3, 2017).

[22] Office of Mgmt. & Budget, 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf; see also id.* at 16 (''[I]t is important to consider retrospective, as opposed to ex ante, estimates of both benefits and costs.'').

[23] Exec. Order No. 13924 of May 19, 2020, 85 FR 31353, 31354 (May 22, 2020).

[24] Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'').

[25] *See also Retrospective Review of Existing Rules,* U.S. Dept. of Health & Human Servs., *https://www.hhs.gov/open/retrospective-review/index.html.*

[26] *See* Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging, 76 FR 25550 (May 5, 2011); *see also* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 FR 27106 (May 12, 2014) (finalizing several rules to remove unnecessary regulatory and reporting requirements previously imposed on hospitals and other health care providers).

[27] Connor Raso, *Assessing regulatory retrospective review under the Obama administration,* Brookings Inst., (Jun. 15, 2017), *https://www.brookings.edu/research/assessing-regulatory-retrospective-review-under-the-obama-administration/.*

[28] *Id.*

[29] *Id.*

[30] *See, e.g.,* Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 7–8 (2008); U.S. Gov't Accountability Off., GAO/GGD–94–105, Regulatory Flexibility Act: Status of Agencies' Compliance 12 (1994) (quoting a 1983 Small Business Administration report that stated that the Department's section 610 review plan was '' 'very general,' and, as a result, 'it is difficult to measure progress and to make recommendations with respect to future review' ''); *see also* Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'').

[31] *E.g.,* Nonrulemaking Docket FDA–2017–N–5093: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, *https://beta.regulations.gov/docket/FDA-2017-N-5093.*

information to assist in identifying existing regulations and related paperwork requirements that could be modified, repealed or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations. The commenters stated these were examples of incomplete regulatory review initiatives.[32] Commenters stated that despite submitting extensive comments that detailed numerous regulations that they believe could be modified, repealed or replaced, the agency did not take any further action.

A review conducted for the Department in 2019 (discussed in more detail in Section C) concluded that related good governance stewardship actions were deprioritized and relegated to ''rainy day'' activities that Department operating divisions would get around to when they could.[33] However, the rainy day in many cases has never arrived.

Scholars have also posited reasons why agencies may be reluctant to perform retrospective reviews. One administrative law expert now at Northwestern University has written:

> [E]ven with sufficient resources, agencies may not be properly incentivized. They are less likely to be found at fault for not conducting rigorous periodic reviews. Many rules, even those with significant effects, are often not on the public's radar once adopted. Challenging agency regulation under the RFA is more difficult than under the Administrative Procedure Act (APA) because there is no comment process and standing is granted to more limited parties. The harm to the public resulting from a cursory analysis is also much less clear. If sufficient interests exist to modify the rule, strong interest groups will directly lobby the agency to modify the rule. But in this case, a brand new rulemaking effort emerges.
>
> There are also political reasons and moral hazard concerns associated with performing retrospective analyses. In most cases, retrospective analyses of existing regulations are routine business matters left to be handled by staff members, rather than political appointees. Political appointees, such as agency heads, tend to come with specific regulatory agendas of their own. By contrast, staff members at regulatory agencies are best viewed as career members who have a vested interest in seeing their agencies continue to exist and thrive. All else equal, they are not inclined to acknowledge that the work of their agency is inefficient or unnecessary, and even less inclined to conduct analyses that may lead to a curtailing of the agency's authority. Whatever the reasons may be, serious ex post reviews are few and far between. A majority of rules, once adopted, will likely persist without significant ex post modification. As to how many agency rules currently implemented may be costing more resources than yielding benefits is anyone's guess.[34]

Thus, the Department concludes that it needs to impose a strong incentive on itself to perform retrospective review, given these countervailing incentives to not perform such reviews and the limited number of retrospective reviews that the Department has performed over the last 40 years. As discussed in more detail in the regulatory impact analysis *infra,* the Department has the resources to periodically review the impacts of its regulations.

C. Limitations in Government Projections Counsel in Favor of Widespread Retrospective Regulatory Review

The Congressional and Presidential directives to periodically review existing regulations are sound policy. When the Department first issues a regulation, it makes an educated guess about the regulation's impact. Several years after the regulation is promulgated, the Department has a somewhat greater basis for assessing its real-world impacts and can refine the regulation or agency enforcement practices, as appropriate. This would further democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation.

Indeed, the literature indicates that government projections of regulatory impacts would benefit from refinement based on experience after the regulations are implemented. The literature suggests the need for refinement is widespread, so widespread review would yield greater benefits than review of a handful of regulations. In 2005, the Office of Management and Budget (OMB) provided an overview of a sample of retrospective analyses based on an examination of forty-seven case studies.[35] OMB considered a pre-regulation estimate to be accurate if the post-regulation estimate was within +/− 25 percent of the pre-regulation estimate.[36] This measure of accuracy reveals the difficulty and uncertainty inherent in prospective cost-benefit analysis. OMB found that agencies often inaccurately estimated the benefits of regulations in its sample of regulations, and agencies were more likely to overestimate benefits than to underestimate them, where benefits were estimated.[37] Agencies overestimated benefits in 19 of 39 sampled regulations, whereas they underestimated benefits in only two of the 39 regulations.[38] In two cases, agencies overestimated benefits by a factor of 10.[39] Second, agencies sometimes overestimated the benefit-cost ratio, and in that sense were a bit too optimistic about the consequences of their rules. Agency estimates were accurate in only 11 rules, while the ratio was overestimated in 22 rules and underestimated in 14 rules.[40] Third, agencies also overestimated and, less frequently, underestimated costs in the sampled regulations. Agency cost estimates were accurate for only 12 rules, overestimated for 16 rules, underestimated for 12 rules, and not estimated for seven rules.[41]

Academic studies have also identified inaccuracies in agency estimates, relative to an ex post re-estimation. For example, one study of sixty-one rules for which benefit-cost ratios could be compared before and after the fact (including some not included in the OMB review) found that the estimated ratios were essentially accurate in only sixteen of the sixty-one cases, though the study found no bias in estimates of benefit-cost ratios.[42] In this analysis, Dr. Harrington criticized certain aspects of the OMB analysis. But it is notable that, even though OMB and Dr. Harrington used somewhat differing methods and reviewed samples of regulations that did not completely overlap, they both found ex ante estimates to be in many cases lacking. Dr. Harrington concluded his analysis by noting that ''the results

[32] *See* Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, 82 FR 42506 (Sept. 8, 2017); FDA–2017–N–5093, *https://beta.regulations.gov/docket/FDA-2017-N-5093.*

[33] *See infra* n.68 and accompanying text.

[34] Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013).

[35] Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005), *http://perma.cc/R8LX-BQMJ* (collecting studies comparing ex ante and ex post analyses of regulations' costs and benefits, including examples where cost and benefit estimates were off by more than a factor of ten).

[36] *Id.* at 42.

[37] *Id.* at 43–46.

[38] *Id.* at 47.

[39] *Id.* at 43.

[40] *Id.* at 47.

[41] *Id.*

[42] Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation,* Res. for the Future, Discussion Paper 06–39, 2006, at 33, *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357.* Dr. Harrington used the same measure of accuracy as OMB. While both OMB and Dr. Harrington noted that using +/− 25% as the measure of accuracy could be arbitrary, it is nonetheless informative that in many cases the ex ante estimates in the sampled regulations differed from ex post estimates by more than +/−25%.

demonstrate the value of *ex post* analysis. It is frustrating that there is so little of it, especially when so many close observers, from all points of view, claim to be in favor of it.'' [43]

A more recent study of a sample of federal regulations found that of the eight regulations for which the author was able to make ex ante and ex post cost comparisons, six regulations involved overestimates of costs, two involved underestimates of costs, and none were deemed accurate.[44] A regulation was deemed accurate if the regulation's regulatory impact analysis fell roughly within +2/−5% of the ex post observation.[45] Of the 18 regulatory requirements for which the author was able to compare benefits (also referred to as ''effectiveness'' in the study) estimates on an ex ante and ex post basis, he found that 10 involved overestimates, six were underestimates, and two were relatively accurate.[46]

These studies all found that in most cases the sampled ex ante estimates were not within +/−25% of the ex post observations. The studies suggest many federal regulations are estimated after the fact to have real-world impacts that differ from the estimated impacts at the time the regulations were promulgated. Although these samples were not necessarily representative, it would not be unreasonable to think that the Department could make major improvements by conducting widespread review of its regulations, rather than merely reviewing the small number of regulations that interested parties ask the Department to consider revising.[47]

Reasons Regulatory Projections Differ From Regulations' Real-World Impacts

There are several reasons why regulations' ex ante cost-benefit estimates tend to be inaccurate. First, changes in the legal landscape can cause government projections to become obsolete. For example, in February 2010, officials in the Centers for Medicare and Medicaid Services' Office of the Actuary (OACT) issued health spending and coverage projections through 2019.[48] A month later, Congress enacted the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (''ACA''), and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029. Largely as a result of the ACA's passage, in October 2010 OACT issued revised projections forecasting that by 2019 the insured share of the population would be 92.7 percent—roughly ten percentage points higher than OACT projected nine months earlier.[49]

Second, changes in technology can also render projections inaccurate. One study has noted that even when an agency's benefit-cost analysis uses sound science and the best available information to estimate the costs associated with a rule, technological innovation can result in an ex post assessment of costs differing from the agency's cost estimates at the time it promulgated the rule.[50] As an example of technology's impact on regulations, in 2019 the Food and Drug Administration (FDA) issued a rule amending requirements for medical device premarket submissions to remove requirements for paper and multiple copies, and replace these requirements with requirements for a single submission in electronic format.[51] Changes in technology had rendered the requirement for multiple copies, whether in electronic format or paper form, no longer necessary.[52] Had the Department reviewed more of its regulations, it might have learned of additional instances where technological changes counsel in favor of amendment. In addition, some scholars have suggested that in some cases changes in technology can reduce the costs of complying with regulatory mandates.[53] If retrospective reviews conclude that technology has reduced compliance costs, that can inform the Department's decision about if or how to amend a regulation.

Yet another reason for potential divergence between prospective and retrospective regulatory impact estimates is non-compliance with the regulation being assessed. One study found differing accuracy for prospective per-unit cost estimates and prospective aggregate cost estimates; where there is substantial non-compliance with the regulation being analyzed, cost estimates per unit can sometimes be reasonably accurate while aggregates are simultaneously overestimated.[54] (Non-compliance would, of course, also affect the accuracy of benefits estimates.[55]) As such, ex post analysis has the potential to inform not just decisions about codified regulatory requirements but also about agency enforcement practices.

Institutionalizing Retrospective Review To Refine Projections That Were Lacking

While the prospective cost-benefit analyses performed in connection with the promulgation of rules are quite useful, former OIRA Administrator Cass Sunstein has explained that ''[w]hen agencies issue rules, they have to speculate about benefits and costs.'' [56] Therefore,[a]fter rules are in place, [agencies] should test those speculations, and they should use what they learn when revisiting a regulation

[43] *Id.* at 34.

[44] Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation,* 9 J. of Benefit Cost Anal., no. 2, 2018, at 294, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/891E36D3DBCEB79C969278488E5E1897/S2194588817000173a.pdf/retrospective_analysis_of_us_federal_environmental_regulation.pdf.*

[45] *Id.*

[46] *Id.; see also* Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf* (finding that the EPA methodology overestimated predicted capital costs from its arsenic rule in most studied cases, especially as the size of the system increases (as measured by the design flow rate)).

[47] This is not to suggest that prospective regulatory impact analyses are not helpful. To the contrary, they add tremendous value and greatly improve agency rule makings. But as explained elsewhere herein, even when an agency's cost-benefit analysis uses sound science and the best available information to estimate the costs, benefits or other impacts associated with a rule, technological innovation or subsequent changes in the law, among other things, can result in an ex post assessment of impacts differing from the agency's estimates at the time it promulgated the rule.

[48] *See* Truffer CJ, et al. *Health Spending Projections Through 2019: The Recession's Impact Continues,* 29 Health Aff. no. 3, 2010, at 522–29, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.1074.*

[49] *See* Sisko, et al., *National Health Spending Projections: The Estimated Impact Of Reforms Through 2019,* 29 Health Aff. no. 10, at 1936, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2010.0788.*

[50] Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.* One example referred to in this study is that technological innovation or regulatory or technical constraints could result in water systems using different treatment technologies for arsenic removal than assumed by the agency when it promulgated a regulation.

[51] Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format, 84 FR 68334 (Dec. 16, 2019).

[52] *Id.* at 68334.

[53] *See, e.g.,* Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 599 (2014).

[54] Winston Harrington, Richard D. Morgenstern and Peter Nelson, *On the Accuracy of Regulatory Cost Estimates,* J. Policy Anal. & Management 2000, 19(2): 297–322.

[55] *See, e.g.,* Si Kyung Seong and John Mendeloff, *Assessing the Accuracy of OSHA's Projections of the Benefits of New Safety Standards,* Am. J. Industrial Medicine 2004, 45(4): 313–328.

[56] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 591 (2014).

or issuing a new one.'' [57] Professor Sunstein described this as ''one of the most important steps imaginable'' for regulatory reform, ''not least because it can reduce cumulative burdens and promote the goal of simplification.'' [58] He has noted that agencies' failure ''until very recently . . . to gather, let alone act on'' retrospective reviews is ''an astonishing fact.'' [59]

Michael Greenstone, who served as Chief Economist on the Council of Economic Advisors between 2009 and 2010, similarly concluded that the ''single greatest problem with the current system is that most regulations are subject to a cost-benefit analysis only in advance of their implementation. This is the point when the least is known and any analysis must rest on many unverifiable and potentially controversial assumptions.'' [60] According to Professor Greenstone, the lack of a regulatory lookback created a system ''largely based on faith, rather than evidence,'' where the agency ''all too frequently takes shots in the dark and we all too infrequently fail to find out if we have hit anything—or even worse, we only find out when things have gone horribly wrong.'' [61] As he explained, ''it is nearly impossible to imagine'' only prospective, and not retrospective, evaluations ''being used in other contexts where people's lives are on the line. For example, I am confident that there would be a deafening uproar of protest if the FDA announced that it would approve drugs without testing them in advance. Yet, this is largely what we do with regulations that affect our health and well-being.'' [62]

If retrospective analysis ''could be firmly institutionalized,'' Professor Sunstein observed, then it ''would count as the most important structural change in regulatory policy since the original requirement of prospective analysis during the Reagan Administration.'' [63]

Other administrative law experts have also urged agencies to more robustly institutionalize retrospective review of regulations. The Administrative Conference of the United States (ACUS) has ''urge[d] agencies to remain mindful of their existing body of regulations and the ever-present possibility that those regulations may need to be modified, strengthened, or eliminated in order to achieve statutory goals while minimizing regulatory burdens.'' [64] More recently, the American Bar Association Section of Administrative Law and Regulatory Practice, has ''*urge*[*d*] [*the Administration*] *to build on the efforts of previous administration[s] and take steps to institutionalize careful, in-depth retrospective review of existing rules.*'' [65]

The Need for a Greater Incentive To Institutionalize Retrospective Review

Despite these many calls for retrospective review, as noted in section II.B., the Department has had limited success in implementing retrospective review in practice.[66] In 2019, the Department piloted an approach to augment expert policy insights with artificial intelligence-driven data analysis of its regulations, which showed the need to more firmly institutionalize retrospective review. The artificial intelligence review found that 85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references in the CFR (*i.e.* CFR sections that reference other CFR sections that no longer exist); more than 50 instances of regulatory requirements to submit paper documents in triplicate or quadruplicate; and 114 parts in the CFR with no regulatory entity listed, 17 of which may be misplaced.[67] The Department concluded that some good governance stewardship recommendations ''were deprioritized and relegated to rainy day activities that [Department operating divisions] would get around to when they could.'' [68] Unfortunately, in many cases the Department has for years not gotten around to addressing these issues.

As one observer recently explained:

> Retrospective review of existing regulations . . . is a perennial favorite target for advice on how to improve OIRA's processes. Every administration since President Carter has developed some program to modify, streamline, or expand existing regulations, and there is no shortage of advice on how to make the process run more efficiently. Yet, despite a few notable one-off successes from past retrospective review efforts, no past retrospective review campaign has ever truly succeeded in creating a long-term culture of retrospective review or of prospectively embedding into new regulations a process for data collection and pre-set targets for future lookbacks. Any future efforts around retrospective review, therefore, should be clear-eyed about past failures.[69]

For the reasons discussed in this final rule, the Department believes a stronger

[57] *Id.*

[58] *Id.*

[59] *Id.* at 588.

[60] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 113 (David Moss & John Cisternino eds., 2009). It should not be inferred, however, that retrospective analysis is free of assumptions (including potentially controversial assumptions) or is generally without challenges, especially with respect to establishing relevant counterfactuals. For discussion and recent examples related to just two of the many areas of Department regulatory activity, *see* Trinided Beleche *et al., Are Graphic Warning Labels Stopping Millions of Smokers? A Comment on Huang, Chaloupka, and Fong,* 15 Econ Journal Watch 129 (2018) and Aaron Kearsley *et al., A Retrospective and Commentary on FDA's Bar Code Rule,* 9 J. Benefit-Cost Analysis 496 (2018). Moreover, to the extent that retrospective analysis is used to inform policy choices going forward, it becomes, or is at least being used as, prospective analysis and thus relies on assumptions about the future, including as regards technology and the legal and regulatory landscape. But since retrospective analysis is conducted after some real-world experience living under the regulation, it can in many cases be an improvement over earlier prospective analysis.

[61] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 111–12 (David Moss & John Cisternino eds., 2009); *see also Office of Mgmt. & Budget,* 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_Benefit Report11_18_2019.docx.pdf* (''The aim of retrospective analysis is to understand and improve the accuracy of prospective analysis and to provide a basis for potentially modifying rules as a result of *ex post* evaluations.'').

[62] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 114 (David Moss & John Cisternino eds., 2009).

[63] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 589 (2014).

[64] Administrative Conference of the United States, Recommendation 2014–5, Appendix—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75114 (Dec. 17, 2014); *see also* ABA Sec. of Admin. Law & Reg. Prac., Improving the Administrative Process: A Report to the President-Elect of the United States (2016), 69 Admin. L. Rev. 205 (2017).

[65] ABA Sec. of Admin. Law & Reg. Prac., *Improving the Administrative Process: A Report to the President-Elect of the United States (2016),* 69 Admin. L. Rev. 205, 219 (2017) (emphasis in original).

[66] *See also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 894 (2013), (''one might think that agencies would faithfully take advantage of [] opportunities to conduct rigorous retrospective [cost-benefit analyses] of their existing regulations and test their effectiveness and efficiency. This would be the surest way of incorporating ex post learning in rule implementation. This is far from the truth in practice, however.'').

[67] Regulatory Streamlining & Analysis (Mar. 2019).

[68] *Id.* at 18

[69] Jason Schwartz, *Enhancing the Social Benefits of Regulatory Review,* Institute for Policy Integrity, at 30 (Oct. 2020), *https://policyintegrity.org/files/publications/Enhancing_the_Social_Benefits_of_Regulatory_Review.pdf.* Several weeks after publishing this article, the author submitted a comment opposing the proposed rule. For the reasons discussed in the responses to public comments, the Department did not find those arguments compelling, but believes the quoted passage is a fair description of the problem this final rule aims to solve. The Department is trying to be clear-eyed about past failures, and has concluded that a strong incentive, such as that included in this final rule, is commensurate with the problem to be solved and to more firmly institutionalize retrospective review.

incentive is needed to achieve the benefits of retrospective review.[70] This final rule creates a mechanism to more firmly institutionalize the retrospective reviews that Professors Sunstein and Greenstone, as well as ACUS and others, have called for.

D. The Experiences of States and Other Jurisdictions With Automatic Expiration or ''Sunset'' Provisions

This mechanism is based in part on the experiences of States and other jurisdictions. Several States incorporate retrospective regulatory review into their laws. New York, for example, requires retrospective review of regulations ''no later than in the fifth calendar year after the year in which the rule is adopted,'' and requires that rules be ''re-reviewed at five-year intervals'' thereafter. N.Y. A.P.A. Law sec. 207. Similarly, Texas requires State agencies to review rules four years after they go into effect and then subsequently at four-year intervals. Tex. Gov't Code sec. 2001.039. In addition to New York and Texas, State law requires some form of retrospective regulatory review in at least Alabama, Arizona, Illinois, Iowa, Michigan, Missouri, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, and Washington.[71]

Some States with retrospective review requirements allow regulations to automatically expire or sunset after a period of time, unless reviewed or readopted. In New Jersey, regulations automatically expire ''seven years following the effective date of the rule'' unless extended by the agency. N.J. Stat. Ann. sec. 52:14B–5.1(b).[72] Indiana allows regulations to expire on January 1 following the seven-year anniversary of their effective dates. Ind. Code sec. 4–22–2.5–2. The Governor of Florida recently instructed Florida government agencies to ''include a sunset provision in all proposed or amended rules,'' which ''may not exceed five years unless otherwise required by existing statute.'' [73]

Experience in the States suggests that sunset provisions can be an important tool to ensure reviews take place. An analysis of regulation in all 50 States found that for a reduction in both regulatory creation and enforcement, ''[t]he single most important policy in a state is the presence of a sunset provision.'' [74] On the other hand, one report stated that, despite their initial popularity in the States,[75] sunset provisions fell out of favor, not because they did not produce more cost-effective, cost-justified regulation, but because sunset requirements did not provide sufficient legislative control over executive agencies.[76] But that observation is inapplicable to the Department, because this final rule concerns the Department's review of its own regulations. Noting the benefits of sunset provisions, the report added that sunset ''provisions have been responsible for the analysis of thousands of state regulations and, on average, the repeal of twenty to thirty percent of existing regulations and the modification of another forty percent.'' [77]

Experience outside the United States also suggests the utility of sunset provisions. The Office for Economic Co-Operation and Development (OECD) analyzed regulatory practices in the European Union. In a 2010 report, the OECD recommended, for ''[t]he management and rationalization of existing regulations,'' that Germany ''[k]eep up the 'spring cleaning' of legislation at regular intervals'' and ''consider the inclusion of a review mechanism in individual draft regulations, or even [include] a sunset clause (beyond which the law automatically expires) where appropriate.'' [78] With respect to the United Kingdom's regulatory program, the OECD noted ''sunset clauses are also helpful'' in order ''to remove unnecessary burdens in legislation.'' [79] Throughout the 2010 report, the OECD repeatedly noted the value of retrospective regulatory review.[80]

In 2019, the OECD published an additional survey regarding regulatory review practices in the European Union. The OECD again noted the utility of sunset provisions, describing them as a ''useful 'failsafe' mechanism to ensure the entire stock of subordinate regulation remains fit for purpose over time.'' [81] The report noted as of its 2019 date that sunset provisions are in place for at least some regulations in nine different countries, including the United Kingdom, France, and Germany.[82]

In 2009, the Republic of Korea (ROK) enacted a law under which about 20% of the existing regulations are to be reviewed on a regular basis (about every 3 to 5 years) and become invalid if they

[70] Regulatory Streamlining & Analysis (Mar. 2019) (it ''appears the current set of governance structures, incentives and processes to promulgate regulatory reform need strengthening to be more effective'').

[71] Ala. Code 41–22–5.2; Ariz. Rev. Stat. 41–1056; 5 Ill. Comp. Stat. Ann. 100/5–130; Iowa Code Ann. 17A.33; Mich. Comp. Laws 10.151; Missouri Rev. Stat., Title XXXVI § 536.175.5; N.J. Stat. Ann. 52:14B–5.1; N.M. Stat. 14–4A–6; N.C. Gen. Stat. 150B–21.3A; N.D. Cent. Code 28–32–18.1; Ohio Rev. Code Ann. 106.03; Okla. Stat. Ann. tit. 75, 307.1; 71 Pa. Stat. Ann. 745.2; R.I. Gen. Laws Ann. tit. 42, ch. 64.13; Tenn. Code Ann. 4–56–102; Wash Rev. Code Ann. 43.70.041, 43.22.052.

[72] Although the New Jersey law permits the Governor, within five days of the expiration of a rule, to restore it, the Department does not include a similar provision in this proposed rule. That is because the RFA contains no such similar provision and the Department is giving itself ten years, as opposed to seven years, to perform Assessments and (when required) Reviews of Regulations.

[73] Letter from Gov. Ron DeSantis to Florida Agency Heads (Nov. 11, 2019), *https://www.floridahasarighttoknow.myflorida.com/content/download/147113/980326/FINAL_Directive_to_Agencies_11.19.pdf.*

[74] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* 36 (Mercatus Ctr., Working Paper No. 12–18, 2012), *https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf.*

[75] Jason A. Schwartz, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemakings,* Inst. for Policy Integrity, Rep. No. 6, at 33 (Nov. 2010), *https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.*

[76] *See id.* (noting that ''North Carolina was first to repeal its sunset law, and many other states quickly followed suit'' after concluding that ''sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control'').

[77] *Id.* at 23–24. The report added, without citing a great deal of empirical evidence, that ''sunset requirements produce perfunctory reviews and waste resources.'' This appears to be based on a law review article that noted, not that retrospective reviews were per se perfunctory, but that ''unless adequate resources are provided, the reviews *may be* relatively perfunctory and meaningless, wasting whatever resources are expended.'' *See* Neil R. Eisner & Judith S. Kaleta, *Federal Agency Reviews of Existing Regulations,* 48 Admin. L. Rev. 139, 160 (1996) (emphasis added). But this law review article noted that adding ''sunset'' dates to regulations unless they are reviewed was ''likely to ensure that a review is done.'' *Id.* As explained herein, the Department intends to commit adequate resources to its reviews if this proposed rule were to be finalized. The law review article said that sunset provisions should be used only in narrowly focused situations where it is determined that it is necessary to apply some ''pressure'' and only where assessments are made of the available resources and the benefits to be derived from the review. *Id.* But the article was written in 1996. As discussed herein, subsequent experience with efforts short of a forcing mechanism suggest that forcing mechanisms are needed to ensure review of a wide array of Department regulations, and that the benefits from these retrospective reviews would be substantial.

[78] OECD, *Better Regulation in Europe: Executive Summaries,* GOV/RPC (2010)13, at 113, *http://www.oecd.org/gov/regulatory-policy/45079126.pdf.*

[79] *Id.* at 46.

[80] *See, e.g., id.* at 107 (''The *ex post* evaluation of regulations which is provided for in the impact assessment process provides a framework in principle for checking what really happens, and whether regulations have actually achieved the objectives originally set.'').

[81] OECD, *Better Regulation Practices across the European Union,* at ch. 4, Box 4.1 (2019), *https://www.oecd-ilibrary.org/sites/9789264311732-en/1/2/4/index.html?itemId=/content/publication/9789264311732-en&_csp_=07701faff9659027b81a5b5ae2ff041c&itemIGO=oecd&itemContentType=book.*

[82] *Id.* at ch. 4, Table 4.1.

are found to lack feasibility.[83] Under the ROK's ''review and sunset,'' there is a duty to carry out a review of a regulation on a specified schedule. This sunset clause was established upon the idea that even a rational regulation needs to be examined periodically to determine its grounds for remaining in force, as its validity may be compromised under any change in circumstances or its characteristics.[84] An OECD report stated that ''[g]iven such rationale, the sunset clause is considered as a critical component of efforts in regulatory quality improvement.'' [85]

These authorities indicate an emerging awareness that sunset provisions are useful in ensuring retrospective regulatory review. This is consistent with the Department's experience over the last 40 years, which suggests that, absent a sunset provision or automatic expiration date, Congressional and Presidential directives to perform periodic retrospective reviews of regulations have limited success.

Indeed, previous Administrations have recognized the benefits of sunset provisions. In a June 2015 report, the Department of Treasury's Office of Economic Policy, the Obama Administration's Council of Economic Advisors, and the Department of Labor discussed sunset provisions as applied to occupational licensing.[86] That report found evidence that sunset reviews that automatically terminate regulatory boards and agencies absent legislative action assist with ''removing unnecessary licensing.'' [87] The report explained that sunset review can be ''useful because, even if licensing was justified when first introduced, technological and economic changes may have rendered it unnecessary or overly restrictive.'' [88] The report found ''[p]eriodic examination of existing rules is thus helpful in maintaining the quality of occupational regulation.'' [89]

Professor Greenstone has similarly recommended the automatic repeal of regulations if their benefits and costs are not periodically assessed:

> [Another] step in reforming our regulatory system is to require that all regulations contain rules specifying the date by which the regulatory review board has to assess their costs and benefits. If the regulatory review board fails to meet one of these deadlines, then the regulation should be repealed by default. The purpose of this sunset provision is to ensure that all regulations are evaluated carefully and do not stay on the books just because they have been on the books in the past.[90]

Professor Greenstone suggested that this review could cause the regulation to be expanded if supported by evidence.[91] According to Professor Greenstone, this would ''ensure that ineffective regulations are removed and that society fully benefits from the effective ones.'' [92]

This final rule seeks to advance democratic values and apply the lessons learned from States, foreign jurisdictions, and the academic community. This final rule would apply the benefits of automatic-expiration-absent-periodic-review to a broader array of regulations than is currently being reviewed by the Department.

E. The Need for Widespread Retrospective Review

The evidence suggests the Department should conduct retrospective review on a broad scale to improve impact estimates and enhance the Department's ability to fulfil the goals motivating its regulations. As explained in Section C, studies of federal regulations consistently find that, in most sampled regulations, the ex ante estimate of costs and benefits is not within +/−25% of the ex post observation. Although these samples were not necessarily representative, taken together they suggest that many federal regulations are estimated after the fact to have real-world impacts that differ from the estimated impacts at the time the regulations were promulgated. Therefore, HHS believes that review should be done on a broad scale, rather than reviewing a handful of regulations that happen to be brought to the Department's attention.

The artificial intelligence review described in this final rule also suggests that large numbers of Department regulations would benefit from retrospective review. The artificial intelligence review identified that 85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references [93] in the CFR; and there are more than 50 instances of HHS regulatory requirements to submit paper documents in triplicate or quadruplicate.[94] This suggests that humans performing a comprehensive review of Department regulations would find large numbers of requirements that

[83] OECD, *Latest Developments on Korea's Regulatory Policy,* at 2, *https://www.oecd.org/gov/regulatory-policy/45347364.pdf.*

[84] OECD Reviews of Regulatory Reform, Regulatory Policy in Korea, Toward Better Regulation, at 86 (2017), *https://publicadministration.un.org/unpsa/Portals/0/UNPSA_Submitted_Docs/2019/4cd3e219-c819-40f3-8246-7a024d9a82a9/2020%20UNPSA_the%20Regulatory%20Reform%20Sinmungo_Evaluation%20Report_27112019_032807_e4d166a9-f6ef-4a6c-9aaf-99748fa94284.pdf?ver=2019-11-27-032807-637.*

[85] *Id.*

[86] *Occupational Licensing: A Framework for Policymakers,* The White House, at 48–50 (July 2015), *https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.*

[87] *Id.* at 48.

[88] *Id.* at 49.

[89] *Id.* The report also suggests that to strengthen sunset provisions in the States, sunset commissions responsible for conducting the cost-benefit analysis should be provided adequate resources; the cost-benefit review process should be insulated against political interference; a minimum number of votes should be required to overrule the sunrise agency's recommendation; and specialized committees within legislatures be appointed to work with the agency in charge of conducting the review. *See id.* at 42. As discussed herein, the Department believes it has adequate resources to conduct the required reviews. As discussed in footnote 92, it is not clear that a federal agency can legally completely insulate its reviews from supervision by the agency's leadership, but the Department believes that its retrospective reviews will generally be performed by career civil servants. Lastly, the Department cannot require Congress to appoint committees to work with the Department officials performing the retrospective reviews, but the Department would welcome the opportunity to discuss reviews with Congressional staff if Congress so chose. The report also suggested ''sunrise'' reviews can be more effective than sunset reviews. But for already-existing regulations, the Department cannot perform sunrise reviews, so the Department is has decided to take advantage of the benefits of sunset reviews. Moreover, the Department already engages in ''sunrise review'' to some extent when it develops regulatory flexibility analyses, *see* 5 U.S.C. 603, 604, and regulatory impact analyses (notably, such reviews did not occur for regulations that preceded the RFA, many of which still remain in effect).

[90] Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 121 (David Moss & John Cisternino eds., 2009).

[91] *Id.*

[92] *Id.* at 123. Professor Greenstone made a separate suggestion that a regulatory review board be created with the authority to assess the effectiveness of regulations and repeal regulations deemed ineffective. The Department considered this in the proposed rule. First, the Department is concerned that such a board raises legal concerns, since many Department regulations can only be repealed by the Secretary, not by an independent board. Second, Professor Greenstone proposed the independent review board on the grounds that (1) it would remove the board's functions as much as possible from political control, and (2) those most deeply involved in implementing a regulation are likely to see the benefits more clearly than the costs. *Id.* at 119–121. While these concerns are understandable, the Department believes it is capable of performing the Review. As an initial matter, those who conduct the Review would not necessarily be those in the Department who implement the Section being Reviewed. Moreover, as described herein, Reviews must be performed in such a manner that they can withstand judicial review under the arbitrary and capricious standard. This would require the Reviews to meet a minimum standard of rigor and require them to consider relevant factors. Moreover, many regulations legally cannot be amended or repealed without authorization by a political appointee.

[93] As discussed below, HHS has roughly 18,000 regulations total.

[94] 85 FR 70102.

would benefit from review, and possibly amendment or rescission.

The HHS response to the COVID–19 pandemic also indicates that the Department should perform widespread retrospective reviews. During the COVID–19 pandemic, the Department's response has largely consisted of waiving regulatory requirements or exercising enforcement discretion to not enforce certain regulatory requirements to enhance the Nation's response to the pandemic. Examples include waivers to increase hospital capacity, ease restrictions on services rendered by medical residents, and allowing patients to seek more services via telehealth.[95] On November 25, 2020, the Department published in the **Federal Register** a non-exhaustive list of 382 enforcement discretion announcements, waivers or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID–19 pandemic and its impact on the healthcare industry. *See* Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A. The Department should learn from the pandemic and conduct widespread reviews to determine whether these or other regulatory requirements could hinder the Nation's response to a future emergency, or otherwise should be amended or rescinded. Determining whether the Department's existing 18,000 regulations are having appropriate impacts is a worthwhile enterprise, even if it somewhat reduces the time spent issuing new regulations. Some commenters at the November 23, 2020 public hearing on the proposed rule suggested that the proposed rule was akin to using a missile to kill a mouse. But the literature and the Department's experience indicate the problem is not a mere mouse.

Thus, there is a need for widespread retrospective review, but it is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,[96] increasing access to health insurance,[97] or increasing the incentive for Temporary Assistance for Needy Families recipients to work.[98] These are all important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department's regulations. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals).

This final rule is not a reversal of a prior Department policy, but in fact an effort to enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations. In any event, this final rule provides the reasoned explanation that would be required if it were a change in policy.[99]

F. Operationalization of This Final Rule

In this section, the Department summarizes aspects of how it will operationalize this final rule.

The proposed rule proposed creating a website where the Department would announce when it has commenced Assessments or Reviews. The proposed rule further proposed that the public could comment on regulations and submit comments requesting that the Department Assess or Review a regulation.[100]

In light of public comments, the Department is making these procedures more robust. Under this final rule, when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the sections of the Code of Federal Regulations whose Assessment or Review it is commencing. The Department shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. Some comments on the proposed rule said that announcements should be made in the **Federal Register**, which the public already monitors, rather than a separate website. Therefore, in response to these comments, in this final rule the Department commits to announcing once a month in the **Federal Register** which new Assessments and Reviews it has commenced. The Department will also create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. These docket numbers will be referenced in the **Federal Register** announcements. The public will be able to submit comments to the dockets of each rulemaking being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department Assess or Review a regulation. This addresses the commenters' concern about commenting on a Department website, rather than via the regular **Federal Register** method. The Department anticipates that the process will be similar to that currently used by the EPA.[101] The Department also intends to publish the results of the Assessments and Reviews in the dockets for the applicable regulations.

To further aid the public and the Department, the Department is placing at *https://www.hhs.gov/regulations/federal-registry/index.html* a list of Department rule makings; the year they were initially promulgated; the last year the rule making was amended; and the **Federal Register** citation from the time the rule making was amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations.

In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews; its progress; and when it expects them to be completed. If they so

[95] *See, e.g.,* Coronavirus waivers and flexibilities, *CMS.gov, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.*

[96] *E.g.,* 21 CFR part 112.

[97] *E.g.,* 45 CFR part 147.

[98] 45 CFR part 261.

[99] *See FCC* v. *Fox TV Stations, Inc.,* 556 U.S. 502, 515–16 (2009) (''[A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy,'' but the agency ''need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates'') (emphasis in original).

[100] *See, e.g.,* 85 FR 70120.

[101] *See, e.g.,* Regulatory Flexibility Act Section 610 Review of the Testing and Labeling Regulations Pertaining to Product Certification of Children's Products, Including Reliance on Component Part Testing, 85 FR 52078 (Aug. 24, 2020).

choose, the public can view this dashboard to see the Department's progress on its Assessments and Reviews of particular regulations. The dashboard will also help to keep the Department on track to timely complete Assessments and Reviews.[102]

Finally, the Department will, within nine months of publication of this final rule, publish in the **Federal Register** its schedule for conducting Assessments and Reviews. The Department's goal is to provide the public with more information on which regulations it intends to Assess or Review in the next 24 months, so that the public can plan ahead for any desired engagement on those regulations. The Department will subsequently publish in the **Federal Register** its schedule for conducting Assessments and Reviews of regulations that the Department does not intend to review in the first 24 months. However, the Department expects that this schedule will be aspirational in nature to ensure Departmental flexibility to depart from the plan if needed to respond to changing circumstances. The Department will update the plan at appropriate intervals based on its progress.

III. Statutory Authority and Legal Basis for This Final Rule

The statutory authorities supporting this final rule are the statutory authorities for the Department's existing regulations.[103] 85 FR 70103. The Department finalizes herein its proposal to amend its regulations to add expiration dates unless the Department periodically conducts the required Assessment or Review of the regulations, or an exception applies. Some of the Department's primary rulemaking authorities include:

- Section 701(a) of the Federal Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 371(a), which authorizes the Secretary to ''promulgate regulations for the efficient enforcement of [the FD&C Act], except as otherwise provided in this section'';
- Section 1102 of the Social Security Act, 42 U.S.C. 1302, which provides that the Secretary ''shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act'';
- Section 1871 of the Social Security Act, 42 U.S.C. 1395hh, which provides that ''the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title''; and
- 5 U.S.C. 301, which provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.''

It complies with the Administrative Procedure Act (APA) to amend regulations to add dates by which the regulations expire unless a review of the regulation is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[104] An agency can also provide that its regulations expire when an event occurs or ceases to occur.[105] That is what this final rule does.

Moreover, Agencies can—and often do—issue one rule that applies to many other agency rules, rather than amending or rescinding each affected regulation individually. To take one example, in 2008 the Department revised the definition of ''entity'' at 42 CFR 411.351. *See* 73 FR 48434, 48751 (Aug. 19, 2008). The revised definition had the effect of changing the meaning of ''entity'' each time it was used in 42 CFR part 411, subpart J. It would be burdensome to specify the meaning of ''entity'' each time it appears in Subpart J, so the Department issued one definition that broadly applied to all sections of Subpart J.

There are many other examples where an Agency issues a regulation that applies to, amends, rescinds, or supersedes many other regulations.[106] This avoids an unnecessarily cumbersome process. A court ruling that agencies must amend each individual regulation would call into question large numbers of agency regulations and impose substantial burdens on agencies (and the Office of the Federal Register, which would be required to print the same text over and over) when promulgating future regulations.

Moreover, in this rule making the Department considered each individual Department regulation, and, as discussed further, decided to exempt certain regulations. The Department concluded that this final rule should apply to and amend its remaining regulations, because this final rule will enhance both (1) the fulfillment of the existing policies that led to those

[102] The Department's information technology personnel are currently undertaking a large data migration that had been planned for a long time. Therefore, the dashboard will not be active as of the date this final rule is published. But the Department intends for this dashboard to be active well in advance of 2026, when the first Assessments and Reviews must be completed.

[103] Including certain ones inadvertently not listed in the proposed rule.

[104] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276, 42277 (July 22, 2005) (amending interim final rule to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council* v. *Pruitt,* 862 F.3d 1, 9 (D.C. Cir. 2017) (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[105] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine, 85 FR 7874, 7874 (Feb. 12, 2020) (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19''); U.S. Dep't of Transp., Final Regulatory Impact Analysis: Amendment to Federal Motor Vehicle Safety Standard 208 Passenger Car Front Seat Occupant Protection, at XII–35 (July 11, 1984), *http://www-nrd.nhtsa.dot.gov/Pubs/806572.pdf* (explaining that ''[i]f mandatory use laws are passed that will cover 67 percent of the population effective September 1, 1989, the rule will be rescinded'').

[106] *See, e.g.,* 21 CFR 1.1(b) (''the definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act''); 7 CFR 786.113 (''*Notwithstanding any other regulation,* interest will be due from the date of the disbursement to the producer or other recipient of the funds''); 40 CFR 455.21

(''*Notwithstanding any other regulation,* process wastewater flow for the purposes of this subpart does not include wastewaters from the production of intermediate chemicals''); 45 CFR 611.12 (''All regulations . . . heretofore issued by any officer of the Foundation which impose requirements designed to prohibit any discrimination against individuals on the ground of race, color, or national origin under any program to which this part applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of such assistance for failure to comply with such requirements, *are hereby superseded* to the extent that such discrimination is prohibited by this part,'' with certain exceptions); 7 CFR 3430.1 (''In cases where regulations of this part conflict with existing regulations of NIFA in Title 7 (*i.e.,* 7 CFR parts 3400 through 3499) of the Code of Federal Regulations, *regulations of this part shall supersede*''); 24 CFR 943.118 (''The participating PHAs must adopt the same fiscal year so that the applicable periods for submission and review of the joint PHA Plan are the same. *Notwithstanding any other regulation,* PHAs proposing to form consortia may request and HUD may approve changes in PHA fiscal years to make this possible'') (emphasis added).

regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations. There is a need for widespread retrospective review, but it is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,[107] increasing access to health insurance,[108] or increasing the incentive for Temporary Assistance for Needy Families recipients to work.[109] These are all important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department's regulations. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). The Department concluded that the benefits of retrospective review, and need to more strongly incentivize it, justified this course of action. Forty years of experience since the RFA's enactment; the decades since relevant Executive Orders were enacted; and other Federal government efforts to spur the Department to conduct more retrospective reviews indicate that, absent this final rule's pushing mechanism, the Department will not conduct as many retrospective reviews as desired. In addition, the Department will consider each individual Section when conducting Assessments and (if needed) Reviews.

The Department also notes the text of 5 U.S.C. 610 indicates Congress believed agencies had the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that the agency had the authority to assess which of its regulations have such an impact).

The Department received comments on the statutory authority for the proposed rule. Below the Department summarizes these comments and responds to them.

IV. Provisions of Proposed Rule and Response to Public Comments [110]

On November 4, 2020, HHS published in the **Federal Register** the proposed rule.[111] Part of the proposed rule had a 30-day public comment period, and part of it had a 60-day comment period to comply with 42 U.S.C. 1395hh(b). In response to the publication of that proposed rule, HHS received 486 comments from industry trade organizations, healthcare providers, businesses, legal/policy think tanks, non-profit public interest groups, and members of the U.S. Congress during the initial 30-day public comment period, and 532 comments total throughout the 60-day comment period. Commenters generally opposed the proposed rule, although some commenters supported it. Roughly a quarter of commenters requested that the Department withdraw the proposed rule. Some commenters requested that the Department extend the public comment period.

The Department also held a public hearing on the proposed rule on November 23, 2020. Twenty-one members of the public, all representing either unions, public-interest groups, or industry trade organizations, spoke. The speakers at the public hearing all either expressed concerns about the proposed rule, opposed it, or requested that the Department withdraw it. Both a transcript and recording of the public hearing are available at *https://beta.regulations.gov/docket/HHS-OS-2020-0012/document.*

In the following sections, HHS includes a summary of the provisions of the proposed rule, the public comments received, HHS's responses to the comments, and any changes made to the regulatory text as a result.

General Purpose of the Proposal and General Comments

5 U.S.C. 610 and Executive Orders 12866 and 13563 direct agencies to devise plans to periodically review certain of their regulations using certain criteria. By requiring the Department to periodically perform such reviews, this final rule implements Congress's and the President's desires for retrospective review of regulations. This final rule will lead to the amendment or rescission, where appropriate, of Department regulations that have a significant economic impact upon a substantial number of small entities. This final rule also furthers democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation.

General Comments and Responses

Comment: A few commenters stated that the retrospective review of regulations proposed by the rule is an important and necessary tool for improving agency regulation and minimizing unnecessary regulatory burdens. Commenters listed the many benefits of this approach, including the refining of regulations using real-world data and experience, improving government accountability, avoiding the natural tendency of agency officials charged with achieving public benefits to focus on pursuing those benefits and not on reducing the burdens of their regulation to the public, and preventing the continued enforcement of obsolete, outdated, and even unintentionally harmful regulations. Some commenters stated that it is axiomatic that periodic retrospective review is essential to the proper functioning of the executive branch.

Response: The Department agrees, and believes this final rule will achieve these benefits.

Comment: A few commenters stated that beyond simply cutting regulatory burdens, the scheduled assessments and, when necessary, reviews of existing HHS regulations afford HHS the opportunity to keep regulations up to date with modern trends. Commenters noted that not only will this rule establish an opportunity for the Department to terminate obsolete regulations that are no longer fit for purpose or that are judged to be ineffective, but it will also give HHS and the public a reliable framework and a set of tools to continually keep regulations up to date with evolving circumstances.

Response: The Department agrees and emphasizes that the benefits of retrospective review—some of which are cited by these commenters—are substantial. As the proposed rule noted, Professor Cass Sunstein, who served as OIRA Administrator from 2009 to 2012, has observed that ''the requirement of retrospective analysis,'' if ''firmly institutionalized,'' ''would count as the most important structural change in regulatory policy since the original

[107] *E.g.,* 21 CFR part 112.

[108] *E.g.,* 45 CFR part 147.

[109] 45 CFR part 261.

[110] The Department proposed to add substantively identical provisions to Titles 21, 42, and 45. For concision, in this section the Department describes these provisions once, rather than repeating the same substantive provisions several times. The Department uses the phrase ''[XX]'' to refer to the fact that substantively identical provisions will be added to chapters in Titles 21, 42, and 45.

[111] *See* 85 FR 70096.

requirement of prospective analysis during the Reagan Administration.'' [112]

Comment: A large number of commenters stated that the proposed rule will cause an additional burden to the Department and a diversion of the Department's personnel resources. Some of these commenters suggested that the regulatory review process could adversely affect the Department's ability to focus on the administration of current programs, to issue new regulations, and to appropriately review current regulations needing modification. Commenters also raised specific concern about the initial review of regulations that are over ten years old within two years after the calendar year in which this rule is finalized. Those commenters expressed concern that HHS would be unable to Assess or Review all 12,400 regulations that the Department estimates will fall under this category because of the high volume of regulations. A number of commenters stated that two years is an arbitrary and inadequate timeline for all 12,400 regulations to be Assessed or Reviewed, and some regulations could expire simply because the Department did not have enough time to conduct an Assessment or Review. Several commenters also stated that they believe the Department's estimate that 12,400 of its regulations are over ten years old is lower than the actual number, although no commenter provided an independent count of HHS regulations to support this assertion. A few commenters pointed out that after an Assessment or Review occurs, there may be additional need for rulemaking or revision of regulations, which is an additional cost the Department does not contemplate in its estimate. A few commenters stated that it was unclear where HHS plans to obtain the funding and personnel resources needed to implement this regulatory review process.

Response: The Department has considered the public comments, and decided that, for regulations that are more than ten years old on the effective date of this final rule, the Department shall have five years, rather two as proposed in the proposed rule, to complete the Assessments and (if needed) Reviews. This will spread out the initial burden and provide the opportunity for more robust Assessments and Reviews. The regulatory impact analysis in this final rule explains how HHS has the resources and personnel to perform the Assessments and Reviews called for by this final rule. Moreover, the Regulatory Flexibility Act already calls for the Department to assess which of its regulations have a significant economic impact upon a substantial number of small entities, and to review those regulations every ten years. Therefore, assuming full compliance with the RFA, this rule does not impose any additional burden on the Department beyond what was already called for in the RFA.

To the extent there are additional burdens resulting from this regulation, HHS believes widespread retrospective review is a worthwhile enterprise. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time of promulgation. The Department should conduct periodic reviews to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Thus, it is sensible to periodically review existing regulations, even if it takes some time away from issuing new regulations (many of which, the literature suggests, would have impacts that differ from their estimated impacts at the time of promulgation).

HHS also notes that courts ''have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.'' *In re Barr Labs., Inc.,* 930 F.2d 72, 76 (D.C. Cir. 1991). For the reasons discussed herein, the Department has done this, and determined that Reviews and Assessments should be a priority.

Lastly, we note that the COVID–19 pandemic imposed a tremendous, unforeseen burden on the Department, yet there has been no material drop in the Department's ability to promulgate new regulations or enforce existing regulations. This suggests that after the pandemic, the Department will be resourceful enough to perform Assessments and Reviews, as well as promulgate new regulations that need to be promulgated and appropriately enforce existing regulations.

Comment: A few commenters stated that the benefits of this final rule are difficult to fully anticipate, and there are a number of reasons to believe that the benefits of this rulemaking will vastly outweigh the costs. For example, if HHS were to find cost savings worth 0.0025 percent of departmental spending or 0.0007 percent of national spending, the regulation would pay for itself and pass a cost-benefit test at the higher end of cost estimates.

Response: The regulatory impact analysis for this final rule describes what the Department expects to be the primary impacts resulting from this final rule.

Comment: A large number of commenters stated that, as proposed, this rule would divert resources from the Department's COVID–19 pandemic response efforts. Many of these commenters stated that it is irresponsible for the Department to create a retrospective regulatory review process at a time when it should be devoting all of its resources to combatting COVID–19.

Response: HHS respectfully disagrees with this comment. Due to the changes made from the proposed rule, under this final rule the first Assessments and Reviews need not be completed until the end of 2026. The Department believes the pandemic will be over by then.

In fact, the COVID–19 pandemic has reinforced the need for this final rule. The Department's response to the pandemic has largely consisted of waiving regulatory requirements or exercising enforcement discretion to not enforce certain regulatory requirements during the pandemic. *See, e.g., Coronavirus waivers and flexibilities, CMS.gov, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers;* Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A (non-exhaustive list of enforcement discretion announcements or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID–19 pandemic and its impact on the healthcare industry). The Department should learn from the pandemic and consider whether to retain regulatory requirements that were waived or where flexibility was provided during the Nation's response to COVID–19, as well as consider the impact its regulations could have on the response to a future pandemic or other emergency.

Comment: A large number of commenters viewed the 30-day comment period (which began on November 4, 2020, the day that the **Federal Register** published the proposed rule and the day after the rule went on public display) as too short. A large number of these commenters stated that the proposed rule should be withdrawn for various reasons, or in the alternative, requested a longer comment period if the proposed rule was not withdrawn. Commenters' reasons for asking for an extension included lack of

[112] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 584 (2014).

advanced notice of the proposed rule, the perceived magnitude of the rule, fewer resources available to commenters due to the COVID–19 pandemic and the Thanksgiving holiday, and the number of topics on which the Department requested comment.

A large number of commenters stated that the 30-day comment period violates the Administrative Procedure Act (''APA'') because it denies meaningful ''opportunity to participate in the rule making'' required by 5 U.S.C. 553(c).[113] A few commenters specifically mentioned that while there is no established minimum comment period prescribed by the APA, Executive Order 12866 states that the public's opportunity to comment, ''in most cases should include a comment period of not less than 60 days,'' although shorter comment periods have been upheld in the face of exigent circumstances.[114] Other commenters said the Department should not finalize the rule until the next Administration enters office.

Response: While HHS understands the commenters' desire for more time, the comment period was adequate. Neither the APA, nor any other statute requires a longer comment period for the proposed rule. Instead, the APA merely requires that ''[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.'' 5 U.S.C. 553(c). This occurred here. The comment period provided ample time for the submission of 486 comments by a variety of interested parties, including extensive comments by a number of entities just by the end of the 30-day period. Those comments offer a broad array of perspectives on the proposed rule. The number and comprehensiveness of the comments received disprove commenters' claim that the 30-day comment period was insufficient time for commenters to provide meaningful comment. Accordingly, after reviewing the public comments and the requests for additional time, the Department does not believe that extending the comment period is or was necessary for the public to receive sufficient notice of, and opportunity to meaningfully comment on, the proposed rule. Nor is there anything that would have required additional outreach outside of the public notice and comment process and the comment period.

Moreover, under this final rule, the public will have a robust opportunity to comment on each regulation during the Assessment or Review process.

HHS respectfully disagrees that Executive Order 12866 requires a 60-day comment period for this rule. Executive Order 12866 repeats the baseline requirement that ''each agency should afford the public a meaningful opportunity to comment on any proposed regulation,'' which ''in most cases should include a comment period of not less than 60 days.'' [115] Neither Executive Order mandates a 60-day comment period. That is why many HHS, and other agency, regulations are issued with shorter comment periods. No commenter pointed to a court decision vacating a rule based on a failure to comply with an Executive Order's supposed 60-day comment period requirement. As explained above, the volume of comments received demonstrates that the public has been afforded a meaningful opportunity to comment.[116]

Moreover, a portion of the proposed rule had a 60-day public comment period because 42 U.S.C. 1395hh(b) requires a 60-day comment period before issuing or amending certain Medicare regulations. The Department did not finalize this rule until after the 60-day comment period closed, and the Department has considered all comments, including those received throughout the 60-day comment period, before finalizing this rule. In all, the Department received 532 comments by the end of the 60-day comment period.

Lastly, past practice has often been to finalize rules that are ready for finalization without waiting for the incoming Administration to take office.[117]

Comment: A few commenters viewed the 30-day comment period as insufficient because some of the regulations that will be amended by this final rule had a comment period that lasted more than 30 days when they were originally promulgated.

Response: HHS respectfully disagrees with these commenters. Not only did the Department not finalize this rule until after the 60-day comment period closed, but the APA does not specify a required length for comment periods when issuing or amending regulations. The APA has already ''established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures.'' *Vt. Yankee Nuclear Power Corp.* v. *Natural Res. Def. Council, Inc.,* 435 U.S. 519, 524 (1978). Neither courts nor regulated entities may ''impose upon [an] agency its own notion of which procedures are 'best' or most likely to further some vague, undefined public good.'' *Id.* at 549. The number and comprehensiveness of the comments received disprove commenters' claim that the comment period was insufficient. A portion of the proposed rule had a 60-day public comment period because 42 U.S.C. 1395hh(b) requires a 60-day comment period before issuing or amending certain Medicare regulations. But for many other Department regulations, Congress has enacted no requirement specifying a particular comment period.

Comment: Several commenters stated that they found it unfair that the proposed rule had a 30-day comment period, but parties regulated by CMS have 60 days to comment on the portion of the proposed rule pertaining to certain CMS regulations. Commenters mentioned that they believed this could present a fundamental due process issue.

Response: As stated in the proposed rule, Congress required a 60-day public comment period before issuing or amending certain Medicare regulations. *See* 42 U.S.C. 1395hh(b); 85 FR at 70104 n.87. No similar statutory requirement applies to most other Department regulations.

Comment: Several commenters stated that seven days' notice prior to the public hearing on the proposed rule was insufficient time to prepare remarks for the public hearing. The same commenters also stated that holding the public hearing 10 days before the close of the comment period on the rule was insufficient time for commenters to

[113] *See N.C. Growers' Ass'n, Inc.* v. *United Farm Workers,* 702 F.3d 755, 770 (4th Cir. 2012) (APA requires ''meaningful'' opportunity to comment); *Petry* v. *Block,* 737 F.2d 1193, 1201 (D.C. Cir. 1984) (relying on Administrative Conference of the United States' view that 30-day comment period is inadequate and 60-day comment period is the reasonable minimum time for comment).

[114] Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 190 (Oct. 4, 1993).

[115] *See also* Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011) (''To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally be at least 60 days.'').

[116] A commenter pointed to 21 CFR 10.40(b)(2) as counseling in favor of a 60-day comment period. But that provision by its terms applies only to the FDA Commissioner. The proposed rule was issued by the Secretary.

[117] For example, fifty-six (56) new rules were finalized in the final two (2) full days of the previous Administration. *See* **Federal Register**, *https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=1%2F18%2F2017&conditions%5Bpublication_date%5D%5Blte%5D=1%2F20%2F2017&conditions%5Btype%5D%5B%5D=RULE.*

meaningfully incorporate the testimony and learnings from the public hearing into their written comments.

Response: HHS respectfully disagrees. While the specific date of the hearing (November 23, 2020) was published in the **Federal Register** on November 16, 2020, notice that a hearing would be held was provided in the proposed rule itself.[118] Thus, commenters were on notice 19 days (November 4, 2020, to November 23, 2020) prior to the hearing and had 19 days to prepare remarks for the hearing. And as these comments themselves show, choosing the date for the public hearing requires a balance between, first, giving the public sufficient time to review the proposed rule, and second, giving the public adequate time to review comments made at the hearing before submitting written comments. Scheduling the hearing on November 23, 2020 reflected an appropriate balance of these considerations.

Comment: Several commenters were supportive of the rule and expressed that the provisions of the Regulatory Flexibility Act should be followed to increase transparency, public participation, and administrative accountability. These commenters appreciated the Department's efforts to ensure recurring attention to the impact of its rules on small and independent businesses, and minimize the regulatory burden it imposes on these entities. These commenters also stated that regulatory review is a laudable goal that administrative agencies should be aiming for.

Several commenters emphasized the importance of periodically reviewing old regulations to determine whether they should be updated to adapt to changing circumstances. For instance, a few commenters stated that the COVID–19 pandemic drew attention to the fact that many of the Health Insurance Portability and Accountability Act (HIPAA) regulations are out-of-date. Some commenters also stated that the process for developing regulatory impact analyses could be improved if, after each regulation is fully implemented, public comments were solicited on the accuracy of the assumptions underlying the original impact analysis. These commenters appreciated the Department's efforts to consider and update its regulatory review process.

Response: HHS agrees with these commenters that the final rule will implement the important goals of the Regulatory Flexibility Act, including transparency, public participation, administrative accountability, and a more streamlined regulatory structure. The process set out in the proposed rule that is now being finalized will create a structured plan to operationalize the Department's longstanding goals of reviewing and updating its regulations and—where needed—eliminating regulations that no longer serve their intended purpose(s) and unduly burden both small entities or the public at large. Requiring the solicitation of comments on the assumptions in regulatory impact analyses is beyond the scope of this final rule, but the public is welcome to submit such comments to the dockets of regulations being Assessed or Reviewed.

Comment: A few commenters stated that the proposed rule does not provide sufficient examples of how this approach has worked in the past. A few commenters point out that the proposed rule cites an article that indicates that states have adopted and then abandoned similar approaches to adding automatic expirations dates. They also state that HHS dismisses this fact in the proposed rule without providing a compelling reason. Commenters stated that the examples where this approach has been used that the Department cites to in the proposed rule (U.S. states, the European Union, and the Republic of Korea) have no bearing or authority over federal rulemaking in the United States, where Congress through the APA has established procedures and standards for promulgating, updating, and rescinding regulations. They also stated that the executive actions reviewing regulations that are cited to in the proposed rule underscore that the Department does not need this rule to compel periodic regulatory review.

Response: HHS respectfully disagrees. As explained in the proposed rule, 85 FR at 70102 & nn.66–69, to the extent that states abandoned automatic expiration dates, they did so for reasons that are inapplicable to this situation, namely, the provisions' failure to enhance legislative control. As explained in the regulatory impact analysis, at least one state that undid its sunset provision (North Carolina) subsequently reenacted a sunset process for regulations. The article that one commenter referenced[119] did not cite any empirical support for the proposition that automatic expirations produce ineffective or inadequate retrospective reviews where sufficient resources and staff are provided (as is the Department's intent here).[120]

Second, the proposed rule referred to other jurisdictions' sunsets to illustrate that (1) adding sunset provisions does not wreak havoc or cause undue uncertainty and (2) experience shows sunset provisions can be effective in achieving the benefits from robust retrospective review of regulations. The legal framework of federal rulemaking under the APA may differ from other jurisdictions, but that does not detract from the point that other jurisdictions' experience shows that sunset provisions can be effective and do not lead to havoc or tremendous uncertainty. For the reasons explained in the proposed rule and this final rule, this final rule complies with the APA.

The Department also disagrees with the commenters' suggestion that the existence of limited and sporadic instances of retrospective review demonstrate this rule is not necessary. As explained in the proposed rule, the Department has failed to engage in comprehensive retrospective review of its rules notwithstanding the RFA and long-standing Executive Orders calling for such reviews. This history of limited compliance shows that the proposed rule being finalized is appropriate.

Comment: Several commenters stated that the proposed rule was a political effort to cause difficulties for the incoming Biden Administration, which will be tasked with implementing this final rule.

Response: HHS respectfully disagrees with these commenters because the purpose of this final rule is to require the Department to periodically review its regulations. The rule is not politically motivated, but is instead an effort to ensure the Department periodically reviews its regulations that have a significant economic impact upon a substantial number of small entities. In any event, based in part on comments received on the proposed rule, in this final rule the Department has extended the deadline to five calendar years to complete the Assessments and (if necessary) Reviews of regulations that are more than ten years old. Thus, the initial deadline will not occur in the next Presidential term.

Comment: A few commenters stated that this rule is advancing the Trump Administration's conservative agenda at the expense of good regulations that regulate health and safety for patients and consumers. Many of these commenters also indicated that the rule would put the interests of Wall Street ahead of the individual Americans who

[118] 85 FR at 70097.

[119] Jason A. Schwartz, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemakings, Inst. for Policy Integrity,* Rep. No. 6, at 33 (Nov. 2010), *https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.*

[120] *See* 85 FR at 70102 n.69.

are affected by HHS regulations and benefit from the regulatory structures they create.

Response: HHS respectfully disagrees. As emphasized in the proposed rule, (and this final rule) the Department intends to timely Assess and Review all covered regulations. Moreover, this final rule does not favor regulations of any particular ideological bent; it applies to all Department regulations, subject to the exceptions listed herein. Regulations that meet the RFA's criteria will not be modified or rescinded. The focus and anticipated result of the proposed rule is to eliminate or streamline unnecessary regulatory burdens on small entities. Retrospective review enjoys bipartisan support and benefits all Americans. Some regulations may bestow privileges upon narrow constituencies by creating barriers to entry in their industry. Such regulations may also disproportionately burden small businesses, because small businesses may be the new entrants such regulations are intended to keep out. If these regulations do not meet the RFA's criteria and are amended, small businesses and consumers may benefit from increased competition.

Comment: A few commenters stated that regulations issued after this rule is finalized should include the date of promulgation to make it easy for the public to determine how old the regulation is and when it will be reviewed.

Response: Rules already include their date of promulgation. To the extent the commenter requests that amendments to existing rules include the original date of promulgation, the Department may include this date in prospective rulemakings. Moreover, in conjunction with this final rule, the Department is placing at *https://www.hhs.gov/regulations/federal-registry/index.html* a list of Department rulemakings, the year they were initially promulgated, the last year the rules were amended, and the **Federal Register** citation from the time the rule was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations.

Comment: One commenter stated that instead of the Department's proposed schedule of regulatory review, each agency within HHS should include retrospective review compliance into its annual objectives and, perhaps, even into periodic Congressional reports.

Response: The Department thanks the commenter for this suggestion, but experience suggests it would not be adequate to solve the problem. As noted in the proposed rule, the failure to adequately review existing significant regulations has already been well documented to Congress.[121] It is also public knowledge.[122] Nonetheless, such ''public shaming,'' if that is what the commenter intends, has not resulted in the Department adequately conducting retrospective review.

Comment: A large number of commenters stated that the proposed rule would be unnecessary and duplicative of the Department's existing efforts to review its regulations. These commenters stated that the Department already updates some of its rules annually, and has updated other non-annual rules in the past. Other commenters believe that HHS is already doing a fulsome review as required by the RFA. Several commenters stated that in 2011, the Department posted its final plan for retrospective review of existing regulations, and from 2012–2016 it provided semi-annual updates on its website listing the rules undergoing or scheduled for review. Some commenters suggested that previous executive orders that called for periodic review of existing regulations are a sufficient means of ensuring the Department is conducting these periodic reviews. Commenters suggested that the Department continue to conduct retrospective reviews using its already established process and provide regular updates to the public on its progress. Other commenters stated that the Department does not address why it failed to perform the required regulatory reviews in the past, nor how the process proposed in the proposed rule will make a difference.

A few commenters noted that even though previous executive orders have prioritized regulatory reviews, most observers to date note that these kinds of reviews have failed to be institutionalized by agencies, including HHS. These commenters cited evidence suggesting that despite efforts to review regulations over the years and to reduce regulatory burdens, the total number of regulatory restrictions that have been issued by HHS continues to grow year after year, except for two brief periods around 1980 and during the mid-1990s (perhaps as part of deregulatory efforts).

Response: The Department respectfully disagrees that this final rule is unnecessary and duplicative. While commenters are correct that HHS annually updates the annual Medicare payment rules, those rules and certain other rules that are updated annually are exempt from this final rule. This final rule also exempts the rules at 42 CFR part 73, since those are periodically reviewed. Regarding the 2011–2016 retrospective review plan and reviews, that effort was helpful but sporadic, not sustained. As explained in the proposed rule, these efforts only resulted in review of a small fraction of rules. *See* 85 FR at 70099. The failure to institutionalize retrospective review further underscores the need for this final rule and the review process it is implementing. A few instances of the Department taking the initiative to review its regulations cannot reasonably be considered a sufficient regulatory review when thousands of regulations that have been promulgated over the decades have not been touched.[123]

Comment: Many commenters questioned the Department's plan for personnel resources to conduct the Reviews prescribed by this final rule. These commenters believe that the Department underestimated the number of people who would be needed to conduct the Reviews, and stated that the personnel resources would be better utilized on other projects. For example, some commenters stated that the Department is already too slow in promulgating certain regulations, and should task its employees with carrying out the Department's existing duties.

Response: The regulatory impact analysis for this final rule describes the personnel resources that the Department envisions being used to conduct Assessments and Reviews. The

[121] *See, e.g.,* Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 7–8 (2008); U.S. Gov't Accountability Off., GAO/GGD–94–105, Regulatory Flexibility Act: Status of Agencies' Compliance 12 (1994) (quoting a 1983 Small Business Administration report that stated that the Department's section 610 review plan was '' 'very general,' and, as a result, 'it is difficult to measure progress and to make recommendations with respect to future review' ''); *see also* Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008),

[122] *See, e.g.,* Connor Raso, *Assessing regulatory retrospective review under the Obama administration,* Brookings Inst., (Jun. 15, 2017), *https://www.brookings.edu/research/assessing-regulatory-retrospective-review-under-the-obama-administration/.*

[123] *See, e.g.,* 85 FR at 70111 (explaining that as of 2019, 85% of Department regulations created before 1990 had not been edited, and the Department had nearly 300 broken citation references in the CFR).

sensitivity analysis therein addresses the possibility that costs could be lower than estimated in the proposed rule. Periodically reviewing regulations with a significant economic impact upon a substantial number of small entities is an existing Department duty. Moreover, as discussed elsewhere herein, retrospective review can yield tremendous benefits. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department should prioritize conducting periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals).

Comment: A few commenters questioned whether the Department should have employees Assess or Review regulations if those employees are not responsible for implementing them. These commenters stated that if reviewers have not worked on matters connected with the regulations they are Reviewing, those reviewers may not have an adequate understanding of the regulations, which could lead to the expiration of regulations that are essential to the successful operation of the Department's programs.

One commenter also disagreed with the premise of the Department's use of career civil servants to conduct regulatory reviews. This commenter stated that the proposed rule was logically inconsistent because it ''maligned'' career public servants at the Department for not reviewing the Department's regulations, but also proposes to task these same individuals with carrying out the proposed review process.

Response: Which Department officials Assess or Review particular regulations will be decided on a case-by-case basis, but those conducting Assessments and Reviews will generally be employees who are familiar with those regulations, as well as technical experts, including economists. The Department strongly disagrees with the comment that the proposed rule ''maligned'' career civil servants. The proposed rule quoted a law professor who was suggesting several reasons why retrospective reviews do not occur as often as desired. The Department believes career civil servants can capably Assess and Review regulations, just as they capably conduct regulatory impact analyses and regulatory flexibility analyses.

Comment: Several commenters stated that the two-year timeline for review of all regulations over ten years old was insufficient. A number of commenters suggested that the timeline be extended to five years.

Response: The Department has considered these comments and has decided to revise the rule in light of them. Under this final rule, regulations issued more than ten years prior to the final rule's effective date will not expire if Assessed and (if necessary) Reviewed within five calendar years of the effective date of this final rule. Moreover, under this final rule, if the Secretary makes a written determination that the public interest requires continuation of the Section (as defined in the text of the final rule) in force beyond the date on which the Section otherwise would expire, the Secretary may continue the Section in force one time for a period stated in the determination, which period shall not to exceed one year.

Comment: Several commenters stated that the proposed rule would cause significant regulatory uncertainty in the healthcare industry, which would not know which regulations may or may not expire. Some commenters stated that the proposed rule would cause uncertainty for states, which implement Federal programs and rely on Federal regulations and funding. Potential regulatory changes could create additional compliance and regulatory costs for healthcare providers which may be forced to adapt to a changing regulatory framework. Changes may also trigger regulated entities to forgo future investments because they lack regulatory clarity. For example, some commenters stated that the uncertainty created around the expiration of regulations, including those that guide eligibility for Medicaid, Medicare provider reimbursements, or certification of hospitals and clinics, could disrupt the efficient operation of critical safety-net programs, create regulatory gaps and inconsistent application of the law, and make accessing safety-net services for our most vulnerable populations even more complicated and difficult than it is today. Some commenters said the poor, people of color, and/or the LGBTQ community, would be particularly affected. Additionally, some commenters stated that the proposed rule would make it difficult for them to advise clients on how to comply with the Department's regulations. These commenters stated that if HHS determined that a regulation required modification, it should clearly publicize its intention to exercise enforcement discretion in not enforcing the then-current iteration of the regulation while the particular regulation is being modified.

Other commenters stated that the regulatory review process set forth in this rule would ensure that HHS reviews regulations as required by the RFA, which means that if HHS were currently complying with the RFA in a satisfactory manner, there would be little additional uncertainty stemming from the proposed rule.

Response: The Department notes that there is always a possibility that regulations could be amended or rescinded, even absent this rule. The Department does not believe uncertainty among the regulated community will add significantly to the costs of this rulemaking for the following reasons. The Department's sporadic use of periodic retrospective review—notwithstanding the RFA and Executive Orders—itself leads to ''uncertainty'' about how robustly the Department implements directives that make for good policy.[124] To the extent that the Department can maintain compliance with its obligations, this should build trust in the Department and reduce uncertainty (offsetting some or all of the uncertainty discussed by the commenters, if such uncertainty exists). Further, as noted above, the Department plans to release information about the 18,000 regulations under its authority and when they were adopted, such that any uncertainty surrounding the expiration dates of the Department's various rulemakings will be reduced substantially, if not entirely. Additional measures to mitigate private costs are discussed in the ''Operationalization of This Final Rule'' section of this final rule. Second, the Department notes that many states and foreign jurisdictions have sunset provisions that are a routine part of their regulatory processes. If the sunset reviews in these other jurisdictions do not create tremendous uncertainty, it stands to reason that neither will this final rule. The regulatory impact analysis for this final rule describes in more detail the sunset provisions from these other jurisdictions.

Under this final rule, the regulated community has five years to adjust to the changes made by this final rule, so any reliance interests are significantly reduced as compared to the proposed rule. Where appropriate, the Department would announce the regulations for

[124] To the extent this uncertainty has been lessened because the public has seen how the Department has implemented these directives over the course of many years, the same can be said for this final rule once it has been implemented for several years.

which it is exercising enforcement discretion.

Comment: A few commenters stated that the Department should allow reasonable reliance on a regulation while that regulation is under review, and for a reasonable time after a decision to amend, rescind or allow a regulation to expire. These commenters also stated that the final rule should allow the Department to extend a regulation for any period of time reasonably necessary for regulated entities relying the regulation to adjust their business practices.

Response: HHS appreciates the commenters' concern regarding the reliance interests of regulated entities; however, HHS respectfully disagrees with the premises of these comments. First, HHS does not intend to allow a regulation to simply expire. And as explained in the proposed rule, the public will have the opportunity to provide comments identifying regulations that the public believes need to be Assessed and Reviewed, which mitigates the risk of inadvertent expiration.

Second, with respect to Sections that, after Review, the Department determines should be amended or rescinded, such Sections will be amended or rescinded through a separate notice-and-comment rulemaking process. Considerations about the effective dates of such amendments or rescissions, including the need to allow adequate time for transition, will be taken into account in that separate rulemaking process. Finally, Review under this final rule expressly considers ''the continued need for the Section,'' so regulated entities' reliance interests will be taken into account during Reviews.

Comment: Several commenters stated that the use of artificial intelligence and machine learning technology in regulatory review is a novel and innovative approach, and members of the public should have been afforded notice of the Deloitte research project and the opportunity to comment on the use of this technology. In particular, these commenters wanted to understand if and how the technology would be used by HHS to identify the regulations that will be reviewed. Some commenters asked HHS to provide additional information regarding the methodology used, and the underlying algorithm. A few commenters stated that all code should be posted on a publicly-accessible website, consistent with best practices among academic researchers in data science.

Response: The Department agrees that the use of artificial intelligence machine learning technology in regulatory review is a novel and innovative approach. The technology discussed in the proposed rule was initially used to perform an internal assessment of Department regulations, which is why the Department did not previously notify the public about this research project. Artificial intelligence will not be used to perform Assessments and Reviews pursuant to this final rule. While artificial intelligence can determine if a regulation has been amended in the last thirty years, it cannot at this time easily determine if a regulation satisfies the criteria listed in 5 U.S.C. 610. The artificial intelligence review was useful, because it suggested that large numbers of Department regulations would benefit from retrospective review. The technology identified that 85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references in the CFR; and there are more than 50 instances of HHS regulatory requirements to submit paper documents in triplicate or quadruplicate. This suggests humans performing a comprehensive review of Department regulations would find large numbers of requirements that would benefit from review, and possibly amendment or rescission.

Regarding the technology used to perform the 2019 analysis, the analysis was performed using a tool called RegExplorer. RegExplorer is an ''augmented intelligence'' tool, meaning it is designed to use artificial intelligence in conjunction with subject matter experts. While RegExplorer is proprietary technology, some of the models deployed within RegExplorer include keyword technology (a structured and iterative approach to process, analyze, and return keyword search results); a clustering algorithm (a cluster is a machine-generated group of regulatory documents that have been algorithmically gathered together based on a set of similar characteristics, such as the relevant sub-agency, placement of text within the regulatory dataset, similarity of text content, and text format and structure); citation extraction and mapping; and similar section analysis.

Comment: A few commenters asked why HHS chose to redact some of the ''Regulatory Streamlining & Analysis'' published by Deloitte in March 2019 that the Department cites in support of the proposed rule. These commenters pointed out that two of three bullet points in the ''executive summary'' slide, and all but 25 of the document's 170 pages are redacted. These commenters asked why this information was not made available to the public, and why HHS did not have a public meeting to discuss the Deloitte findings and solicit feedback on its regulatory reform ideas back in 2019.

Response: The Department was transparent by including the Deloitte analysis in the docket for this rulemaking. The redacted information is information protected by applicable privileges, is confidential information, trade secret information, or not relevant to this rulemaking. As can be seen from the Table of Contents for the analysis, the redacted information does not relate to the machine learning analysis that was conducted to enhance regulatory reform that was discussed in the proposed rule. In November 2020, the Department held a public hearing on the proposed rule, which referred to the Deloitte presentation. The public was able to opine on the analysis at that public hearing. The Department did not have a public meeting to discuss the Deloitte findings and solicit feedback in 2019, because the Department was at the time still undergoing its internal deliberative process.

Comment: A few commenters stated that ideally the systematic evaluation of regulations should be a regular part of the rulemaking process, with the evaluation criteria and timeline embedded within each new rule so that the regulated community has an opportunity to opine on how and when each regulation will be reviewed. Commenters suggested that HHS identify up front what data it will use to track the progress of the regulation, and commit to continually collecting the same kinds of data over time. Such a process would make future evaluation of regulations and programs easier. It would also improve public accountability because the public would have a clearer sense of what the regulation is designed to achieve, and can monitor HHS's progress.

Response: HHS agrees with the commenters' focus on the need to systematically evaluate the effectiveness of agency regulations—indeed, the Department has proposed the instant rule in order to make such evaluations more frequent and comprehensive. The timeline for Review of a given Section is set forth in section [XX](c)(1), and the criteria for Review are set forth in [XX](d). As is current practice, the Department intends to explain in the preambles to future rules what goals the rules are intended to achieve. This will enable the public to know what goals each regulation is designed to achieve. However, the data necessary to evaluate a particular rule will differ from rule to rule, and the Department cannot

generally commit to such collection in advance and in the abstract, although it may be useful to do so in particular cases.

Comment: One commenter suggested that HHS consider performing a cost-savings analysis for regulations receiving a Review under the proposed rule, or for that subset of Assessed regulations that are deemed significant or economically significant. Such analysis could include estimates of the costs, cost savings, and the net cost savings of the regulation.

Response: For purposes of this final rule, the Department has decided to limit the Review criteria to the criteria listed in 5 U.S.C. 610, plus whether the regulation complies with applicable law. These are the criteria that Congress directed the Department to use in its periodic reviews, plus a review for compliance with the law. Determining the regulation's costs, as well as cost savings from amendment or rescission, will often be subsumed in the five criteria listed in 5 U.S.C. 610.

Comment: A large number of commenters stated that the proposed rule would negatively impact programs if review efforts are underfunded, or that the proposed rule was costly and unfunded.

Response: The Department disagrees that regulatory review efforts would be underfunded. As explained in the regulatory impact analysis, this final rule will impose relatively low costs on the Department.

Comment: Several commenters, including Tribal governments and representatives, affiliated groups of Indian Tribes, and the IHS Tribal Self-Governance Advisory Committee, stated that the Department should have consulted with Tribal governments on the rule and failed to notify Tribal leaders and representatives of the proposed rule in violation of HHS's duty as a federal agency to consult with Tribal nations under Exec. Order No. 13175 of Nov. 6, 2000, 65 FR 67249 (Nov. 9, 2000) (E.O. 13175) and the Department's own Tribal consultation policy.

Response: The Department and Indian Tribes share the goal to establish clear policies to further the government-to-government relationship between the Federal Government and Indian Tribes. True and effective consultation shall result in information exchange, mutual understanding, and informed decision-making on behalf of the Tribal governments involved and the Federal Government. The importance of consultation with Indian Tribes was affirmed through Presidential Memoranda in 1994, 2004 and 2009,[125] and E.O. 13175. HHS believes that neither the proposed nor the final rule violate the Department's Tribal consultation policy or E.O. 13175. Subject to certain exceptions, the policy and E.O. 13175 require consultation before any action that will significantly affect Indian Tribes, or before promulgating any regulation that has Tribal implications. HHS believes that this final rule does not significantly affect Indian Tribes or have Tribal implications, as those terms are used in the policy and E.O. 13175. This final rule amends existing regulations to provide that the regulations will expire if not Assessed and (if necessary) Reviewed by certain dates. HHS intends that all rules will be Assessed and (if necessary) Reviewed timely. Therefore, this final rule would have no direct impact on Indian Tribes, beyond their costs of participation in the monitoring, Assessment, and Review processes. As explained in this final rule's regulatory impact analysis, the estimated total monitoring costs to the public over ten years is estimated to range from $52.2 million to $156.7 million using a 7% discount rate, or $58.8 million to $176.3 million over ten years using a 3% discount rate (all figures using $2020). The U.S. Census estimates that in 2019, 1.7% of the U.S. population was all or partially American Indian or Alaska Native.[126] 1.7% of the estimated monitoring costs would be roughly $887,400 to $2.66 million over ten years using a 7% discount rate, or $999,600 to roughly $3 million over ten years using a 3% discount rate (and the cost to Tribes could be less since not every American Indian or Alaska Native is affiliated with a Tribe). Tribes will be able to comment on regulations during the Assessment and Review processes.

Comment: A commenter stated that the rule would allow for the sunset of regulations that merely implement statutory requirements, such as Indian preference. The commenter cited as examples 42 CFR 136.41–43, 42 CFR 121, 42 CFR 136a.41–43, all of which, the commenter stated, are mandated by 25 U.S.C. 5117.

Response: The Department respectfully disagrees. This final rule exempts from the Assessment and Review requirement ''Sections whose expiration pursuant to this section would violate any other Federal law.'' *See* Section [XX](g). In any event, the Department is not convinced the statutory provision cited by the commenter mandates the cited regulations. There is no obligation imposed on HHS in 25 U.S.C. 5117 to prescribe any particular regulations on Indian preference. Rather, section 5117 provides that ''any employee entitled to Indian preference who is within a retention category established under regulations prescribed under such subsection to provide due effect to military preference shall be entitled to be retained in preference to other employees not entitled to Indian preference who are within such retention category.'' Neither 25 U.S.C. 5117 nor 25 U.S.C. 5116 (which is referenced in 25 U.S.C. 5117) are cited as statutory authorities for the regulations cited by the commenter.

Comment: A few commenters stated that agencies (including HHS) have long ignored the retrospective review mandate of the RFA and have failed to perform such reviews. One reason for this, according to the commenters, is that the RFA does not create incentives for federal agencies to review their regulations. These commenters stated that this final rule would solve that problem by providing a clear incentive for agencies within HHS to review their regulations to prevent their automatic expiration. Commenters stated that without such a consequence, agencies will continue to fail to conduct retrospective reviews of their regulations.

Response: The Department cannot speak for other federal agencies and would not state that the Department has completely ignored retrospective review. But the Department would agree that it has not performed reviews as often as Congress intended. The Department agrees that this final rule will address this problem by providing an incentive to perform retrospective reviews.

Comment: A few commenters stated that the Department failed to analyze the potential costs of rescinding regulations, and only focuses on the costs of conducting voluntary Assessments and Reviews. A few commenters stated that HHS did not assess the potential forgone benefits of expired regulations.

Response: This is addressed in the regulatory impact analysis for this final rule.

[125] Presidential Memoranda on Government-to-Government Relations With Native American Tribal Governments, 85 FR 22951 (May 4, 1994), Presidential Memorandum, Government-to-Government Relationship with Tribal Governments, September 23, 2004, *https://www.govinfo.gov/content/pkg/WCPD-2004-09-27/pdf/WCPD-2004-09-27-Pg2106.pdf,* Presidential Memorandum on Tribal Consultation, 74 FR 57879 (Nov. 9, 2009).

[126] *ACS Demographic and Housing Estimates,* U.S. Census Bureau, *https://data.census.gov/cedsci/table?q=United%20States&g=0100000US&tid=ACSDP1Y2019.DP05&hidePreview=true.*

Comment: A few commenters stated that the Department should consider doing a regulatory impact analysis when reviewing rulemakings that predate the Regulatory Flexibility Act and have a significant economic impact upon a substantial number of small entities (''SEISNOSE''). These commenters also noted that conducting additional regulatory impact analyses would impose an additional cost to the Department, which it should account for if it chooses to do additional analysis on Pre-RFA rulemakings.

Response: As explained in the proposed rule, more resources will be required to review regulations that predate the RFA.[127] The regulatory impact analysis for this final rule accounts for the additional resources required to conduct Reviews of rule makings that predate the RFA. But the criteria listed in 5 U.S.C. 610 are the criteria that Congress directed the Department to use when reviewing regulations that predate the RFA. Therefore, for rule makings that predate the RFA and have a SEISNOSE, this final rule requires that the Review consider the factors listed in 5 U.S.C. 610, as well as whether the component Sections within those rulemakings comply with applicable law.

Comment: A few commenters asked for clarification on whether a regulation that is identified for amendment through the regulatory review process set forth in this final rule would be prioritized over new regulations the Department is promulgating.

Response: In the scenario described by commenters, the Department would aim to amend the referenced regulation and also promulgate new regulations that the Department believes should be promulgated. Experience shows the Department is able to amend existing regulations and promulgate new ones at the same time.

Comment: A few commenters asked if regulations that are sunset because they were not Assessed or Reviewed by the deadline would have to go through notice-and-comment rule making to be reissued if they were otherwise unchanged. These commenters also asked how these regulations would be prioritized by the Department.

Response: As explained throughout the proposed rule (and this final rule), the Department is committed to dedicating adequate resources to timely Assess and Review its regulations. If a regulation did automatically expire, though, the Department would be required to undertake notice-and-comment rule making to reissue the regulation, unless one of the exceptions to notice-and-comment rule making in 5 U.S.C. 553 applies.

Furthermore, allowing for automatic reissuance of an expired regulation threatens to undermine the efficacy of this final rule. If there were no costs or obstacles to simply resurrecting an expired regulation in its original, pre-expiration form, then there would be no compelling incentive to timely Assess and Review Department regulations.

It is impossible to say at this point how the Department might ''prioritize'' re-issuance of expired regulations, without knowing which regulation is at issue and what other competing priorities the Department might have at the time. That said, the Department anticipates it will prioritize re-issuance of expired regulations in line with the public need for such regulation, balancing the same considerations it always does in allocating its policy-making resources. As noted above, the risk that important, ''priority'' regulations—those that meaningfully impact regulated entities—will expire is mitigated by the fact that interested members of the public can alert the Department to a needed Assessment or Review. Commenters have also flagged regulations to review during the public comment process on this rule.

Comment: A few commenters stated that the Department should clarify how it will reconcile or update applicable guidance documents associated with rescinded regulations. If guidance documents remain in existence or are not updated to account for the regulatory changes resulting from the process established in this final rule, it could lead to confusion for regulated entities. A few commenters asked for clarification on whether the Department is considered to have Reviewed a regulation if the Department issues a guidance document on that particular regulation.

Response: The Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute. The Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation.[128] Therefore, any guidance document based on an expired regulation has no effect. If a guidance document addresses expired regulations as well as regulations still in effect, the Department would seek to expeditiously revise the guidance document.

The Department is not considered to have Reviewed a Section simply because the Department issues a guidance document concerning that particular Section. The Department is only considered to have Reviewed a Section if, with respect to the Section, the Department has followed the procedures specified in section [XX](f) of this final rule. The Department must publish the results of the Review, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), in the **Federal Register**.

Comment: A few commenters asked how other enforcement agencies, such as the Office of the Inspector General or the Department of Justice, and federal healthcare program contractors, would be affected by the proposed rule. Commenters stated that a lack of coordination between agencies and other entities with equities in an expired regulation could lead to different and possibly contrary conclusions about how to proceed. These commenters also stated that this could lead to conflicting requirements, resulting in different rules in different jurisdictions. Commenters asked the Department to clarify how corporate compliance programs should advise their organizations if a regulation expires.

Response: This final rule applies to the HHS Office of Inspector General (OIG), which is a component of HHS, although certain regulations for which OIG has enforcement responsibility are exempt, such as 42 CFR 1001.952. For regulations that were issued in coordination with another Agency, that function in concert with another Agency's regulations, or that have a specific, direct impact on regulations issued by another Federal agency, the Department shall consult with that other Agency when undertaking the Assessment or Review, and consider the other Agency's views when considering the factors described in section [XX](d). In addition, when Assessing or Reviewing regulations that require review and approval by the Attorney General under Exec. Order No. 12250 of

[127] *See* 85 FR 70115 (''Of the 273 rulemakings subject to Reviews in the first two years, the Department estimates roughly 16%, or 44, of those rulemakings were promulgated prior to the requirement for prospective regulatory flexibility analyses. As described further below, those 44 Reviews will require more Department resources than the estimated 229 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect'').

[128] Department of Health and Human Services Good Guidance Practices, 85 FR 78785 (Dec. 7, 2020).

Nov. 2, 1980, 45 FR 72995 (Nov. 4, 1980), the Department will consult with the Department of Justice (DOJ) and provide a draft of the findings to DOJ well in advance of the Assessment or Review deadline so DOJ can review and approve prior to the publication of the findings. If an HHS regulation is amended, rescinded, or expires, no other governmental body may take a different view of the regulation's legal effect.

Regarding how corporate compliance programs should advise their organizations if a regulation expires, an HHS regulation that expires no longer has legal effect and cannot be enforced by any governmental body against a regulated entity.

Comment: One commenter stated that HHS observes that the proposed rule's review requirements ''do not impose new burdens . . . if incomplete compliance [with the Regulatory Flexibility Act] is not accounted for in the regulatory baseline.'' [129] But HHS's entire rationale for the proposed pule, according to the commenter, is that incomplete compliance with existing review requirements is and will continue to be a problem under the regulatory baseline (*i.e.,* absent the proposed rule).

Response: HHS maintains that the proposed rule, as well as this final rule, does not impose new burdens if incomplete compliance with the RFA is not accounted for in the regulatory baseline. HHS recognizes that, after implementation of this final rule, the Department's Assessments and Reviews will likely result in an additional resource expenditure beyond what would occur absent promulgation of this final rule. This was analyzed in the Regulatory Impact Analysis of the proposed rule and in more detail (largely due to comments received) in the Regulatory Impact Analysis of this final rule. It is worth noting, though, that the burdens resulting from this final rule are burdens that Congress already intended for the Department to bear.

Comment: A few commenters stated that the Department does not cite any reason why a regulatory review should be triggered by the age of a regulation or why ten years should be the trigger. Some commenters stated that a regulatory review could also be based on the subject matter of the regulation, its economic impact, or the number of people it affects. Other commenters pointed out that the Department also could have used a different time period other than ten years to conduct its reviews. Commenters point to the Department's citation to a number of foreign and sub-national entities that mandate the reviews of regulations after five or seven years. These commenters stated that since there are other options for the frequency of regulatory review, the proposal to have such rules automatically expire after ten years is arbitrary and capricious.

Response: HHS respectfully disagrees. The proposed rule explained why the Department chose ten years:

> The Department proposes to perform the Assessment and (if required) the Review on each Regulation every ten years. Some states provide that, unless readopted or re-reviewed, their regulations expire in seven years,[130] while at least one state uses a ten-year time period.[131] The Department proposes to perform the Assessment and (if required) the Review every ten years, because ten years is the period listed in 5 U.S.C. 610. The Department has many Regulations, some of which are complex, so having to perform the Assessment and Review more than once every ten years could unduly burden the Department and increase the likelihood that a Regulation inadvertently expires because it is not Assessed or Reviewed.[132]

This rationale still holds. In this final rule, the Department decides to Review rules that have a SEISNOSE, because those are the rules that the RFA directed HHS to review.

Comment: A few commenters stated that the proposed rule interferes with the RFA's procedure for regulatory review. 5 U.S.C. 610–611. These commenters note that those sections require agencies to publish plans for regulatory review, provide a schedule for revision that varies by agency, give agency heads the right to delay review for one-year periods, up to a maximum of five years, identify multiple factors that must be considered in reviewing each rule, prescribe the terms of public notice via the **Federal Register**, and specify judicial appeal procedures and criteria, including standing rights and remedies. These commenters also stated that the Department's proposed rule would scrap that process and replace it with a default of across-the-board regulatory repeal in case of inaction, without recourse, using a completely different system of judicial review premised on the underlying APA, rather than the RFA. Commenters stated that this would be a usurpation of Congress's role, and would raise constitutional questions involving balance of power between the branches. According to commenters, the Department must address this issue or else promulgating this final rule would be arbitrary and capricious.

Response: HHS respectfully disagrees. This final rule is consistent with the RFA's requirement to publish a plan for periodic review—it *is* such a plan, and the RFA does not prohibit the Department from including expiration dates in its regulations. The Review process considers the five factors enumerated in the RFA. *See* 5 U.S.C. 610(b). This final rule requires publication in the **Federal Register** of the results of Assessments and Reviews under section [XX](f). This final rule does not supplant or purport to foreclose any available judicial review under 5 U.S.C. 611. And with respect to section 610 compliance, the RFA's judicial-review provisions expressly cross-reference the broader APA judicial-review provisions. *See* 5 U.S.C. 611(a)(1) (''For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 *in accordance with chapter 7.*'') (emphasis added). Because this rule is consistent with the RFA, it does not usurp Congress's role or raise constitutional separation-of-power concerns. To the contrary, it implements Congressional intent for periodic review of regulations. Section II.F of this final rule further addresses the commenters' concerns in discussing how the Department will operationalize this final rule.

Comment: Several commenters stated that the proposed rule violates the RFA's intent as expressed by Congress. In passing the RFA, Congress expressly made the following finding: ''the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation.'' [133] These commenters stated that the proposed rule departs from the Congressional intent in passing the RFA because the proposed rule would subject every regulation to mandatory review as well as repeal by default. In this way, the proposed rule ''treats all regulated businesses, organizations, and governmental jurisdictions as equivalent'' by terminating all

[129] 85 FR 70112.

[130] *See, e.g.,* N.J. Admin. Code § 1:30–6.4 (2020) (regulations expire every seven years unless readopted, subject to certain exceptions); Ind. Code 4–22–2.5–2 (imposing seven-year expiration date on regulations unless readopted).

[131] N.C. Gen. Stat. 150B–21.3A.

[132] 85 FR at 70106.

[133] Public Law 96–354, 94 Stat. 1164, 1164 (1980) (as amended 1996).

regulations, without considering the unique set of stakeholders affected by each regulation.

Response: HHS respectfully disagrees with these comments because these commenters fundamentally misunderstand the operation of this final rule, as well as the Congressional finding they quote. This final rule does not repeal regulations by default. As explained in this final rule, the Department intends to timely complete the necessary Assessments and Reviews and has built in safeguards to mitigate the risk of inadvertent expiration. Under this final rule, the Department must Assess which of its rule makings have a significant economic impact upon a substantial number of small entities, and then perform the more robust Reviews on those rule makings. Therefore, the Department is paying special attention to those regulations which have a significant economic impact upon a substantial number of small entities. As explained in the proposed rule, the Department cannot know which regulations currently have a SEISNOSE without Assessing its regulations.[134] This process is consistent with the RFA, which instructs agencies to review ''the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.''

Reviews consider the five factors expressly included within the RFA, as well as an additional factor that is indisputably beneficial and appropriate: ''Whether the rulemaking complies with applicable law.'' *See* Section [XX](d). Subjecting regulations with a SEISNOSE to Review does *not* ''treat all regulated businesses, organizations, and governmental jurisdictions as equivalent'' because the findings of the Review will be tailored to the regulation.[135]

The commenters also quote the language from the Congressional findings and declaration of purpose out of context. Congress was clearly focused on agencies ignoring the distinction between ''large scale entities'' and small entities.[136] Given that this rule closely tracks the RFA's goal of minimizing undue burden on small entities, it aligns with the Congressional intent behind the RFA.

Comment: A commenter stated that automatic expiration of Department regulations could frustrate the RFA's purpose by inappropriately sunsetting rules that increase economic benefits for small entities. This commenter stated that the proposed rule does not sufficiently address this concern. This commenter also stated that the proposed rule undermines congressional intent because the proposed rule does not consider that the Department may be impeding its ability to conduct reviews under the RFA by instituting added procedural requirements and broadly applicable regulatory sunsets. This commenter further stated that expiration dates are particularly contrary to effectuating RFA compliance because the Department will need to prioritize assessing rules without any impact on small entities simply due to their imminent expiration, rather than using Department resources efficiently to focus on rules requiring the Department's review under the RFA.

Response: The Department respectfully disagrees. The RFA calls on the Department to periodically review regulations that have a significant economic impact upon a substantial number of small entities. This final rule intends to increase the number of such reviews that occur, and directs the Department to review using the criteria specified in 5 U.S.C. 610(b) (plus whether the rule making complies with applicable law). As for Assessing regulations not previously determined to have a SEISNOSE, implicit in 5 U.S.C. 610 is the requirement to determine which regulations have a SEISNOSE.[137] Without performing the Assessment, the Department may not know which regulations have or will have a significant economic impact upon a substantial number of small entities. Due to changed circumstances, a regulation that did not have such an impact at the time it was promulgated may now have such an impact.[138] The Department does not intend for any regulations to inadvertently sunset, and it is unlikely that any regulations with significant benefits would slip through the cracks. The regulatory impact analysis addresses this in more detail.

Comment: A few commenters stated that beyond simply cutting regulatory burdens, the scheduled regulatory review of existing HHS regulations will afford HHS the opportunity to keep regulations up to date with modern trends. These commenters noted that not only will this rule establish an opportunity for the Department to terminate obsolete regulations that are no longer fit for purpose or that are judged to be ineffective, but it will also give HHS and the public a reliable framework and a set of tools to continually keep regulations up to date with evolving circumstances.

Response: The Department agrees with these comments and emphasizes that the benefits of retrospective review—some of which are cited by these commenters—are substantial. As the proposed rule noted, Professor Cass Sunstein, who served as OIRA Administrator from 2009 to 2012, has observed that ''the requirement of retrospective analysis,'' if ''firmly institutionalized,'' ''would count as the most important structural change in regulatory policy since the original requirement of prospective analysis during the Reagan Administration.''[139]

Comment: A few commenters stated that regulatory review does not create as much benefit to regulated entities as the proposed rule suggests, because many of the costs of regulatory compliance have already been factored into the cost of doing business, and are essentially evanescent over time.

Response: While some costs of regulatory compliance may have been factored into the cost of doing business, this comment overlooks many of the benefits of retrospective review. For example, economic, technological, or legal changes can make a regulation obsolete over time. Retrospective review is widely acknowledged to be beneficial by scholars across the ideological spectrum, many of whom are cited in the proposed and this final rule.

Comment: A commenter asked for greater detail on the Assessment and Review process, especially planning of what is to be included and excluded in the retrospective review process. The commenter also asked for greater explanation of how the Department will provide notification of what rules have been Assessed. The commenter also asked what would happen if a part of a rule was reviewed but not other parts of it.

[134] *See* 85 FR 70107.

[135] Under the commenters' argument, the fact that the RFA sets forth five factors to be considered (*see* 5 U.S.C. 610(b)) would also supposedly be inconsistent with Congressional intent.

[136] *See* Public Law 96–354, 94 Stat. 1164, 1164 (1980) (as amended 1996), Sec. 2(a)(2) (''laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities''); Sec. 2(b) (''It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'').

[137] 85 FR 70112.

[138] 85 FR 70107.

[139] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 584 (2014).

Response: Section II.F of this final rule's preamble provides greater detail on the Assessment and Review process and the Department's planning for Assessments and Reviews. Examples of Section 610 reviews conducted by the EPA are instructive on how the Department anticipates the five factors set forth in 5 U.S.C. 610(b) will be analyzed.[140] The results of all Assessments and Reviews conducted in a calendar year will be published in a single document in the **Federal Register** during that calendar year. The Department also intends to place the results of an Assessment or Review in the docket for the rule on *Regulations.gov*. Lastly, this final rule defines ''Assess'' as a determination as to whether the ''Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter)'' currently have a significant economic impact upon a substantial number of small entities. This final rule defines ''Review'' as a process the purpose of which is to determine whether ''Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter)'' should be continued without change, amended, or rescinded. Thus, while Sections are what expire if they are not timely Assessed or Reviewed, the Department should be Assessing or Reviewing all Sections that were part of the same rulemaking (and any amendments or additions that may have been issued thereafter), not just some of them.

Comment: One commenter stated that it previously advocated for the review and modernization of some of the Department's regulations covering Medicare health and safety standards. For example, according to the commenter, the Medicare Conditions of Participation regulations for psychiatric hospitals do not align their requirements with modern psychiatric care. However, the commenter stated that no substantive revisions to the provisions have occurred since the requirements for psychiatric hospitals were first implemented, meaning that a comprehensive review of these regulations has not occurred for at least 40 years, when psychiatric care was delivered much differently. This commenter stated that this is a clear example of why regular regulatory reviews are necessary.

Response: The Department thanks the commenter for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: A few commenters applauded the Department for continuing the bipartisan work on regulatory review to ensure federal agencies are continually held accountable to taxpayers and that regulations remain relevant and updated to innovation and changes in market conditions. The commenters also asked when the planning and drafting of the proposed rule began, any recent regulatory actions that would demonstrate the effects that regulatory reviews, suspensions, or updates can have on the health care industry, or the economy more broadly, and a list of Department regulations suspended during the pandemic.

Response: The Department thanks the commenters for the first part of this comment. Second, for a non-exhaustive list of 382 enforcement discretion announcements, waivers or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID–19 pandemic and its impact on the healthcare industry, *see* Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A. The planning and drafting of the proposed rule is subject to the deliberative process privilege, but evolved out of the 2019 regulatory streamlining analysis discussed in the proposed rule.

Technical Legal Comments

Comment: A large number of commenters stated that the proposed rule would violate the Administrative Procedure Act (APA), because it would allow the Department to revise or rescind thousands of regulations at one time instead of conducting notice and comment rulemaking on each existing individual rule it chooses to repeal. Some of these commenters also mentioned that the APA requires agencies to use substantially the same process to repeal a rule as they used to promulgate a rule, so a process that allows for automatic expiration of a rule would not meet this statutory requirement. A commenter stated that ''Revocation constitutes a reversal of the agency's former views as to the proper course'' and ''[w]hile the agency is entitled to change its view on [a matter], it is obligated to explain its reasons for doing so. . . . [A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change'' and ''[g]enerally, one aspect of that explanation would be a justification for rescinding the regulation . . .'' (quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 41, 42, 52, 56 (1983)). Commenters stated that this rule would be arbitrary and capricious on these grounds. One commenter stated that if the Department does not perform an affirmative action to prevent expiration of a regulation, the Department would fail to articulate a satisfactory explanation for its expiration, making the agency action arbitrary and capricious.

Response: This final rule complies with the APA. The APA generally requires, with certain exceptions, notice and comment prior to finalizing a ''rule making,'' 5 U.S.C. 553, which is defined as ''formulating, amending, or repealing a rule.'' 551(5). *See Motor Vehicles Mfrs. Ass'n of U.S.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 41 (1983) (''We believe that the recession or modification of an [agency rule] is subject to the same test.''). The APA has already ''established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures.'' *Vt. Yankee Nuclear Power Corp.* v. *Nat. Res. Def. Council, Inc.,* 435 U.S. 519, 524 (1978). Neither courts nor regulated entities may ''impose upon [an] agency its own notion of which procedures are 'best' or most likely to further some vague, undefined public good.'' *Id.* at 549.

The Department agrees with commenters who stated the APA generally requires agencies to use substantially the same process to amend or repeal a rule as they used to promulgate a rule. The Department is complying with this requirement. *See Clean Air Council* v. *Pruitt,* 862 F.3d 1, 9 (2017) (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking). In this rule making, the Department has gone through notice-and-comment rule making to amend its regulations by establishing conditions under which the regulations will either be Assessed and/

[140] *See Results of EPA's Section 610 Review of the Final Rule for Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel,* EPA Off. of Transp. & Quality (Sept. 2014), *https://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0642-0003; Regulatory Flexibility Act Section 610 Review of the National Pollutant Discharge Elimination System (NPDES) Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs),* EPA Off. of Water (June 3, 2014), *https://www.regulations.gov/document?D=EPA-HQ-OW-2012-0813-0216; Results of EPA's Section 610 Review of the Final Rule for Lead; Renovation, Repair, and Painting Program,* EPA Off. of Pollution Prevention and Toxics (Apr. (April 2018), *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0019.*

or Reviewed or expire. This is permissible. The Department is going through notice-and-comment rule making to amend its regulations to apply expiration dates unless certain conditions are satisfied. Agencies already promulgate regulations that expire upon the satisfaction of a future event or non-event.[141] Nothing in the APA forecloses agencies from including conditional expirations dates in regulations. It would call into question many rules—and be extremely disruptive—if courts held that conditional expiration dates violate the APA.

The Department also rejects the argument that it cannot revise many regulations in one rule making, but instead must conduct notice-and-comment rule making on each individual regulation it seeks to amend or rescind. The APA does not include such a requirement. When 5 U.S.C. 551(5) defines ''rule making'' as an ''agency process for formulating, amending, or repealing *a rule*'' (emphasis added), that includes formulating, amending, or repealing ''rules.'' *See* 1 U.S.C. 1 (''In determining the meaning of any Act of Congress, unless the context indicates otherwise—words importing the singular include and apply to several persons, parties, or things''). Agencies can—and often do—issue one rule that applies to many other agency rules, rather than amending or rescinding each affected regulation individually. To take one example, in 2008 the Department revised the definition of ''entity'' at 42 CFR 411.351. *See* 73 FR 48434, 48751 (Aug. 19, 2008). The revised definition had the effect of changing the meaning of ''entity'' each time it was used in 42 CFR part 411, subpart J. It would be burdensome to specify the meaning of ''entity'' each time it appears in subpart J, so the Department issued one definition that broadly applied to all sections of subpart J. There are many other examples where an Agency issues a regulation that applies to, amends, rescinds, or supersedes many other regulations.[142] This avoids an unnecessarily cumbersome process. A court ruling that Agencies must amend each individual regulation would call into question large numbers of Agency regulations and impose substantial burdens on agencies (and the Office of the Federal Register, which would be required to print the same text over and over) when promulgating future regulations. In addition, the Department will consider each individual regulation when conducting Assessments and (if needed) Reviews.

Moreover, in this rule making the Department considered each individual Department regulation, and, as discussed further, decided to exempt certain regulations from this final rule. The Department concluded that the benefits of retrospective review, and need to more strongly incentivize it, justified applying this final rule to the Department's remaining regulations. In this rule making, the Department is considering the important factors. It issues this final rule because, for the reasons described herein, the Department believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a regulation inadvertently expiring is justified by the benefit of institutionalizing retrospective review in this manner. Forty years of experience since the RFA's enactment; the decades since relevant Executive Orders were enacted; and other Federal government efforts to spur the Department to conduct more retrospective reviews indicate that, absent such a pushing mechanism, the Department will not conduct as many retrospective reviews as desired. Indeed, this final rule, rather than being a revocation of prior regulations, will enhance the fulfillment of the existing policies that led to the Department's regulations subject to this final rule.

Comment: Many commenters stated that the proposed rule could create legal uncertainty regarding the validity and enforceability of regulations that the Department, after conducting a Review, determines should be amended or rescinded. Commenters stated this could have negative effects on the HHS programs, the healthcare industry, and states which administer Medicaid and CHIP. Some of these commenters stated that HHS admits that enforcing a Regulation deemed to require amendment or rescission in some cases could raise concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the regulation (or portions thereof) could arguably run counter to the evidence before the agency. However, these commenters stated that, HHS provides no insight or explanation on how it would address this conundrum.

Response: The Department respectfully disagrees. The commenters' concerns only apply where the Department has announced, after Review, that a regulation should be amended or rescinded. Where that is the case, the announced results will suggest what portions of the regulation may need revision and the Department anticipates that commenters will generally be able to participate in subsequent rule making regarding amending or rescinding the regulation. The basis for amendment or rescission will suggest the extent to which continued enforcement in the interim is appropriate. That is why the proposed rule states the Department would exercise enforcement discretion ''on a case-by-case basis as appropriate.''[143] Consistent with Department practice, the Department would announce if it is exercising enforcement discretion to not enforce a regulation.

Comment: Several commenters stated that if Congress's intent was to effectuate results similar to those in the proposed rule, it could have included sunset provisions in its statutes. By not including sunsets in its statutes, Congress must not have perceived a need for Congressionally-directed

[141] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine 85 FR 7874, 7874 (Feb. 12, 2020) (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19''); U.S. Dep't of Transp., Final Regulatory Impact Analysis: Amendment to Federal Motor Vehicle Safety Standard 208 Passenger Car Front Seat Occupant Protection, at XII–35 (July 11, 1984), *http://www-nrd.nhtsa.dot.gov/Pubs/806572.pdf* (explaining that ''[i]f mandatory use laws are passed that will cover 67 percent of the population effective September 1, 1989, the rule will be rescinded'').

[142] *See, e.g.,* 21 CFR 1.1(b) (''the definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act'').''); 7 CFR 786.113 (''*Notwithstanding any other regulation,* interest will be due from the date of the disbursement to the producer or other recipient of the funds''); 40 CFR 455.21 (''*Notwithstanding any other regulation,* process wastewater flow for the purposes of this subpart does not include wastewaters from the production of intermediate chemicals''); 7 CFR 3430.1 (''In cases where regulations of this part conflict with existing regulations of NIFA in Title 7 (*i.e.,* 7 CFR parts 3400 through 3499) of the Code of Federal Regulations, *regulations of this part shall supersede*''); 45 CFR 611.12 (''All regulations . . . heretofore issued by any officer of the Foundation which impose requirements designed to prohibit any discrimination against individuals on the ground of race, color, or national origin under any program to which this part applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of such assistance for failure to comply with such requirements, *are hereby superseded* to the extent that such discrimination is prohibited by this part,'' with certain exceptions).

[143] 85 FR 70108.

rulemaking to expire in the foreseeable future, or at least not automatically.

Response: HHS disagrees that Congress's choice to not include automatic sunset provisions in its statutes undercuts or forecloses the proposed rule. The RFA requires the Department to develop ''a plan for the periodic review of the rules issued by the agency which have or will have a'' SEISNOSE, but leaves the details of said plan to the Department. 5 U.S.C. 610(a). The RFA demonstrates Congress's intent that agencies conduct retrospective review, and the Department has determined, for the reasons explained in the proposed rule, that sunset provisions are a practical and effective way to ensure that Congressional intent is honored. The commenters' position suggests it is improper to take steps to effectuate Congressional intent if Congress itself has not expressly legislated such steps—but, of course, agencies frequently fill in the details of a statutory regime implemented by Congress.

Comment: One commenter stated that the proposed rule is misleading, which thwarts public comment and violates the APA. This commenter stated that it was misleading and irrational for HHS to suggest that it is hypothetical whether any regulation would sunset under the rule, because every regulation would sunset unless a timely Assessment or Review occurs. This commenter suggested that the rule's description is inadequate to meet the notice standard required by the APA. This commenter reasoned that the Department's explanation of the proposed rule and its reasoning did not provide the public with a meaningful opportunity to participate in rulemaking through the submission of comments, which violates the notice and comment requirement of the APA. 5 U.S.C. 553.

Response: HHS respectfully disagrees. ''The APA requires that the notice of proposed rulemaking contain 'reference to the legal authority under which the rule is proposed' and 'either the terms or substance of the proposed rule or a description of the subjects and issues involved.' '' *Little Sisters of the Poor Saints Peter and Paul Home* v. *Pa.,* 140 S. Ct. 2367, 2384 (2020) (quoting 5 U.S.C. 553(b)(2)–(3)). The notice of proposed rulemaking, which spanned 29 pages of the **Federal Register**, did just that. The adequacy of the notice is demonstrated by the fact that the agency received 532 comments—both critical and in support of the proposed rule—that raised general issues as well as commented on specific provisions of the proposed rule. The volume of comments also demonstrates that the public had ample, meaningful opportunity to participate in this rulemaking. There is nothing misleading in the Department's statement that it intends to timely Assess and (where required) Review its Sections. The proposed rule and this final rule adequately explain the basis for this final rule.

Comment: One commenter stated that the proposed rule is arbitrary and capricious because the stated rationale of incentivizing retrospective regulatory review is implausible. This commenter stated that it is wrong to think that the Department is incentivized to Assess or Review its regulations, because the Department may want its regulations to expire. The commenter said that the penalty for failure to review regulations actually falls on the regulated industry, not the Department. The commenter stated that HHS unlawfully ignored the predictable effects of the proposed rule on third parties.

Response: HHS respectfully disagrees. The proposed rule amply explained the benefits of retrospective review. It also explained why sunset deadlines were necessary to incentivize retrospective review (including, for example, the Department's experience with under-utilization of retrospective review). This rationale is not implausible because of the speculative possibility that the Department will intentionally forego Assessments and Reviews. If the Department wanted its regulations to expire, it would have conducted rulemakings to rescind its regulations. The proposed rule and this final rule demonstrate the Department's commitment to timely Assess and (where necessary) Review its regulations. For example, the proposed rule and final rule include (among other things) a clear-eyed analysis of the resources and staff time required to conduct Assessments and Reviews, and provide a mechanism for the public to request the Department to conduct Assessments and Reviews on certain regulations.

Comment: A few commenters stated that the proposed regulatory review process is arbitrary and capricious, because it elevates the need to undertake RFA reviews above any other purpose served by the Department's regulations, which commenters state is disproportionate to the problem at hand. These commenters state that since HHS estimates that only 11% of its regulations have a SEISNOSE and would be subject to the RFA, it is arbitrary and capricious to subject the other 89% of regulations to possible rescission.

Response: HHS respectfully disagrees. As explained in the proposed rule and this final rule's preamble, there is a need for widespread retrospective regulatory review. It is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Those regulations were motivated by important policy goals that the Department wishes to achieve. This final rule will further these goals. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Therefore, this final rule is in fact an effort to enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations.

As for conducting Assessments on many regulations, and not just Reviewing those regulations previously determined to have a SEISNOSE, the proposed rule explained that ''[w]ithout performing the Assessment, the Department may not know which regulations have or will have a significant economic impact upon a substantial number of small entities. Due to changed circumstances, a regulation that did not have such an impact at the time it was promulgated may now have such an impact.'' [144]

Comment: One commenter stated that the Department may not finalize the proposed rule without conducting a review under the National Environmental Policy Act (NEPA) or considering how the proposed rule is consistent with Executive Orders 13045 or 12898.

This commenter stated that HHS violated its obligations under NEPA because commenters believe the rule is a major federal action. According to the commenter, the proposed rule stated that it ''will not have a significant impact on the environment'' without providing additional explanation.[145] The commenter stated that the FDA's own NEPA regulations require it to conduct *at least* an environmental assessment before promulgating certain

[144] 85 FR 70107.

[145] 85 FR 70118.

regulations, and FDA cannot rescind those regulations without conducting NEPA review. *See* 21 CFR 25.20.

This commenter also stated that the proposed rule does not adequately consider Executive Orders 13045 or 12898. Executive Order 13045 imposes requirements on agencies to protect children from environmental health risks and safety risks.[146] The commenter stated that because the Department did not mention Executive Order 13045 in its proposed rule, it must have failed to consider it. Executive Order 12898 directs federal agencies to make environmental justice part of their mission, and to identify and address the disproportionate environmental and health effects of their activities.[147] This commenter expressed that HHS did not consider whether the proposed sunset rule will cause ''disproportionately high and adverse human health or environmental effects . . . on minority populations and low-income populations'' [148] even though the commenter believes there is every reason to think that the sunset rule will cause such adverse effects.

Response: HHS respectfully disagrees that further analysis under NEPA, E.O. 12898 (''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations''), and/or E.O. 13045 (''Protection of Children From Environmental Health Risks and Safety Risks''), is required. The commenter's position is based on a fundamental misunderstanding of how the final rule functions. As explained in the notice of proposed rulemaking, this rule does not in and of itself rescind any regulations; it provides that certain regulations will expire if not Assessed and (if required) Reviewed by certain dates.

Thus, there is no basis to say that this final rule itself ''significantly affect[s] the quality of the human environment,'' 42 U.S.C. 4332(C); may cause ''disproportionately high and adverse human health or environmental effects . . . on minority populations and low-income populations,'' E.O. 12898, Sec. 1–101; or ''concern[s] an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children,'' E.O. 13045 Sec. 2–202(b).[149]

The commenter says an environmental assessment may be necessary, including consideration of alternatives as required by section 102(2)(E) of NEPA, 40 CFR 1501.5(c)(2), if it is unclear whether the rule will significantly affect the environment. But it is clear that this rule alone does not have a significant environmental impact. Any rescissions or amendments pursuant to Assessments and Reviews will be effected through notice-and-comment rulemaking independent of this rule and include any required environmental (and other) analyses. In any event, the Department adequately explained the alternatives it considered in its proposed rule,[150] as well as in the regulatory impact analysis for this final rule.

Comment: A few commenters stated that HHS mistakenly exempts the proposed rule from the regulatory review process it creates. The proposed rule states that it ''cannot, absent other actions, directly impose on the public costs that exceed benefits . . . [o]nly the failure to perform an Assessment or Review in the future could theoretically impose on the public costs that exceed benefits.'' [151] These commenters stated that it was a mistake for HHS to assume that the proposed rule will not ''directly impose on the public costs that exceed benefits'' because costs would be imposed on the public unless Assessment or Review of Regulations take place. These commenters took the position that the Department's regulations would expire by default, and that expiration would impose a cost that would exceed benefits.

Response: HHS respectfully disagrees. This final rule would not become obsolete due to economic, technological, or legal changes the way that many other rules can. For the reasons discussed herein, the Department believes the process set forth in this final rule will enable the Department to Assess and (where required) Review its regulations. It is a mistake, and bereft of evidence, to assume that the Department's regulations would expire by default.

Comment: Several commenters stated that the Department did not adequately explain its reasoning for the proposed rule. Some of these commenters stated that HHS did not acknowledge the facts and circumstances that motivated the initial promulgation of its regulations, nor did HHS discuss in the proposed rule the serious reliance interests that have been created by some of these regulations. Commenters asserted that the Department claims that it ''is considering the important factors''—without articulating what those factors are—and asserts that it ''believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review in this manner.'' [152] A few commenters asked HHS to identify the regulations that are vulnerable to rescission under the rule, and to describe the nature and magnitude of the harm that might result from their expiration.

Response: The Department believes the proposed rule adequately explained the facts and circumstances that motivated issuing the proposed rule, and adequately showed that the Department considered the relevant factors. The same is true for the preamble to this final rule, which provides additional explanation for why the Department is issuing this final rule and the factors it considered. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,[153] increasing access to health insurance,[154] or increasing the incentive for Temporary Assistance for Needy Families recipients to work.[155] These are all important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department's regulations. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Outside of the exempted regulations, no particular regulations are more ''vulnerable to rescission'' than others under this final rule. This final rule is agnostic as to all Department regulations. They must all be Assessed and, if they have a SEISNOSE, Reviewed using the criteria specified in section [XX](d).

[146] Exec. Order No. 13045 of Apr. 21, 1997, 62 FR 19885 (Apr. 23, 1997) (E.O. 13045).

[147] Exec. Order No. 12898 of Feb. 11, 1994, 59 FR 7629 (Feb. 16, 1994) (E.O. 12898).

[148] *Id.*

[149] *See also* 85 FR 70118 (''HHS has determined that the proposed rule will not have a significant impact on the environment.'').

[150] *See* 85 FR 70116–17.

[151] 85 FR 70109.

[152] 85 FR 70106.

[153] *E.g.,* 21 CFR part 112.

[154] *E.g.,* 45 CFR part 147.

[155] 45 CFR part 261.

Comments on the Statutory Authority for This Final Rule

Comment: Several commenters stated that the Department does not have the authority to propose automatic expiration of its regulations. Some commenters stated that HHS fails to explain how Congress's grants of authority to the Department to ''promulgate,'' 21 U.S.C. 371(a), to ''make and publish,'' 42 U.S.C. 1302(a), or to ''prescribe,'' 42 U.S.C. 1395hh(a), regulations also give it the authority to rescind those regulations, with that rescission subject to future reversal at the Department's discretion. Other commenters stated that the proposed rule not only falls outside these grants of rulemaking authority, but squarely contradicts Congress's instructions that HHS ''shall'' promulgate certain regulations. *E.g.,* 21 U.S.C. 371, 42 U.S.C. 1395hh(a). Some commenters cited to section 1102 of the Social Security Act, which directs the Secretary of HHS to issue regulations ''not inconsistent with this Act'' to implement the Medicaid and CHIP programs but does not provide specific statutory authority for the Secretary to write automatic expiration dates into regulations.

Response: The Department respectfully disagrees. As explained in the proposed rule, the statutory authorities supporting this rule making are the statutory authorities for the Department's existing regulations.[156] Moreover, the Department believes that the relevant portions of the proposed rule, as finalized herein, are fully consistent with 42 U.S.C. 1302(a). Indeed, it specifically cited this provision as one source of statutory authority for promulgating the proposed rule (85 FR at 70103), and does so in this final rule. The commenters' position is incorrect for multiple reasons. First, the commenters' assertion seems to suggest that *any* action by the Department to repeal or amend Medicaid or CHIP regulations, by the mere act of amendment or rescission, is ''inconsistent'' with those programs. That position is untenable.[157] In fact, this final rule is the promulgation of a regulation that will contribute to ''the efficient administration of'' the Department's functions under the Social Security Act, because the Reviews called for by this final rule will take into account both the continued need for particular regulations, as well as whether the burden of those regulations on small entities can be minimized (among several other factors that will enhance efficiency, such as the complexity of the Regulation or whether it is duplicative). For the same reasons, this final rule is the promulgation of a regulation for ''the efficient enforcement'' of the Federal Food Drug, and Cosmetic Act and necessary to carry out the administration of the Medicare program. *See* 21 U.S.C. 371(a); 42 U.S.C. 1395hh(a)(1). This final rule will enhance the fulfillment of the policies that motivated the regulations issued pursuant to 42 U.S.C. 1302, 42 U.S.C. 1395hh, and 21 U.S.C. 371.

Comment: Several commenters stated that the proposed rule exceeds the statutory authority of the RFA, because the RFA only affects regulations that ''have a significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 602, 604, 605. However, according to the commenters, the proposed rule does not limit its reach to those regulations covered by the RFA because it adds expiration dates to *all* HHS regulations, not just those that ''have a significant economic impact upon a substantial number of small entities.'' [158] These commenters added that the RFA also does not mandate the automatic expiration of regulations that have not undergone agency review.

Response: The primary statutory authorities for this final rule are the statutory authorities for the Department's existing regulations. The Department also notes, though, that the text of 5 U.S.C. 610 indicates Congress believed agencies have the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that agencies have the authority to assess which of their regulations have such an impact). *See* 5 U.S.C. 610(a)–(b). The commenters are correct that the RFA does not mandate the automatic expiration of rules; however, the RFA also does not foreclose this final rule's approach. As explained throughout the proposed rule and in this final rule, decades of experience, empirical evidence, and scholarly commentary all support the Department's view that this final rule will enhance compliance with the RFA's directive to periodically review regulations with a SEISNOSE.

Comment: A few commenters stated that the proposed rule does not cite the RFA (5 U.S.C. 610) as a source of its statutory authority. These commenters stated that they believe the Department omitted the RFA it its list of statutory authority because the rule is contrary to the statute.

Response: The proposed rule cited 5 U.S.C. 610 as one of the statutory bases for the proposed rule.[159] The statutory bases for this rulemaking also include the existing statutory authorities for the Department's regulations. This final rule is consistent with the RFA, because it sets forth a plan for the periodic review of the regulations issued by the Department which have or will have a significant economic impact upon a substantial number of small entities. *See* 5 U.S.C. 610(a). Moreover, this final rule requires such review to consider the factors set forth in 5 U.S.C. 610(b). The text of 5 U.S.C. 610 indicates Congress believed agencies have the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that agencies have the authority to assess which of their regulations have such an impact). *See* 5 U.S.C. 610(a)–(b).

Specific Provisions of the Proposed Rule and Final Rule

Section [XX](a)

In the proposed rule, HHS proposed to add Section [XX](a), which provided that the proposed rule would apply to and amend all Regulations issued by the Secretary or his delegates or sub-delegates in this title. HHS received no comments specific to Section [XX](a). However, in this final rule HHS replaces ''this title'' with ''this chapter,'' and amends the relevant chapters of Titles 21, 42, and 45, rather than amending all regulations that were issued by the Secretary (or his delegates or sub-delegates) in the titles. HHS makes this change to increase clarity and precision. For example, certain chapters in Title 21 contain Drug Enforcement Administration, not HHS or FDA regulations. Although the proposed rule's use of the language ''Regulations issued by the Secretary or his delegates or sub-delegates in this title'' addressed this by limiting the scope of the

[156] 85 FR 70103.

[157] *See, e.g.,* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 FR 27106, 27153 (May 12, 2014) (citing 42 U.S.C. 1302 as statutory authority for the removal of certain regulatory text); Medicare Program; Amendment to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011 76 FR 1366, 1367 (Jan. 10, 2011) (relying on 42 U.S.C. 1302 and 42 U.S.C. 1395hh, among other statutory provisions, to amend or remove regulatory text); Color Additives; D&C Green No. 6; Uniform Specifications, 51 FR 37908, 37909 (Oct. 27, 1986) (citing 21 U.S.C. 371 as statutory authority for amending and removing regulatory text).

[158] *See* 85 FR 70123; *id.* at 70104–05 (defining ''Regulations'' as ''a section of the Code of Federal Regulations'').

[159] *See* 85 FR 70119, 70120, 70121, 70123.

proposed rule to regulations issued by the *HHS* Secretary or his delegates or sub-delegates, HHS in this final rule amends the chapters belonging to HHS, rather than the entirety of the titles. This is not a substantive change and does not cause the application of the final rule or the rights and obligations it creates to differ from the proposed rule.[160]

Similarly, HHS clarifies that it is amending its other regulations through the provisions in this final rule by generally applying an expiration date to those regulations, if certain conditions are not met, rather than asking the Office of the Federal Register to literally amend each other regulation, which would be unnecessarily burdensome and resource intensive. Accordingly, this final rule states that it applies to and ''shall be deemed to amend'' all regulations issued by the Secretary or his delegates or sub-delegates in the applicable chapters. This is not a substantive change and does not affect the application of the final rule or the rights and obligations it creates.

HHS received no comments specific to section [XX](a) of the proposed rule.

Accordingly, HHS finalizes section [XX](a) to read, ''[t]his section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.''

Section [XX](b)

HHS proposed to add section [XX](b), which defined several terms used in the proposed rule.

i. Section [XX](b)(1)

HHS proposed to define ''Assess'' as ''a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.''

5 U.S.C. 610 directs agencies to have plans to periodically review those regulations that have or will have a significant economic impact upon a substantial number of small entities. Accordingly, in order to determine which regulations to periodically review using 5 U.S.C. 610's criteria, the Department must first determine which rules have a significant economic impact upon a substantial number of small entities. When promulgating regulations, the Department is required to determine whether a rule will have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).[161] The Assessment refers to an essentially identical determination. In making the Assessment, the Department can look to the determination of the regulation's impact on small entities made at the time of promulgation, as well as experience since promulgation.

Comments on Section [XX](b)(1)

HHS received the following comment on the proposed definition of ''Assess.''

Comment: A few commenters stated that HHS should clarify that periodic Assessments *must* look to the determination of the regulation's impact on small entities made at the time of promulgations, *as well as* experience since promulgation.[162] These commenters stated that HHS should clarify that any Assessment that only contemplates the former and ignores the latter will be deficient.

Response: Assessments must analyze the regulation's impact on small entities at the time the regulation is being Assessed. The Department believes this is clear from the text of the proposed rule, which defined ''Assess'' as ''a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) *currently* have a significant economic impact upon a substantial number of small entities'' (emphasis added). Accordingly, the Department adopts in this final rule the definition of ''Assess'' from the proposed rule, except that the term ''Regulations'' in the proposed rule is changed to ''Sections'' in this final rule. The determination made at the time of promulgation about whether a rulemaking had a SEISNOSE may be a useful data point in assessing the regulation's current impact on small entities.

Accordingly, HHS is finalizing the definition of ''Assess'' as proposed, with the technical amendment just mentioned.

ii. Section [XX](b)(2)

HHS proposed to define ''Review'' as a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether the Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Regulations upon a substantial number of small entities.

HHS received no comments specific to the proposed definition of ''Review.''

Accordingly, HHS is finalizing the definition of ''Review'' as proposed, except that it replaces the term ''Regulations'' with ''Sections,'' to conform this provision to the rest of this final rule.

iii. Section [XX](b)(3)

HHS proposed to define ''Regulation'' as ''a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.'' This definition was proposed to make clear that a section of the CFR, as opposed to a part, subpart, or paragraph within a section, is the unit that must be Assessed and (if required) Reviewed, or will otherwise expire. Defining ''Regulation'' in this objective way makes it easier for the Department and the public to know what exactly has to be Assessed or Reviewed by the dates listed in the proposed rule. Had the Department used the Administrative Procedure Act's (APA's) definition of ''rule,''[163] it could be unclear in certain circumstances what precisely needed to be reviewed.

In the final rule, HHS changes the term ''Regulation'' to ''Section'' for the reasons previously discussed.

[160] In addition, whereas the proposed rule added certain regulatory text to Title 45, Part 6, this final rule adds the text to Title 45, Part 8. This is not a substantive change. Since the Department anticipates that, for good governance and streamlining reasons, Part 6 soon may soon be subsumed into Part 5, the Department in this final rule adds the relevant text to Part 8.

[161] 5 U.S.C. 605(b) refers to rules that have a ''significant economic impact *on* a substantial number of small entities,'' whereas 5 U.S.C. 610 refers to rules that have ''significant economic impact *upon* a substantial number of small entities.'' This does not appear to be a material difference.

[162] *See A Guide for Government Agencies: How To Comply With The Regulatory Flexibility Act,* U.S. SBA Off. of Advoc., at 80–81 (2017), *https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf,* (''If Congress meant to limit periodic reviews, it would have simply required agencies to review rules that originally had a significant impact, rather than rules that now have a significant impact.'').

[163] 5 U.S.C. 551(4) (providing that '' 'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing'').

Comments on Section [XX](b)(3)

HHS received the following comments on the proposed definition of ''Regulation.''

Comment: A few commenters stated that HHS arbitrarily chose to reject the APA's definition of ''Regulation'' and adopted its own definition of ''Regulation'' for the purposes of this rule, defining regulation as ''a section of the Code of Federal Regulations.'' Some commenters stated that using a different definition in this rule from the definition in the APA (and incorporated in Executive Order 12866 and Executive Order 13771) is confusing. Commenters stated that the Department's explanation that it used a special definition of ''Regulation'' to avoid confusion that could be created by using the APA's definition was insufficient and lacked statutory basis.

Response: To avoid any confusion, HHS uses ''Section,'' rather than ''Regulation,'' in this final rule to refer to a section of the Code of Federal Regulations. It is crucial to the proper function of this final rule that the Department and public clearly understand the scope and timing of the Assessment and Review process. Such understanding is made easier with a bright-line definition of the agency issuances that are subject to Assessment and Review. The Department's use of ''Section'' endeavors to provide such clarity by using a readily available and well-established system of organization, the Code of Federal Regulations. It is clear when a section of the Code of Federal Regulations was first promulgated.

The use of ''Section,'' rather than ''Regulation,'' in this final rule is not a substantive change from the proposed rule. Rather, it is an attempt to bring additional clarity by using ''Section'' to refer to a section of the Code of Federal Regulations, rather than using the term ''Regulation.''

Comment: One commenter expressed concern over the proposed rule's definition of ''Regulation,'' stating that the definition is too narrow. This commenter stated that under the proposed rule, each Regulation would be Assessed or Reviewed without the context of the preamble language that was included in the rulemaking.

Response: HHS respectfully disagrees. ''Assessment'' and ''Review'' are defined in this final rule as determinations with respect to ''Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter).'' In the proposed rule, ''Regulation'' was defined as a section of the Code of Federal Regulations so the Department and public can know what units would expire absent Assessment or (if needed) Review. But the text of the final rule makes clear that a single Assessment or Review should be performed on all Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter). The Department disagrees with the commenters who stated that, under the proposed rule, each Regulation would be Assessed or Reviewed without the context of the preamble language that was included in the rulemaking. Under this final rule, the Department may consider this information when conducting Assessments and Reviews.

Accordingly, HHS is finalizing the definition proposed, except that it defines the term ''Section'' rather than ''Regulation.''

iv. Section [XX](b)(4)

HHS proposed to define ''Year of the Regulation's Promulgation'' to mean the calendar year the Regulation first became effective, irrespective of whether it was subsequently amended. The purpose of this proposed definition was to provide clarity to the Department and the public. If a regulation were amended, questions could arise whether the clock for re-reviewing the rule making in which the regulation was first promulgated begins on the date the rule making was first promulgated; the date it was last amended; or whether the clock for reviewing the amended portion begins on a different date than the portion that was initially enacted. The proposed definition is more clear for the Department and the public, because this definition, in conjunction with section [XX](c) of the proposed rule, makes clear that the clock starts for the retrospective review of a regulation on the date that the rule making from which the regulation originates was first promulgated, even if it is subsequently amended.

If, for example, the Department issues a regulation as a part of a rule making and amends it nine years later, the Department may wish to conduct the regulatory review of the entire rule making at the time of amendment of a specific regulation initially promulgated in that rule making, particularly since the Department is presumably already performing a regulatory impact analysis with regard to the amendment. Since the Department is already conducting a regulatory impact analysis, performing the regulatory review at that time may save Department resources and spare the Department from having to perform the Review on the regulation the next year. In fact, any time the Department amends a regulation, it could perform the regulatory review at that time, thereby conserving Department resources.

HHS received no comments specific to the proposed definition of ''Year of the Regulation's Promulgation.''

Accordingly, HHS is finalizing the definition of ''Year of the Regulation's Promulgation'' as proposed, except that it changes the term ''Regulation'' to ''Section.''

v. Section [XX](b)(5)

HHS proposed to define ''[s]ignificant economic impact upon a substantial number of small entities'' as having the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

HHS received the following comments on the proposed definition of ''Significant economic impact upon a substantial number of small entities.''

Comment: A few commenters stated that neither the proposed rule, nor the RFA gives a clear definition of ''significant impact'' or of ''small entity,'' and asked that HHS clarify the definition of these terms in the final rule.

Response: HHS declines to add definitions of these terms within this final rule. ''Significant economic impact'' and ''small entity'' are terms within the RFA, which has been in existence for over forty years. These terms have been applied by the Department and other agencies since the RFA's enactment. Definitions pertinent to ''small entity'' appear at 5 U.S.C. 601. As explained in the proposed rule, the Department has considered a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities.[164]

Comment: One commenter stated that the citation in the definition of ''Significant economic impact upon a substantial number of small entities'' found at 21 CFR 6.1(b)(5), 42 CFR 1.1(b)(5), 42 CFR 404.1(b)(5), and 45 CFR 6.1(b)(5) was incorrect. The proposed rule cited the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996). This commenter stated that because the definition in the RFA appears in section 610 of title 5 of the U.S. Code, the correct citation is to the code. This commenter also stated that the definition of ''Significant economic impact upon a substantial number of

[164] *See* 85 FR at 70117.

small entities'' shall be defined to have the meaning ''of'' that term in 5 U.S.C. 610, rather than the meaning ''ascribed to'' that term in 5 U.S.C. 610.

Response: HHS appreciates the comments and agrees that citation to the Code is proper. This final rule incorporates this suggestion, and replaces the citation in the proposed rule with ''5 U.S.C. 610.'' It also incorporates the comment to use ''of'' instead of ''ascribed to.'' This revised definition may provide increased clarity.

Accordingly, in this final rule HHS is finalizing the definition of ''[s]ignificant economic impact upon a substantial number of small entities'' to provide that this term shall have the meaning of that term in section 610 of title 5 of the United States Code.

Section [XX](c)

i. Section [XX](c)(1)–(2)

In the proposed rule, HHS proposed that unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of either (1) two calendar years after the year that this rule first becomes effective, (2) ten calendar years after the Year of the Regulation's Promulgation, or (3) ten calendar years after the last year in which the Department Assessed and (if Review of the Regulation is required pursuant to paragraph (d)) Reviewed the Regulation, whichever is latest. The last year in which the Department Assessed and (if Review of the Regulation is required) Reviewed the Regulation shall be the year during which the findings of the Assessment and, if required, the Review of the Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

In other words, under the proposed rule the Department must Review all its regulations (subject to the exceptions listed below) that have a significant economic impact upon a substantial number of small entities every ten years, or such regulations shall expire. To determine which regulations have a significant economic impact upon a substantial number of small entities, the proposed rule stated that the Department must Assess all its regulations (subject to the exceptions listed below) every ten years, or such regulations shall expire if not Assessed. The Department believes all of its regulations (subject to the exceptions) should be Assessed and, if they have a significant economic impact upon a substantial number of small entities, Reviewed. The proposed rule stated that Assessments and Reviews should not be performed only on those regulations issued after the proposed rule goes into effect. After all, it is likely that some regulations promulgated decades ago may have become outdated.[165]

Section [XX](c) of the proposed rule made clear that Department regulations (subject to the exceptions listed below) shall expire if their Assessment and (if required) Review are not timely performed. Both 5 U.S.C. 610 and executive orders by multiple presidents over several decades direct the Department to devise plans to periodically review many of its regulations.[166] Although the Department retrospectively reviewed a very limited number of its regulations, observers have over the decades noted that the Department has not always performed retrospective review to a satisfactory extent, and many of its regulations have not been reviewed. Therefore, the Department concluded in the proposed rule that it was appropriate to impose on itself a stronger incentive to ensure it complies with the purposes animating the RFA and the executive orders, as well as to ensure its regulations are not unduly burdening the public. As a CRS report put it, ''[w]ithout some type of enforcement of the review requirement, agencies are unlikely to conduct many more reviews than have occurred pursuant to Section 610.'' [167] This is one reason why analyses have found that sunset provisions are an effective way to improve governance and reduce undue regulatory burdens.[168] States have imposed similar expiration dates for many of their regulations unless they are reviewed or readopted.

It complies with the APA to amend regulations to specify dates by which regulations expire unless the Assessment and/or Review is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[169] An agency can also provide that its regulations expire upon the occurrence of a condition.[170] That is what the Department proposed

[165] *See, e.g.,* Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005), *http://perma.cc/R8LX-BQMJ;* Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs, 5 J. Benefit Cost Anal.* no. 2, 2014, at 259–84, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.*

[166] The RFA and the Executive Orders direct agencies to review overlapping, but not identical, sets of regulations. The RFA directs agencies to have plans to review regulations that have a ''significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610. By contrast, Executive Order 12866 directed agencies to submit to OIRA programs to periodically review ''significant regulations.'' Exec. Order 12866, Sec. 5(a). ''Significant regulations'' are not necessarily those that have a ''significant economic impact upon a substantial number of small entities.'' *Id.* at Sec. 3(f) (defining ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.''). Executive Order 13563 also directed agencies to review ''significant regulations.'' Exec. Order 13563, Sec. 6. The Department has proposed to Review those regulations that satisfy the RFA criteria, since those are the regulations that Congress directed agencies to have plans to review. The Department requested comment on whether additional regulations, such as significant regulations, should also be Reviewed.

[167] Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 11 (2008); *see also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013) (setting forth possible reasons why agencies, even when they have adequate resources, may be reluctant to perform retrospective reviews).

[168] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* 36 (Mercatus Ctr., Working Paper No. 12–18, 2012), *https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf;*); *Occupational Licensing: A Framework for Policymakers,* The White House, at 48–50 (July 2015), *https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.*

[169] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276, 42277 (July 22, 2005) (amending interim final rule, to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council,* 862 F.3d at 9 (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[170] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine 85 FR 7874, 7874 (Feb. 12, 2020 (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19'').

in the proposed rule. To be sure, an agency generally must ''articulate a satisfactory explanation'' for its action, ''including a rational connection between the facts found and the choice made,'' and cannot ''entirely fail[] to consider an important aspect of the problem.'' [171] The Department anticipates that if a regulation expires because the Department does not timely complete its regulatory review, a litigant might object to the expiration on the grounds that the Department by definition did not ''articulate a satisfactory explanation'' or ''failed to consider an important factor,'' because in not performing an Assessment or Review, the Department failed to consider any factors. The Department rejects such arguments. In this rulemaking, the Department is considering the important factors. For the reasons described in the proposed rule and in this final rule, the Department believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a regulation inadvertently expiring is justified by the benefit of institutionalizing retrospective review in this manner. Forty years of experience since the RFA's enactment; the decades since relevant Executive Orders were enacted; and other Federal government efforts to spur the Department to conduct more retrospective reviews indicate that, absent such a forcing mechanism, the Department will not conduct as many retrospective reviews as desired.

The Department will mitigate this risk by setting up two web pages on the Department's website by the date this final rule is published; one that lists the dates of promulgation of all of its rulemakings, and a second that lists the rulemakings that contain regulations (called ''Sections'' in this final rule) that the Department has decided to Assess or Review. The Department will regularly update the web page listing the rulemakings containing Sections that it has decided to Assess or Review with all additional rulemakings containing Sections that it begins to Assess or Review. The Department will also create a docket on *Regulations.gov*, to which the public may direct any comments requesting that the Department begin the Assessment or Review of regulations. This requirement is described in more detail in the discussion of section [XX](h).

Therefore, in this rulemaking process, which amends Department regulations through the notice-and-comment process, the Department is considering the important factors. In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews, its progress, and when it expects them to be completed. The Department also intends to create a dashboard showing its progress on conducting Assessments and Reviews. *See* Section II.F. for more detail on the dashboard.

The Department proposed to perform the Assessment and (if required) the Review on each regulation every ten years. Some states provide that, unless readopted or re-reviewed, their regulations expire in seven years,[172] while at least one state uses a ten-year time period.[173] The Department proposed to perform the Assessment and (if required) the Review every ten years, because ten years is the period listed in 5 U.S.C. 610.

The proposed rule provided that regulations promulgated more than ten years ago will expire at the end of two calendar years from the date the proposed rule, if finalized, became effective, unless an Assessment and (if required) the Review is performed on them. In the proposed rule, the Department requested public comment on whether two years is an appropriate time period to Assess and (if required) Review Regulations promulgated more than ten years ago.

The Department has decided that all of its regulations (subject to the exceptions listed below) should be periodically Assessed to determine whether they have a significant economic impact upon a substantial number of small entities. Without performing the Assessment, the Department may not know which regulations have or will have a significant economic impact upon a substantial number of small entities. Due to changed circumstances, a regulation that did not have such an impact at the time it was promulgated may now have such an impact. The Department is also aware of literature suggesting that agencies have not been consistent in deciding which rules have a significant economic impact on a substantial number of small entities, or have avoided such a finding in order to avoid complying with the RFA's requirements.[174] By Assessing all of its regulations (subject to the exceptions described herein) and publishing the results of the Assessments, the Department can avoid concern that the Department is failing to Assess or Review regulations that have a significant economic impact upon a substantial number of small entities.

The Department should in many cases perform a single Assessment (and, where required, a single Review) that considers all regulations issued as part of the same rulemaking. That would generally make sense from an economic perspective, for the same reasons that the Department in many cases does a single regulatory impact analysis on all regulations that are issued as part of the same rulemaking. That is why the proposed rule and this final rule define ''Assess'' and ''Review'' as determinations regarding ''Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter)'' (except that the term ''Regulations'' is replaced with ''Sections'' in this final rule). Indeed, 5 U.S.C. 605(c) provides that ''[i]n order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.'' Thus, if a series of regulations were issued as part of the same rulemaking and one of those regulations was subsequently amended, the Department would in many cases take the view that the series of regulations could be Assessed or Reviewed together for purposes of this final rule.

The same is true for the converse. Consider, for example, the 2015 rulemaking Preventive Controls for Human Food that established 21 CFR part 117 and also amended or revised individual regulations in Parts 1, 106, 110, 114, 120, 123, 129, 179, and 211 that were originally issued before 2015.[175] If the Department so chose, when the deadline approaches for Assessing and (if required) Reviewing the amended regulations in 21 CFR part

[171] *Little Sisters of the Poor Saints Peter and Paul Home* v. *Pa.,* 140 S. Ct. 2367, 2383–84 (2020) (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)).

[172] *See, e.g.,* N.J. Admin. Code § 1:30–6.4 (2020) (regulations expire every seven years unless readopted, subject to certain exceptions); Ind. Code 4–22–2.5–2 (2020) (imposing seven-year expiration date on regulations unless readopted).

[173] N.C. Gen. Stat. 150B–21.3A (2020).

[174] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

[175] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 FR 55,907 (Sept. 17, 2015). *https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human.*

106, the Department could, as part of the same Assessment or Review, also assess or review the other regulations that were amended in this rulemaking.

For regulations that were issued in coordination with another Agency, that function in concert with another Agency's regulations, or that have a specific, direct impact on regulations issued by another Federal agency, the proposed rule proposed that the Department would consult with that other Agency when undertaking the Assessment or Review, and consider the other Agency's views when considering the factors described in section [XX](d). An example of regulations that have a specific, direct impact on regulations issued by another Federal agency are the Department's ACA regulations concerning the operation of Exchanges that affect eligibility for the advance premium tax credit. Such regulations have a specific, direct impact on Department of the Treasury regulations.[176]

The Department's understanding is that the decisions based upon Reviews, including the amendment, repeal, or continuance of regulations without change, will constitute final agency action. First, the decisions will mark the consummation of the agency's decisionmaking process with respect to whether a regulation satisfies the criteria described in section [XX](d). Second, the decisions constitute action by which rights or obligations have been determined, or from which legal consequences will flow. This is because if the Review is not performed, the regulation would expire.[177] Therefore, because the decisions based upon Reviews constitute final agency action, they must be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.[178]

Similarly, if an Assessment concludes that a regulation does not have a significant economic impact upon a substantial number of small entities, that would mark the consummation of the Department's decisionmaking process with respect to whether a Review must be performed on the regulation. Such an Assessment's findings would also constitute action by which rights or obligations have been determined, or from which legal consequences will flow, because if the Assessment is not performed, the regulation would expire. Therefore, Assessments must also be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.

The Department proposed to perform the Assessment and (if required) the Review on each Regulation every ten years. Some states provide that, unless readopted or re-reviewed, their regulations expire in seven years,[179] while at least one state uses a ten-year time period.[180] The Department proposed to perform the Assessment and (if required) the Review every ten years, because ten years is the period listed in 5 U.S.C. 610. The Department has many regulations, some of which are complex, so having to perform the Assessment and Review more than once every ten years could unduly burden the Department and increase the likelihood that a Regulation inadvertently expires because it is not Assessed or Reviewed.

Comments and Responses Regarding Section [XX](c)

HHS received the following comments on Section [XX](c) of the proposed rule.

Comment: Several commenters asked the Department to extend, from two years to five years, the timeframe for Assessment or Review of regulations that are over ten years old.

Response: The Department considered this comment, and has decided to make this change. Under this final rule, regulations that are more than ten years old when this final rule becomes effective shall expire if not Assessed and (if needed) Reviewed within five calendar years of the year that this final rule becomes effective. This will spread out the initial burden on the Department and provide the opportunity for more robust Assessments and Reviews. It also reduces any harm to reliance interests, since the public will now be on notice further in advance of the initial Assessment and Review deadlines.

Comment: Several commenters stated that the final rule should provide the Secretary with the authority to make one-time, case-by-case exceptions to the automatic expiration of a rule.

Response: HHS appreciates this comment and has decided to include within this final rule a provision that allows the Secretary—on a non-delegable basis—to extend on a one-time, case-by-case basis the automatic expiration date of a Section by one year. The Department shall promptly publish in the **Federal Register** any such determination by the Secretary to extend the expiration date.

Comment: A large number of commenters stated that the process established in the proposed rule could result in important regulations slipping through the cracks and expiring, which could have implications for other rules. These commenters stated that the Assessment and Review process established in the proposed rule would be complicated and time-consuming to put into practice, which could result in the automatic expiration of some regulations. A large number of commenters specifically mentioned regulations at 42 CFR 435.603, on which multiple insurance affordability programs, including Medicaid and CHIP, rely to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. According to the commenters, the expiration of that regulation would allow programs to redefine MAGI household and income counting rules, with no standards, consistency, or accountability, which commenters fear could wreak havoc in HHS programs. Another commenter stated that if some critical regulations, such as the Medicare health and safety standards which provide a baseline for patient safety sunset, this could threaten patient safety. A large number of commenters suggested that safeguards be put in place to ensure that regulations that are critical to the operation of safety net providers do not simply expire because an Assessment or Review was not completed in time.

Response: HHS appreciates the theoretical possibility raised by these commenters that important regulations (such as MAGI methodologies or Medicare health and safety standards) could expire inadvertently. But as explained throughout the proposed rule and in this final rule, the Department intends to timely complete the required Assessments and Reviews. As noted in the proposed rule, as an additional safeguard, in the unlikely event it appears HHS has overlooked an impending deadline, interested members of the public can raise the need to Assess or Review specific regulation through public comment. As

[176] *See, e.g.,* 45 CFR 155.340 (regarding administration of advance payments of the premium tax credit and cost-sharing reductions and requiring the Exchange to comply with Treasury regulations).

[177] *See U.S. Army Corps of Engineers* v. *Hawkes Co., Inc.,* 136 S. Ct. 1807, 1813 (2016) (to have final agency action, ''First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow'' (quoting *Bennett* v. *Spear,* 520 U.S. 154, 177–78 (1997)).

[178] *See* 5 U.S.C. 704 (final agency action is reviewable); 5 U.S.C. 706 (a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

[179] 85 FR 70,105.

[180] *Id.*

an additional safeguard, the Department adds in this final rule that if, prior to the expiration of a Section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under this final rule, the Secretary may continue the Section in force one time for a period stated in the determination, which period shall not exceed one year.

Comment: Several commenters expressed concern about the precedent created by an automatic expiration date, which they believe could allow future administrations to reject regulations by simply letting them lapse. These commenters stated that this scenario would allow the Department to bypass the regulatory process and deprive the American people of the opportunity for comment and input.

Response: HHS respectfully disagrees that this is a significant enough risk to outweigh the tremendous benefits from retrospective review. The commenters' concerns assume a lack of good faith by future administrations. There would also likely be a tremendous public outcry if many beneficial regulations were permitted to expire.

This final rule does not bypass the regulatory process or deprive the American people of the opportunity for comment and input. In this rulemaking, the Department is going through the APA's ordinary notice-and-comment process. This final rule reflects that the Department accepted and considered over 500 public comments on the proposed rule. The Department also held a public hearing on the proposed rule and considered the comments made there in promulgating this final rule. In addition, this final rule institutionalizes an ongoing opportunity for public comment during this regulatory review process.

Comment: Several commenters stated that public harm could result from removing regulations that protect the public health and consumers. A few commenters suggested that the Assessments and Reviews conducted by the Department should specifically consider consumer protection.

Response: For the reasons explained in the preamble and regulatory impact analysis for this final rule, this final rule implements a process by which the Department will Assess and Review its regulations. HHS intends to undertake a careful Assessment, and (if necessary) Review of each regulation subject to this final rule to determine if the regulation should be continued without change, amended, or rescinded. HHS has no intention to rescind regulations that appropriately protect the public health or consumers. Reviews will consider the factors described in 5 U.S.C. 610(b) (as well as whether the regulation complies with applicable law). These are the factors that Congress directed the Department to consider when periodically reviewing regulations that have a SEISNOSE. Considerations with respect to consumer protection will often be subsumed in this analysis.

Comment: A few commenters suggested that instead of the proposed timeframe for review, the Department should instead Review regulations on a rolling basis but not less than 10 years from the date of first promulgation or substantial amendment.

Response: HHS respectfully disagrees. Clear and specific deadlines are needed to ensure the efficacy of this rule and to secure robust retrospective review of agency regulations. Moreover, the commenters' suggestion that review occur no *less* than 10 years from the date of promulgation or substantial amendment is, in the Department's view, an undue time lapse. It threatens to leave long outdated and burdensome regulations in place for too long.

Comment: One commenter stated that the proposed timeline for reviewing regulations is inconsistent with the proposed rule's goal of reviewing regulations based on the likelihood of their obsolescence. This commenter stated that the proposed rule assumes that the passage of time increases the likelihood of regulatory obsolescence, but the proposed rule defines a Regulation's age based on the date on which it was originally promulgated, regardless of subsequent amendments. Therefore, some regulations that have been subsequently amended could reach their time for review earlier than regulations that were promulgated and never amended. For example, a Medicaid regulation first adopted in 1968 but revised repeatedly and as recently as 2020 would need to be Assessed, possibly Reviewed, and possibly revised again even though it was just amended.

This commenter said this timing is also incongruent with specific provisions in the RFA. The RFA defines a ''rule'' to include ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b),'' which explicitly includes regulatory amendments. *See* 5 U.S.C. 553(b) and 551(5). The commenter stated that this statutory provision requires the proposed rule's ''clock'' for 10-year review to be reset based on the most recent regulatory amendment that went through APA notice and comment procedures.

Response: HHS respectfully disagrees. As an initial matter, 5 U.S.C. 610 refers to review ''within'' ten years; it does not foreclose reviewing regulations sooner. Second, this rule seeks to balance the desire to review older regulations first, while also specifying clear, easily-ascertainable deadlines for Assessments and Reviews. It would be harder for the Department and the public to determine the Assessment and Review deadlines if the deadlines changed each time a regulation were amended. Providing that the ''clock'' begins to run from the year a Section was first promulgated is a reasonable way to balance these considerations. Tying deadlines to the amendments of Sections threatens to make the rule completely unwieldy—leaving an open question of when certain parts of a rule are up for Assessment and Review.

Also, as explained in the proposed rule, if the Department is amending a regulation close in time to its ten-year Assessment or Review date, then the Department can conduct Assessment and Review alongside the amendment, thereby restarting the ten-year clock if it publishes the findings in the **Federal Register** in the manner specified in this final rule.[181]

Amendments to Section [XX](c)

After considering the public comments on the two year time period to Assess and (if required) Review regulations that are more than ten years old, the Department has decided to extend this time period to five calendar years after the year that this section first becomes effective. Furthermore, in this final rule the Department amends section [XX](c) to read ''this chapter,'' rather than ''this title,'' as was used in the proposed rule. The Department makes this change to conform to the fact that this final rule amends certain chapters, rather than entire titles. The Department finalizes sections [XX](c)(1)–(2) as amended.

ii. Section [XX](c)(3)

After considering the public comments received on the proposed rule, the Department decided to add a new Section [XX](c)(3) to this final rule.

Section [XX](c)(3) states that if, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time

[181] 85 FR 70105.

for a period stated in the determination, which shall not exceed one calendar year. This final rule requires the Department to promptly publish any such written determination in the **Federal Register**. The authority of the Secretary to make this written determination is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law. This provision, like other provisions of this final rule, is severable.

The Department adds this provision so that, if a pandemic, emergency, or other development arises that prevents the Department from timely Assessing or Reviewing certain Sections and the public interest requires their continuation, the Department can have additional time to Assess and (if needed) Review those Sections.

A. Section [XX](d)

HHS proposed in Section [XX](d) of the proposed rule that the Department would be required to Review those Regulations that the Department Assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the proposed rule stated that the Department's Review shall consider (1) the continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules; (2) the nature of complaints or comments received concerning the Regulation from the public; (3) the complexity of the Regulation; (4) the extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation since the Regulation was promulgated or the last time the Regulation was Reviewed by the Department; (6) whether the Regulation complies with applicable law; and (7) other considerations as required by relevant executive orders and laws.

This largely mirrors the review described in 5 U.S.C. 610. It is also consistent with ACUS' recommendation that agencies ''consider whether the [existing] regulations are accomplishing their intended purpose or whether they might, to the extent permitted by law, be modified, strengthened or eliminated in order to achieve statutory goals more faithfully, minimize compliance burdens on regulated entities, or more effectively confer regulatory benefits.'' [182] Prior to finalization, OIRA may review Reviews, including to coordinate inter-agency participation in the Review process where there are significant inter-agency equities or as otherwise appropriate.[183] For example, when Assessing or Reviewing regulations that require Executive Order 12250 review and approval by the Attorney General, the Department will consult with the Department of Justice (DOJ) and provide a draft of the findings to DOJ well in advance of the Assessment or Review deadline, so that DOJ can review and approve prior to the publication of the findings. It may be appropriate for OIRA to coordinate this process.

Proposed section [XX](d) of the proposed rule provided that the Department shall consider the continued need for the Regulation, ''consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules.'' The quoted phrase is not found in 5 U.S.C. 610, but the Department included it in the proposed rule to clarify that determining the continued need for a regulation includes determining the extent to which it defines terms or sets standards used in or otherwise applicable to other Federal rules. However, this was not meant to be the only factor the Department should consider when determining the continued need for a regulation. Under the proposed rule, the Department shall consider any factors that, for a particular regulation, are relevant to determining whether there is a continued need for the regulation.

In addition to this phrase, two factors listed in section [XX](d) of the proposed rule were not found in 5 U.S.C. 610. The first is that section [XX](d) of the proposed rule stated that the Review should take into account ''whether the Regulation complies with applicable law.'' Since applicable law may have changed since a regulation was promulgated, the Department wants to ensure that its regulations are regularly reviewed to ensure that they comply with applicable law.

Second, section [XX](d) of the proposed rule stated that the Review should take into account ''other considerations as required by relevant executive orders and laws.'' The proposed rule stated that to the extent Executive Orders or laws enacted since the RFA require the Department to consider additional factors when performing retrospective review of particular regulations, the Department wishes to comply with those Executive Orders and laws. A recent Department of Transportation rule similarly required that agency, when periodically reviewing its regulations, to consider ''[o]ther considerations as required by relevant executive orders and laws.'' *See* 49 CFR 5.13(d)(2)(vi). Upon further consideration, the Department has decided not to finalize this seventh factor. First, this factor is not included in the RFA.[184] Second, this factor is potentially unclear and could be open to multiple interpretations. Third, this final rule already requires the Department to consider whether the rulemaking complies with applicable law. Thus, the seventh factor is not only susceptible to multiple interpretations, but seems largely (if not entirely) subsumed by other factors in this final rule.

The Department anticipates that the Reviews would be similar to the section 610 analyses currently performed by agencies. The Reviews would benefit from real-world data and information gathered since the regulations were promulgated to potentially discern the impact of the regulation on small entities and on society more generally.

Section [XX](d) of the proposed rule requires that only regulations that have a significant economic impact upon a substantial number of small entities be Reviewed, because those are the regulations that 5 U.S.C. 610 requires agencies have a plan to periodically review.

Comments on Section [XX](d)

HHS received the following comments on Section [XX](d) of the proposed rule.

Comment: Several commenters suggested that HHS consult with trade

[182] Administrative Conference of the United States, Recommendation 2014–5, 79 Fed. App'x—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75117 (Dec. 17, 2014).

[183] OIRA may also coordinate inter-agency participation in the Assessment process where there are significant inter-agency equities or as otherwise appropriate.

[184] The RFA also does not include ''whether the Regulation complies with applicable law'' as a factor. But it seems uncontroversial to require the Department to consider whether its regulations comply with applicable law, and this phrase has a clear meaning.

groups and other specialty societies to consider the policy recommendations of providers and others in the healthcare industry to understand the implications of modifying or rescinding existing regulations. Some of these commenters brought up certain regulations for which they care deeply and would like to see rescinded or maintained.

Response: HHS appreciates these comments and wishes for the public to have the opportunity to provide meaningful feedback on regulatory changes that the Department may consider as it conducts its Assessments and Reviews. To achieve that goal, the proposed rule, as finalized, includes a process of soliciting robust public comments and feedback, which HHS will consider and incorporate into its Assessment and Review decisions. As stated in [XX](d)(2), ''[t]he nature of complaints or comments received concerning the Regulation from the public'' is one of the factors that the Department is required to consider under this rule when it conducts its Assessments and Reviews. HHS is committed to ensuring that the public has ample opportunity to opine on its regulations, and looks forward to thoughtfully considering public comments during the regulatory review process resulting from this final rule.

Comment: A few commenters stated that the Department's process for reviewing regulations that have a SEISNOSE was unclear from the proposed rule. These commenters asked that the Department provide at least one example of how factors would be considered and how HHS would conduct its decision-making process.

Response: Based in part on these comments, in this final rule the Department removes the final factor specified in the proposed rule (''other considerations as required by relevant executive orders and laws''). The Department does so because this factor's meaning could be unclear, it is not in the RFA, and it adds little beyond what is already more clearly stated in other factors, such as whether the rulemaking complies with applicable law. Beyond removing this factor, HHS respectfully declines to provide additional clarity within this final rule as to the exact contours of the Review process. As explained in the proposed rule, the Review takes into account factors that already exist under 5 U.S.C. 610(b), along with a consideration of whether the rulemaking complies with applicable law, a factor whose meaning is clear and uncontroversial. It is anticipated that the Review process will track the Department's and other agencies' past practice with respect to Section 610 analyses. In particular, examples of Section 610 reviews conducted by the EPA are instructive on how the Department anticipates the five factors set forth in 5 U.S.C. 610(b) will be analyzed.[185] The Review decision-making process will be implemented in a manner appropriate for the regulation in question, including but not limited to input from subject-matter experts within the Department and the public.

Comment: A few commenters asked for clarification regarding the Department's decision-making process as to whether a regulation would be identified as requiring a rescission or amendment based on the factors provided. For example, if HHS were to identify overlap or duplication between a regulation under Review and other Federal regulations, how would HHS assess the factors to make a decision to rescind or amend? These commenters also asked for clarification on how the Department would determine that a regulation is duplicative.

Response: The factors specified in the final rule will be balanced, and a determination as to whether to amend or rescind a Section will be made on a case-by-case basis. No one factor by itself is dispositive (unless the Section does not comply with applicable law). The balancing of a series of considerations, sometimes complex and wide-ranging, is inherent in the Department's policy-making functions, even beyond the context of the Review process set out in this final rule. In the prior comment, the Department provided examples of how the Reviews will consider the relevant factors. The concept of regulatory duplication, which has been in the RFA, 5 U.S.C. 610(b)(4) for over forty years, is largely self-explanatory. A regulation may be considered duplicative, if, for instance, it serves the same function or overlaps with another regulation.[186] Amending or rescinding duplicative regulations can reduce complexity and regulatory burden.

Comment: Some commenters asked HHS to clarify how it would consider public comments about a regulation, and whether there would be numerical or content benchmarks that HHS would use to guide its decision-making regarding the public feedback it receives.

Response: The Department will create dockets on *Regulations.gov* for its Assessments and Reviews, and the public may submit comments to those dockets in the same manner as it can submit comments on notices of proposed rulemaking. The Department's Reviews will be holistic and consider the five factors specified in 5 U.S.C. 610(b), as well as compliance with applicable law. No one factor by itself is dispositive (unless the Section does not comply with applicable law). The weight that the Department gives to comments will be a case-by-case determination. For example, fifty complaints about a major rule that also had 500 supportive comments might not counsel in favor of amending or rescinding the rule. But fifty complaints about a rule that had no comments supporting it might weigh in favor of amendment or rescission, particularly if the other section 610 factors do not counsel strongly in favor of continuing the regulation without change. The public-comment process, and how much weight to give to various comments, is familiar to the Department and the public from the many instances of public comment on Department policymaking actions. A similar standard will be applied here.

Accordingly, the Department finalizes section [XX](d) of the proposed rule as proposed, except that it removes (d)(7), which proposed that Reviews consider ''[o]ther considerations as required by relevant executive orders and laws.'' Moreover, in the finalized section [XX](d), the Department replaces the term ''Regulation'' with ''rulemaking.'' This is in response to comments previously discussed expressing concerning about potential ambiguity caused by the use of the term ''Regulation.'' This change is also made to conform section [XX](d) to the fact that ''Reviews'' are defined as determinations as to ''whether Sections[187] that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter)'' should be continued without change, amended, or rescinded. Reviews are therefore not of individuals sections but of the sections

[185] *See Results of EPA's Section 610 Review of the Final Rule for Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel,* EPA Off. of Transp. & Quality (Sept. 2014), *https://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0642-0003; Regulatory Flexibility Act Section 610 Review of the National Pollutant Discharge Elimination System (NPDES) Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs),* EPA Off. of Water (June 3, 2014), *https://www.regulations.gov/document?D=EPA-HQ-OW-2012-0813-0216; Results of EPA's Section 610 Review of the Final Rule for Lead; Renovation, Repair, and Painting Program, EPA Off. of Pollution Prevention and Toxics* (Apr. (April 2018), *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0019.*

[186] *Duplicative,* Black's Law Dictionary (11th ed. 2019) (defining ''duplicative'' as ''Having or characterized by having overlapping content, intentions, or effect'').

[187] ''Regulations'' in the proposed rule.

issued as part of the same rulemaking. Thus, this revision to section [XX](d) is made for clarity but is not a substantive change from the proposed rule.

Section [XX](e)

In the proposed rule, HHS proposed that if the Review concludes that a Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the Review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. The proposed rule further stated that if the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

The Department included this provision in the proposed rule because, if the Review concludes that a Regulation should be amended or rescinded, the Regulation should in fact be amended or rescinded. The Department believes that two years will generally be an adequate amount of time to amend or rescind a Regulation, since the Department will have already conducted a Review of the Regulation. In circumstances where amendment is not feasible within that time period, the proposed rule stated that the Secretary could so certify in a statement published in the **Federal Register** and extend the completion date by one year at a time for a total of not more than five years.

As stated in the proposed rule, when the Review determines that a regulation should be amended or rescinded, the Department would, on a case-by-case basis as appropriate, use enforcement discretion to not enforce the regulation or a portion of the regulation until it is amended or rescinded. This is because in many cases the Department would not want to enforce regulations (or portions of regulations) that it determines should be amended or rescinded. The Department noted that enforcing a regulation deemed to require amendment or rescission in some cases raises concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the regulation (or portions thereof) would arguably ''run[ ] counter to the evidence before the agency.'' [188]

Comments on Section [XX](e)

HHS received the following comments on Section [XX](e) of the proposed rule.

Comment: Some commenters stated that the Department should limit the length of time for amending or rescinding a Regulation from two years with three one-year extensions for a total of not more than five years to two years with the possibility to extend for one year (for a total of not more than three years). One commenter also stated that the current text is ambiguous as to whether it is a maximum of five years (two years plus three one-year extensions) or a maximum of seven years (two years plus five one-year extensions).

Response: HHS appreciates these comments and, in this final rule, modifies the rule's text to clarify that, if a Review concludes that a Section should be amended or rescinded, the maximum time for amending or rescinding the Section (including all possible extensions) is five years. That is, there is a two-year period to amend or rescind, which can be extended no more than three times for one year each time.

The Department believes the two-year default period is appropriate and declines to further limit the number of possible extensions. If the Department concludes that a regulation should be amended or rescinded, it does not want to unduly delay doing so. The Department believes that two years will generally be an adequate amount of time to amend or rescind such regulations, since the Department has already Reviewed them. However, given the complexity of some Department regulations and competing priorities, in some circumstances it may not be feasible to amend or rescind a regulation within two years. In circumstances where amendment or rescission is not feasible within that time period, the Secretary can so certify in a statement published in the **Federal Register** and extend the completion date by one year at a time no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

Accordingly, after considering the public comments, the Department chose to clarify the language in section [XX](e) of the proposed rule with respect to the time period for extension of the completion of an amendment or rescission. Where the proposed rule stated that the Secretary ''may extend the completion date by one year at a time for a total of not more than five years,'' the final rule clarifies that the Secretary ''may extend the completion date by one year at a time, *no more than three times,* for a total of not more than five years *(inclusive of the initial two-year period)*'' (emphasis added). This change does not alter the time period for extending the completion date of an amendment or rescission, but HHS believes that this language clarifies the length of time that the completion may be extended. The Department finalizes Section [XX](e) of the proposed rule, with this clarifying language.

Section [XX](f)

Section [XX](f) of the proposed rule provided that the results of all Assessments and Reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The proposed rule stated that the document shall be organized in a manner that enables both the Department and the public to readily determine which Assessments and Reviews were conducted during that calendar year. It further proposed that the document shall also specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed.

The Department included this requirement in the proposed rule so that both the Department and the public could readily know which Regulations were Assessed and Reviewed each year. If Assessments and Reviews were published in disparate places throughout the year, it could become extraordinarily difficult for both the Department and the public to know which Regulations were Assessed and Reviewed each year. Section [XX](f) was proposed to enable both the Department and the public to look in one place to know which Assessments and Reviews were conducted each calendar year, and know the findings of those Assessments and Reviews.

The proposed rule stated that when publishing the findings of an Assessment or Review, the Department should include the full underlying analyses and data used to support the results, subject to any applicable privilege, protections for confidential business information, or explicit prohibition on disclosure. This will increase transparency and permit the public to see how the Department reached its conclusion. By requiring publication of the Reviews and the underlying analyses and data, the Department also incorporated ACUS'

[188] *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

suggestion that ''[a]gencies should disclose relevant data concerning their retrospective analyses'' so as to ''allow private parties to recreate the agency's work and to run additional analyses concerning existing rules' effectiveness.'' [189] The Department does not believe that the deliberative process privilege would generally bar disclosing the final underlying analyses and data referred to in section [XX](f).[190]

Section [XX](f) of the proposed rule also provides that the document published in the **Federal Register** shall specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed. This can be particularly helpful if the Department conducts an Assessment or Review of a Regulation prior to the deadline year.

Comments on Section [XX](f)

HHS received the following comments on Section [XX](f) of the proposed rule.

Comment: A few commenters suggested that the results of each Assessment and Review should be published separately in the **Federal Register** as they are completed, with a title clearly identifying the affected regulation and the Department's responses to the public comments received.

Response: HHS respectfully disagrees that the results should be published on a rolling basis. Announcing the results of all Assessments and Reviews within a single document makes it easier for the public (and the Department) to determine (1) which Sections were Assessed and Reviewed, (2) the dates by which they were Assessed and Reviewed, and (3) when they next need to be Assessed and (if needed) Reviewed. Interested parties need only refer to a single source of information for a given year. Publishing all Assessments and Reviews for a given year in a single document also reduces the risk that a Section will inadvertently expire.

The commenters' concerns about the Reviews including the Department's responses to public comments was already addressed in the proposed rule. Section [XX](d) of the proposed rule directed the agency to consider, as part of Reviews, ''the nature of complaints or comments received concerning the Regulation from the public.'' And the document published in the **Federal Register** shall include the ''full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure.'' Section [XX](d)'s requirement to consider the nature of complaints or comments only applies to Reviews, not Assessments. Assessments are preliminary determinations that only focus on whether a rule making has a SEISNOSE, and do not require as extensive an analysis as Reviews. If the Department receives comments during the Assessment process, it would endeavor to take them into account in determining whether a rule making has a SEISNOSE. Moreover, as the proposed rule proposed,[191] the document published in the **Federal Register** will be organized in a manner that enables both the Department and the public to readily determine which Assessments and Reviews were conducted during each calendar year.

Comment: Some commenters stated that the Department should commit to publishing results of Reviews as they are completed, or on no less than a monthly basis, so that the interested public can truly contemplate each regulation now in question.

Response: The Department intends to publish the results of the Assessments and Reviews in the dockets for the applicable regulations. However, as compared to publishing Assessments and Reviews in the **Federal Register** on a rolling basis, announcing the results of all Assessments and Reviews within a single document makes it easier for the public (and the Department) to determine (1) which Sections were Assessed and Reviewed, (2) the dates by which they were Assessed and Reviewed, and (3) when they next need to be Assessed and (if needed) Reviewed. Interested parties need only refer to a single source of information for a given year. Publishing all Assessments and Reviews for a given year in a single document also reduces the risk that a Section will inadvertently expire. The Department will announce on a periodic basis when it has commenced the process of performing an Assessment or Review.

Comment: A few commenters asked what role the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) would have in reviewing the reports, and any proposed revisions to standing regulations.

Response: As noted in the proposed rule, ''Prior to finalization, OIRA may review Reviews, including to coordinate inter-agency participation in the Review process where there are significant inter-agency equities or as otherwise appropriate.'' [192]

Accordingly, after considering the public comments, HHS finalizes section [XX](f) as proposed.

Section [XX](g)

HHS proposed in Section [XX](g) of the proposed rule that paragraph (c) of the proposed rule would not apply to Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For such Regulations that are adopted after the effective date of this section, the proposed rule stated that the Federal law described shall be cited in the notice of adoption. Section [XX](g) of the proposed rule also provided that paragraph (c) of the proposed rule would not apply to (1) Regulations whose expiration pursuant to this section would violate any other Federal law; (2) this section; (3) Regulations that involve a military or foreign affairs function of the United States; (4) Regulations addressed solely to internal agency management or personnel matters; (5) Regulations related solely to Federal Government procurement; and (6) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

Section[XX](g)(1) of the proposed rule excepted Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. This is only the case in rare circumstances. Because the Department lacks discretion over what is contained in these Regulations and cannot rescind them, they are exempted from section [XX](c). For such Regulations that are promulgated after the effective date of this final rule, the Department shall describe in the Regulation's notice of adoption the Federal law that results in

[189] 79 FR 75114, 75117 (Dec. 17, 2014); *see also* Exec. Order 13563, Sec. 6(a) (Jan. 18, 2011) (''retrospective analyses, including supporting data, should be released online whenever possible''). Although this final rule incorporates several ACUS' recommendations, it does not incorporate all of them. This final rule does not set forth a prioritization scheme, although the Department intends to subsequently set forth a schedule for conducting Assessments and Reviews.

[190] *See, e.g., Coastal States Gas Corp.* v. *Dep't of Energy,* 617 F.2d 854, 866 (D.C. Cir. 1980) (''[E]ven if the document is predecisional at the time it is prepared, it can lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public.'').

[191] *See, e.g.,* 85 FR 70121.

[192] 85 FR 70108.

the Department having no discretion as to whether to promulgate the Regulation and what is prescribed by the Regulation. The proposed rule included this requirement so the public has notice that such Regulations are exempt from section [XX](c).

Section [XX](g) of the proposed rule likewise also exempted from section [XX](c) any Regulation whose expiration pursuant to this section would violate any other Federal law. The exceptions listed in sections [XX](g)(1) and [XX](g)(2) of the proposed rule are not satisfied simply because the statutory authority for the regulation provides that the Secretary ''shall'' prescribe regulations. For example, section 804(b) of the Federal Food Drug & Cosmetic Act, 21 U.S.C. 384(b), provides that the ''Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, *shall* promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States'' (emphasis added). However, although the statute was enacted in 2003, as of January 1, 2020 the Department had not issued any regulations implementing it, indicating the Department's view that section 804(b) did not require the Department to issue regulations. Similarly, Section 1102 of the Social Security Act, 42 U.S.C. 1302, provides that the Secretary ''*shall* make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act'' (emphasis added). But the Department does not believe every regulation promulgated pursuant to section 1102 is required to have been issued, or that it would violate Federal law to rescind such regulations.

Section [XX](g) of the proposed rule also exempted the proposed rule from section [XX](c). Assuming that no rules expire due to lack of Assessment or Review, the proposed rule stated that this rule cannot, absent other actions, directly impose on the public costs that exceed benefits, since the proposed rule merely would require the Department to periodically Assess and, in some cases, Review its Regulations. Only the failure to perform an Assessment or Review in the future could theoretically impose on the public costs that exceed benefits (assuming expired Regulations were on balance benefiting the public). The proposed rule stated that it would improve the Department's regulations by requiring the Department to evaluate the impact of its regulations and amend or rescind those regulations with a significant economic impact upon a substantial number of small entities that the Department determines should be amended or rescinded. Therefore, the rationale for periodic review would not apply to the proposed rule to the extent it applies to other Department regulations. The Department realizes that certain members of the regulated community might rely on particular regulations, but the Department proposed that it would take that into account when performing Assessments and Reviews. The Department proposed that it would only determine that a regulation should be amended or rescinded if the regulation's burdens outweigh these reliance interests and the other benefits of the regulation or if other factors, such as a change in law, might compel amendment or rescission. The Department stated in the proposed rule that it does not intend to avoid Assessing or, if required, Reviewing any regulation and does not anticipate that an important regulation would expire due to failure to Assess or Review it. Accordingly, the Department proposed to exempt the proposed rule from Section [XX](c).

The Department also proposed in Section [XX](g) of the proposed rule to exempt Regulations that involve a military or foreign affairs function of the United States. For purposes of the proposed rule (as well as in this final rule), ''a military or foreign affairs function of the United States'' has the same meaning as that phrase has under 5 U.S.C. 553(a). Regulations that involve a military or foreign affairs function of the United States were exempted from the proposed rule for the same reasons that Congress exempted them from the requirements of 5 U.S.C. 553.

Section [XX](g) of the proposed rule also exempted Regulations addressed solely to internal agency management or personnel matters and Regulations related solely to Federal Government procurement. Because such Regulations do not directly impact the public, the rationale for retrospective review is weaker with respect to these Regulations.

The portion of the proposed rule applying to Title 42 also exempted 42 CFR 1001.952 from expiration. 42 CFR 1001.952 provides a safe harbor for various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. The Department proposed to exempt this regulation because it was concerned that certain otherwise permissible behavior could become criminal simply because the Department did not Review this Regulation. The portion of the proposed rule applying to Title 42 also exempted 42 CFR part 73. 42 U.S.C. 262a provides that, with respect to Part 73, the ''Secretary shall review and republish [a list of certain biological agents and toxins] biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.'' Since those regulations are already being reviewed biennially, there was no need for the proposed rule to apply to 42 CFR part 73. Similarly, the portion of the proposed rule applying to Title 42 also exempted the annual Medicare Part A and Part B payment methodology update rules. Since these rules are amended annually, it does not make sense to Review them every ten years. Lastly, the portion of the proposed applying to Title 42 also exempted 42 CFR 100.3, since the statutory basis for this regulation provides that it cannot be amended unless (1) a proposed regulation is provided to the Advisory Committee on Childhood Vaccines (ACCV) and the ACCV is provided at least 90 days to make recommendations and comments, and (2) there is subsequently a 180-day public comment period. *See* 42 U.S.C. 300aa–14(c). For these reasons, these regulations are also exempted from this final rule.

Section [XX](g) of the proposed rule also exempted any Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency. This is because the Department cannot on its own rescind or amend a Regulation issued jointly with another Federal agency. An example of regulations issued with other agencies because of a legal requirement to consult with those other agencies are the regulations issued jointly by the Department and the Departments of Labor and the Treasury in accordance with section 104 of the Health Insurance Portability and Accountability Act (HIPAA). This provision directs the Secretaries of HHS, Labor and the Treasury to ensure that regulations issued pursuant to provisions where the Secretaries share interpretive jurisdiction (which includes many of the provisions in Title XXVII of the Public Health Service (PHS) Act) are administered to have the same effect at all times.[193] An example of jointly-issued regulations are regulations governing State innovation waivers under section 1332 of the

[193] *See* Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 (1996).

Patient Protection and the Affordable Care Act.[194]

The Department retains these exemptions for the reasons discussed in the proposed rule. For the reasons discussed below, this final rule also exempts certain other regulations from this final rule.

Comments on Section [XX](g)

HHS received the following comments on Section [XX](g) of the proposed rule.

Comment: Several commenters asked for further clarity on the proposed exemptions from the proposed rule. These commenters stated that it is unclear how the public would know which regulations are eligible for an exemption under the proposed rule. They suggested that the Department may be interpreting ''Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed in the Regulation'' very narrowly, because the proposed rule stated that it is ''rare'' that the Department has ''no discretion as to whether to promulgate [a] regulation and what is prescribed by the regulation.'' [195] These commenters stated that the examples given in the proposed rule were insufficient and open to interpretation, and members of the public should not be expected to be able to conduct their own statutory analysis. Some commenters specifically asked for at least one example of a regulation that would be exempted under this rule. Commenters also asked for examples of regulations that ''were issued in consultation with other agencies because of a legal requirement to consult with that other agency.''

Response: The Department thanks these commenters for their comments. Regulations that ''involve a military or foreign affairs function of the United States'' are regulations that would satisfy that standard under 5 U.S.C. 553(a)(1). ''Regulations addressed solely to internal agency management or personnel matters'' refers to regulations that would satisfy the ''matter relating to agency management or personnel'' standard under 5 U.S.C. 553(a)(2).[196]

An example of regulations issued with other agencies because of a legal requirement to consult with those other agencies are the regulations issued jointly by the Department and the Departments of Labor and the Treasury in accordance with section 104 of HIPAA. This provision directs the Secretaries of HHS, Labor and the Treasury to ensure that regulations issued pursuant to provisions where the Secretaries share interpretive jurisdiction (which includes many of the provisions in Title XXVII of the PHS Act) are administered to have the same effect at all times.[197] Such regulations constitute a small percentage of the Department's overall number of regulations (although they may have an outsize impact), and the Department is not aware of many regulations outside those promulgated pursuant to the relevant HIPAA provisions that would satisfy this exception. Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the regulation and as to what is prescribed in the regulation is also a very small category.

Comment: A few commenters stated that it was disingenuous for HHS to specifically decide to exempt this rule from the assessment and review process. These commenters stated that this decision is at best disingenuous or at worst an attempt to permanently impose a rigid review structure.

Response: HHS respectfully disagrees. This final rule does not permanently impose a rigid review structure, because this rule can be amended or rescinded under the APA. As explained in the notice of proposed rulemaking, the nature of this rule means that ''the rationale for periodic review does not apply to this proposed rule to the extent it applies to other Department regulations.'' [198] This final rule would not become obsolete due to economic, technological, or legal changes the way that many other rules can.

Comment: Several commenters stated that they do not want the annual Notice of Benefits and Payment Parameters (NBPP) rule to be subject to this rule.

Response: The Department agrees and has decided to exempt the annual Notice of Benefit and Payment Parameters update rules. Just as the proposed rule exempted the annual Medicare payment rules, this final rule need not apply to NBPP rules that are already reviewed and updated annually. The 2021 NBPP annual rules can be found at 85 FR 29164 (May 14, 2020). These and the equivalents for other years are exempt from this final rule.

Final Section [XX](g)

Based in part on comments, the Department has decided in the portion of the final rule applying to Title 21, Chapter I to also exempt the following provisions from this final rule:

- 21 CFR parts 131, 133, 135–137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163–166, 168, 169.
- 21 CFR parts 331–333, 335–336, 338, 340–341, 343–344, 346–350, 352, 355, 357, 358.
- 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 895, 898.

Based in part on comments, the Department decided in the portion of the file rule applying to Title 45, Subchapter A, to also exempt the annual Notice of Benefit and Payment Parameters update rules.

The first three bullets encompass FDA's food standard, device-specific, and over-the-counter drug regulations that specify characteristics of certain foods, devices, and over-the-counter drugs. These are regulations that specify the characteristics of particular foods, devices, and over-the-counter drugs. Many of the device regulations are already required to be reviewed in some way every five years.[199] Similarly, FDA is already undergoing a process to establish a set of general principles for food standards for FDA to use when considering whether to establish, revise, or eliminate a food standard.[200] Thus, there is less need to review these regulations every ten years, since these are being reviewed, or new processes for reviewing these regulations are being established. In addition, the exempt food standard, device, and OTC drug regulations simply create product identities.

As explained *supra,* the annual Notice of Benefit and Payment Parameters update rules are also now being exempt because those are already updated

[194] *See, e.g.,* 77 FR 11700 (Feb. 27, 2012).

[195] 85 FR 70109.

[196] *See, e.g.,* regulations amended in Update of Organizational References, 50 FR 8993 (Mar. 6, 1985) (''Because these amendments related to internal agency management and personnel and because the amendments are not substantive, the rule is exempt from the notice and comment and delayed effective date requirements of section 553(b) and (d)(3) of the Administrative Procedure Act'').

[197] *See* Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 (1996). *See also* 85 FR 70110.

[198] 85 FR at 70109.

[199] *See, e.g.,* 21 U.S.C. 360(l) (providing that ''at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the **Federal Register**, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness''; 21 U.S.C.(m) (providing that the Secretary, ''at least once every 5 years thereafter, as the Secretary determines appropriate [ ] publish in the **Federal Register** a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness'').

[200] *See https://www.federalregister.gov/documents/2020/04/20/2020-08182/food-standards-general-principles-and-food-standards-modernization-extension-of-comment-period.*

annually. Thus, there is no need to Assess or Review them every ten years.

In addition, whereas the proposed rule exempted in Title 42 the ''annual Medicare Part A and Part B payment methodology update rules,'' this final rule exempts the ''annual Medicare payment update rules.'' All annual Medicare payment update rules are revised annually, so there is no need to require Assessment or Review of them every ten years.

Other than adding or revising these exemptions and changing the term ''Regulation'' to ''Section,'' the Department finalizes Section [XX](g) as proposed.

Section [XX](h)

HHS proposed in Section [XX](h) of the proposed rule that when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Regulation(s) whose Assessment or Review it is commencing. As proposed, the public would be able to submit comments regarding these Regulation(s) in the manner specified on this website. HHS proposed that members of the public could also submit comments in the manner specified on the website requesting that the Department begin the Assessment or Review of a Regulation, particularly if they are concerned that the deadline is nearing and the Department has not stated that it has commenced the Assessment or Review.

The Department included this provision in the proposed rule so that, when the Department is Assessing or Reviewing a regulation, the public can submit comments for the Department's consideration. The Department stated in the proposed rule that it believes this will maximize transparency, public participation, and the Department's knowledge of the real-world impacts of its regulations.

The Department also proposed in this provision to allow the public to submit comments on the Department website requesting that the Department begin the Assessment or Review of a regulation. The Department stated that it considered the risk that a regulation could expire because the Department inadvertently did not Assess or Review it. The Department proposed to mitigate this risk by allowing members of the public to submit comments requesting that the Department commence the Assessment or Review of a regulation. If a person is concerned that the Department has not announced the Assessment or Review of a Regulation and the deadline is nearing, the person can request that the Department to conduct the Assessment or Review.

The Department stated in the proposed rule that it intends to timely Assess and, where required, Review all its regulations. The Department noted, however, that if it has not announced that it is Assessing or Reviewing a Regulation, and the deadline is nearing, those who rely on the regulation are on notice that it might expire, just as the public is on notice that a regulation might be rescinded when an agency issues a notice of proposed rulemaking to rescind the Regulation.

Comments on Section [XX](h)

HHS received the following comments on section [XX](h) of the proposed rule.

Comment: Several commenters questioned the adequacy of the proposed process for soliciting comments on the regulations that are reaching their time for Assessment or Review. Some of these commenters stated that the public should be given ample notice of upcoming Assessments and Reviews, and a clear and adequate timeframe for providing comments. Other commenters expressed concern about the process of posting information regarding Assessments and Reviews to a Department-managed website. Some commenters stated that instead of providing notice of Assessments and Reviews and instructions on how to submit public comments exclusively on a Department-managed website, the Department should also put this information on the **Federal Register**.

Several commenters stated that members of the public should not be responsible for monitoring an HHS website to see if Assessment or Review of a particular regulation is commencing. Some commenters cited the added expense on the regulated industry that would be created if an additional review process is created by this rule, which would disproportionately fall on small businesses. One commenter even suggested this was a purposeful decision by the Department to create a system that favors well-funded special interests that can afford lawyers and lobbyists to advocate for their favored policies. Commenters stated that although HHS proposes to create a website to enable the public to comment and request a review when the deadline for assessing a rule is approaching, this website would not be governed by APA rules and the Department would not be required to meaningfully respond to those comments. Commenters stated that, as a result, rules that govern the administration of Medicaid and CHIP and affect access to care for millions of beneficiaries could automatically expire without public comment.

A potential solution suggested by one commenter is that the Department could include in the final rule a requirement that it include a notice of all regulations scheduled for review during the next 12 months in its semi-annual regulatory agendas published in the **Federal Register**. This commenter also suggested that HHS publish semi-annually in the **Federal Register** a list of regulations that are scheduled to expire in the next 12 months if they are not Assessed and Reviewed.

Other commenters requested clarification on how HHS will treat the comments it receives. For example, some commenters asked whether the comments would be included as a part of the public record. Other commenters mentioned that the proposed rule does not clarify whether HHS will be required to respond to all comments made by the public. These commenters asked the Department to ensure that it publicly display the comments it receives.

Response: The Department appreciates these comments and seeks to minimize costs for the public. Accordingly, this final rule makes some revisions in response to these comments. Under this final rule, when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Section(s) whose assessment or Review it is commencing. It shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. These docket numbers will be referenced in the **Federal Register** announcements. The public will be able to submit comments to the dockets of each rule making being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department Assess or Review a regulation. These changes address the concern about putting the information on a Department website, rather than in the **Federal Register**. The Department anticipates that the process will be similar to that currently used by the EPA.[201] The Department also intends to

[201] *See, e.g.,* Regulatory Flexibility Act Section 610 Review of the Testing and Labeling Regulations Pertaining to Product Certification of Children's

publish the results of the Assessments and Reviews in the dockets for the applicable regulations.

Separately, in conjunction with this final rule, the Department is placing at *https://www.hhs.gov/regulations/federal-registry/index.html* a list of Department rule makings, the year they were initially promulgated, the last year the rule making was amended, and the **Federal Register** citation from the time the rule making was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations. The schedule for Assessment and Review is discussed in Section II.F.

HHS disagrees that this final rule is for the benefit of well-financed special interests. As the Department observed in the proposed rule, empirical evidence confirms that, due to the inherent advantage from economies of scale, large, well-capitalized entities are better positioned to absorb compliance costs than small entities.[202] By announcing Assessments and Reviews on *Regulations.gov*, and putting the dockets for Assessments and Reviews on *Regulations.gov*, this final rule reduces the costs associated with having to monitor two separate websites. The regulatory impact analysis for this final rule addresses the estimated impacts for this final rule, including monitoring and comment costs.

Comment: A few commenters suggested that instead of the process set forth in the proposed rule, HHS should provide a means of soliciting public comment at least every ten years on the Department's existing rules, which the Department would then be required to consider.

Response: The Department is incorporating aspects of this suggestion. This final rule makes the nature of complaints or comments on a regulation one of the factors to be considered when performing Reviews. But the commenters' suggestion by itself would not be adequate to address the problem. The Department's rules have always been open for public comment under 5 U.S.C. 553(e), yet only limited retrospective review has taken place, contrary to Congressional intent. The suggestion that the Department take a passive role in retrospective review is inconsistent with the RFA, which intends for HHS to engage in this analysis on its own initiative.

Comment: Several commenters stated that, according to the process set forth in the proposed rule, it would be difficult, if not impossible, for the public to accurately determine whether a regulation is subject to an Assessment, and if so, the deadline for informing the agency and commenting. These commenters surmise that there could be scenarios where a regulation was not Assessed, but it is unclear whether it has expired or was exempt from the regulatory review process and is still in place. This could leave regulated entities subject to the regulation without guidance on what is expected of them, or could result in regulations being inadvertently removed with negative impacts on beneficiaries, consumers, and the public in general.

Response: The Department respectfully disagrees. Again, as stated above, the Department intends to timely Assess and (if needed) Review its regulations. This final rule provides that un-Reviewed and un-Assessed Sections expire based on the time elapsed since the Year of the Section's promulgation. To aid the public, in conjunction with this final rule the Department is placing at *https://www.hhs.gov/regulations/federal-registry/index.html* a list of Department rule makings, the year they were initially promulgated, the last year the rule making was amended, and the **Federal Register** citation from the time the rule making was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list is meant to be an aid to the public and the Department, but the **Federal Register** and Code of Federal Regulations are what have legal force and determine the dates of promulgation. Moreover, a regulated entity can use the **Federal Register** and Code of Federal Regulations to determine the year in which a Section was promulgated. From there, the regulated entity can determine the year by which a Section must be Assessed and (if needed) Reviewed. The regulated entity can consult the **Federal Register** document containing the findings of the Department's Assessments and Reviews from that year to determine if the Section was timely Assessed and (if needed) Reviewed. This is less burdensome than many legal research activities that regulated entities need to do to determine whether they are in compliance with the law. Regulated entities frequently must determine whether a particular statute or regulation is still in effect, has been amended, or whether there is a proposed change to the statute or regulation before Congress or in front of an agency.

Comment: Several commenters had comments related to APA petitions. A commenter stated that the APA also includes a process for the public to petition for retrospective review of existing rules. *See* 5 U.S.C. 553(e). Other commenters noted the APA does not specify the process for receiving petitions. As a result, according to the commenters, how petitions are received and treated varies across—and even within—agencies. These commenters stated that to date, HHS has not adopted any particular regulations concerning the form that petitions under section 553(e) must take. Nor has HHS adopted recommendations by the Administrative Conference of the United States for receiving, processing, and responding to petitions. A few commenters noted that they had submitted petitions but no action had been taken to date on their request. For example, one commenter stated that it filed citizen petitions in August 2016 and February 2017 asking the agency to remove outdated recordkeeping requirements. Another commenter stated that in February 2018 it commented to the Food and Drug Administration Center for Veterinary Medicine (CVM) on regulations that the commenter claimed are outdated or needing improvement.

Response: The Department respectfully disagrees with the commenters' suggestion that the petition mechanism in 5 U.S.C. 553(e) somehow undercuts or forecloses this final rule. Indeed, the substantive point of these comments—that the agency should retrospectively review its rules to determine whether amendment or rescission is necessary, especially where pressed to do so by the public—is fully consistent with this final rule. The commenters who stated they petitioned the Department to amend or rescind regulations, yet the Department took no action, further supports why this final rule is needed (although the Department takes no position in this final rule on whether any particular commenters' petition had merit).[203] The comments

Products, Including Reliance on Component Part Testing, 85 FR 52078 (Aug. 24, 2020).

[202] 85 FR 70118 & n.145.

[203] *See also* Maeve P. Carey, Cong. Rsch. Serv., R46190, Petitions for Rulemaking: An Overview 1 (2020) (describing § 553(e) as ''arguably

Continued

suggest the Department is not examining its existing regulations as often as is desired. Moreover, 5 U.S.C. 553(e)'s petition process does not make this final rule unnecessary, because there is reason to believe that even some rules that have not been the subject of any petitions would benefit from amendment or rescission.[204] The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time of promulgation.

Some HHS components have regulations governing petitions.[205] But whether the Department should have additional or different petition procedures is outside the scope of this final rule, which, like 5 U.S.C. 610, operates independently of 5 U.S.C. 553(e)'s petition process.

Comment: Some commenters stated that it was arbitrary for HHS to not meaningfully consider other ''strong incentives'' to revisit its own rules besides the process it proposes. For example, commenters suggested that HHS could have explored creating a petition process whereby parties could request review of certain rules, or could have convened a Federal Advisory Committee to advise the Department on which rules merit review. In both these scenarios, HHS could incentivize itself to act by giving parties a right of judicial review if the Department failed to respond to a petition or a Committee recommendation.

Response: HHS respectfully disagrees. The APA itself already affords a process for petitioning for review of rules. 5 U.S.C. 553(e) (''Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.''). And denials of such petitions may be subject to the APA's judicial review procedures.[206] Notwithstanding the existence of section 553(e), comprehensive retrospective review of agency rules has not taken hold. The literature suggests large numbers of Department regulations are having impacts that differ from their estimated impacts. It is unlikely that a Federal Advisory Committee could undertake the scale of review needed to comprehensively advise on which regulations merit review.

Comment: Some commenters stated that the Department should provide clear notice to the public of when a Regulation may be about to expire, and provide actual notice of rescissions.

Response: The Department reiterates its previous response to a similar comment. The Department intends to timely Assess and, where required, Review all its regulations. However, if the Department has not announced that it is Assessing or Reviewing a regulation, and the deadline is nearing, the public is on notice that it might expire, just as the public is on notice that a regulation might be rescinded when an agency issues a notice of proposed rulemaking to rescind the regulation.[207] Moreover, section [XX](f) requires that the Department, in announcing the results of Assessments and Reviews, ''shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.''

The Department plans to periodically announce in the **Federal Register** regulations that have expired, and have the Code of Federal Regulations revised accordingly.

Final Section [XX](h)

Accordingly, based on public comments, HHS finalizes section [XX](h) to provide that when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Section(s) whose Assessment or Review it is commencing. It shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. The public will be able to submit comments to the dockets of each rule making being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

Section [XX](i)

Lastly, the proposed rule included a severability clause. The Department stated in the proposed rule that it believes the proposed rule fully complies with applicable law, but does not wish to see the entire proposed rule vacated in the event that a portion of it is vacated. For example, the Department does not wish to see the entire final rule vacated because one of the exceptions listed in section [XX](g) is invalidated. However, the Department requested comment in the proposed rule on whether the amendments to add expiration dates should be severable from other portions of the proposed rule, including the requirements to perform Assessments and Reviews. The Department stated that it was requesting comments on this because it is not clear that the proposed rule could properly function without the expiration dates.

HHS received no comments specific to Section [XX](i) of the proposed rule.

Accordingly, for the reasons stated in the proposed rule, HHS finalizes the provisions of Section [XX](i) as proposed.

Additional Comments on Particular Regulations

Comment: Commenters identified certain regulations that they would not want to expire under the proposed rule. These regulations include, but are not limited to:

- Regulations implementing Medicare, Medicaid, CHIP, and other large programs that HHS administers.
- Regulations implementing the Affordable Care Act (ACA).
- Regulations that operate Temporary Assistance for Needy Families (TANF) program, the Child Care and Development Fund (CCDF) program, Head Start and Early Head Start Programs, and the Family Violence Prevention and Services (FVPSA) Program.
- FDA Regulations at 21 CFR Chapter 1.
- Provisions at 42 CFR 435.603 which determine financial eligibility using the Modified Adjusted Gross Income (MAGI) methodologies.
- Regulations implementing Income and Eligibility Verification requirements at 42 CFR 435.940–435.965.
- 42 CFR 435.907, related to Medicaid application requirements.
- Medicaid cost-sharing regulations.
- Regulations governing Medicaid waivers, including Section 1115 and Section 1332 waivers and Home & Community-Based Services (HCBS) waivers.
- Fair Hearings for Applicants and Beneficiaries requirements in 42 CFR 431 Subpart E.
- Confidentiality regulations in 42 CFR part 431 Subpart F.
- Regulations relating to comparability or services for groups of

underused''); ACUS, ''Adoption of Recommendations,'' 79 FR 75114, 75117–18 (describing long-standing problems in agencies' handling of § 553(e) petitions).

[204] *See* Section II, *supra.*

[205] *See, e.g.,* 21 CFR 10.20, 10.30, 10.33.

[206] *See, e.g., Am. Horse Protection Assoc.* v. *Lyng,* 812 F.2d 1 (D.C. Cir. 1987). Case law also suggests that an agency's failure to respond may also be subject to judicial redress. *See* Jason A. Schwartz and Richard L. Revesz, ''Petitions for Rulemaking—Final Report to the Administrative Conference of the United States'' at 13 & n.55, 28–29 (Nov. 5, 2014).

[207] 85 FR 70110.

beneficiaries and sufficiency of amount, duration, and scope of Medicaid services, found at 42 CFR 440.230–440.250.

• The Medicaid balanced billing regulation at 42 CFR 447.15.

• Regulations that shape children's access to care in a wide range of areas, including but not limited to: 42 CFR 438.1–438.930—Medicaid Managed Care; 42 CFR 447.56—Limitations on premiums and cost sharing; 42 CFR 447.203—Documentation of access to care and service payment rates; 42 CFR 447.204—Medicaid provider participation and public process to inform access to care; 42 CFR 447.400—Payments for Primary Care Services Furnished by Physicians; 42 CFR 410.78—Telehealth services; 45 CFR 156.10–156.1256—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges.

• Regulations concerning infant formula, including: 21 CFR 101: Food Labeling; 21 CFR 105.65: Infant Foods; 21 CFR 106: Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control; Procedures, Quality Factors, Records and Reports, and Notifications; 21 CFR 107: Infant Formula; and 21 CFR 312: Investigational New Drug Application.

• Regulations implementing the Vaccines for Children Program at 42 CFR 441.600–441.615 and Grants for Childhood Immunization Programs at 42 CFR 51b.201–51b.206.

• Regulations implementing title IV–E programs that HHS administers, which provide funds for States and Tribes to provide foster care, transitional independent living programs for children, guardianship assistance, and adoption assistance for children with special needs at 45 CFR part 1356.

• Regulations that pertain to maternal and child health project grants administered by the Health Resources and Services Administration's Maternal and Child Health Bureau at 42 CFR 51a.1–42 CFR 51a.8.

• Medicaid regulations that outline the mandatory and optional benefits that States commonly use to finance home visiting services, such as: Extended pregnancy services (42 CFR 440.210, 42 CFR 440.220); Targeted case management (42 CFR 440.169(b)); Medical or other remedial care by licensed practitioners (42 CFR 440.60); Early and Periodic Screening, Diagnostic and Treatment (42 CFR 440.40(b)); Medicaid Administrative Claiming (42 CFR 433.15); and Managed care (42 CFR part 438).

• Regulations in 45 CFR Subchapter B that require insurance coverage of essential health benefits (EHBs) such as preventive health services, prohibit preexisting condition exclusions, and establish fair practices in setting health insurance premiums and mental health parity, among other protections.

• Regulations in 42 CFR part 441, which sets forth State Medicaid plan requirements and Federal Financial Participation for specific services. Commenters specifically mentioned Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) regulations found throughout Part 441, which provide essential comprehensive and preventive services to children who are covered by Medicaid.

• Regulations that protect nursing home patients by requiring reasonable promptness for medical assistance fair hearing obligations (42 CFR 435.930(a), 42 CFR 431.10(c)(3); 435.1200(b).

• Regulations found in 42 CFR part 483 protecting long term care facility residents, and specifically Subpart G, which protects children in psychiatric residential treatment facilities (PRTFs) from restraint and seclusion used as a means of ''coercion, discipline, convenience or retaliation.''

• Regulations found in 42 CFR part 460, implementing Programs of All-Inclusive Care for the Elderly (PACE).

• Regulations implementing the Medicare Low Income Subsidy program under 42 CFR part 423.

• Regulations at 42 CFR part 438 which implement Medicaid Managed Care.

• Regulations related to food ingredients, including color additives (21 CFR parts 70–82), Generally Recognized as Safe (GRAS) regulations, and procedural regulations governing the agency's premarket review functions, among others.

• Regulations implementing the Food Safety Modernization Act (FSMA), Good Manufacturing Practices (GMPs), low acid canned foods/acidified foods (LACF/AF), Hazard Analysis and Critical Control Point (HACCP) regulations for juice and seafood, Dietary Supplement GMPs, import/export requirements, and infant formula, among others).

• Nutrition labeling regulations.

• Regulations implementing Food Standards of Identity and Quality (*e.g.,* dairy standards, bottled water (21 CFR 165.110), cacao products, and other food categories).

• Regulations implementing the Family Smoking Prevention and Tobacco Control Act (the ''TCA'').

• Regulations governing the Indian health system, the Indian Health Service's (IHS) Tribal Self-Governance program, and Indian specific provisions in the Medicaid, Medicare CHIP and Marketplace regulations.

• Regulations implementing the Indian Child Welfare Act, which impacts all Indian Health Service regulations (42 CFR parts 136 and 136a) and the Department's Tribal Self-Governance regulations (42 CFR part 137).

• Regulations implementing the Mental Health Parity and Addiction Equity Act (MHPAEA), which requires that mental health and substance use disorder coverage be comparable to general medical coverage.

• Regulations that implement programs authorized by the Developmental Disabilities Assistance and Bill of Rights Act that help ensure people with intellectual or developmental disabilities and their families have access to needed community services and individualized supports, and other programs that are important to people with disabilities, such as the Independent Living programs and critical safety net programs such as Medicaid.

• 42 CFR 457.520, relating to cost sharing for well-baby and well-child care services.

• Regulations in 42 CFR part 407 relating to Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, Part B enrollment including so-called state buy-in plans would harm seniors, and retroactive liability for Part B premiums when a beneficiary loses eligibility for a buy-in plan.

• Provisions found at 45 CFR 146.136 that apply the federal law requiring parity between private health insurance coverage for physical ailments and for mental illness and substance use disorders would be at risk.

• Regulations that implement the Title X Family Planning Program.

• Regulations guiding the practice of social work.

• Regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), found in 45 CFR parts 160, 162, and 164, particularly 45 CFR 164.502, which clarifies and strengthens privacy protections people with HIV.

• Preadmission Screening and Resident Review (PASRR) regulations found at 483.100 through 483.138.

• Regulations protecting the confidentiality of Substance Use Disorder (SUD) patient records, found at 42 CFR part 2.

• Regulations that prohibit insurance plans and issuers from imposing

financial requirements or treatment limitations on mental health and SUD benefits that are more restrictive than those that apply to medical/surgical benefits.

• Office of Human Research Protections (OHRP) regulations in 45 CFR part 46, and FDA regulations at 21 CFR part 50, which protect human research subjects.

• Regulations in 45 CFR part 96, which govern block grants.

• 42 CFR 489.24, related to the special responsibilities of Medicare hospitals in emergency cases.

• Regulations concerning Section 1557 of the Affordable Care Act, which prevents discrimination on the basis of race, sex, sexual orientation, and gender identity in healthcare settings.

• Regulations implementing the Ryan White Program

• Regulations governing Medicare's Six Protected Classes.

• Regulations related to the Congregate and Home-Delivered Nutrition Programs.

• Regulations related to over-the-counter medicine products.

• Regulations at 42 CFR 425.612 identify the circumstances under which specific payment regulations are waived under the accountable care organization (ACO) program.

• Regulations related to non-emergency medical transportation (NEMT).

• Regulations affecting the domestic and global seafood industry.

• Regulations affecting the pet food industry.

• Regulations implementing the Medicare Modernization Act, such as 42 CFR 422.2268, which establishes standards for marketing by MA plans.

• Regulations requiring CMS programs to include an extraordinary circumstances exception (ECE) policy for natural disasters and other circumstances (*see* 42 CFR 412.140(c)(2) for the inpatient quality reporting (IQR) program and 42 CFR 412.160(c)(1)–(4) for the value-based purchasing program).

• Regulations at 42 CFR 441.62, which require, according to the commenters, that states assure transportation for periodic screening and treatment for Medicaid eligible children, and regulations at 42 CFR 440.170(a), which provide the definition for what constitutes transportation, *e.g.,* ambulance, taxicab, common carrier or other appropriate means, as well as meals and lodging for both the child and necessary attendant.

• 42 CFR 440.230(b)–(d), which requires that services be ''sufficient in amount, duration, and scope to reasonably achieve their purpose,'' directs states not to ''arbitrarily deny or reduce the amount, duration, or scope of such services to an otherwise eligible individual solely because of the diagnosis, type of illness, or condition,'' and permits states to place appropriate limits on a service based on such criteria as ''medical necessity'' or on utilization review criteria.

• 42 CFR 435.831, which establishes the standards for determining eligibility for the ''medically needy''—an optional category that may enable aged, blind and disabled persons in certain states who have ''excess income'' above the Medicaid limits to qualify for Medicaid, if they incur certain medical expenses.

• 42 CFR 415.174 Exception: Evaluation and management services furnished in certain centers.

• 42 CFR 457.496—Parity in mental health and substance use disorder benefits.

• 42 CFR 457.410—Health benefits coverage options.

• What commenters characterized as many highly important and sensitive Medicare provisions in Title 42, CFR parts 400–499 that directly impact beneficiaries and health care providers. Some of these provisions include beneficiary and provider appeal rights (Part 405); Part A eligibility and entitlement provisions (Part 406); Part B enrollment and entitlement provisions (Part 407); provisions that outline the scope of Part A Benefits, including hospital and skilled nursing facility coverage (Part 409); Medicare Advantage coverage rules and enrollee protections (Part 422); and, Part D prescription drug parameters (Part 423).

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations.

Comment: Commenters identified certain regulations for which they would like the Department to prioritize amendment through its proposed retrospective regulatory review process. These regulations include, but are not limited to:

• Regulations mandated for review by the 21st Century Cures Act, Public Law 114–255, sec. 2034, 130 Stat. 1033 (2016). Section 2034 of that Act requires the Secretary to lead a review by research funding agencies of all regulations and policies related to the disclosure and reporting of financial conflicts of interest to reduce administrative burden on federally funded researchers. It also calls for the Secretary to harmonize the differences between the Basic HHS Policy for the Protection of Human Research Subjects (45 CFR part 46, subpart A) and the FDA regulations for the protection of human subjects (21 CFR parts 50 and 56). Commenters stated that these regulations are well overdue for assessment and review.

• Regulations covering access to skilled therapy services, which commenters say must be updated to reflect the national settlement in the *Jimmo* v. *Sebelius* litigation to codify the fact that skilled services are covered for Medicare beneficiaries not just to improve function, but to maintain or prevent deterioration in function.

• The dockets established by FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine on Sept. 8, 2017,[208] in which the Centers requested comments and information to assist in identifying existing regulations and related paperwork requirements that could be modified, repealed or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations are examples of incomplete regulatory review initiatives.[209] Commenters stated that despite submitting extensive comments that detailed numerous regulations that they believe could be modified, repealed or replaced, the agency did not take any further action.

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: Commenters identified certain regulations that they would want amended or rescinded. These regulations include, but are not limited to:

• What the commenters characterized as unnecessary burdens in post-acute care (PAC) regulations.

• What the commenters characterized as the outdated and inappropriate ''in the home'' requirement for coverage of durable medical equipment (DME), which commenters believe significantly limits the mobility devices available to beneficiaries with mobility disabilities.

[208] *E.g.,* Nonrulemaking Docket FDA-2017-N-5093: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, *https://beta.regulations.gov/docket/FDA-2017-N-5093.*

[209] *See* Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, 82 FR 42506 (Sept. 8, 2017); FDA-2017-N-5093, *https://beta.regulations.gov/docket/FDA-2017-N-5093.*

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: Some commenters provided feedback on what baseline the Department could use when conducting an analysis of an existing regulation. Commenters suggested that HHS could simply conduct an ex ante analysis of how the regulation is likely to perform going forward compared with the baseline scenario of what would happen if the regulation were allowed to expire. The benefits of this approach, according to the commenters, are that HHS already produces ex ante analyses (so this approach would not be departing from present practices), the analysis could still include a backward-looking component to the extent that data on past performance could be used to forecast the regulation's future performance, and the regulation's future performance is what should ultimately determine whether the regulation should continue as-is or be amended or rescinded. Another option, according to commenters, is that the Department could perform a retrospective cost-benefit analysis that looks at how the regulation performed relative to the baseline of what would have happened in the absence of the regulation, or relative to the regulation as it stood before it was last significantly amended.

Response: The Department appreciates this comment. The comments suggest different approaches may make sense for different regulations. Accordingly, the Department declines to adopt in this final rule a single method for conducting retrospective reviews. Reviews must be conducted in a manner that is not arbitrary and capricious under the APA, so that will provide a minimum level of rigor that all Reviews will have to meet, though different methodologies may be appropriate in different cases. The Department intends to take into account these comments when conducting Reviews pursuant to this final rule.

V. Regulatory Impact Analysis (Executive Orders 12866, 13563, 13771)

A. Executive Order 12866 Determination

Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary and not prohibited by statute, to select regulatory approaches that maximize net benefits. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''). OMB has designated this rule as economically significant for the purposes of Executive Order 12866. This regulatory impact analysis fulfills analytical obligations under section 3(f) of Executive Order 12866 for economically significant rulemakings.[210]

B. Need for Regulation

The first principle of regulation, according to Executive Order 12866, is that ''Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.'' The regulation being finalized by the Department addresses lax compliance with periodic review requirements under the Regulatory Flexibility Act (RFA) of 1980 and the need to periodically review existing regulations to determine if they are having their intended impacts. Section 610 of the RFA calls upon the Department to have a plan to conduct periodic reviews of its regulations that have or will have a significant economic impact upon a substantial number of small entities (SEISNOSE). The RFA directs agencies to consider the following factors as part of those reviews: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates or conflicts with other rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

A review of department semi-annual agenda reports over the last ten years, as well as a review of specific rules identified in those agendas as completed rulemakings resulting from section 610 reviews, indicated three completed final rulemakings that emanated from section 610 reviews since 2011.[211] (These rules are presented in table 1 below). To put this in context, the Department estimates it has roughly 18,000 regulations under its purview and that five regulations on average are part of the same rulemaking. Further, (as discussed in more detail below) the Department estimates approximately 11% of its regulations have a SEISNOSE, which suggests that approximately 396 Department rulemakings have a SEISNOSE. The three rules in table 1 amend approximately 130 sections of the CFR. (If an average rulemaking contains five sections, 130 sections correspond to the number of sections on average in approximately 26 rulemakings.) Given that Section 610 of the RFA sets a 10-year schedule for review of rulemakings, one might expect that roughly ten percent of regulations with a SEISNOSE would be reviewed each year, which would be approximately 40 rulemakings every year.[212] Moreover, many of these regulations should likely be updated to reflect evolving circumstances. However, this does not appear to be occurring.[213]

[210] This analysis was informed by public comments and also by work of Dr. James Broughel.

[211] Note that some rules labeled as 610 reviews in Department semi-annual agendas were not, in actuality, a result of section 610 reviews.

[212] There are roughly 3,600 rulemakings (18,000 divided by 5). 11% of this figure is 396. Ten percent of 396 is roughly 40.

[213] A review of Department semiannual regulatory agendas issued between June of 2016 and August of 2020 confirms the three rules listed in table 1 are the only three final rulemakings to be completed in the last five years that are also associated with section 610 reviews. One rule, 0938–AT23, was merged with another rule, 0938–AS21. *See* Dept. Health & Human Servs., Semiannual Regulatory Agenda, 81 FR 37,294 (Jun. 9, 2016); 81 FR 94742 (Dec. 23, 2016); 82 FR 40278 (Aug. 24, 2017); 83 FR 27126 (Jun. 11, 2018); 83 FR 58020 (Nov. 16, 2018); 84 FR 29624 (Jun. 24, 2019); 84 FR 71130 (Dec. 26, 2019); and 85 FR 52704 (Aug. 26, 2020).

TABLE 1—FINAL ACTIONS AS A RESULT OF SECTION 610 REVIEWS SINCE 2011

Name of rulemaking	CFR citation and RIN	Year	Regulatory changes made as a result of Section 610 reviews
Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care.	42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494. RIN 0938–AT23	2019 (Final Rule)	Reformed Medicare regulations that were identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, and increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care. Updated fire safety standards for Medicare and Medicaid participating End-Stage Renal Disease (ESRD) facilities by adopting the 2012 edition of the Life Safety Code and the 2012 edition of the Health Care Facilities Code, and updated the requirements that hospitals and Critical Access Hospitals must meet to participate in the Medicare and Medicaid programs. Requirements were intended to conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.
Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies.	42 CFR Parts 409, 410, 418, 440, 484, 485 and 488. RIN 0938–AG81	2017 (Final Rule)	Revised the conditions of participation that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The new requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements.
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities.	42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489. RIN 0938–AR61	2016 (Final Rule)	Revised the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety.

The Department's limited success in performing retrospective regulatory review is further supported by a regulatory reform project the Department piloted, which utilized AI-driven data analysis. Machine-learning algorithms identified over 1,200 CFR section citations that merited consideration for reform and 159 CFR sections that could benefit from regulatory streamlining based on their similarities to other sections.[214] That project uncovered that 85% of Department regulations created before 1990 have not been edited, and that the Department has nearly 300 broken citation references in the CFR (*i.e.,* CFR sections that reference other CFR sections that no longer exist).[215] These findings are consistent with a 2018 study by the same consulting firm that estimated that 68 percent of federal regulations have never been updated.[216] These findings suggest regulations are not being updated to reflect evolving economic conditions and technology, even though this is a goal of the RFA.

Machine-learning tools also demonstrate the complexity of Department rules—and reducing complexity is another goal of the RFA. *See, e.g.,* 5 U.S.C. 610(b)(3). Data from the Mercatus Center show that the Department's regulations in 2019 received a Shannon entropy score of 8.2. Shannon Entropy is a measure of complexity based on the amount of information contained in text. It can be thought of as measuring the number of new ideas that are introduced in a document, or, alternatively, how much computational effort would be required to understand a document. To put the Shannon entropy score into context, a typical Shakespeare play receives a Shannon entropy score of 8.0. The complexity of Department regulations is not entirely surprising given that regulations often involve science, engineering, or other highly technical material. However, having regulations that are more complex than a typical Shakespeare play would seem to be at odds with various directives that fall on the Department for regulations to be simple, easy to understand, and written in plain language.[217]

TABLE 2—2019 SHANNON ENTROPY SCORE FOR HHS REGULATIONS

Department	Shannon entropy score
Department of Health and Human Services	8.2

Source: *Quantgov.org.*

Without a consistent process for periodically reviewing regulations, there is no guarantee that regulations will be

[214] Regulatory Streamlining & Analysis, at 11 (Mar. 2019).

[215] *Id.*

[216] William D. Eggers & Mike Turley, *The Future of Regulation: Principles for Regulating Emerging Technologies,* Deloitte Ctr. for Gov't Insights (2018), *https://www2.deloitte.com/content/dam/Deloitte/lu/Documents/risk/lu-future-of-regulation.pdf.*

[217] *See, e.g.,* Exec. Order No. 12866; Exec. Order 13563, sec. 1; and various presidential memoranda and guidance on plain language.

reviewed and revised to align with technological, economic, and other developments. Section 5 of Executive Order 12866 requires agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving regulatory objectives, less burdensome, or in greater alignment with the President's priorities and principles. Section 6 of Executive Order 13563 similarly requires agencies to submit to OIRA a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving regulatory objectives.

However, existing executive orders have not institutionalized a process for retrospective review and periodic updating of regulations, as evidenced by the fact that relatively few Department regulations are updated. Furthermore, every president since Jimmy Carter, including all those elected after enactment of 5 U.S.C. 610, has ordered some form of retrospective review of regulations,[218] with mixed effects. This suggests that stronger incentives and forcing mechanisms are needed to ensure retrospective review occurs to an appropriate extent.

Some commenters suggested that a review of existing regulations does not make sense during a pandemic, but this misses the broader point that the Department has waived, suspended, or exercised enforcement discretion not to enforce many regulations in order to respond to the pandemic.[219] Had the Department not done so, this may have hampered the Department's ability to respond nimbly, flexibly and quickly to the emergency.[220] For example, the Department has issued waivers or exemptions, or exercised enforcement discretion with respect to, certain Medicare, Medicaid, CHIP, and HIPAA restrictions, including waivers to increase hospital capacity, ease restrictions on services rendered by medical residents, and allow patients to seek more services via telehealth. Meanwhile, other regulations that may have facilitated pandemic response have remained in place.

The Department's position is that retrospective review would require some change from the status quo, and unless there is a strong incentive to change, continuing business as usual is the path of least resistance.[221] Thus, the status quo is maintained. Moreover, rescinding a regulation that has already been promulgated is likely to meet greater resistance than resistance to foregoing promulgating a regulation not yet enacted. This reflects a phenomenon known as loss aversion.[222]

The Department's determination is that this final rule will address these issues by changing the choice architecture facing the Department by enacting a new default rule when the Department fails to conduct retrospective reviews. Sunset provisions change the default from rules staying on the books indefinitely to rules being eliminated after some predetermined amount of time unless evidence is presented for why rules should continue. When a default rule is changed, the choice architecture confronting decision makers is altered and can spur changes in behavior. A consistent finding in the literature on behavioral anomalies is that choice architecture and default rules have an important influence on decision making.[223] Changes in the Department's choice architecture can ultimately result in changes in public wellbeing.

To conclude, this final rule is intended to address a failure to periodically review regulations as often as desired in line with the RFA and other directives for retrospective review. The Department believes that this final rule, by changing the default for regulations from continued existence to expiration unless periodic review is conducted, will result in more widespread retrospective review of regulations. Requiring the expiration of rules that have not been assessed or reviewed in accordance with section 610 of the RFA should result in more regulations being updated to reflect evolving circumstances.

C. Alternatives Considered

The Department considered several alternatives to the proposed regulation. First, it considered not issuing this final rule. However, the RFA and certain Executive Orders direct the Department to periodically review certain Department regulations. Moreover, the literature and the Department's experience suggest that large numbers of regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated, so many regulations should be periodically reviewed.[224] The Department's experience over the last forty years is that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations.

Next, the Department considered seeking to perform the reviews called for by the RFA without implementing a new forcing mechanism. Given past experience, however, it seems unrealistic to assume this would bring about meaningful change. First, the fact that these reviews are not already occurring is evidence they are unlikely to occur in the future. Second, as discussed above, there is a strong bias towards the status quo in governmental action, and this may stand in the way of behavior changes. Third, the literature suggests that enforcement mechanisms are needed to spur more periodic reviews, and specifically that sunset provisions are a useful enforcement mechanism.[225] Moreover,

[218] *See* Exec. Order No. 12044 of Mar. 23, 1978, 43 FR 12661 (Mar. 24, 1978) (President Carter) (revoked by Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193 (Feb. 19, 1981) (President Reagan)); Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992) (President H.W. Bush); Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 190 (Oct. 4, 1993) (President Clinton); Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011) (President Obama); Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339 (Feb. 3, 2017) (President Trump).

[219] *See* Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720, at Attachment A (Nov. 25, 2020).

[220] *See, for example,* Alec Stapp, ''Timeline: The Regulations—and Regulators—That Delayed Coronavirus Testing,'' *The Dispatch* (March 20, 2020).

[221] *See also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013) (positing reasons why agencies may be reluctant to perform retrospective reviews).

[222] Daniel Kahneman et al., *Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias,* 5 J. Econ. Persp. 193 (1991).

[223] Richard H. Thaler et al., *Choice Architecture, in* The Behavioral Foundations of Public Policy 428, (Eldar Shafir ed., 2012).

[224] Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005), *http://perma.cc/R8LX-BQMJ* (collecting studies comparing ex ante and ex post analyses of regulations' costs and benefits, including examples where cost and benefit estimates were off by more than a factor of ten); Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation* 33 (Res. for the Future, Discussion Paper 06–39, 2006), *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357.*; Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation,* J. of Benefit Cost Anal. 9 no. 2, 2018, at 285.

[225] Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act (2008); Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 113 (David Moss & John Cisternino eds., 2009); Australian Gov't Att'y Gen.'s Dep't, Guide to Managing the Sunsetting of Legislative Instruments, at 3 (July

Continued

even if the Department conducted the reviews called for by the RFA absent a new forcing mechanism, there might be benefits to this final rule, albeit ones that are hard to quantify. For example, this final rule could guard against a decrease in the frequency of Department retrospective reviews in future years.

Another alternative the Department considered is conducting in-depth Reviews of all of its Regulations (absent those that are exempt from this rulemaking), not just those designated as having a SEISNOSE. The Department sees value in conducting such widespread Reviews. However, the Department has opted not to require a complete Review of all Department regulations at the present time, although it leaves open the option to require such Reviews in the future.

The Department also considered conducting Reviews of significant regulations, as that term is defined in Executive Order 12866. The Department is choosing to Review those regulations that have a SEISNOSE, in order to maintain a close connection between this final rule and the RFA. The Department sought comment on whether to Review additional regulations, such as those that are significant under Executive Order 12866. Given limited responses to this request, the Department will not Review other regulations at this time beyond those designated as having a SEISNOSE. However, the Department leaves open the possibility to conduct Reviews of other regulations in the future.

The Department considered only Reviewing those regulations that, at the time of promulgation, the Department determined had a SEISNOSE. However, such determinations were not made for regulations that were promulgated prior to the passage of the RFA,[226] and some post-RFA regulations that did not have such a SEISNOSE at the time of promulgation might have such a SEISNOSE today. One commenter suggested that an alternative to the proposed rule would be to attach sunset dates only prospectively for regulations finalized after the effective date of this rule. The same commenter suggested requiring retrospective reviews only for those regulations specifically identified by stakeholders as problematic. But as a general matter, the Department believes that older regulations are more likely to be obsolete. As a result, the Department believes that this final rule should apply to them. Moreover, only reviewing regulations identified by stakeholders is unlikely to suffice. Regulations are known to create entry barriers into industries and these barriers often affect small businesses disproportionally.[227] Therefore, the Department believes stakeholder input cannot be the only source of information to spur reviews. Concentrated interest groups will lobby to protect regulations that have been specifically constructed for their benefit. Meanwhile, consumers, small businesses, and the public more generally often experience dispersed costs that are not taken into account by these stakeholders. The work of political scientist Mancur Olson explains why these groups that comprise broader society, because they are larger, face collective action problems and often find it costly to organize and lobby on behalf of their own interests.[228] Meanwhile, more narrow, concentrated interests find it relatively easier to organize and lobby for their own interests. Thus, stakeholders may not identify to the Department many regulations that are unduly burdensome to the public at large.[229]

The Department is also aware of literature suggesting that agencies have not been consistent in deciding which rules have a SEISNOSE or have avoided such a finding in order to avoid the RFA's requirements.[230] Moreover, 5 U.S.C. 610 presupposes the agency will make a determination about which regulations have or will have a SEISNOSE. This suggests there is good reason to Assess most of the Department's regulations. For these reasons, the Department has chosen to Assess all of its Regulations (subject to the exceptions listed herein) to determine which have a SEISNOSE and to Review those Regulations that have a SEISNOSE using the criteria listed in 5 U.S.C. 610 (as well as whether they comply with applicable law).

Finally, some commenters suggested that the Department include a provision granting the Secretary the authority to extend the expiration date in certain circumstances. Other commenters suggested that the proposed rule's two-year Assessment and Review period affecting some of the Department's older regulations was too short. In response, the Department has made several modifications to the final rule from its proposed form. First, regulations older than ten years will expire after five years, as opposed to expiring after two years, if these Regulations are not Assessed and (when necessary) Reviewed. Second, this final rule grants the Secretary a one-time option to push back this expiration date by one year for a given Regulation. Both of these modifications have the effect of lowering some costs of this final rule as compared to the proposed rule, because these changes lengthen the expected Assessment and Review period, pushing some costs into the future. This reduces the present value of these costs.

D. Cost Analysis

5 U.S.C. 610 already directs the Department to undertake periodic reviews of its regulations. Nevertheless, because the Department believes this final rule will stimulate a behavior change at the Department and among the public, the regulation has some costs associated with it. Therefore, the Department performed the following analysis to estimate the costs and burdens to the Department and the public from (1) Assessing which Department regulations have a SEISNOSE, and (2) Reviewing those regulations.

The Department has roughly 18,000 regulations, the vast majority of which it believes would need to be Assessed.[231] Roughly 12,400 of these

2020), *https://www.ag.gov.au/sites/default/files/2020-07/Guide%20to%20Managing%20Sunsetting%20of%20Legislative%20Instruments.pdf.*

[226] The Department estimates that 16% of its regulations that are more than ten years old were promulgated prior to 1980, when Congress passed the RFA.

[227] *See, e.g., Regulatory Reform: Hearings on S. 104, S. 262, S. 755, S. 1291 Before the Subcomm. on Admin. Practice & Procedure of the Comm. on the Judiciary,* 96th Cong. 3–4 (1979) (statement of Peter J. Petkas, Director, The Regulatory Council) (describing the disproportionate impact on small businesses and uncertainty about benefits resulting from burdensome regulations); 142 Cong. Rec. S1637 (daily ed. Mar. 7, 1996) (statement of Sen. Bond) (''The SBA chief counsel for advocacy released a report that said that small businesses bear a disproportionate share of the regulatory burden.''); Nicole V. Crain & W. Mark Crain, *The Impact of Regulatory Costs on Small Firms,* (U.S. Small Bus. Admin., Office of Advocacy, Washington, DC), at 55, 57 (2010) (finding that ''regulations cost small firms an estimated $10,585 per employee. Regulations cost medium-sized firms $7,454 per employee, and large firms $7,755 per employee,'' and that in the health care sector, the cost per employee is 45 percent higher in small firms than in medium-sized firms, and 28 percent higher in small firms than in large firms).

[228] Mancur Olson, The Logic of Collective Action (Harv. U. Press 1971).

[229] The Department welcomes comments from all members of the public on (1) regulations being Assessed or Reviewed pursuant to this final and (2) future notices of proposed rulemaking. The Department will consider comments received from all members of the public. We merely make this observation to explain why relying solely on stakeholders may not enable the Department to identify certain regulations that should be amended or rescinded.

[230] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

[231] *See* Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal

regulations are over ten years old, and roughly 17,200 are more than five years old.[232] The vast majority of these would need to be Assessed within five years of this final rule's effective date (or six years if the optional extension is exercised by the Secretary). The Department estimates that roughly five regulations on average are part of the same rulemaking due to the number of unique **Federal Register** citations associated with its regulations. This would suggest the Department would have to perform roughly 3,440 Assessments in the first five years (or six for certain of these regulations if the extension is exercised by the Secretary, and 3,600 Assessments in total.

However, some of these rulemakings are exempt from this final rule. The Department estimates that approximately 66 parts of the CFR that the Department actively updates contain the vast majority of the regulations that are exempt from this final rule. According to analysis from the Mercatus Center, however, the Department has approximately 8,574 active parts of the CFR.[233] 66 parts are therefore less than 1% of the Department's active parts. As a result, the Department does not believe the exemptions will significantly alter the costs of this final rule.[234]

To help estimate the impact of this final rule, the Department conducted a limited randomized sampling[235] of its regulations and assessed whether the sampled regulations would be exempt from this final rule and whether, at the time of issuance, the regulations were: Economically significant; found to have a SEISNOSE; or subject to the Unfunded Mandates Reform Act (UMRA) of 1995. This information is included in table 3. Also included in table 3 is the estimated impact of the regulations when they were first promulgated.

TABLE 3—SAMPLED DEPARTMENT REGULATIONS

Title	Rulemaking	Citation	Exempt from this Final Rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
21	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products.	73 FR 63886	No	No	No	No	"[O]ne-time costs will range from approximately $38.0 million to $49.6 million and annual costs will range from $12.4 million to $46.3 million." [236]
21	Unique Device Identification System	78 FR 58786	No	Yes	Yes	Yes	"Over 10 years, the estimated present value of the total domestic costs is $642.2 million using a 7 percent discount rate and $737.7 million using a 3 percent rate, and the annualized costs are $85.7 million using a 7 percent discount rate and $84.1 million using a 3 percent discount rate." [237]
21	Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	81 FR 60170	No	No	No	No	"We estimate one-time total costs of $59.7 million and recurring costs of $0.5 million. These costs represent total annualized costs of $9 million when calculated at a 7-percent discount rate over 10 years, and $7.5 million when calculated using a 3-percent discount rate. The largest cost elements will be for registrants reading and understanding the final rule and making changes to their standard operating procedures." [238]
21	Human Tissue Intended for Transplantation.	62 FR 40429	No	No	No	No	FDA confirmed "that the only economic impact of the rule would be related to record-keeping burdens" that already existed.[239]
42	Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care.	70 FR 57368	No	Yes	No	No	"The Congress provided $142,000,000 for the loan program effective July 1, 2004 through September 30, 2008, and not more than $2,000,000 may be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008)." [240]

HHS slide) (the sum of the numbers listed in the table under the column denoted "#" is 17,890 Department regulations).

[232] *See id.* (adding the figures listed in the "#" columns for the 1950s, 1960s, 1970s, 1980s, 1990s, and 2000s yields 12,383 regulations. 17,200 regulations are estimated to have been issued by the end of 2016).

[233] These data are available at *Quantgov.org.*

[234] The exempt parts may on average have more Sections than other parts. But even still, it seems unlikely the exemptions would significantly alter the costs of this final rule. If the Department were incorrect about this assumption, costs from this final rule would likely be lower than estimated herein. Similarly, the Department does not have enough information at present to determine whether the CFR sections that could potentially benefit from regulatory streamlining based on their similarities to, overlap with, or duplicativeness of other Sections will lead to a reduction in Department costs of Assessments and Reviews, due to duplication of work. The initial Assessment of all non-exempt regulations would determine whether this is the case.

[235] With the aid of a random number generator, the Department selected Department regulations in each of its three main titles (21, 42, and 45) of the Code of Federal Regulations. The random number generator was used to identify the relevant part of each title of the CFR to assess.

TABLE 3—SAMPLED DEPARTMENT REGULATIONS—Continued

Title	Rulemaking	Citation	Exempt from this Final Rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
42	Organ Procurement and Transplantation Network.	63 FR 16296	No	Yes	No	No	Although incremental effects attributable to the rule were not estimated, impact categories would have included life-years saved by non-renal organ transplants, quality of life improvements for kidney recipients, and the admittedly expensive costs of transplantation.[241]
42	Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement.	53 FR 47199	No	No	No	N/A (rule issued prior to UMRA being enacted).	N/A: "We have determined that a regulatory impact analysis is not required for these rules because they would not have an annual impact of $100 million or more."[242]
45	Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage.	56 FR 8926	No	No	No	N/A (rule issued prior to UMRA being enacted).	"[T]he cost of implementation is expected to be insignificant."[243]
45	Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.	76 FR 53256	No	No	No	No	Estimated annual cost of $23,236,238.[244]
45	Rate Increase Disclosure and Review	76 FR 29964	No	No	No	No	"CMS estimates that issuers will incur approximately $10 million to $15 million in one-time administrative costs, and $0.6 million to $5.5 million in annual ongoing administrative costs related to complying with the requirements of this final rule from 2011 through 2013. In addition, States will incur very small additional costs for reporting the results of their reviews to the Federal government, and the Federal government will incur approximately $0.7 million to $5.9 million in annual costs to conduct reviews of justifications filed by issuers in States that do not perform effective reviews."[245]

None of the sampled regulations would be exempt from this final rule, meaning all sampled rules would need to be Assessed. This is consistent with the assumption that few enough regulations would be exempt from this final rule to significantly affect the cost estimates presented here. At the time the ten sampled regulations were promulgated, the Department believed that one of the ten had a SEISNOSE. If the Assessments' findings mirror the findings from the time of issuance, one of the ten sampled regulations would need to be Reviewed. Similarly, an academic study found 11.1% of Department final rules issued in 1993 had a SEISNOSE.[246] A more recent study found that 92% of agency rules were found to not be subject to the RFA, suggesting agencies believe roughly 8% of their regulations have a SEISNOSE.[247]

Assuming the Department has roughly 3,600 total rulemakings that are subject to this final rule; 3,440 of these are more than five years old (*i.e.* would be ten years old by the end of 2026); and that roughly 11% [248] have a SEISNOSE, then the Department might have to perform roughly 396 Reviews in total, of which 378 would have to be completed in the five years after this rule is finalized. However, some of these rulemakings might be reviewed as part of section 610 reviews even in absence of this final rule (*i.e.,* in the baseline scenario). As noted above, the Department estimates that the three completed rulemakings emanating from section 610 reviews over the last decade amend approximately 130 sections of the CFR.

[236] Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 73 FR 63,886, 63,892 (Oct. 28, 2008).

[237] Unique Device Identification System, 78 FR 58786, 58811 (Sept. 24, 2013).

[238] Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, 81 FR 60170, 60171 (Aug. 31, 2016).

[239] Human Tissue Intended for Transplantation, 62 FR 40429, 40442 (Jul. 29, 1997).

[240] Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care, 70 FR 57368, 57372 (Sept. 30, 2005).

[241] Organ Procurement and Transplantation Network, 63 FR 16296, 16321–29 (Apr. 2, 1998).

[242] Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, 53 FR 47199, 47201 (Nov. 22, 1988).

[243] Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage, 56 FR 8926, 8929 (Mar. 4, 1991).

[244] Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 FR 53256, 53280 (Aug. 25, 2011).

[245] Rate Increase Disclosure and Review, 76 FR 29964, 29978 (May 23, 2011).

[246] Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1217 (2006).

[247] Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 69 (2015).

[248] The Department chooses 11%, rather than 8% or 10%, because the study that found 11.1% of Department regulations had a significant economic impact upon a substantial number of small entities was focused solely on the Department's regulations.

If the decade following implementation of this final rule is similar to the previous decade, then the Department can expect to review and amend 130 sections of the CFR, which is equivalent to 26 average rulemakings if 5 regulations correspond with one rulemaking on average. These 26 rulemakings are assumed to be what would be Reviewed in the baseline scenario. Therefore, the Department expects to conduct 370 Reviews in total, of which 353 would have to be completed in the five years after this rule is finalized.[249]

Of the 353 rulemakings subject to Reviews in the first five years (or six years if the Secretary exercises the one-year extension authority), the Department estimates roughly 44 rulemakings were promulgated prior to the requirement for prospective regulatory flexibility analyses. Those 44 Reviews will require more Department resources than the estimated 309 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect.

Therefore, as a result of this final rule, the Department expects to have to conduct 370 Reviews in total. These include approximately 44 rulemakings that were promulgated prior to the requirement for prospective regulatory flexibility analyses, and 326 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect. Of these 326, the Department assumes most Reviews will occur earlier in the coming ten years such that 309 Reviews are conducted in the first five calendar years following implementation of this final rule and 17 of the Reviews occur in the second five calendar years. This is consistent with the fact that the vast majority, roughly 95 percent, of Department regulations are older than five years (and therefore will be more than ten years old by the end of 2026).

1. Costs Related to Section 610 Reviews of Regulations More Than Five Years Old

The majority of the Reviews conducted in response to this regulation will have to be conducted in the first five calendar years following implementation of this regulation, because the vast majority of the Department's regulations were finalized before the end of 2016. A full initial Regulatory Flexibility Act (RFA) analysis requires 250 to 500 hours to complete because federal agencies must analyze the impact of their regulatory actions on small entities (small businesses, small non-profit organizations and small jurisdictions of government) and, where the regulatory impact is likely to be ''significant'' and affecting a ''substantial number'' of these small entities, seek less burdensome alternatives for them. This involves defining the market and determining costs for each small entity. The section 610 review is a more streamlined analysis because the regulatory flexibility analysis is the starting point. The section 610 review focuses on five areas of analysis: (1) Whether there is a continued need for the rule, (2) the number and nature of complaints, (3) the complexity of the regulation, (4) whether there is duplication, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule, as well as whether the Regulation complies with applicable law. As such, the Department estimates that a Review will require significantly less time than a full RFA analysis.

The Department recognizes that some regulations were promulgated prior to when the requirement for prospective regulatory analysis went into effect, and that a section 610 review of such rulemakings may be more time intensive. The Department estimates 309 rulemakings from 2016 or earlier will be subject to section 610 review where some prospective analysis has been performed, in which case such reviews will take 40 to 100 hours. The Department estimates it will undertake section 610 reviews of 44 rules for which no prospective regulatory analysis was performed. The Department assumes that between 250 to 500 hours may be required for these reviews, even though the section 610 review is more circumscribed than a full regulatory flexibility analysis and will therefore generally take less time to perform. The Department also notes that there could be costs associated with publishing the notices of Assessments and Reviews to the Department's website and the **Federal Register** for public comment, but that such costs will be minimal and would not require the hiring of additional personnel.

Therefore, the Department estimates that a total of between 23,360 and 52,900 hours will be spent on Reviews outside the Assessment process during the first five years (the number of hours may ultimately be slightly less if the Secretary exercises the optional one-year extension with respect to some regulations), which will clear the backlog of section 610 reviews for regulations at least five years old. The Department assumes 40 to 100 hours per Review for the estimated 309 Reviews for which an initial prospective analysis was performed. The Department assumes 250 to 500 hours per Review for the estimated 44 Reviews where no such initial prospective analysis was performed.

The Department estimates that the fully-loaded cost per hour to the Department to employ a person to conduct a Review or Assessment is $244.98 per hour (referred to as ''*LaborCost*'').[250] Assuming the 23,360 to 52,900 estimated hours are spread evenly across the first five years following implementation of this final rule, and assuming a 7 percent discount rate, the present value of these costs ranges from $4.7 to $10.6 million in total. Without discounting, this is equal to 20.1 to 45.6 full-time equivalents (FTEs) working at *LaborCost* to initiate and conduct Reviews of regulations in the first 5 years.

2. Costs Related to Rulemakings That ''Age In'' To Section 610 Review

The Department estimates 17 rulemakings would ''age in''[251] to the section 610 review requirement during years six through ten after this rule is finalized. The Department estimates it will require between 680 to 1,700 hours to Review these rules, because the Department assumes those 17 Reviews would take between 40 to 100 hours per Review, as each of those rulemakings were promulgated after prospective regulatory analysis was required. Assuming hours reviewing these rulemakings are spread equally across years six through ten, the Department estimates the present value of the cost of Reviewing 17 rulemakings in years six through ten to be between $0.1 million and $0.3 million at a seven percent discount rate. Without discounting, this represents 0.6 to 1.5 FTEs working at *LaborCost* to conduct 17 Reviews of rules that age into the Review requirement during the decade following implementation of this regulation.

[249] Since approximately 95 percent of Department rules were finalized before 2016, this analysis assumes 25 Reviews in the baseline scenario would occur in the first five years following implementation of this final rule, and one Review would occur in the subsequent five years.

[250] Here, the Department uses the reported ''FY 2021 average fully supported cost to [FDA of] $284,174 per FTE,'' divided by 1,160 ''Net Supported Direct FDA Work Hours Available for Assignments'' per year to arrive at $244.98 per hour. Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2021, 85 FR 46669, 46670 (Aug. 3, 2020).

[251] ''Age in,'' meaning that the rules become ten years old during years six through ten.

3. Costs Related to Assessments

In addition to conducting Reviews of rulemakings that have a SEISNOSE, the Department will allocate resources towards conducting Assessments of its rulemakings to determine whether a Review is required. At the time of promulgation, regulations are evaluated as to whether they had a SEISNOSE under the RFA. However, some regulations were promulgated prior to the RFA, while others were certified exempt from having to produce a regulatory flexibility analysis because they were certified as not having a SEISNOSE. This final rule will require the Department to make a determination as to whether covered rulemakings currently have a SEISNOSE and, if so, to Review those regulations. Because circumstances could change over time, the designation that a regulation has a SEISNOSE is likely to change for some rules. As a result, this final rule requires the Department to timely Assess all of its regulations (subject to the exceptions in this final rule) to determine whether they have a SEISNOSE, otherwise the regulations would expire. As discussed above, some rulemakings may overlap with or be duplicative of one another, reducing the number of Reviews that will be eventually required. However, the Department believes an initial Assessment of all rulemakings (subject to this final rule's exceptions) will likely be required first to determine the extent of such overlap or duplication.

The Department believes each Assessment will require between three and 10 hours to perform. The Department estimates that it will have to conduct roughly 3,062 Assessments in the first five years after this rule is finalized, and an additional 142 Assessments in the subsequent five years, for a total of 3,204 Assessments across ten years.[252]

As such, the Department believes 9,186 to 30,620 hours will be spent on Assessments in the first five years. The Department believes 426 to 1,420 hours will be spent on Assessments in the following five years. Assuming these hours are spread evenly across their respective ranges of years, the present value of costs associated with these Assessments ranges from $1.9 to $6.4 million at a 7 percent discount rate. Without discounting, this represents 8.3 to 27.6 FTEs working on a total of 3,204 Assessments over ten years. If, as seems plausible, Assessments of regulations more than ten years old will disproportionately occur in the latter half of the 2021–2026 time period, the present value of the cost of Assessments will be slightly less than estimated herein.

4. Costs Related to Review of Additional Rulemakings Found To Have a SEISNOSE

Depending on the outcome of the Assessments, the Department may have to Review additional rulemakings. The Department estimates roughly 5% of Assessments of Regulations not initially found to have a SEISNOSE will conclude that a Review is required. The Department believes this is a reasonable estimate because the 5% rate is roughly half of the percentage of all Department regulations that the Department currently believes have a SEISNOSE. Accordingly, the Department estimates 153 Reviews will be required in the first five years,[253] and seven Reviews will be required in the subsequent five years,[254] for a total of 160 additional Reviews. The Department estimates the 153 Reviews will require 6,120 to 15,300 hours,[255] and that the seven Reviews will require 280 to 700 hours in the subsequent five years.

Assuming these hours are spread evenly across the corresponding time frames, multiplying these hour estimates by *LaborCost* and discounting at a seven percent discount rate yields an estimated $1.3 to $3.2 million over ten years, which corresponds with 5.5 to 13.8 FTEs for additional post-Assessment Reviews over ten years (without discounting). If, as seems plausible, Reviews of regulations in this category will not be spread evenly across the corresponding time frames but will disproportionately occur in the latter half of the time frames, the present value of the cost of these Reviews will be slightly less than estimated herein.

5. Monitoring Costs

Some commenters argued that the proposed rule's regulatory impact analysis underestimated the costs of this rulemaking, because it did not consider the costs to the regulated community of: Monitoring which regulations may expire; commenting either during the Assessment and Review process or to request that the Department conduct an Assessment or Review; and, when necessary, writing and submitting comments on regulations amended as a result of retrospective reviews conducted pursuant to this final rule.

The Department believes the cost of monitoring Assessments will be relatively trivial. This final rule requires the Department to announce on its website, as well as on *Regulations.gov*, when it has commenced Reviews and Assessments. Making the announcement on *Regulations.gov* (as opposed to only on the Department's website, as proposed) will reduce the monitoring costs raised by the commenters, because the regulated community already monitors *Regulations.gov*.

Moreover, in conjunction with this final rule, the Department is placing at *https://www.hhs.gov/regulations/federal-registry/index.html* a list of Department regulations, the year they were initially promulgated, the last year the rule was amended, and the **Federal Register** citation from the time the rule was initially promulgated. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list can be used to easily create a schedule of expiration dates, so that the monitoring public does not need to identify these dates itself. Announcements of this kind conform to Organisation for Economic Co-operation and Development guidelines that recommended creating a predetermined schedule for when regulations are due for assessment and review.[256] This type of ''programmed review'' would give both the Department and the public ample time to prepare for the Review and to submit comments as needed. It would also reduce the time and effort required of the public to track those regulations that are set to expire or be revised. As such, the monitoring public should not bear any significant expense keeping track of when regulations are set to expire or reminding the Department of when regulations are set to expire. Additionally, monitoring costs associated with Assessments are likely to not be significant because Assessments are unlikely to result in amendments of regulations, absent a subsequent Review also occurring. This final rule only mandates amendment or rescission of certain regulations that have been Reviewed.

In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews, its progress, and when it

[252] 3,062 is 3,440 total Department rulemakings older than 2016, minus 25 rulemakings Reviewed in the baseline scenario, minus the 353 rulemakings Reviewed in the first five years. 142 is 160 rulemakings affected by this final rule in the second five years, minus one rulemaking Reviewed in the baseline scenario, minus the 17 rulemakings expected to be Reviewed in the second five years.

[253] 5% of 3,062 is 153.

[254] 5% of 142 is 7.

[255] Each review will take 40–100 hours.

[256] Organisation for Economic Co-operation and Development, ''Reviewing the Stock of Regulation'' (2020).

expects them to be completed. If they so choose, the public can view this dashboard to see the Department's progress on its Assessments and Reviews of particular regulations. The dashboard will also help to keep the Department on track to timely complete Assessments and Reviews.

Based on the experience of North Carolina,[257] the Department estimates that approximately 10 percent of Reviewed rulemakings will be rescinded and 30 percent of Reviewed rulemakings will be amended in some way. Since 530 rulemakings are expected to be Reviewed in total,[258] this suggests 53 regulations will be rescinded and 159 will be updated.

To estimate how much interest these expiring and amended regulations are likely to generate, the Department notes that it received 486 comments on the proposed rule as of the close of the 30-day public comment period. A typical commenter is likely to be someone with a legal background. According to the Bureau of Labor Statistics,[259] the mean hourly wage of a lawyer is $71.60 (2020$). Assuming base salary constitutes one half of fully-loaded wages,[260] this suggests the fully loaded cost per hour of writing comments is $143.20.

If a typical comment takes 5 to 15 hours to write, and if the 486 comments the Department received on the proposed rule is a good proxy for the interest the Department will receive on the 159 rulemakings expected to be amended as a result of this final rule over the next decade, then the total (undiscounted) monitoring cost related to writing comments on those 159 regulations is $55.3 to $166.0 million.[261] However, rulemakings are not likely to all be amended at the same time. Further, if the Secretary determines that completion of an amendment or a rescission is not feasible by the required date, he or she can certify this in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times.

Assuming the Secretary does not extend the completion date (this assumption is relaxed in the sensitivity analysis below), the Department expects 152 of the amended rulemakings will be Reviewed in the first five years and seven regulations Reviewed in the second five years. Assuming monitoring costs are spread equally across these timeframes (with the understanding that this may overestimate costs somewhat since rulemakings are likely to be amended after they are Reviewed, which would push amendment to the later end of the timeframe) the present value of these monitoring costs ranges from $44.8 to $134.3 million at a seven percent discount rate.

The Department expects it will receive less interest in regulations that are rescinded after being Reviewed, given that many regulations that are sunset in states often face little resistance from the public, perhaps because their rescission is uncontroversial. For example, the state of Idaho underwent a sunset review process for its entire regulatory code in 2019. As a result of the review, 19 percent of rule chapters, 10 percent of pages, and more than 19,000 regulatory restrictions were rescinded when the code was rewritten in the summer of 2019.[262] This occurred with little controversy, suggesting many regulations that were rescinded were obviously outdated or counterproductive, such that their removal was uncontroversial.[263]

The North Carolina experience, which has been ongoing for several years, may be a better representation of what the Department can expect from its reviews, since the circumstances in Idaho were somewhat unique. Nonetheless, the 10 percent of reviewed rules being rescinded in North Carolina is comparable to the 10 percent of pages of rules repealed during Idaho's mid-2019 review. The Department assumes rescinded regulations will receive half as many comments as amended regulations. In that case, 53 rescinded regulations, of which 51 are expected in the first five years, should generate costs of $7.5 to $22.4 million (discounted at a 7 percent discount rate, assuming rescinded regulations are spread across corresponding timeframes in a manner consistent with the amended regulations described above). Thus, the total cost of monitoring is likely to range from $52.2 to $156.7 million (at a seven percent discount rate).

6. Total Estimated Costs From Implementing This Rulemaking

The Department estimates a total cost of between $60.2 to $199.3 million over ten years in order to do the following: (a) Conduct section 610 Reviews for Department rulemakings from 2016 or earlier in years 1 to 5, (b) conduct section 610 Reviews of rulemakings that ''age in'' to section 610 review in years 6 to 10, (c) conduct Assessments of rulemakings in years 1 to 10, and (d) conduct section 610 Reviews of rulemakings deemed to be subject to Review following an Assessment in years 1 to 10. The total number of Department employees required to conduct these activities is estimated to be 34.5 to 88.5 FTEs over ten years. The Department has also estimated the cost of increased monitoring falling on regulated entities. Results are presented in table 4 below, which also includes cost estimates discounted at a 3 percent discount rate for sensitivity purposes.[264]

TABLE 4—PRESENT VALUE OF ESTIMATED COST OF ASSESSING AND REVIEWING DEPARTMENT REGULATIONS OVER TEN YEARS (MILLIONS OF 2020$), AT 3 AND 7 PERCENT DISCOUNT RATES

Type of cost	Cost (7%)	Cost (3%)	FTEs
Department Costs:			

[257] Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the process,* The John Locke Found.: The Locker Room (July 22, 2019), *https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/.*

[258] This is 370 Reviews from rules that were initially identified as having a SEISNOSE plus the 160 Reviews from Assessments determining that additional rulemakings have a SEISNOSE.

[259] *See* Bureau of Labor Statistics, Occupational Employment Statistics, 23–1011 Lawyers. *https://www.bls.gov/oes/current/oes231011.htm.*

[260] This assumption is in line with Department guidelines on regulatory analysis. *See* U.S. Dep't of Health & Hum. Servs., Guidelines for Regulatory Impact Analysis, at 28 (2016).

[261] This is 159 rulemakings × 486 commenters × $143.20 per hour × 5 to 15 hours per comment.

[262] Office of Gov. Brad Little, Idaho's Historic Regulatory Cuts (July 2019).

[263] The fact that there seemed to be little controversy surrounding rescinded rules may imply some of those rescissions were fairly trivial in some cases. While data on the extent to which rescissions were trivial or nontrivial are unavailable, news stories provide some basis for this belief. Note that rescinded rules being relatively trivial is not evidence that amended rules were trivial. *See, e.g.,* Editorial, Idaho Quits Worrying About Snails, Wall St. J., June 28, 2019, *https://www.wsj.com/articles/idaho-quits-worrying-about-snails-11561763217.*

[264] The Office of Management and Budget recommends a 7 percent base-case default discount rate be used in regulatory impact analysis. OMB also recommends a 3 percent consumption rate of interest be used as an alternative. See Office of Mgmt. & Budget, Circular A–4, Regulatory Analysis (Sept. 17, 2003).

TABLE 4—PRESENT VALUE OF ESTIMATED COST OF ASSESSING AND REVIEWING DEPARTMENT REGULATIONS OVER TEN YEARS (MILLIONS OF 2020$), AT 3 AND 7 PERCENT DISCOUNT RATES—Continued

Type of cost	Cost (7%)	Cost (3%)	FTEs
A. Costs Related to Section 610 Reviews of Regulations More Than Five Years Old.	$4.7 to $10.6 million.	$5.2 to $11.9	20.1 to 45.6.
B. Costs Related to Rulemakings That "Age In" to Section 610 Review	$0.1 to $0.3	$0.2 to $0.4	0.6 to 1.5.
C. Costs Related to Assessments	$1.9 to $6.4	$2.1 to $7.1	8.3 to 27.6.
D. Costs Related to Review of Additional Rulemakings Found to Have a SEISNOSE.	$1.3 to $3.2	$1.4 to $3.6	5.5 to 13.8.
Private Costs:			
E. Cost to Monitoring Public	$52.2 to $156.7	$58.8 to $176.3	N/A.
Total	$60.2 to $177.2	$67.7 to $199.3	34.5 to 88.5.

These figures can also be presented on an annualized basis, calculations of which are presented in table 5 below. Annualized costs are estimated to range from $7.9 million to $25.2 million per year over the decade following implementation of this final rule.

TABLE 5—ACCOUNTING STATEMENT: ANNUALIZED COSTS OF FINAL RULES

Present value (millions of 2020$)	Discount rate (percent)	Time horizon	Annualized, millions of 2020$ per year
$60.2 to $177.2	7	2021–2030	$8.6 to $25.2.
$67.7 to $199.3	3	2021–2030	$7.9 to $23.4.

7. Sensitivity Analysis

One commenter noted that conducting a retrospective analysis can be as time-consuming and expensive as a prospective regulatory analysis, suggesting the Department's estimates of the time and expense of Reviews may be understated. The Department believes that on average Reviews of rulemakings implemented after the RFA are likely to be less time consuming than those implemented before. Moreover, 250 to 500 hours is the amount of time estimated to produce a full initial RFA analysis, which requires more time than a section 610 review, even one where no RFA analysis was conducted when the rulemaking was promulgated. Nevertheless, for the sake of testing the sensitivity of the cost estimates for Reviews, the Department calculates the costs of Reviews assuming all Reviews take 250 to 500 hours, rather than the assumption of 40 to 100 hours for post-RFA regulations made above. In this case, the present value of the total cost of Reviews (A, B and D in table 4) would rise to $26.5 to $53.0 million from $6.1 to $14.1 million (at a seven percent discount rate), and would rise to $29.7 to $59.4 million from $6.8 to $15.8 million (at a three percent discount rate).

However, there are also reasons to believe the costs estimated in table 4 are overestimated. First, this final rule permits the Secretary to extend by up to one year the expiration date for particular regulations. Having this option might have the effect of pushing back the time horizon for certain Reviews and Assessments by one year. This would suggest the costs presented in table 4 above are overestimated to the extent that the present value of these costs will fall as some costs are pushed into the future. Assuming all costs are pushed back by one year, discounting the total costs by one additional year at a seven percent discount rate yields a present value of total costs in the range of $56.3 million to $165.6 million, and at a three percent rate yields a present value of total costs in the range of $65.7 to $193.5 million. These potential reduced costs are one reason the Department has decided to modify the final rule from its proposed form.

Similarly, the costs of monitoring might be pushed into the future if the Secretary exercises his or her right to extend the completion date by one year at a time, up to three times, with respect to amendment or rescission of regulations after Review. Assuming amended or rescinded regulations are pushed back three years in the future, the present value of monitoring costs would fall to $42.6 to $127.9 million at a seven percent discount rate and to $53.8 to $161.3 million at a three percent discount rate. If, as some commenters stated, this final rule resulted in the Department issuing fewer new notices of proposed rulemaking, the reduction in commenting costs from the reduction in new notices of proposed rulemaking would cause the monitoring costs from this final rule to drop.

8. Other Possible Costs

Some commenters noted that there might be other sources of cost associated with this rulemaking other than those cited in the regulatory impact analysis accompanying the proposed rule. Some of these costs have been accounted for above, such as the cost of monitoring or the potential for Reviews to take longer than estimated in the proposed rule. Other commenters cited increased uncertainty to businesses and members of the regulated community as a possible cost due to the increased chance that rules may expire in the future. The Department does not believe uncertainty among the regulated community will add significantly to the costs of this rulemaking for the following reasons. The Department's sporadic use of periodic retrospective review—notwithstanding the RFA and Executive Orders—itself leads to "uncertainty" about how robustly the Department implements directives that make for good policy.[265] To the extent that the Department can maintain compliance with its obligations, this should build trust in the Department

[265] To the extent this uncertainty has been lessened because the public has seen how the Department has implemented these directives over the course of many years, the same can be said for this final rule once it has been implemented for several years.

and reduce uncertainty (offsetting some or all of the uncertainty discussed by the commenters, if such uncertainty exists). Further, as noted above, the Department plans to release information about the 18,000 regulations under its authority and when they were adopted, such that any uncertainty surrounding the expiration dates of the Department's various rulemakings will be reduced substantially, if not entirely. Additional measures to mitigate private costs are discussed in the ''Operationalization of This Final Rule'' section of this final rule.

Second, the Department notes that many states have sunset provisions that are a routine part of their regulatory processes. New Jersey, Indiana, and North Carolina have sunset provisions for their regulations. Missouri has a sunset provision for regulations, which is tied to a periodic review requirement.[266] Colorado, California, and Texas have sunset review processes for entire boards, commissions, and agencies. Some states have an annual sunset review process for their entire administrative code.[267] Although the sunset clause is rarely exercised, there nevertheless is always the possibility the entire regulatory code will expire in these states in any particular year. In fact, two states (Idaho and Rhode Island) replaced their regulatory codes in recent years as part of sunset processes, and these experiences seemed to work relatively seamlessly.[268]

Similarly, many major federal laws have sunset clauses attached to them. Notable among these are the Patriot Act, enacted in the aftermath of the 9/11 terrorist attack, and tax laws passed as part of the budget reconciliation process under the Byrd Rule in the U.S. Senate. Federal agencies like the Food and Drug Administration within the Department periodically go through a reauthorization process, not unlike a sunset review.[269] Sunset provisions are also routinely used in other countries, notably in Australia, Canada and the United Kingdom. A recent OECD report noted that just under half of OECD member countries have some form of sunsetting arrangements in place.[270] In Australia, since the passage of the Legislation Act of 2003,[271] all regulations (known as legislative instruments), with some exceptions, automatically expire 10 years after enactment unless parliament acts to extend the period or a replacement instrument is adopted.[272] The Australian Federal Register of Legislation (the equivalent of the **Federal Register** in the United States) maintains the sunset dates for qualifying legislation and provides notice about legislative instruments set to expire soon.[273] The Department also plans to provide advance notice of expiration dates, and will provide updates on its progress conducting its regulatory reviews.

The Australian government also notes that sunset provisions are a useful way to spur periodic review of regulations, stating in a report that ''Sunsetting provides an opportunity for agencies to review and streamline legislative instruments. It is an important mechanism for reducing red tape, delivering clearer laws and aligning existing legislation with current government policy.'' [274]

The Republic of Korea (ROK) enacted regulatory sunset legislation in the late 1990s and formed a Regulatory Reform Committee (RRC) to review newly-introduced regulations and to improve the quality of existing regulations.[275] According to a report from the OECD, ''The overall aim of the sunset clause is to periodically review regulations in order to determine whether it will be retained or abolished.'' [276] In 2009, ROK broadened the scope of its regulatory sunset process by tying in requirements for retrospective analysis.[277] About 20 percent of existing regulations are reviewed every three to five years and rescinded if found to ''not serve the originally intended purpose.'' [278] Moreover, according to the OECD, ''[i]n 2014, the RRC set goals to reduce the economic regulations by 10% . . . As a result, 995 out of 9,876 economic regulations were improved, which amounts to 10.1% of the total.'' [279]

These jurisdictions' sunset provisions do not all work identically to this final rule. However, in some ways this final rule is more lax than these other jurisdictions' sunset provisions, because the requirements to extend expiration dates are more modest compared to some other jurisdictions. For example, conducting an Assessment, and when necessary, a Review, is a relatively easy way to extend an expiration date compared to having to initiate an entirely new rulemaking. If the sunset reviews in these other jurisdictions do not create tremendous uncertainty, it stands to reason that neither will this final rule.

Some commenters expressed concern that regulations might accidentally expire due to the Department not timely conducting an Assessment or Review. The Department intends to review all regulations subject to this final rule, and that any regulations that are eliminated will be formally rescinded following the Review process. This is consistent with the experiences of other jurisdictions with sunset provisions, where rules (or boards or commissions) are first subjected to a review process before they are reauthorized or rescinded. As an example, Idaho recently conducted a sunset review of its entire regulatory code. While a significant number of rule chapters were eliminated as part of that effort, those chapters were rescinded as part of a deliberate review process.

New Jersey is a state that attaches a 7-year sunset provision to regulations. According to the Office of Administrative Law in the state, it is a relatively rare phenomenon that rules expire due to administrative error.[280] Similarly, accidental expiration of rules appears to be uncommon in Missouri, a state that connects a sunset provision to a periodic review requirement, much like this final rule.[281]

Data from North Carolina's sunset review process can be informative about the extent to which rules are likely to be rescinded, modified, or kept without change as part of a sunset review. A North Carolina public policy organization found that 19,361 rules were reviewed as part of that state's sunset review process in recent years.[282]

[266] Missouri Revised Statutes, Title XXXVI § 536.175.5.

[267] Utah Code Ann. § 63G–3–502(2) (2020); Idaho Code Ann. § 67–5292 (2020).

[268] James Broughel, *The Mighty Waves of Regulatory Reform: Regulatory Budgets and the Future of Cost-Benefit Analysis,* 3 Bus. Entrepreneurship & Tax L. Rev. 206, at 216 (2019).

[269] *See* FDA Reauthorization Act of 2017, Public Law 115–52 (Aug. 18, 2017).

[270] OECD, Reviewing the Stock of Regulation, at 25 (2020).

[271] *Legislation Act 2003* (Cth) (Austl.)

[272] Australian Gov't Att'y Gen.'s Dep't, Guide to Managing the Sunsetting of Legislative Instruments, at 6 (July 2020), *https://www.ag.gov.au/sites/default/files/2020-07/Guide%20to%20Managing%20Sunsetting%20of%20Legislative%20Instruments.pdf.*

[273] ''Federal Register of Legislation,'' Australian Government, accessed November 30, 2020, *https://www.legislation.gov.au/Browse/Results/BySunsetDate/LegislativeInstruments/SunsettingSoon/2022/0/0/.*

[274] *Id.* at 3.

[275] OECD, Regulatory Policy in Korea: Towards Better Regulation (2017).

[276] *Id.* at 20.

[277] *Id.*at 71.

[278] *Id.* at 41.

[279] *Id.* at 84.

[280] Personal communication with an official from the New Jersey Office of Administrative Law (Dec. 9, 2020).

[281] Personal communication with an official from the Missouri Office of the Attorney General (Dec. 31, 2020).

[282] Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the*

Continued

Of these, 5,542 were sent back through the rule adoption process (28.6%), presumably to be updated, and 11,811 rules were automatically re-upped with no change (61.0%). About 10 percent of regulations reviewed under the recent sunset review process were rescinded,[283] and this occurred under the supervision of the state Rules Review Commission that was overseeing the process.

These numbers reinforce that there is little empirical basis to support fears that thousands of regulations might accidentally expire as a result of the Department's final regulation. The experiences in Idaho, New Jersey, Missouri and North Carolina demonstrate that sunset reviews tend to be orderly processes. Even in states like Idaho and Rhode Island, where significant portions of their regulatory codes were eliminated in recent years, these processes took place in an orderly fashion under the supervision of the state budget offices in those states.

Moreover, the Department has built in safeguards to prevent inadvertent expiration of regulations, such as seeking comment on the proposed rule regarding regulations that are important to Assess and Review, and enabling the public to submit comments requesting that the Department commence an Assessment or Review. Most importantly, the Department plans to release a list of when all of the regulations under its authority were created and last modified. This can be used to easily determine the expiration date of all regulations under its authority, which will significantly lower the chance any regulation might expire accidentally. The fact that a schedule of the Department's rules, along with their corresponding creation and modification dates, will be made public by the Department means the public will also be aware of which rules are scheduled to expire and when, thereby providing an additional safeguard against accidental expirations. Additionally, the timeline for initial reviews of older regulations has also been extended to five years in this final rule, with the option of a one-year extension, which should give the Department ample time to conduct Assessments and Reviews and should result in few, if any, accidental expirations.

One might worry that periodic reviews may distract from other potentially beneficial rulemakings, which could impose a cost that the Department has not fully considered in the proposed rule. However, there is some indication that when regulators are undergoing retrospective review efforts, if a rulemaking is an urgent priority to them, they often find ways to justify it as part of their reviews, even if the rulemaking would have occurred absent the review.[284] In other words, regulators maintain some flexibility to enact necessary new regulations by folding them into retrospective reviews, including the amendment and rescission process, alleviating some of the concern raised by the commenters. To the extent that any new rulemaking is displaced as a result of reviews required by the current regulation, it is likely to be the case that relatively lower priority rulemakings are displaced first (as presumably the Department will first implement high priority regulations before moving on to lower priority regulations).

Unfortunately, it is unknown with certainty whether Department rules impose benefits in excess of costs on average. The vast majority of Department rules do not have cost-benefit reports associated with them. Even for those that do, there are large uncertainties, and the literature suggests that many regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated.[285] This suggests that if a regulation did expire accidentally, this could be a cost or a benefit of this final rule, depending on the circumstances, since it is unknown whether the net benefits of the preponderance of Department rules are positive or negative. Regulations that are rescinded through sunset procedures are sometimes obviously problematic, such that their removal is uncontroversial. And if a regulation accidentally expired, it could very well be because neither the Department nor interested members of the public saw a discernible benefit from the regulation. Regulations with discernible benefits are unlikely to go under the radar.

A related concern in comments is that Assessments and Reviews will take Department time and resources away from responding to the COVID–19 pandemic. Under this final rule, no Assessments or Reviews need to be completed until the end of 2026, well after the COVID–19 pandemic is likely to have subsided. Hence it is unlikely that this final rule will hamper the response to the pandemic.

The Department recognizes that this final rule requires the Department to undertake certain tasks. But given the importance of retrospective review, the Department believes that review should be a priority and it is willing to commit the necessary resources towards performing Assessments and Reviews.[286]

The expertise of Department analysts may also be best leveraged through Assessments and Reviews that could facilitate the Department's response to future pandemics or emergencies. As noted earlier, the Department waived or exercised enforcement discretion with respect to many regulations as part of its response to the pandemic. A review of those regulations is entirely appropriate to determine whether those regulations are undermining Department goals. Additionally, the COVID–19 pandemic has raised serious questions about whether certain Department regulations are protecting public health or otherwise achieving their objectives. In fact, it is possible that in the coming years even absent this final rule the Department would find it necessary to conduct in-depth reviews of Department regulations given the need to suspend, waive, or exercise enforcement discretion with respect to certain regulations during the COVID–19 pandemic. If such reviews would have taken place even absent this final rule, the cost of this final rule could be significantly lower than estimated (since those costs would be built into the baseline scenario).

Some commenters cited a report that stated ''sunset requirements produce perfunctory reviews and waste

process, The John Locke Found.: The Locker Room (July 22, 2019), *https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/.*

[283] Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the process,* The John Locke Found.: The Locker Room (July 22, 2019), *https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/.*

[284] Randall Lutter, *Regulatory Policy: What Role for Retrospective Analysis and Review?,* 4 J. Benefit-Cost Analysis 17 (2013).

[285] Office of Mgmt. & Budget, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities,* at 46–47 (2005) *http://perma.cc/R8LX-BQMJ* (collecting studies comparing ex ante and ex post analyses of regulations' costs and benefits, including examples where cost and benefit estimates were off by more than a factor of ten); Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation,* at 33 (Resources for the Future, Discussion Paper No. 06–39, 2006), *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357.;* Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation,* 9 J. Benefit-Cost Analysis 285, at 294 (2018).

[286] *See also In re Barr Labs., Inc.,* 930 F.2d 72, 76 (D.C. Cir. 1991) (courts ''have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.'').

resources.'' [287] Indeed, the same report was cited in the preamble of the proposed version of this rule. However, as noted in the proposed rule's preamble, this statement from the report does not appear to be supported by the evidence. For example, the report noted that some states have repealed their sunset provisions, highlighting that ''North Carolina was first to repeal its sunset law, and many other states quickly followed suit,'' and concluded that ''sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control.'' [288] However, North Carolina reenacted a sunset process for regulations in 2013 [289] (after the report in question was published). Moreover, not every jurisdiction uses sunset provisions as a mechanism for enhancing legislative control. As already noted, the purpose of sunset provisions is often to spur retrospective review and analysis of regulation or legislation, not necessarily to empower the legislative branch of government. Nor is it the Department's intention with this final rule to enhance legislative control, but instead to encourage more retrospective review and improve outcomes resulting from the Department's regulations.

Sunset provisions are set up in institutionally diverse ways across diverse jurisdictions. Different jurisdictions set different expiration time horizons on rules and grant authority to different governing bodies to decide whether regulations should be extended or not. New Jersey and Indiana grant the authority to renew regulations to the regulating agency, not the legislature (similar to this final rule). Meanwhile, Idaho and Tennessee task the legislature with renewing regulations.

While legal scholars have sometimes argued that sunset provisions have a useful role to play in strengthening legislative control,[290] sunset provisions' benefits in terms of improving the impacts of regulations are equally if not more important than these legislative oversight or separation of powers issues. It may be the case that sometimes legislators do not want or do not have time to devote to in-depth reviews of large numbers of regulations, which is perhaps why sunset reviews that engage the legislature have sometimes turned into pro forma exercises.[291] In other words, it seems likely that the criticisms of sunset provisions that have appeared sporadically in the academic literature may relate to whether sunsets spur legislative engagement in rulemaking, rather than whether they are useful in terms of spurring retrospective review (where there seems to be less controversy).

To conclude, the Department acknowledges that some categories of costs have not been quantified here. While other categories of costs do exist than those calculated in table 4, they may be subject to greater uncertainty, be more challenging to estimate, or be relatively minor such that their estimation would not substantially alter the conclusions of this cost analysis.

As is common practice, this regulatory impact analysis has not sought to quantify the benefits of this final rule, but the Department believes they will be substantial.

E. Summary of Regulatory Impact Analysis

A forcing mechanism will help ensure robust compliance with the Department's statutory obligations, which will strengthen the rule of law in the United States. Given how much of federal spending is driven by Department spending, regulatory reviews may also constitute a way to cut the federal budget deficit. If the Department is not able to review its own regulations in a timely manner, it is not clear how any member of the public can be expected to comply with all of the regulations the Department has written for them (plus all of the regulations issued by other federal, state, and local agencies). Fortunately, the Department intends to timely Assess and (where needed) Review those regulations not exempt from this final rule. Even if for some reason the Department cannot, it has provided itself an opportunity to delay the expiration date where the public interest requires so doing.

Regulatory Flexibility Act

The Department has examined the economic implications of this final rule as required by the RFA (5 U.S.C. 601–612). The RFA generally requires that when an agency issues a proposed rule, or a final rule pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6). Except for such small government jurisdictions, neither State nor local governments are ''small entities.'' Similarly, for purposes of the RFA, individual persons are not small entities. The requirement to conduct a regulatory impact analysis does not apply if the head of the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the rule, ''along with a statement providing the factual basis for such certification.'' *Id.* If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).

The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. Department regulations impact at least NAICS industry sectors 11, 31–33, 42, 44–45, 48–49, 52, 54, 62, 81, and 92.

The Regulatory Impact Analysis in the prior section also satisfies the Department's obligation to conduct a regulatory flexibility analysis under section 604. For the reasons described in this final rule, this final rule will benefit small entities.

Congressional Review Act

The Congressional Review Act (CRA) defines a ''major rule'' as ''any rule that the Administrator of the Office of Information and Regulatory Affairs

[287] Jason A. Schwartz, *52 Experiments with Regulatory Review,* Inst. for Pol'y Integrity, at 24 (Nov. 2010), *https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.*

[288] *Id.* at 33.

[289] Regulatory Reform Act of 2013, H.B. 74, 2013 Gen. Assemb., 2013 Sess. (N.C. 2013).

[290] Jonathan H. Adler & Christopher Walker, *Delegation and Time,* 105 Iowa L. Rev. 1931 (2020).

[291] Robert W. Hahn, *State and Federal Regulatory Reform: A Comparative Analysis,* 29 The J. Legal Stud. 873 (2000).

(OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA. The Department will comply with the CRA's requirements to inform Congress.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $156 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule.

National Environmental Policy Act (NEPA)

HHS has determined that the proposed rule will not have a significant impact on the environment.

Executive Order 12988: Civil Justice Reform

HHS has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this final rule complies with this Executive Order.

Executive Order 13132: Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct costs on State and local governments or has federalism implications. The Department has determined that this final rule does not impose substantial direct costs on State and local governments or have federalism implications as defined in Executive Order 13132. The final rule requires the Department to periodically review certain of its regulations, and provides that if the regulations are not reviewed by a certain date, they will expire. Any rescission of a regulation would only occur because of acts independent of this final rule—either the findings of a Review determining a regulation should be amended, or a failure to perform an Assessment or Review. Thus, this final rule would impose no substantial direct costs on State and local governments.

The Department notes, though, that this final rule might indirectly have beneficial federalism implications. Among other things, the Reviews called for by this final rule require the Department to determine if certain Department regulations overlap, duplicate or conflict with State and local government rules and, if so, to consider that when determining whether to amend or rescind the regulations. If a Review conducted pursuant to this final rule were to find that a Department regulation should be amended or rescinded, the Department would comply with Executive Order 13132 in amending or rescinding the regulation.

Plain Writing Act of 2010

Under the Plain Writing Act of 2010 (Pub. L. 111–274, October 13, 2010), executive departments and agencies are required to use plain language in documents that explain to the public how to comply with a requirement the federal government administers or enforces. The Department has attempted to use plain language in promulgating this proposed rule, consistent with the Federal Plain Writing Act guidelines.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. Section 601 (note) required agencies to assess whether a regulatory action (1) impacted the stability or safety of the family, particularly in terms of marital commitment; (2) impacted the authority of parents in the education, nurturing, and supervision of their children; (3) helped the family perform its functions; (4) affected disposable income or poverty of families and children; (5) was justified if it financially impacted families; (6) was carried out by State or local government or by the family; and (7) established a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.

This final rule would apply to and amend certain Department regulations to add dates by which they would expire unless the Department periodically reviews the regulations using certain criteria. Standing alone, absent the failure to perform an Assessment or Review, this final rule would have no direct impact, other than resulting in the Department amending or rescinding Regulations that it determines do not satisfy the Review criteria.

If the family well-being determination requirement were still in force, for the reasons described in this final rule's Regulatory Impact Analysis, the Department concludes that the benefits to the public, including families, that flow from periodic Assessments and Reviews of Regulations far outweigh any potential adverse impact on family well-being that might result from a regulation expiring because the Department did not Assess or Review it. The Department believes that impacted families benefit greatly when a regulatory body considers the real-world impacts of its regulations, and whether changes in technology, the economy, or the legal landscape counsel in favor of amending or rescinding regulations. It is conceivable that a regulation affecting the disposable income or poverty of families or children could expire. It is also possible that the expiration of a regulation that the Department does not Review could have beneficial impacts on family well-being. If, pursuant to this final rule, the Department amends or rescinds a regulation, it would conduct any required assessment of the policy on families at the time of such rulemaking.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), HHS has reviewed this final rule and has determined that there are no new collections of information contained therein.

List of Subjects

21 CFR Part 6

Administrative practice and procedure.

42 CFR Part 1

Administrative practice and procedure.

42 CFR Part 404

Administrative practice and procedure.

42 CFR Part 1000

Administrative practice and procedure.

45 CFR Part 8

Administrative practice and procedure.

45 CFR Part 200

Administrative practice and procedure.

45 CFR Part 300

Administrative practice and procedure.

45 CFR Part 403

Administrative practice and procedure.

45 CFR Part 1010

Administrative practice and procedure.

45 CFR Part 1390

Administrative practice and procedure.

For the reasons set forth in the preamble, the Department amends 21 CFR, chapter I, 42 CFR chapters I, IV, and V; 45 CFR subtitle A; and 45 CFR subtitle B, chapters II, III, IV, X, and XIII, as follows:

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 1. Add part 6 to read as follows:

PART 6—REVIEW OF REGULATIONS

Sec.
6.1 Retrospective Review of Existing Regulations.
6.2 through 6.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 15 U.S.C. 402; 15 U.S.C. 409; 15 U.S.C. 1261–1276; 15 U.S.C. 1333; 15 U.S.C. 1451–1461; 15 U.S.C. 4402; 18 U.S.C. 1905; 19 U.S.C. 1490–1491; 19 U.S.C. 2531–2582; 21 U.S.C. 41–50; 21 U.S.C. 141–149; 21 U.S.C. 301 *et seq.;* 21 U.S.C. 355 note; 21 U.S.C. 301–397; 21 U.S.C. 467f; 21 U.S.C. 679; 21 U.S.C. 821; 21 U.S.C. 1034; 21 U.S.C. 1401–1403; 28 U.S.C. 2112; 35 U.S.C. 156; 42 U.S.C. 201–262; 42 U.S.C. 263a; 42 U.S.C. 263b–263n; 42 U.S.C. 264; 42 U.S.C. 265; 42 U.S.C. 271; 42 U.S.C. 300aa–28; 42 U.S.C. 300u–300u–5; 42 U.S.C. 4321; 42 U.S.C. 4332, 42 U.S.C. 7671 *et seq.;* Sec. 121, Pub. L. 105–115, 111 Stat. 2296; Pub. L. 107–109; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 108–155; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776; Secs. 901(b) and 906(d), Pub. L. 111–31; Pub. L. 111–353, 124 Stat. 3885, 3889; Pub. L. 113–54.

§ 6.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not

feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) 21 CFR parts 131, 133, 135–137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163–166, 168, and 169.

(9) 21 CFR parts 331–333, 335–336, 338, 340–341, 343–344, 346–350, 352, 355, 357, and 358.

(10) 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 895, and 898.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 6.2 through 6.5 [Reserved].

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 2. Add part 1 to read as follows:

PART 1—REVIEW OF REGULATIONS

Sec.
1.1 Retrospective Review of Existing Regulations
1.2 through 1.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610, 8 U.S.C. 1182, 8 U.S.C. 1222, 29 U.S.C. 670(a), 30 U.S.C. 957, 31 U.S.C. 9701, 42 U.S.C. 216, 42 U.S.C. 241, 42 U.S.C. 300a-4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 1395hh, 42 U.S.C. 702(a), 42 U.S.C. 702(b)(1)(A), 42 U.S.C. 706(a)(3), 42 U.S.C. 243, 42 U.S.C. 247b, 247c, 42 U.S.C. 247d–6e, 31 U.S.C. 1243 note, 42 U.S.C. 252, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 256b, 42 U.S.C. 263, 42 U.S.C. 263a, 42 U.S.C. 264–271, 42 U.S.C. 273–274d; 42 U.S.C. 274e; 42 U.S.C. 290aa(m), 42 U.S.C. 284g, 42 U.S.C. 285a–6(c)(1)(E), 42 U.S.C. 285a–7(c)(1)(G), 42 U.S.C. 285b–4, 42 U.S.C. 285c–5, 42 U.S.C. 285c–8, 42 U.S.C. 285d–6, 42 U.S.C. 285e–2, 42 U.S.C. 285e–3, 42 U.S.C. 285e–10a, 42 U.S.C. 285f–1, 42 U.S.C. 285g–5, 42 U.S.C. 285g–7, 42 U.S.C. 285g–9, 42 U.S.C. 285m–3, 42 U.S.C. 285o–2, 42 U.S.C. 286a–7(c)(1)(G), 42 U.S.C. 287c–32(c), 42 U.S.C. 288, 42 U.S.C. 289a, 42 U.S.C. 289b, 42 U.S.C. 290aa, *et seq.,* 42 U.S.C. 290aa(d), 42 U.S.C. 290aa(m), 42 U.S.C. 290cc–21, *et seq.,* 42 U.S.C. 290dd–2, 42 U.S.C. 290kk, *et seq.,* 42 U.S.C. 300 through 300a-6, 42 U.S.C. 300cc–16, 42 U.S.C. 300mm-300mm-61, 42 U.S.C. 300x–21, et seq, 42 U.S.C. 7384n, 42 U.S.C. 7384q, 42 U.S.C. 6939a.

§ 1.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if

required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) 42 CFR part 73.

(9) 42 CFR 100.3.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 1.2 through 1.5 [Reserved]

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 3. Add part 404 to subchapter A to read as follows:

PART 404—REVIEW OF REGULATIONS

Sec.

404.1 Retrospective Review of Existing Regulations
404.2 through 404.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 31 U.S.C. 9701; 42 U.S.C. 263a; 42 U.S.C. 273; 42 U.S.C. 300e; 42 U.S.C. 300e–5; 42 U.S.C. 300e–9; 42 U.S.C. 405(a), 42 U.S.C. 1302; 42 U.S.C. 1306; 42 U.S.C. 1315a; 42 U.S.C. 1320a–7; 42 U.S.C. 1320a–7j; 42 U.S.C. 1320b–8; 42 U.S.C. 1320b–12; 42 U.S.C. 1395; 42 U.S.C. 1395aa(m); 42 U.S.C. 1395cc; 42 U.S.C. 1395d(d); 42 U.S.C. 1395ddd; 42 U.S.C. 1395eee(f); 42 U.S.C. 1395f(b); 42 U.S.C. 1395ff; 42 U.S.C. 1395g; 42 U.S.C. 1395hh; 42 U.S.C. 1395i; 42 U.S.C. 1395i–3; 42 U.S.C. 1395*l*(a), (i), (n), and (t); 42 U.S.C. 1395jjj; 42 U.S.C. 1395kk; 42 U.S.C. 1395m; 42 U.S.C. 1395nn; 42 U.S.C. 1395rr; 42 U.S.C. 1395rr(b)(l); 42 U.S.C. 1395tt; 42 U.S.C. 1395w–5; 42 U.S.C. 1395w–101 through 1395w–152; 42 U.S.C. 1395ww; 42 U.S.C. 1395ww(k); 42 U.S.C. 1395x; 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)); 42 U.S.C. 1395x(v); 42 U.S.C. 1395y(a); 42 U.S.C. 1396r; 42 U.S.C. 1396r–8; 42 U.S.C. 1396u–4(f); 44 U.S.C. Chapter 35; Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–

148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat 1029); Pub. L. 112–202 amendments to 42 U.S.C. 263a; sec. 105, Pub. L. 114–10, 129 Stat. 87.

§ 404.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) The annual Medicare payment update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 404.2 through 404.5 [Reserved]

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 4. Add subpart A to part 1000 to read as follows:

PART 1000—Introduction, General Definitions

Subpart A—Review of regulations

Sec.
1000.1 Retrospective Review of Existing Regulations
1000.2 through 1000.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 31 U.S.C. 6101 note; 42 U.S.C. 262a; 42 U.S.C. 405(a); 42 U.S.C. 405(b); 42 U.S.C. 405(d); 42 U.S.C. 405(e); 42 U.S.C. 1302; 42 U.S.C.1320; 42 U.S.C. 1320a–7d(b); 1320b–10; 42 U.S.C. 1320c–5; 42 U.S.C. 1395cc(b)(2)(D), (E), and (F); 42 U.S.C. 1395cc(j); 42 U.S.C. 1395dd(d)(1); 42 U.S.C. 1395hh; 42 U.S.C. 1395mm; 42 U.S.C. 1395nn(g); 42 U.S.C. 1395ss(d); 42 U.S.C. 1395u(j); 42 U.S.C. 1395u(k); 42 U.S.C. 1395w–104(e)(6); 42 U.S.C. 1395w–141(i)(3); 42 U.S.C. 1395y(d); 42 U.S.C. 1395y(e); 42 U.S.C. 1396(a)(4)(A); 42 U.S.C. 1396a(p); 42 U.S.C. 1396a(a)(39); 42 U.S.C. 1396a(a)(41); 42 U.S.C. 1396a(a)(61); 42 U.S.C. 1396b(a)(6); 42 U.S.C. 1396b(b)(3); 42 U.S.C. 1396b(i)(2); 42 U.S.C. 1396b(m); 42 U.S.C. 1396b(q); 42 U.S.C. 1842(j)(1)(D)(iv); 42 U.S.C. 1842(k)(1); 42 U.S.C. 11131(c); 42 U.S.C. 11137(b)(2).

§ 1000.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the

Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) 42 CFR 1001.952.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 1000.2 through 1000.5 [Reserved]

Title 45—Public Welfare

Subtitle A—Department of Health and Human Services

■ 5. Add part 8 to read as follows:

PART 8—REVIEW OF REGULATIONS

Sec.
8.1 Retrospective Review of Existing Regulations
8.2 through 8.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 504(c)(1); 5 U.S.C. 552; 5 U.S.C. 552a; 5 U.S.C. 553; 5 U.S.C. 5514; 5 U.S.C. 7301; 8 U.S.C. 1182(e)); 8 U.S.C. 1182(j)(2)(A); 18 U.S.C. 207(j); 18 U.S.C. 1905; 20 U.S.C. 91; 20 U.S.C. 1405; 20 U.S.C. 1681 *et seq.;* 20 U.S.C. 1681 through 1688; 21 U.S.C. 1174; 22 U.S.C. 2151b(f) (*e.g.,* Pub. L. 116–6, Div. F, sec. 7018); 22 U.S.C. 2451 *et seq.;* 22 U.S.C. 7631(d); 22 U.S.C. 7631(f); 26 U.S.C. 36B; 26 U.S.C. 5000A(d)(2); 28 U.S.C. 2672; 29 U.S.C. 669(a)(5); 29 U.S.C. 794; 31 U.S.C. 1243 note; 31 U.S.C. 1352; 31 U.S.C. 3711(d); 31 U.S.C. 3720A; 31 U.S.C. 3720D; 31 U.S.C. 3721; 31 U.S.C. 3801–3812; 31 U.S.C. 6506; 31 U.S.C. 7501–7507; 31 U.S.C. 9701; 40 U.S.C. 121(c); 40 U.S.C. 318–318d; 40 U.S.C. 484; 40 U.S.C. 484(k); 40 U.S.C. 486; 42 U.S.C. 216; 42 U.S.C. 216(b); 42 U.S.C. 238n; 42 U.S.C. 263a(f)(1)(E); 42 U.S.C. 280g–1(d); 42 U.S.C. 289(a); 42 U.S.C. 289b–1; 42 U.S.C. 290bb–36(f); 42 U.S.C. 290dd–2; 42 U.S.C. 299c–4; 42 U.S.C. 300a–7; 42 U.S.C. 300aa–11; 42 U.S.C. 300gg through 300gg–63; 42 U.S.C. 300gg–1 through 300gg–5; 42 U.S.C. 300gg–11 through 300gg–23; 42 U.S.C. 300gg–18; 42 U.S.C. 300gg–91; 42 U.S.C. 300gg–92; 42 U.S.C. 300gg–94; 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 42 U.S.C. 300jj–52; 42 U.S.C. 300w *et seq.;* 42 U.S.C. 300x *et seq.;* 42 U.S.C. 300y *et seq.;* 42 U.S.C. 618; 42 U.S.C. 622(b); 42 U.S.C. 629b(a); 42 U.S.C. 652(a); 42 U.S.C. 652(d); 42 U.S.C. 654A; 42 U.S.C. 671(a); 42 U.S.C. 701 *et seq.;* 42 U.S.C. 1302; 42 U.S.C. 1302(a); 42 U.S.C. 1306(c); 42 U.S.C. 1310; 42 U.S.C. 1315; 42 U.S.C. 1315a; 42 U.S.C. 1320a–1; 42 U.S.C. 1320a–7e; 42 U.S.C. 1320c–11; 42 U.S.C. 1395cc(f); 42 U.S.C. 1320d–2 (note); 42 U.S.C. 1320d–1320d–9; 42 U.S.C. 1395i–3; 42 U.S.C. 1395i–5; 42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1395w–26; 42 U.S.C. 1395w–27; 42 U.S.C. 1395x; 42 U.S.C. 1396a; 42 U.S.C. 1396a(a); 42 U.S.C. 1396a(w)(3); 42 U.S.C. 1396f; 42 U.S.C. 1396r; 42 U.S.C. 1396r–2; 42 U.S.C. 1396s(c)(2)(B)(ii); 42 U.S.C. 1396u–2(b)(3)(B); 42 U.S.C. 1397 *et seq.;* 42 U.S.C. 1397j–1(b); 42 U.S.C. 2000d *et seq.;* 42 U.S.C. 2000d–1; 42 U.S.C. 2942; 42 U.S.C. 3334; 42 U.S.C. 3505; 42 U.S.C. 3535(d); 42 U.S.C. 5106i(a); 42 U.S.C. 6101 *et seq.;* 42 U.S.C. 8621 *et seq.;* 42 U.S.C. 9858; 42 U.S.C. 9901 *et seq.;* 42 U.S.C. 11101–11152; 42 U.S.C. 11411; 42 U.S.C. 14406; 42 U.S.C. 18021–18024; 42 U.S.C. 18031–18033; 42 U.S.C. 18041(a); 42 U.S.C. 18041–18042; 42 U.S.C. 18044; 42 U.S.C. 18051; 42 U.S.C. 18054; 42 U.S.C. 18061 through 18063; 42 U.S.C. 18071; 42 U.S.C. 18081–18083; 42 U.S.C. 18113; 42 U.S.C. 18116; 48 U.S.C. 1469a; 50 U.S.C. App. 2061–2171; 27 Stat. 395; Sec. 1(a), 80 Stat. 306; secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix; Sec. 203, 63 Stat. 385; Section 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Pub. L. 91–646, 84 Stat. 1894 (42 U.S.C. 4633) as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100–17, 101 Stat. 246–256 (42 U.S.C. 4601 note); Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539: 42 U.S.C. 217b; Sec. 602, 78 Stat. 252; Sec. 501 of Pub. L. 100–77, 101 Stat. 509–10, 42 U.S.C 11411; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988); 5 U.S.C. 301, Pub. L. 100–259, 102 Stat. 28 (Mar. 22 1988); Public Law 101–410, Sec. 701 of Public Law 114–74, 31 U.S.C. 3801–3812; Section 5301 of Pub. L. 100–690, the Anti–Drug Abuse Act of 1988, 102 Stat. 4310, 21 U.S.C. 853a; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148); Section 1103 of the Patient Protection and Affordable Care Act (Pub. L. 111–148); secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917; Title I of the Affordable Care Act, Sections 1311, 1312, 1411, 1412, Pub. L. 111–148, 124 Stat. 119; Medicare Advantage (*e.g.,* Pub. L. 115–245, Div. B, sec. 209); the Weldon Amendment (*e.g.,* Pub. L. 115–245, Div. B, sec. 507(d)); 5 U.S.C. 610.

§ 8.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this subtitle.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in

consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) The annual Notice of Benefit and Payment Parameters update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by

which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 8.2 through 8.5 [Reserved]

Subtitle B—Regulations Relating to Public Welfare

CHAPTER II—OFFICE OF FAMILY ASSISTANCE (ASSISTANCE PROGRAMS), ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 6. Add part 200 to read as follows:

PART 200—REVIEW OF REGULATIONS

Sec.
200.1 Retrospective Review of Existing Regulations
200.2 through 200.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 24 U.S.C. 321–329; 31 U.S.C. 7501 *et seq.;* 42 U.S.C. 301; 42 U.S.C. 303; 42 U.S.C. 601; 42 U.S.C. 601 note; 42 U.S.C. 602; 42 U.S.C. 602 (note); 42 U.S.C. 602(a)(44); 42 U.S.C. 603; 42 U.S.C. 603(a)(4); 42 U.S.C. 604; 42 U.S.C. 605; 42 U.S.C. 606; 42 U.S.C. 607; 42 U.S.C. 608; 42 U.S.C. 609; 42 U.S.C. 610; 42 U.S.C. 611; 42 U.S.C. 612; 42 U.S.C. 613; 42 U.S.C. 613(i); 42 U.S.C. 616; 42 U.S.C. 619; 42 U.S.C. 654; 42 U.S.C. 862a; 42 U.S.C. 1202; 42 U.S.C. 1203; 42 U.S.C. 1301; 42 U.S.C. 1302; 42 U.S.C. 1306(a); 42 U.S.C. 1308; 42 U.S.C. 1313; 42 U.S.C. 1316; 1320b–7: 42 U.S.C. 1973gg–5; 42 U.S.C. 1337; 42 U.S.C. 1352; 42 U.S.C. 1353; 42 U.S.C. 1382 (note); 42 U.S.C. 1383 (note); sections 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 67 Stat. 631; Secs. 1–11, 74 Stat. 308–310; Sec. 302, 75 Stat. 142, sec. 1102, 49 Stat. 647; sec. 6 of Pub. L. 94–114, 89 Stat. 579; Pub. L. No. 97–248, 96 Stat. 324, and Pub. L. No. 99–603, 100 Stat. 3359; sec. 4 of Pub. L. 97–458, 96 Stat. 2513; sec. 2 of Pub. L. 98–64, 97 Stat. 365; sec. 1883 of Pub. L. 99–514, 100 Stat. 2916; sec. 15 of Pub. L. 100–241, 101 Stat. 1812; sec. 105(f) of Pub. L. 100–383, 102 Stat. 908; sec. 206(d) of Pub. L. 100–383, 102 Stat. 914; sec. 105(i) of Pub. L. 100–707, 102 Stat. 4693; sec. 1(a) of Pub. L. 101–201, 103 Stat. 1795; sec. 10405 of Pub. L. 101–239, 103 Stat. 2489; sec. 501(c) of Pub. L. 101–392, 104 Stat. 831; sec. 6(h)(2) of Pub. L. 101–426, 104 Stat. 925; and sec. 471(a) of Pub. L. 102–325, 106 Stat. 606; Sec. 7102, Pub. L. 109–171, 120 Stat. 135; Public Law 111–5; Sec. 4004, Pub. L. 112–96, 126 Stat. 197; 49 Stat. 647.

§ 200.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting.The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 200.2 through 200.5 [Reserved]

CHAPTER III—OFFICE OF CHILD SUPPORT ENFORCEMENT (CHILD SUPPORT ENFORCEMENT PROGRAM), ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 7. Add part 300 to read as follows:

PART 300—REVIEW OF REGULATIONS

Sec.

300.1 Retrospective Review of Existing Regulations
300.2 through 300.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 25 U.S.C. 1603(12); 25 U.S.C. 1621e; 42 U.S.C. 609(a)(8); 42 U.S.C. 651 through 658; 42 U.S.C. 652(a)(4) and (g); 42 U.S.C. 654(15)(A); 42 U.S.C. 655(f); 42 U.S.C. 658a; 42 U.S.C. 659a; 42 U.S.C. 660; 42 U.S.C. 663; 42 U.S.C. 664; 42 U.S.C. 666 through 669A; 42 U.S.C. 1301; 42 U.S.C. 1302; 42 U.S.C. 1396a(a)(25); 42 U.S.C. 1396b(d)(2); 42 U.S.C. 1396b(o); 42 U.S.C. 1396b(p); 42 U.S.C. 1396(k).

§ 300.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination,

which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 300.2 through 300.5 [Reserved]

CHAPTER IV—OFFICE OF REFUGEE RESETTLEMENT, ADMINISTRATION FOR CHILDREN AND FAMILIES DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 8. Add part 403 to read as follows:

PART 403—REVIEW OF REGULATIONS

Sec.
403.1 Retrospective Review of Existing Regulations
403.2 through 403.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 6 U.S.C. 279; 8 U.S.C. 1103(a)(3); 8 U.S.C. 1232; 8 U.S.C. 1255a note; 8 U.S.C. 1522 note; 8 U.S.C. 1522(a)(9); 42 U.S.C. 15607(d).

§ 403.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 403.2 through 403.5 [Reserved]

CHAPTER X—OFFICE OF COMMUNITY SERVICES, ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 9. Add part 1010 to read as follows:

PART 1010—REVIEW OF REGULATIONS

Sec.
1010.1 Retrospective Review of Existing Regulations
1010.2 through 1010.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 42 U.S.C. 604 nt.; 42 U.S.C. 9901 *et seq.;* 42 U.S.C. 11302 (101 Stat. 485); 42 U.S.C. 11461–11464; 42 U.S.C. 11472 (101 Stat. 532–533).

§ 1010.1 Retrospective Review of Existing Regulations

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 1010.2 through 1010.5 [Reserved]

CHAPTER XIII—ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 10. Add subchapter A to read as follows:

SUBCHAPTER A—[include your preferred subchapter heading]

PART 1300—REVIEW OF REGULATIONS

Sec.

1300.1 Retrospective Review of Existing Regulations.
1300.2 through 1390.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 29 U.S.C. 709; 29 U.S.C. 3343; 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.;* 42 U.S.C. 1302; 42 U.S.C. 1395b–4; 42 U.S.C. 2991, *et seq.;* 42 U.S.C. 3001 *et seq.;* Title III of the Older Americans Act; 42 U.S.C. 3001; Title VI, Part A of the Older Americans Act; 42 U.S.C. 3001; Title VI Part B of the Older Americans Act; 42 U.S.C. 3515e; 42 U.S.C. 5701; 42 U.S.C. 9801 *et seq.;* 42 U.S.C. 10401 *et seq.;* 42 U.S.C. 15001 *et seq.*

§ 1300.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(b) For purposes of this section,

(1) *Assess* shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Sections issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) *Review* shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section first became effective, irrespective of whether it was subsequently amended.

(5) *Significant economic impact upon a substantial number of small entities* shall have the meaning of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

(i) Five calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Section's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this section) reviewed the Section, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors:

(1) The continued need for the rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the rulemaking from the public;

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the rulemaking since the rulemaking was

promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) of this section to amend or rescind the Section. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Sections that involve a military or foreign affairs function of the United States.

(5) Sections addressed solely to internal agency management or personnel matters.

(6) Sections related solely to Federal Government procurement.

(7) Sections that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 1300.2 through 1300.5 [Reserved]

Dated: January 8, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00597 Filed 1–15–21; 8:45 am]

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Part VIII

Bureau of Consumer Financial Protection

12 CFR Part 1006

Debt Collection Practices (Regulation F); Final Rule

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1006

[Docket No. CFPB–2019–0022]

RIN 3170–AA41

Debt Collection Practices (Regulation F)

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretation.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is issuing this final rule to revise Regulation F, which implements the Fair Debt Collection Practices Act (FDCPA). The final rule governs certain activities by debt collectors, as that term is defined in the FDCPA. Among other things, the final rule clarifies the information that a debt collector must provide to a consumer at the outset of debt collection communications, prohibits debt collectors from bringing or threatening to bring a legal action against a consumer to collect a time-barred debt, and requires debt collectors to take certain actions before furnishing information about a consumer's debt to a consumer reporting agency.

DATES: This rule is effective on November 30, 2021.

FOR FURTHER INFORMATION CONTACT: Joel Singerman, Counsel, or Dania Ayoubi, Joseph Baressi, Seth Caffrey, Brandy Hood, David Jacobs, Courtney Jean, Adam Mayle, Kristin McPartland, Michael Silver, Senior Counsels, Office of Regulations, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of the Final Rule

The Bureau is finalizing amendments to Regulation F, 12 CFR part 1006, which implements the FDCPA.[1] The amendments prescribe Federal rules governing the activities of debt collectors, as that term is defined in the FDCPA (debt collectors or FDCPA debt collectors). The final rule clarifies the information that a debt collector must provide to a consumer at the outset of debt collection communications and provides a model validation notice containing such information. The final rule also addresses consumer protection concerns related to passive collections (*i.e.,* the practice of furnishing information about a debt to a consumer reporting agency before communicating with the consumer about the debt) and the collection of debt that is beyond the statute of limitations (*i.e.,* time-barred debt). On November 30, 2020, the Bureau published a final rule in the **Federal Register** that focused on debt collection communications and related practices by debt collectors (November 2020 Final Rule). The November 2020 Final Rule reserved certain sections of Regulation F in anticipation of this final rule.

As discussed in the November 2020 Final Rule, in 1977, Congress passed the FDCPA to eliminate abusive debt collection practices by debt collectors, to ensure that those debt collectors who refrain from using abusive debt collection practices are not competitively disadvantaged, and to promote consistent State action to protect consumers against debt collection abuses.[2] The statute was a response to ''abundant evidence of the use of abusive, deceptive, and unfair debt collection practices by many debt collectors.'' [3] According to Congress, these practices ''contribute to the number of personal bankruptcies, to marital instability, to the loss of jobs, and to invasions of individual privacy.'' [4]

The FDCPA established specific consumer protections, enabling consumers to establish controls on when and how debt collectors contact them, establishing privacy protections surrounding the collection of debts, and protecting consumers from certain collection practices. The FDCPA also established broad consumer protections, prohibiting harassment or abuse, false or misleading representations, and unfair practices. In the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), Congress provided the Bureau with authority under the FDCPA to prescribe substantive rules with respect to the collection of debts by debt collectors. The Bureau issues this final rule, like the November 2020 Final Rule, to implement and interpret the FDCPA.

A. Coverage and Organization of the Final Rule

The final rule is based primarily on the Bureau's authority to issue rules to implement the FDCPA and, consequently, covers debt collectors, as that term is defined in the FDCPA.

As revised in the November 2020 Final Rule, Regulation F contains four subparts. Subpart A contains generally applicable provisions, such as definitions that apply throughout the regulation. Subpart B contains rules for FDCPA debt collectors. Subpart C is reserved for any future debt collection rulemakings. Subpart D contains certain miscellaneous provisions. This final rule adds additional provisions in subparts A, B, and D.

B. Scope of the Final Rule

FDCPA section 809(a) requires that a debt collector send a written notice containing certain information about the debt and actions the consumer may take in response (the validation notice) to a consumer within five days of the initial communication, unless such validation information was provided in the initial communication or the consumer has paid the debt.[5] The final rule clarifies the information about the debt and the consumer's rights with respect to the debt that a debt collector must provide to a consumer at the outset of debt collection communications, including (if applicable) on a validation notice. The final rule also requires a debt collector to provide prompts that a consumer can use to dispute the debt, request information about the original creditor, or take certain other actions. The final rule provides a safe harbor for compliance with these disclosure requirements for debt collectors who use the model validation notice or certain variations of the notice.

The final rule also prohibits a debt collector from suing or threatening to sue a consumer to collect time-barred debt. In addition, the final rule prohibits a debt collector from furnishing information about a debt to a consumer reporting agency before engaging in specific outreach to the consumer about the debt. The final rule also addresses certain other disclosure-focused provisions, such as clarifying how a debt collector may respond to a consumer's request for original-creditor information if the original creditor is the same as the current creditor. Additionally, the final rule interprets the definition of consumer under the FDCPA to include deceased natural persons and, relatedly, provides that, if a debt collector knows or should know that the a consumer is deceased, and the debt collector has not previously provided the validation information to the deceased consumer, the debt collector must provide that information to a person who is authorized to act on behalf of the deceased consumer's estate.

[1] 15 U.S.C. 1692 *et seq.*

[2] 15 U.S.C. 1692(e).

[3] 15 U.S.C. 1692(a).

[4] *Id.*

[5] 15 U.S.C. 1692g(a).

II. Background

A. Debt Collection Market Background

A consumer debt is commonly understood to be a consumer's obligation to pay money to another person or entity. Sometimes a debt arises out of a closed-end loan. Other times, a debt arises from a consumer's use of an open-end line of credit, commonly a credit card. And in other cases, a debt arises from a consumer's purchase of goods or services with payment due thereafter. Often there is an agreed-upon payment schedule or date by which the consumer must repay the debt.

For a variety of reasons, consumers sometimes are unable or unwilling to make payments when they are due. Collection efforts may directly recover some or all of the overdue amounts owed to debt owners and thereby may indirectly help to keep consumer credit available and more affordable to consumers.[6] Collection activities also can lead to repayment plans or debt restructuring that may provide consumers with additional time to make payments or resolve their debts on more manageable terms.[7]

The November 2020 Final Rule provides an extensive overview of the debt collection market (including the roles of creditors, third-party debt collectors, debt buyers, and a variety of service providers in the market), methods of debt collection, and consumer protection concerns in debt collection.[8] Below the Bureau summarizes information regarding debt collection methods and consumer protection concerns specifically related to the topics addressed in this final rule.

B. Debt Collection Methods

If a consumer's payment obligations remain unmet, a creditor may send the account to a third-party debt collector to recover on the debt in the third-party debt collector's name. A creditor typically stops communicating with a consumer once responsibility for an account has moved to a third-party debt collector. Active debt collection efforts typically begin with the debt collector attempting to locate the consumer, usually by identifying a valid telephone number or mailing address, so that the debt collector can establish contact with the consumer. Once a debt collector has obtained contact information for a consumer, the debt collector typically will seek to communicate with the consumer to obtain payment on some or all of the debt.

As already noted, FDCPA section 809(a) generally requires a debt collector to provide certain information to a consumer either at the time that, or shortly after, the debt collector first communicates with the consumer in connection with the collection of a debt. The required information includes: (1) Certain details about the debt, such as the amount of the debt and the name of the creditor to whom the debt is owed; and (2) a description of consumer protections, such as the consumer's rights to dispute the debt and to request information about the original creditor. A debt collector may send a validation notice containing the required information as the initial communication to the consumer or send the required information in a validation notice within five days after the initial communication. Currently, validation notices include little or no information about the debt beyond the information specifically listed in FDCPA section 809(a). This information may not be sufficient for the consumer to recognize the debt, particularly if, for example, the amount owed has changed over time due to interest, fees, payment, or credits, or if the debt collector has changed since an original collection attempt.

A debt collector may tailor the collection strategy depending on a variety of factors, including the size and age of the debt and the debt collector's assessment of the likelihood of obtaining money from the consumer. For example, rather than engage in active debt collection efforts by affirmatively locating and contacting consumers, some debt collectors collecting relatively small debts—such as many medical, utility, and telecommunications debts—report the debts to consumer reporting agencies and then wait for consumers to contact them after discovering the debts on their consumer reports.[9]

As discussed in the November 2020 Final Rule, a debt owner may also try to recover on a debt through litigation.[10] And debt collectors sometimes attempt to collect debt for which the applicable statute of limitations has expired. The length of the limitations period for debt collection claims usually varies by State and debt type; most limitations periods are between three and six years, although some are as long as 15 years. Currently, in most States, expiration of the statute of limitations, if raised by the consumer as an affirmative defense, precludes the debt collector from recovering on the debt through litigation, but it does not extinguish the debt itself. If the debt is not extinguished, a debt collector may use non-litigation means, such as letters and telephone calls, to collect a time-barred debt, as long as those means do not violate the FDCPA or other laws.[11]

C. Consumer Protection Concerns

As discussed in the November 2020 Final Rule, each year consumers submit tens of thousands of complaints about debt collection to Federal regulators.[12] A significant proportion of those complaints involve debts that consumers believe they do not owe, which may be because the debt is being collected in error or because the consumer does not recognize the debt. Consumers also file thousands of private actions each year against debt collectors who allegedly have violated the FDCPA, including many cases alleging violations related to the validation notice. Since the Bureau began operations in 2011, it has brought numerous debt collection

[6] *See* Bureau of Consumer Fin. Prot., *Fair Debt Collection Practices Act: CFPB Annual Report 2013,* at 9 (Mar. 20, 2013), *https://www.consumerfinance.gov/data-research/research-reports/annual-report-on-the-fair-debt-collection-practices-act/* (2013 FDCPA Annual Report).

[7] *See id.*

[8] *See* 85 FR 76734, 76735–37 (Nov. 30, 2020).

[9] Bureau of Consumer Fin. Prot., *Consumer Credit Reports: A Study of Medical and Non-Medical Collections,* at 35–36 (Dec. 2014), *http://files.consumerfinance.gov/f/201412_cfpb_reports_consumer-credit-medical-and-non-medical-collections.pdf* (CFPB Medical Debt Report).

[10] *See* 85 FR 76735, 76736 (Nov. 30, 2020).

[11] *See* 85 FR 12672, 12672–73 (Mar. 3, 2020).

[12] *See, e.g.,* Bureau of Consumer Fin. Prot., *Fair Debt Collection Practices Act: CFPB Annual Report 2020,* at 13 (Mar. 2020), *https://files.consumerfinance.gov/f/documents/cfpb_fdcpa_annual-report-congress_03-2020.pdf* (2020 FDCPA Annual Report); Fed. Trade Comm'n, *2019 Consumer Sentinel Network Databook,* at 7 (Jan. 2020), *https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-2019/consumer_sentinel_network_data_book_2019.pdf;* Bureau of Consumer Fin. Prot., *Fair Debt Collection Practices Act: CFPB Annual Report 2019,* at 15–16 (Mar. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_fdcpa_annual-report-congress_03-2019.pdf* (2019 FDCPA Annual Report); Fed. Trade Comm'n, *2018 Consumer Sentinel Network Databook,* at 4, 7 (Feb. 2019), *https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-2018/consumer_sentinel_network_data_book_2018_0.pdf;* Bureau of Consumer Fin. Prot., *Fair Debt Collection Practices Act: CFPB Annual Report 2018,* at 14–15 (Mar. 2018), *https://files.consumerfinance.gov/f/documents/cfpb_fdcpa_annual-report-congress_03-2018.pdf* (2018 FDCPA Annual Report); Fed. Trade Comm'n, *2017 Consumer Sentinel Network Databook,* at 3, 6 (Mar. 2018), *https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-2017/consumer_sentinel_data_book_2017.pdf;* Bureau of Consumer Fin. Prot., *2017 Fair Debt Collection Practices Act: CFPB Annual Report 2017,* at 15–16 (Mar. 2017), *https://files.consumerfinance.gov/f/documents/201703_cfpb_Fair-Debt-Collection-Practices-Act-Annual-Report.pdf* (2017 FDCPA Annual Report); Fed. Trade Comm'n, *Consumer Sentinel Network Data Book for January–December 2016,* at 3, 6 (Mar. 2017), *https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-january-december-2016/csn_cy-2016_data_book.pdf.*

cases against third-party debt collectors, alleging both FDCPA violations and unfair, deceptive, or abusive debt collection acts or practices in violation of the Dodd-Frank Act.[13] In many of these cases, the Bureau has obtained civil penalties, monetary compensation for consumers, and other relief. In its supervisory work, the Bureau similarly has identified many FDCPA violations during examinations of debt collectors. Over the past decade, the Federal Trade Commission (FTC) and State regulators also have brought numerous additional actions against debt collectors for violating Federal and State debt collection and consumer protection laws.

D. FDCPA and Dodd-Frank Act Protections for Consumers

Federal and State governments historically have sought to protect consumers from harmful debt collection practices. From 1938 to 1977, the Federal government primarily protected consumers through FTC enforcement actions against debt collectors who engaged in unfair or deceptive acts or practices in violation of section 5 of the FTC Act.[14] When Congress enacted the FDCPA in 1977, it found that ''[e]xisting laws and procedures for redressing . . . injuries [were] inadequate to protect consumers.'' [15] Congress found that ''[t]here [was] abundant evidence of the use of abusive, deceptive, and unfair debt collection practices by many debt collectors'' and that these practices ''contribute to the number of personal bankruptcies, to marital instability, to the loss of jobs, and to invasions of individual privacy.'' [16]

The FDCPA was enacted, in part, ''to eliminate abusive debt collection practices by debt collectors, [and] to insure that those debt collectors who refrain from using abusive debt collection practices are not competitively disadvantaged.'' [17] Among other things, the FDCPA: (1) Prohibits debt collectors from engaging in harassment or abuse, making false or misleading representations, and engaging in unfair practices in debt collection; (2) restricts debt collectors' communications with consumers and others; and (3) requires debt collectors to provide consumers with disclosures concerning the debts they owe or allegedly owe.

The FDCPA, in general, applies to debt collectors as that term is defined under the statute. As discussed further in the section-by-section analysis of § 1006.2(i) of the November 2020 Final Rule, the FDCPA generally provides that a debt collector is any person: (1) Who uses any instrumentality of interstate commerce or the mails in any business the principal purpose of which is the collection of any debts (*i.e.,* the ''principal purpose'' prong), or (2) who regularly collects, or attempts to collect, directly or indirectly, debts owed or due or asserted to be owed or due to another (*i.e.,* the ''regularly collects'' prong). FDCPA section 803(6) also sets forth several exclusions from the general definition.

Until the creation of the Bureau, no Federal agency was authorized to issue regulations to implement the substantive provisions of the FDCPA. Courts have issued opinions providing differing interpretations of various FDCPA provisions, and there is considerable uncertainty with respect to how the FDCPA applies to communication technologies that have developed since 1977. The Dodd-Frank Act amended the FDCPA to provide the Bureau with authority to ''prescribe rules with respect to the collection of debts by debt collectors.'' [18]

III. Summary of the Rulemaking Process

A. The November 2020 Final Rule

The Bureau issued the November 2020 Final Rule to finalize certain provisions of the proposed rule that the Bureau published in the **Federal Register** on May 21, 2019, to amend Regulation F.[19] Specifically, the November 2020 Final Rule primarily addressed debt collection communications and related practices by debt collectors. The November 2020 Final Rule reserved certain sections of Regulation F in anticipation of this final rule.

B. The 2019 Proposal and 2020 Supplemental Proposal

As noted, on May 21, 2019, the Bureau published a proposed rule (the May 2019 proposal or proposal) in the **Federal Register** to amend Regulation F.[20] The proposal provided a 90-day comment period that would have closed on August 19, 2019. To allow interested persons more time to consider and submit their comments, the Bureau issued an extension of the comment period until September 18, 2019.[21] In response to the May 2019 proposal, the Bureau received more than 14,000 comments from consumers, consumer groups, members of Congress, other government agencies, creditors, debt collectors, industry trade associations, and others. As discussed below, the Bureau has considered those comments in deciding to issue this final rule.

As relevant to this final rule, in the May 2019 proposal, the Bureau proposed to implement and interpret FDCPA section 809(a) and (b) regarding the information that debt collectors must provide to consumers at the outset of debt collection communications and debt collectors' obligations to respond to consumers' disputes and requests for original-creditor information, including if the consumer obligated or allegedly obligated to pay the debt has died. The Bureau also proposed to prohibit debt collectors from bringing or threatening to bring a legal action against a consumer to collect a debt that the debt collector knows or should know is a time-barred debt. And the Bureau proposed to prohibit debt collectors from furnishing information regarding a debt to a consumer reporting agency before communicating with the consumer about the debt.

On February 21, 2020, the Bureau released a supplemental notice of proposed rulemaking to amend Regulation F to require debt collectors to make certain disclosures when collecting time-barred debts (the February 2020 proposal).[22] The February 2020 proposal provided a 60-day comment period that would have closed on May 4, 2020. To allow interested persons more time to consider and submit their comments, the Bureau issued two extensions of the comment period, the first until June 5, 2020, and the second until August 4,

[13] *See, e.g.,* Stipulated Final Judgment and Consent Order, *Consumer Fin. Prot. Bureau* v. *Encore Capital Grp., Inc.,* 3:20–cv–01750 (S.D. Cal. Oct. 15, 2020), *https://www.courtlistener.com/recap/gov.uscourts.casd.686719/gov.uscourts.casd.686719.5.1.pdf;* Consent Order, *In re Asset Recovery Assocs.,* 2019–BCFP–0009 (Aug. 28, 2019), *https://www.consumerfinance.gov/documents/7938/cfpb_asset-recovery-associates_consent-order_2019-08.pdf;* Consent Order, *In re Encore Capital Grp., Inc.,* 2015–CFPB–0022 (Sept. 9, 2015), *http://files.consumerfinance.gov/f/201509_cfpb_consent-order-encore-capital-group.pdf;* Consent Order, *In re Portfolio Recovery Assocs., LLC,* 2015–CFPB–0023 (Sept. 9, 2015), *http://files.consumerfinance.gov/f/201509_cfpb_consent-order-portfolio-recovery-associates-llc.pdf;* Complaint, *Consumer Fin. Prot. Bureau* v. *Nat'l Corrective Grp., Inc.,* 1:15–cv–00899–RDB (D. Md. Mar. 30, 2015), *http://files.consumerfinance.gov/f/201503_cfpb_complaint-national-corrective-group.pdf.*

[14] 15 U.S.C. 45.

[15] 15 U.S.C. 1692(b).

[16] 15 U.S.C. 1692(a).

[17] 15 U.S.C. 1692(e).

[18] FDCPA section 814(d), 15 U.S.C. 1692*l*(d).

[19] *See* 84 FR 23274 (May 21, 2019).

[20] *Id.*

[21] 84 FR 37806 (Aug. 2, 2019).

[22] *See* 85 FR 12672 (Mar. 3, 2020).

2020.[23] In response to the February 2020 proposal, the Bureau received approximately 90 comments from consumers, consumer groups, members of Congress, other government agencies, creditors, debt collectors, industry trade associations, and others. As discussed below, the Bureau has considered those comments in adopting this final rule.

C. Consumer Testing

The Bureau has undertaken two rounds of qualitative disclosure testing and one round of quantitative disclosure testing, all of which have informed this final rule.

First, as discussed in more detail in the May 2019 proposal, the Bureau in 2014 contracted with a third-party vendor, Fors Marsh Group (FMG), to assist with developing, and to conduct qualitative consumer testing of the model validation notice.[24] This initial qualitative testing included focus group testing, cognitive testing, and usability testing conducted by FMG.[25] Through the testing, the Bureau sought insight into consumers' understanding of debt collection protections and how consumers would interact with the forms if the forms were incorporated into a final rule. Specific findings from the consumer testing are discussed in more detail in part V where relevant. In conjunction with the release of the May 2019 proposal, the Bureau made available a report prepared by FMG regarding the focus group testing,[26] the cognitive testing,[27] the usability testing,[28] and a report prepared by FMG summarizing the focus group testing, cognitive testing, and usability testing.[29]

Second, to obtain additional information about consumer comprehension and decision-making in response to sample debt collection disclosures relating to time-barred debt, in 2017 the Bureau contracted with ICF International, Inc. (ICF) to conduct a web survey of approximately 8,000 individuals possessing a broad range of demographic characteristics.[30] This quantitative testing concluded in late September 2019, and, in conjunction with the release of the February 2020 proposal, the Bureau [31] and ICF [32] published detailed reports summarizing the testing methodology and results. The February 2020 proposal provides an extensive overview of the quantitative testing.[33]

Third, to further evaluate the effectiveness of the model validation notice, the Bureau contracted with FMG again in 2019 to conduct an additional round of qualitative testing. Because of the COVID–19 pandemic, FMG conducted this consumer testing by telephone, completing 51 one-on-one usability interviews between October 5 and October 15, 2020. The qualitative testing showed, among other things, that 80 percent of participants shared positive initial reactions to the model validation notice and indicated that the information in the notice was clear and available actions were obvious. In addition, 88 percent of participants rated the overall model validation notice as ''very easy'' or ''easy'' to understand, and no participants rated the notice as ''difficult'' or ''very difficult'' to understand. Finally, 77 percent of participants answered correctly over 90 percent of the time when, after reviewing the notice, they were asked to answer certain questions about information included on the notice. In conjunction with release of this final rule, the Bureau is making available a report prepared by FMG regarding the qualitative testing.[34]

D. Other Outreach [35]

In November 2013, the Bureau began the rulemaking process with the publication of an Advance Notice of Proposed Rulemaking (ANPRM) regarding debt collection.[36] As discussed in the May 2019 proposal, the ANPRM sought information about a wide variety of both first- and third-party debt collection practices. The Bureau received more than 23,000 comments in response to the ANPRM, which the Bureau considered when developing the proposals.

To better understand the operational costs of debt collection firms, including law firms, the Bureau also surveyed debt collection firms and vendors and published a report based on that study in July 2016 (CFPB Debt Collection Operations Study or Operations Study).[37] The Operations Study focused on understanding how debt collection firms obtain information about delinquent consumer accounts and attempt to collect on those accounts.

In August 2016, the Bureau convened a Small Business Review Panel (Small Business Review Panel or Panel) with the Chief Counsel for Advocacy of the Small Business Administration (SBA) and the Administrator of the Office of Information and Regulatory Affairs with

[23] *See* 85 FR 17299 (Mar. 27, 2020) (first extension); 85 FR 30890 (May 21, 2020) (second extension).

[24] The Bureau also tested a statement of consumer rights disclosure, but the Bureau decided not to propose to require debt collectors to provide such a disclosure to consumers. Instead, the Bureau proposed in the May 2019 proposal to require certain debt collectors to provide with the validation information a statement referring consumers to a Bureau-provided website that would describe certain consumer protections in debt collection. *See* the section-by-section analysis of § 1006.34(c)(3)(iv). Because the Bureau did not propose to require debt collectors to provide consumers with a statement of consumer rights disclosure, the Bureau did not summarize testing related to that disclosure in the May 2019 proposal.

[25] *See* 84 FR 23274, 23279 (May 21, 2019).

[26] *See generally* Fors Marsh Grp., *Debt Collection Focus Groups* (Aug. 2014), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collection_fmg-focus-group-report.pdf* (FMG Focus Group Report). The focus group testing was conducted in accordance with OMB control number 3170–0022, Generic Information Collection Plan for the Development and/or Testing of Model Forms, Disclosures, Tools, and Other Similar Related Materials.

[27] *See generally* Fors Marsh Grp., *Debt Collection Cognitive Interviews* (n.d.), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collection_fmg-cognitive-report.pdf* (FMG Cognitive Report). The cognitive testing was conducted in accordance with OMB control number 3170–0022, Generic Information Collection Plan for the Development and/or Testing of Model Forms, Disclosures, Tools, and Other Similar Related Materials.

[28] *See generally* Fors Marsh Grp., *Debt Collection User Experience Study* (Feb. 2016), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collection_fmg-usability-report.pdf* (FMG Usability Report). Like the other testing, the usability testing was conducted in accordance with OMB control number 3170–0022, Generic Information Collection Plan for the Development and/or Testing of Model Forms, Disclosures, Tools, and Other Similar Related Materials.

[29] *See generally* Fors Marsh Grp., *Debt Collection Validation Notice Research: Summary of Focus Groups, Cognitive Interviews, and User Experience Testing* (Feb. 2016), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collection_fmg-summary-report.pdf* (FMG Summary Report).

[30] OMB approved the Bureau's request to conduct the survey on May 7, 2019. *See* Office of Information & Regulatory Affairs, Office of Mgmt. & Budget, *ICR—OIRA Conclusion, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201902-3170-001#* (last visited Feb. 18, 2020).

[31] *See* Bureau of Consumer Fin. Prot., *Disclosure of Time-Barred Debt and Revival: Findings from the CFPB's Quantitative Disclosure Testing* (Feb. 2020), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collection-quantitative-disclosure-testing_report.pdf* (CFPB Quantitative Testing Report).

[32] *See* ICF Int'l, Inc., *Quantitative Survey Testing of Model Disclosure Clauses and Forms for Debt Collection: Methodology Report* (Jan. 21, 2020), *https://files.consumerfinance.gov/f/documents/cfpb_icf_debt-survey_methodology-report.pdf.*

[33] *See* 85 FR 12672, 12676–77 (Mar. 3, 2020).

[34] *See generally* Fors Marsh Grp., *Consumer Financial Protection Bureau (CFPB) Usability Testing Report: Model Validation Notice* (Nov. 20, 2020), *https://files.consumerfinance.gov/f/documents/cfpb_model-validation-notice_report_2020-12.pdf* (November 2020 Qualitative Testing Report).

[35] The preamble to the May 2019 proposal includes a more thorough discussion of the outreach the Bureau conducted prior to issuing the proposal. *See* 84 FR 23274, 23278–80 (May 21, 2019).

[36] 78 FR 67848 (Nov. 12, 2013).

[37] *See generally* Bureau of Consumer Fin. Prot., *Study of Third-Party Debt Collection Operations* (July 2016), *https://www.consumerfinance.gov/documents/755/20160727_cfpb_Third_Party_Debt_Collection_Operations_Study.pdf* (CFPB Debt Collection Operations Study).

the Office of Management and Budget (OMB).[38] As part of this process, the Bureau prepared an outline of proposals under consideration and the alternatives considered (Small Business Review Panel Outline or Outline),[39] which the Bureau posted on its website for review by the small entity representatives participating in the Panel process and by the general public. The Panel gathered information from the small entity representatives and made findings and recommendations regarding the potential compliance costs and other impacts on those entities of the proposals under consideration. Those findings and recommendations are set forth in the Small Business Review Panel Report, which is part of the administrative record in this rulemaking and is available to the public.[40] The Bureau considered these findings and recommendations in preparing the proposals and this final rule.

The Bureau has also met on many occasions with various stakeholders, including consumer advocates, debt collection trade associations, industry participants, academics with expertise in debt collection, Federal prudential regulators, and other Federal and State consumer protection regulators. The Bureau also received a number of comments specific to the debt collection rulemaking in response to its Request for Information Regarding the Bureau's Adopted Regulations and New Rulemaking Authorities[41] and its Request for Information Regarding the Bureau's Inherited Regulations and Inherited Rulemaking Authorities;[42] the Bureau considered these comments in developing the proposals and this final rule. In addition, the Bureau has engaged in general outreach, speaking at consumer advocate and industry events and visiting consumer organizations and industry stakeholders. The Bureau has provided other regulators with information about the proposals and this final rule, has sought their input, and has received feedback that has helped the Bureau to prepare this final rule.

Under the Dodd-Frank Act, the Bureau is required to conduct an assessment of significant rules within five years of the rule's effective date. The Bureau anticipates that this final rule may be significant and therefore may require an assessment within five years of the rule's effective date. The Bureau is preparing now for this possible assessment. Specifically, the Bureau is considering how best to obtain information now to serve as a baseline for evaluation of the costs, benefits, and other effects of the final rule. The Bureau expects to collect data and other information from consumers, debt collectors, and other stakeholders to understand whether the rule is achieving its goals under the FDCPA and the Dodd-Frank Act, and to help the Bureau measure the costs and benefits of the rule. Topics of data collection could include: whether consumers are better able to identify a debt when receiving validation information after the rule compared to before the rule; whether debt collectors are receiving higher or lower rates of consumer disputes after the rule compared to before the rule; whether greater clarity about FDCPA requirements helps reduce litigation related to the validation notice after the rule compared to before the rule; and costs of the rule, both anticipated and unexpected, for consumers or for industry. The Bureau expects to conduct outreach in 2021 to explore how best to obtain such data, including potentially through surveying consumers or firms or by collecting operational data.

IV. Legal Authority

The Bureau is issuing this final rule primarily pursuant to its authority under the FDCPA and the Dodd-Frank Act. As amended by the Dodd-Frank Act, FDCPA section 814(d) provides that the Bureau ''may prescribe rules with respect to the collection of debts by debt collectors,'' as defined in the FDCPA.[43] Section 1022(a) of the Dodd-Frank Act provides that ''[t]he Bureau is authorized to exercise its authorities under Federal consumer financial law to administer, enforce, and otherwise implement the provisions of Federal consumer financial law.''[44] Section 1022(b)(1) of the Dodd-Frank Act provides that the Director may prescribe rules and issue orders and guidance, as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.[45] ''Federal consumer financial law'' includes title X of the Dodd-Frank Act and the FDCPA.[46] No provisions in this final rule are based on section 1031 of the Dodd-Frank Act.[47]

These and other authorities are discussed in greater detail in parts IV.A through C below. Part IV.A discusses the Bureau's authority under sections 806 through 808 of the FDCPA. Parts IV.B through C discuss the Bureau's relevant authorities under the Dodd-Frank Act.

A. FDCPA Sections 806 Through 808

As discussed in part V, the Bureau is finalizing several provisions, in whole or in part, pursuant to its authority to interpret FDCPA sections 806 through 808, which set forth general prohibitions on, and requirements relating to, debt collectors' conduct and are accompanied by non-exhaustive lists of examples of unlawful conduct. The November 2020 Final Rule provides an overview of how the Bureau interprets FDCPA sections 806 through 808.

FDCPA section 806 generally prohibits a debt collector from ''engag[ing] in any conduct the natural consequence of which is to harass, oppress, or abuse any person in connection with the collection of a

[38] The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), as amended by section 1100G(a) of the Dodd-Frank Act, requires the Bureau to convene a Small Business Review Panel before proposing a rule that may have a substantial economic impact on a significant number of small entities. *See* Public Law 104–121, tit. II, 110 Stat. 857 (1996) (as amended by the Small Business and Work Opportunity Act of 2007, Public Law. 110–28, tit. VIII, subtit. C, sec. 8302, 121 Stat. 204 (2007)).

[39] Bureau of Consumer Fin. Prot., *Small Business Review Panel for Debt Collector and Debt Buyer Rulemaking: Outline of Proposals Under Consideration and Alternatives Considered* (July 28, 2016), *https://files.consumerfinance.gov/f/documents/20160727_cfpb_Outline_of_proposals.pdf* (Small Business Review Panel Outline). The Bureau also gathered feedback on the Small Business Review Panel Outline from other stakeholders, members of the public, and the Bureau's Consumer Advisory Board and Community Bank Advisory Council.

[40] Bureau of Consumer Fin. Prot., U.S. Small Bus. Admin. & Office of Mgmt. & Budget, *Final Report of the Small Business Review Panel on the CFPB's Proposals Under Consideration for the Debt Collector and Debt Buying Rulemaking* (Oct. 2016), *https://files.consumerfinance.gov/f/documents/cfpb_debt-collector-debt-buyer_SBREFA-report.pdf* (Small Business Review Panel Report).

[41] 83 FR 12286 (Mar. 21, 2018).

[42] 83 FR 12881 (Mar. 26, 2018).

[43] 15 U.S.C. 1692*l*(d). As noted, the Bureau is the first Federal agency with authority to prescribe substantive debt collection rules under the FDCPA. Prior to the Dodd-Frank Act's grant of rulemaking authority to the Bureau, no agency had authority to issue substantive rules with respect to the collection of debts by debt collectors under the FDCPA, but the FTC published various materials providing guidance on the FDCPA. The FTC's materials have informed the Bureau's rulemaking and, if relevant to particular provisions, are discussed in part V.

[44] 12 U.S.C. 5512(a).

[45] 12 U.S.C. 5512(b)(1).

[46] 12 U.S.C. 5481(12)(H), (14).

[47] The Bureau proposed to rely on its Dodd-Frank Act section 1031 authority (relating to unfair, deceptive, or abusive acts or practices in connection with consumer financial products or services) to support two interventions in the May 2019 proposal. The Bureau has not finalized any provisions of this final rule (or, as discussed in the November 2020 Final Rule, of that final rule), pursuant to its authority under Dodd-Frank Act section 1031.

debt.'' [48] Then, ''[w]ithout limiting the general application of the foregoing,'' it lists six examples of conduct that violate that section.[49] Similarly, FDCPA section 807 generally prohibits a debt collector from ''us[ing] any false, deceptive, or misleading representation or means in connection with the collection of any debt.'' [50] Then, ''[w]ithout limiting the general application of the foregoing,'' section 807 lists 16 examples of conduct that violate that section.[51] Finally, FDCPA section 808 prohibits a debt collector from ''us[ing] unfair or unconscionable means to collect or attempt to collect any debt.'' [52] Then, ''[w]ithout limiting the general application of the foregoing,'' FDCPA section 808 lists eight examples of conduct that violate that section.[53] Consistent with the approach in the November 2020 Final Rule [54] and as proposed in the May 2019 proposal,[55] the Bureau interprets FDCPA sections 806 through 808 in light of: (1) The FDCPA's language and purpose; (2) the general types of conduct prohibited by those sections and, where relevant, the specific examples enumerated in those sections; and (3) judicial decisions.[56]

In particular, the Bureau notes that, by their plain terms, FDCPA sections 806 through 808 make clear that their examples of prohibited conduct do not ''limit[ ] the general application'' of those sections' general prohibitions. The FDCPA's legislative history is consistent with this understanding,[57] as are opinions by courts that have addressed this issue.[58] Accordingly, the Bureau may interpret the general provisions of FDCPA sections 806 to 808 to prohibit conduct that the specific examples in FDCPA sections 806 through 808 do not address if the conduct violates the general prohibitions. In addition, the Bureau uses the specific examples to inform its understanding of the general prohibitions. The Bureau also interprets FDCPA sections 806 through 808 in light of the significant body of existing court decisions interpreting those sections, including, where applicable, cases discussing the collection of time-barred debt.[59] Finally, consistent with the majority of courts, the Bureau interprets FDCPA sections 806 through 808 to incorporate an objective, ''unsophisticated'' or ''least sophisticated'' consumer standard.[60]

B. Dodd-Frank Act Section 1032

Dodd-Frank Act section 1032(a) provides that the Bureau may prescribe rules to ensure that the features of any consumer financial product or service, ''both initially and over the term of the product or service,'' are ''fully, accurately, and effectively disclosed to consumers in a manner that permits consumers to understand the costs, benefits, and risks associated with the product or service, in light of the facts and circumstances.'' [61] Under Dodd-Frank Act section 1032(a), the Bureau is empowered to prescribe rules regarding the disclosure of the ''features'' of consumer financial products and services generally. Accordingly, the Bureau may prescribe rules containing disclosure requirements even if other Federal consumer financial laws do not specifically require disclosure of such features. Dodd-Frank Act section 1032(c) provides that, in prescribing rules pursuant to Dodd-Frank Act section 1032, the Bureau ''shall consider available evidence about consumer awareness, understanding of, and responses to disclosures or communications about the risks, costs, and benefits of consumer financial products or services.'' [62] The Bureau is finalizing §§ 1006.34 and 1006.38 based in part on its authority under Dodd-Frank Act section 1032.

C. Other Authorities Under the Dodd-Frank Act

Section 1022(b)(1) of the Dodd-Frank Act provides that the Bureau's Director ''may prescribe rules and issue orders and guidance, as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.'' [63] ''Federal consumer financial laws'' include the FDCPA and title X of the Dodd-Frank Act.[64] Section 1022(b)(2) of the Dodd-Frank Act prescribes certain standards for rulemaking that the Bureau must follow in exercising its authority under Dodd-Frank Act section 1022(b)(1).[65] See part VII for a discussion of the Bureau's standards for rulemaking under Dodd-Frank Act section 1022(b)(2).

V. Section-by-Section Analysis

Subpart A—General

Section 1006.1 Authority, Purpose, and Coverage

1(c) Coverage

In the November 2020 Final Rule, the Bureau adopted § 1006.1(c)(1) to specify that, except as provided in § 1006.108 and appendix A, Regulation F applies to debt collectors, as defined in § 1006.2(i), other than a person excluded from coverage by section 1029(a) of the Consumer Financial Protection Act of 2010, title X of the Dodd-Frank Act (12 U.S.C. 5519(a)).[66] The Bureau also noted that it was not finalizing, as part of the November 2020 Final Rule, proposed § 1006.1(c)(2), which provided that certain provisions of Regulation F applied to debt collectors only when they were collecting consumer financial product or service debt, as defined in § 1006.2(f). The Bureau explained that it was not finalizing § 1006.1(c)(2) as part of the November 2020 Final Rule because all of the provisions of that final rule apply to debt collectors as defined in § 1006.2(i). The Bureau nevertheless reserved § 1006.1(c)(2) so that the Bureau could clarify which provisions of this final rule, if any, apply to debt collectors only if they are collecting debt related to a consumer financial product or service.

For the reasons discussed in the section-by-section analysis of § 1006.34, two provisions of that section (§ 1006.34(c)(2)(iii) and (3)(iv)) apply to debt collectors only if they are collecting debt related to a consumer

[48] 15 U.S.C. 1692d.

[49] 15 U.S.C. 1692d(1)–(6).

[50] 15 U.S.C. 1692e.

[51] 15 U.S.C. 1692e(1)–(16).

[52] 15 U.S.C. 1692f.

[53] 15 U.S.C. 1692f(1)–(8).

[54] *See* 85 FR 76734, 76738 (Nov. 30, 2020).

[55] 84 FR 23274, 23281–82 (May 21, 2019).

[56] Where the Bureau prescribes requirements pursuant only to its authority to implement and interpret sections 806 through 808 of the FDCPA, the Bureau does not take a position on whether such practices also would constitute an unfair, deceptive, or abusive act or practice under section 1031 of the Dodd-Frank Act.

[57] *See, e.g.,* S. Rep. No. 382, 95th Cong., 1st Sess. 2, 4 (1977), *reprinted in* 1977 U.S.C.C.A.N. 1695, 1698 (S. Rep. No. 382) (''[T]his bill prohibits in general terms any harassing, unfair, or deceptive collection practice. This will enable the courts, where appropriate, to proscribe other improper conduct which is not specifically addressed.''). Courts have also cited legislative history in noting that, ''in passing the FDCPA, Congress identified abusive collection attempts as primary motivations for the Act's passage.'' *Hart* v. *FCI Lender Servs., Inc.,* 797 F.3d 219, 226 (2d Cir. 2015).

[58] *See, e.g., Stratton* v. *Portfolio Recovery Assocs., LLC,* 770 F.3d 443, 450 (6th Cir. 2014) (''[T]he listed examples of illegal acts are just that—examples.'').

[59] *Id. See, e.g., Holzman* v. *Malcolm S. Gerald & Assocs.,* 920 F.3d 1264 (11th Cir. 2019); *Tatis* v. *Allied Interstate, LLC,* 882 F.3d 422 (3d Cir. 2018); *Pantoja* v. *Portfolio Recovery Assocs., LLC,* 852 F.3d 679 (7th Cir. 2017), cert. denied, 138 S. Ct. 736 (2018); *Daugherty* v. *Convergent Outsourcing Inc.,* 836 F.3d 507 (5th Cir. 2016); *Buchanan* v. *Northland Grp., Inc.,* 776 F.3d 393 (6th Cir. 2015); *McMahon* v. *LVNV Funding, LLC,* 744 F.3d 1010, 1020 (7th Cir. 2014).

[60] 85 FR 76734, 76740 (Nov. 30, 2020); 84 FR 23274, 23282–83 (May 21, 2019).

[61] 12 U.S.C. 5532(a).

[62] 12 U.S.C. 5532(c).

[63] 12 U.S.C. 5512(b)(1).

[64] 12 U.S.C. 5481(14).

[65] 12 U.S.C. 5512(b)(2).

[66] 85 FR 76734, 76742 (Nov. 30, 2020).

financial produce or service as defined in § 1006.2(f). Therefore, the Bureau is finalizing § 1006.1(c)(2) to provide that certain provisions of Regulation F apply to debt collectors only if they are collecting debt related to a consumer financial product or service as defined in § 1006.2(f), and to specify that those provisions are § 1006.34(c)(2)(iii) and (3)(iv).

Section 1006.2 Definitions

2(e) Consumer

FDCPA section 803(3) defines a consumer as any natural person obligated or allegedly obligated to pay any debt.[67] The Bureau proposed § 1006.2(e) to implement this definition and to interpret it to include a deceased natural person who is obligated or allegedly obligated to pay a debt.[68] The Bureau explained that this interpretation would ensure that individuals trying to resolve a deceased consumer's debts have the same legal right to receive the validation notice, and to dispute the debt and request information about the original creditor, as the deceased consumer would have had.

As the Bureau noted in the November 2020 Final Rule, the Bureau received a number of comments regarding its proposal to interpret the term consumer to include deceased natural persons. The Bureau also noted that it had proposed that interpretation, in large part, to facilitate delivery of validation notices under proposed § 1006.34 if the consumer obligated, or allegedly obligated, on the debt has died. Further, the Bureau noted that it planned to address comments received regarding that interpretation, and to determine whether to finalize that interpretation, as part of this final rule. Thus, as finalized in the November 2020 Final Rule, § 1006.2(e) provides that the term consumer means any natural person obligated or allegedly obligated to pay any debt.[69] The Bureau now addresses comments received regarding its proposal to interpret the definition to include deceased natural persons.

Several commenters supported the Bureau's proposed interpretation. One industry commenter stated that, in the decedent debt context, the person acting on behalf of a deceased consumer's estate should have the same rights regarding validation notices and disputes as the consumer would have had if the consumer were still living. Another industry commenter reported that many debt collectors currently attempt to treat deceased consumers as ''consumers'' under the FDCPA and explained that the proposal would provide additional clarity that would benefit both consumers and debt collectors in resolving the debts of deceased consumers. A group of consumer advocates supported clarifying the rights of executors, administrators, and personal representatives regarding validation notices and disputes. However, as discussed below, these consumer advocate commenters opposed the proposed interpretation and suggested a different way to address the issue.

Other commenters opposed interpreting the term consumer to include deceased natural persons who are obligated or allegedly obligated to pay a debt. One industry commenter asserted that the proposed interpretation would serve no purpose because deceased consumers lacked privacy interests. A trade group commenter stated that no evidence of confusion existed in the decedent debt context, and that the Bureau's interpretation would expand the class of individuals entitled to sue debt collectors for violations of the FDCPA and the final rule. Finally, a group of consumer advocates suggested that the Bureau's interpretation was unnecessary because proposed comments 34(a)(1)–1 and 38–1 would clarify that a person who is authorized to act on behalf of the deceased consumer's estate operates as the consumer for purposes of §§ 1006.34(a)(1) and 1006.38.[70] These commenters also stated that, if the Bureau were attempting to change the class of individuals who may bring civil actions against debt collectors, the FDCPA already allows any ''person'' to bring such claims.

For the reasons discussed below, the Bureau is revising § 1006.2(e), as set forth in the November 2020 Final Rule, to clarify that the definition of consumer includes deceased natural persons. As explained in the May 2019 proposal, the FDCPA does not specify whether a consumer, as defined in section 803(3), includes a deceased consumer (or whether a natural person, as that term is used in section 803(3), includes a deceased natural person).[71] Because the definition of consumer in FDCPA section 803(3) is silent with respect to deceased consumers, other FDCPA provisions that refer to a debt collector's obligations to a consumer lack clarity in the decedent debt context. For example, FDCPA provisions requiring debt collectors to provide validation information, and to respond to disputes and requests for original-creditor information, do not address situations in which the person obligated or allegedly obligated to pay the debt is deceased. Uncertainty surrounding these provisions increases the risk of consumer harm in the decedent debt context. Specifically, without validation information and an opportunity to dispute the debt, individuals trying to resolve debts in a deceased consumer's estate will lack information needed to determine whether they are being asked to pay the right debt, in the right amount, and to the right debt collector, and, consequently, whether they should assert dispute rights.

Accordingly, to increase clarity and to decrease the risk of consumer harm, the Bureau is revising § 1006.2(e) to provide that the term consumer means any natural person, whether living or deceased, obligated or allegedly obligated to pay any debt. The Bureau also is revising § 1006.2(e) to delete the statement that the Bureau may further define the term to clarify its application when the consumer is deceased, since this final rule contains that further definition.[72] Relatedly, the Bureau is finalizing the commentary to §§ 1006.34(a)(1) and 1006.38 that clarifies that a person who is authorized to act on behalf of the deceased consumer's estate, such as the executor, administrator, or personal representative, operates as the consumer for purposes of §§ 1006.34(a)(1) and 1006.38.

Regarding the comment that deceased consumers have no privacy rights, the Bureau disagrees. In its Policy Statement on Decedent Debt, the FTC prohibited debt collectors from openly referring to a deceased consumer's debts in communications with third parties, instead adopting an approach that ''balance[d] the legitimate needs of the collector with the privacy interests of

[67] 15 U.S.C. 1692a(3).

[68] *See* 84 FR 23274, 23288 (May 21, 2019).

[69] For the reasons discussed in the November 2020 Final Rule, § 1006.2(e) as finalized in that rule also provides that, for purposes of § 1006.6, the term consumer includes the persons described in § 1006.6(a). To account for any revisions adopted in this final rule, it also specifies that the Bureau may further define the term in Regulation F to clarify its application when the consumer is deceased. *See* 85 FR 76734, 76744–45, 76888 (Nov. 30, 2020).

[70] *See* the section-by-section analyses of §§ 1006.34 and 1006.38.

[71] *See* 84 FR 23274, 23288 (May 21, 2019).

[72] In the proposal, the Bureau explained that its interpretation was ''consistent with a modern trend in the law that favors recognizing, as a default, the continued existence of a natural person after death.'' 84 FR 23274, 23288 (May 21, 2019). Consumer advocates pointed out that the authority cited for this proposition comes from contexts other than the FDCPA. But these commenters do not explain why this fact undermines the existence of the trend described by the Bureau.

the decedent.'' [73] In the November 2020 Final Rule, the Bureau took a similar approach regarding location communications for decedent debt.[74]

Moreover, interpreting the term consumer in § 1006.2(e) to include deceased natural persons is supported by more than concern for a decedent's privacy; it also clarifies debt collector's obligations to a consumer and, in turn, to those authorized to act on the consumer's behalf, if the consumer has died. This includes clarifying a debt collector's obligations under the FDCPA's provisions, as implemented in this final rule and in the November 2020 Final Rule, regarding validation information and disputes and requests for original-creditor information, which help to ensure that consumers are not paying the wrong debt, in the wrong amount, to the wrong debt collector.

This interpretation also clarifies the application of § 1006.22(f)(4), which the Bureau adopted in the November 2020 Final Rule to prohibit debt collectors from communicating or attempting to communicate with a person in connection with the collection of a debt through a social media platform if the communication or attempt to communicate is viewable by the general public or the person's social media contacts.[75] In adopting that provision, the Bureau discussed that a consumer advocate commenter had stated that the Bureau should broaden the prohibition to apply to deceased consumers, such that debt collectors would be prohibited from posting publicly about a deceased consumer's alleged debt on the consumer's social media page. The consumer advocate commenter stated that a debt collector's only reason for doing so would be to pressure surviving relatives to pay the debt, either to protect the deceased consumer's reputation or out of a sense of moral obligation.[76]

In finalizing § 1006.22(f)(4) in the November 2020 Final Rule, Bureau noted that the prohibition applied to communications and attempts to communicate with ''a person,'' and that person, as defined in § 1006.2(k), includes a consumer. The Bureau again noted that it had received a number of comments regarding its proposal to interpret the term consumer to include deceased natural persons and that it would address such comments in this final rule. In determining to revise § 1006.2(e) to include a deceased natural person who is obligated or allegedly obligated to pay a debt, the Bureau thus also clarifies that the prohibition in § 1006.22(f)(4) includes deceased consumers.

The Bureau disagrees with the industry commenter that there is no evidence of confusion about the definition of consumer in the decedent debt context. As explained above, the FDCPA's current lack of clarity in the decedent debt context creates uncertainty in several situations arising during the collection of debts belonging to deceased consumers. Therefore, the Bureau determines that additional clarity will improve the debt collection system for all parties.

Nor does § 1006.2(e) expand the class of potential plaintiffs who may bring suit under the FDCPA and Regulation F, as an industry commenter alleged. The civil liability provision of the FDCPA already creates liability for violations committed against any person.[77] As noted in the proposal, the trend in the law has been to recognize, as a default, the continued existence of a natural person after death for purposes of bringing civil actions, particularly for remedial statutes like the FDCPA.[78] This commenter did not explain how the Bureau's interpretation would result in a lawsuit by someone other than a ''person'' under the statute.

Finally, the Bureau disagrees, as suggested by certain commenters, that the commentary to §§ 1006.34(a)(1) and 1006.38 (final comments 34(a)(1)–1 and 38–3) provide adequate clarity without interpreting the term consumer to include deceased natural persons. In fact, interpreting the term consumer to include deceased natural persons is a necessary predicate to provide that the persons identified in those comments operate as the consumer for purposes of the requirements relating to validation information, disputes, and requests for original-creditor information.

Commenters raised additional issues related to § 1006.2(e). A few industry commenters suggested that the Bureau's proposed interpretation was inconsistent with the Bureau's mortgage servicing rules regarding successors in interest. One trade group commenter stated that allowing any individual authorized to act on behalf of a deceased consumer's estate to meet Regulation F's definition of consumer under § 1006.2(e) will complicate and potentially impede the existing successor in interest process under Regulations X and Z. The commenter explained that, under proposed comment 34(a)(1)–1, mortgage servicers who are also debt collectors under Regulation F would have to send validation information to the person authorized to act on behalf of the deceased consumer's estate but would not be able to send foreclosure-related disclosures required under State law to the same person, unless that person had assumed ownership of the obligation. The commenter also suggested that, under proposed comment 38–1, debt collectors would be required to focus resources on verifying the identify of an individual asserting to be a person authorized to act on behalf of the deceased consumer's estate, which would take away from legitimate efforts to respond to disputes and requests for original-creditor information.

Another trade group commenter stated that the clarification in proposed comment 34(a)(1)–1 to send the validation notice to the person authorized to act on behalf of the deceased consumer's estate if the debt collector knows or should know that the consumer is deceased would, unlike the Bureau's mortgage servicing rules, appear to create an affirmative obligation for mortgage servicers to track down information about potential successors in interest and cloud requirements for mortgage servicers under Regulation X. For this reason, a third trade group commenter suggested that, if a required notice must be sent and no individual has come forward as a potential or confirmed successor in interest, the Bureau should permit mortgage servicers to address a validation notice to the deceased consumer or ''the estate of'' the deceased consumer rather than require a search for an individual to whom to address the notice.

As the Bureau has previously explained, while many mortgage servicers are not subject to the FDCPA, mortgage servicers that acquired a mortgage loan at the time that it was in default may be subject to the FDCPA with respect to that mortgage loan.[79] As discussed below, the Bureau concludes that including a deceased natural person who is obligated or allegedly obligated to pay a debt within the definition of consumer under § 1006.2(e) is not inconsistent with the Bureau's mortgage servicing rules on successors in interest.

[73] Fed. Trade Comm'n, *Statement of Policy Regarding Communications in Connection with the Collection of Decedents' Debts* at 44921 (July 27, 2011), *https://www.ftc.gov/sites/default/files/documents/federal_register_notices/statement-policy-regarding-communications-connection-collection-decedents-debts-policy-statement/110720fdcpa.pdf* (FTC Policy Statement on Decedent Debt).

[74] *See* 85 FR 76734, 76797–00, 76890, 76900 (Nov. 30, 2020).

[75] *See id.* at 76836–39, 76892.

[76] *See id.* at 76836–39.

[77] 15 U.S.C. 1692k.

[78] *See* 84 FR 23274, 23288 (May 21, 2019).

[79] *See* 85 FR 76734, 76758 (Nov. 30, 2020); 81 FR 71977, 71978 (Oct. 19, 2016).

Although one commenter asserted that finalizing this definition as proposed would complicate and potentially impede the existing successor in interest process, the commenter failed to explain why that would be the case and the Bureau does not believe that to be the case.

Regarding delivery of validation information, as discussed below, comment 34(a)(1)–1 clarifies that, if a debt collector knows or should know that a consumer is deceased, and if the debt collector has not previously provided the validation information to the deceased consumer, then in such circumstances, to comply with § 1006.34(a)(1), a debt collector must provide the validation information to an individual whom the debt collector identifies by name and who is authorized to act on behalf of the deceased consumer's estate.[80] A person who is authorized to act on behalf of a deceased consumer's estate may include the executor, administrator, or personal representative. However, as discussed in the November 2020 Final Rule, for purposes of Regulations X and Z, a successor in interest is, in general, a person to whom an ownership interest either in a property securing a mortgage loan subject to subpart C of Regulation X, or in a dwelling securing a closed-end consumer credit transaction under Regulation Z, is transferred under specified circumstances including, for example, after a consumer's death or as part of a divorce.[81] Therefore, a person who is authorized to act on behalf of a deceased consumer's estate for purposes of Regulation F may or may not also be a successor in interest under Regulations X and Z, depending on whether an ownership interest in a property securing a mortgage loan or a dwelling securing a closed-end consumer credit transaction is transferred to that person under the circumstances specified in Regulations X and Z.[82]

Comment 34(a)(1)–1 provides debt collectors clarity regarding to whom the validation information must be provided in the narrow circumstance in which the debt collector knows or should know that a consumer is deceased and the debt collector has not previously provided the validation information to the deceased consumer. According to the comment, under these circumstances, a debt collector who is collecting the debt of a deceased consumer must determine who is authorized to act on behalf of a deceased consumer's estate. These efforts, however, do not create an affirmative obligation under the Bureau's mortgage servicing rule for a mortgage servicer that is subject to the FDCPA with respect to a mortgage loan to seek out potential successors in interest within the meaning of the mortgage servicing rules. Under the mortgage servicing rules, a mortgage servicer is not required to conduct a search for potential successors in interest if the mortgage servicer has not received actual notice of their existence.[83] If, in the course of determining who is authorized to act on behalf of a deceased consumer's estate for purposes of § 1006.34(a)(1), a mortgage servicer receives actual notice of the existence of a potential successor in interest, the mortgage servicer must, as required under Regulation X, maintain policies and procedures reasonably designed to ensure that the servicer can retain this information and promptly facilitate communication with the potential successor in interest.[84] However, because a mortgage servicer that is subject to the FDCPA with respect to a mortgage loan may comply with both this final rule and the applicable successor in interest provisions under Regulations X and Z, the Bureau concludes there is no conflict with the mortgage servicing rules. Additionally, nothing in this final rule is intended to alter the successor in interest provisions in Regulations X and Z or to impose additional requirements under Regulations X and Z.

In response to the commenter's concern regarding the burdens under comment 38–1 of determining who is authorized to act on behalf of a deceased consumer's estate before responding to a dispute or request for original-creditor information, the potential burdens associated with responding to such incoming disputes and requests will be significantly reduced once a debt collector has procedures in place to make that threshold determination or has already made that determination for purposes of providing the validation information as described in comment 34(a)(1)–1.

The Bureau declines to adopt the suggestion to allow mortgage servicers to address a validation notice to the deceased consumer or to ''the estate of'' the deceased consumer. As discussed in the proposal, the Bureau shares the view of the FTC, which stated in its Policy Statement on Decedent Debt that individuals who lack the authority to resolve the estate but who wish to be helpful are likely to open communications addressed to the decedent's estate, or to an unnamed executor or administrator, which makes such communications insufficiently targeted to a consumer with whom the debt collector may generally discuss the debt.[85] The Bureau, therefore, shares the view of the FTC that ''communication[s] addressed to the decedent's estate, or an unnamed executor or administrator, [are] location communication[s] and must not refer to the decedent's debts.'' [86] Accordingly, comment 34(a)(1)–1 specifies that a debt collector must provide the validation information to an individual that the debt collector identifies by name who is authorized to act on behalf of the deceased consumer's estate.

A group of consumer advocates stated that certain other provisions of the Bureau's proposal, such as § 1006.14(e)'s prohibition on publishing lists of consumers who allegedly refuse to pay debts and § 1006.18(b)(1)(iv)'s prohibition on falsely representing or implying that the consumer committed any crime or other conduct in order to disgrace the consumer, should apply to deceased consumers. But, these commenters claimed, other provisions, like § 1006.6(b)(1)'s restrictions on communicating at inconvenient times or places, were nonsensical as applied to deceased consumers. Therefore, these commenters argued, the Bureau's interpretation in proposed § 1006.2(e) was overbroad.

The Bureau acknowledges that there may be certain provisions in the November 2020 Final Rule and in this final rule that refer to a consumer that simply will be inapplicable in the context of a deceased consumer.[87] Nevertheless, as consumer advocates acknowledged, other provisions that

[80] *See* the section-by-section analysis of § 1006.34(a)(1).

[81] *See* 85 FR 76734, 76758–59 (Nov. 30, 2020). *See also* 12 CFR 1024.31, 1026.2(a)(27)(i). A confirmed successor in interest, in turn, means a successor in interest once a mortgage servicer has confirmed the successor in interest's identity and ownership interest in the property that secures the mortgage loan or in the dwelling. *See* 12 CFR 1024.31, 1026.2(a)(27)(ii).

[82] 12 CFR 1024.31, 1026.2(a)(27).

[83] 12 CFR 1024.38(b)(1)(vi); comment 38(b)(1)(vi)–1.

[84] *Id.* The general servicing policies, procedures, and requirements in 12 CFR 1024.38 do not apply to a mortgage servicer that qualifies as a small servicer pursuant to 12 CFR 1026.41(e). *See* 12 CFR 1024.30(b)(1).

[85] *See* 84 FR 23274, 23334 (May 21, 2019).

[86] FTC Policy Statement on Decedent Debt, *supra* note 73, at 44920.

[87] For example, § 1006.6(b) restricts, among other things, the times at which debt collectors can communicate or attempt to communicate with consumers. *See* 85 FR 76734, 76889 (Nov. 30, 2020). To the extent that ''communicate'' includes having a conversation, the Bureau believes it is obvious that this prohibition is simply inapplicable in the case of a deceased consumer (but does apply to having a conversation with the executor or administrator of the consumer's estate).

refer to a consumer will apply to deceased consumers. For example, as discussed above, interpreting the term consumer in § 1006.2(e) to include deceased natural persons means that, as applied to § 1006.22(f)(4), debt collectors are prohibited from posting publicly about a deceased consumer's alleged debt on a deceased consumer's public-facing social media page. In situations that are currently unclear, such as delivery of validation information, the final rule adopts commentary clarifying debt collectors' obligations.

This group of consumer advocates also recommended that the Bureau require debt collectors to provide a validation notice to the person authorized to act on behalf of the deceased consumer's estate even if validation information already was provided to the consumer. These commenters also asked the Bureau to provide that the validation period starts from the date the person authorized to act on behalf of the deceased consumer's estate receives the validation notice, and to require debt collectors to respond to disputes and requests for original-creditor information submitted by this person, even if a response already was provided to the consumer. The Bureau declines to adopt these suggestions because the Bureau finds that, in the scenario described, the debt collector has already satisfied the debt collector's obligations to the consumer as set forth in FDCPA section 809 and §§ 1006.34 and 1006.38. Depending on the facts, the debt collector could be required to provide a validation notice or dispute response to the person authorized to act on behalf of the deceased consumer's estate,[88] but the Bureau declines to require debt collectors to do so in all cases. Nevertheless, the Bureau notes that debt collectors who voluntarily provide validation notices after a consumer dies (as some industry commenters reported is done), and who, in doing so, start a new validation period, do not thereby violate the FDCPA or Regulation F.

For the reasons discussed above, and pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors, the Bureau is finalizing § 1006.2(e) as proposed to interpret the definition of consumer in FDCPA section 803(3) to mean any natural person, whether living or deceased, who is obligated or allegedly obligated to pay any debt.

2(f) Consumer Financial Product or Service

As discussed in the November 2020 Final Rule, the Bureau proposed § 1006.2(f) to define consumer financial product or service debt to mean any debt related to any consumer financial product or service, as consumer financial product or service is defined in section 1002(5) of the Dodd-Frank Act.[89] As also discussed in the November 2020 Final Rule, the Bureau did not finalize § 1006.2(f) as part of that rulemaking because the Bureau did not finalize in that rulemaking any provisions for which the definition in proposed § 1006.2(f) would have been relevant.

For the reasons discussed in the section-by-section analyses of §§ 1006.1(c) and 1006.34, the Bureau is adopting in this final rule two provisions (§ 1006.34(c)(2)(iii) and (3)(iv)) that apply to debt collectors only if they are collecting debt related to a consumer financial product or service. This includes, for example, debt collectors collecting debts related to consumer mortgage loans or credit cards.[90] To facilitate compliance with those provisions, the Bureau is adopting § 1006.2(f) to provide that consumer financial product or service has the meaning in section 1002(5) of the Dodd-Frank Act (12 U.S.C. 5481(5)).

The Bureau notes that it originally proposed § 1006.2(f) to define the term ''consumer financial product or service debt.'' However, because the relevant defined term in the Dodd-Frank Act is ''consumer financial product or service,'' and because certain commenters observed that including two definitions of the term ''debt'' in the rule would be confusing, the Bureau is finalizing § 1006.2(f) to provide that the defined term in the rule is ''consumer financial product or service'' and that the term has the same meaning given to it in section 1002(5) of the Dodd-Frank Act.

Subpart B—Rules for FDCPA Debt Collectors

Section 1006.26 Collection of Time-Barred Debts

The May 2019 proposal and the February 2020 proposal both addressed the collection of time-barred debt. In the May 2019 proposal, the Bureau proposed to define several terms (proposed § 1006.26(a)) and to prohibit debt collectors from bringing or threatening to bring legal actions against consumers to collect certain time-barred debts (proposed § 1006.26(b)). In the February 2020 proposal, the Bureau proposed to require debt collectors to provide disclosures if collecting certain time-barred debts (proposed § 1006.26(c)). The February 2020 proposal also included model language and forms that debt collectors could use to comply with the proposed disclosure requirements. In the November 2020 Final Rule, the Bureau noted that it planned to address its proposals regarding time-barred debt in this final rule, and the Bureau reserved § 1006.26 for that purpose. After considering the comments received in response to both the May 2019 and February 2020 proposals, the Bureau is now finalizing proposed § 1006.26(a) and (b) with modifications as described below. The Bureau is not finalizing proposed § 1006.26(c).

26(a) Definitions

Proposed § 1006.26(a) defined two terms not defined in the FDCPA: Statute of limitations and time-barred debt. The Bureau proposed to define these terms to facilitate compliance with proposed § 1006.26(b) and (c). As discussed below, the Bureau is finalizing § 1006.26(a) as proposed. The Bureau is finalizing § 1006.26(a) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors.

26(a)(1) Statute of Limitations

Proposed § 1006.26(a)(1) defined the term statute of limitations to mean the period prescribed by applicable law for bringing a legal action against the consumer to collect a debt.[91]

Statutes of limitation, which typically are established by State law, provide time limits for bringing suit on legal claims. As the Bureau explained in the May 2019 proposal, statutes of limitation serve several purposes.[92] First, statutes of limitations advance a defendant's interest in repose. That is, they reflect a legislative judgment that it is ''unjust to fail to put the adversary on notice to defend within a specified period of time.'' [93] Second, statutes of limitations eliminate stale claims. That is, they protect defendants and the courts from having to deal with cases in which ''the search for truth may be seriously impaired by the loss of evidence, whether by death or disappearance of witnesses, fading

[88] *See* the section-by-section analysis of § 1006.34(b)(5).

[89] 85 FR 76734, 76745 (Nov. 30, 2020).

[90] *See* 84 FR 23274, 23286 (May 21, 2019).

[91] *See* 84 FR 23274, 23327–28 (May 21, 2019).

[92] *See generally Rotella* v. *Wood,* 528 U.S. 549, 555 (2000) (identifying ''the basic policies of all limitations provisions'' as ''repose, elimination of stale claims, and certainty'').

[93] *United States* v. *Kubrick,* 444 U.S. 111, 117 (1979).

memories, disappearance of documents, or otherwise.'' [94] Third, statutes of limitations provide ''certainty about a plaintiff's opportunity for recovery and a defendant's potential liabilities.'' [95] For debt collection claims, the length of the applicable statute of limitations often varies by State and, within each State, by debt type. Although most statutes of limitations applicable to debt collection claims are between three and six years, some are as long as 15 years.

Several commenters addressed proposed § 1006.26(a)(1). One industry commenter confirmed that the proposed definition of statute of limitations comported with debt collectors' understanding of the term. A number of other industry commenters requested that the Bureau modify the definition to account for the fact that it can be challenging to determine the applicable statute of limitations in certain circumstances. For example, two industry commenters requested that the Bureau clarify that, in determining the applicable statute of limitations, a debt collector need only conduct a reasonable investigation based on objectively ascertainable facts, and that a debt collector would only be charged with knowing that the statute of limitations has expired if the law is clearly established. The commenters also requested that the Bureau more specifically define certain elements of the term statute of limitations to lessen the burden on debt collectors of determining whether a debt is time barred. For example, they suggested defining ''applicable law'' as the law of the jurisdiction where the consumer resides or is believed to reside at the time collections begin, or the law of the jurisdiction in which the consumer signed any underlying contract. Commenters suggested that these changes would make it easier for a debt collector to determine the statute of limitations applicable to a particular debt while protecting a debt collector from liability when it is difficult determine the exact date on which a debt becomes time barred.

The Bureau is finalizing § 1006.26(a)(1) as proposed. As industry commenters confirmed, the definition of statute of limitations in § 1006.26(a)(1) is consistent with debt collectors' understanding of the term. The Bureau declines to modify the definition to identify the type of investigation a debt collector must or should undertake to ascertain the applicable statute of limitations. The Bureau also declines to define the term ''applicable law'' in the manner requested by commenters. The Bureau recognizes that, in some cases, it can be challenging and costly for a debt collector to determine what statute of limitations applies to a legal action against the consumer to collect a particular debt, and that, in some cases, the commenters' suggestions could reduce those challenges and costs. The Bureau declines, however, to address the challenges and costs associated with determining whether a debt is time barred by modifying the definition of statute of limitations, a term with a meaning widely understood by debt collectors, or by defining new terms. Comments relating to the difficulty of determining whether a debt is time barred are discussed further in the section-by-section analysis of § 1006.26(b).

26(a)(2) Time-Barred Debt

Proposed § 1006.26(a)(2) defined the term time-barred debt to mean a debt for which the applicable statute of limitations has expired.[96]

As the Bureau explained in the May 2019 proposal, many debt collectors already determine whether the statute of limitations applicable to a debt has expired. Some do so to comply with State and local disclosure laws that require them to inform consumers when debts are time barred.[97] Others do so to assess whether they can sue to collect the debt, which may affect their collection strategy. In addition, the information that debt buyers generally receive when bidding on and purchasing debts, and the information that other debt collectors generally receive at placement, may allow them to determine whether the applicable statute of limitations has expired.[98]

Several commenters addressed proposed § 1006.26(a)(2). An industry commenter confirmed that the proposed definition comported with debt collectors' understanding of the term. Two other industry commenters expressed concern that the term time-barred debt may imply that a debt collector has no right at all to collect the debt, whereas in most jurisdictions a debt's time-barred status only limits the debt collector's right to recover on the debt through a lawsuit. Several industry commenters expressed concern that the proposal seemed to contemplate that a debt is a single amount that becomes time barred at a single moment in time and noted that not all debts operate in that manner. For example, these commenters stated that an installment loan could become time barred on a rolling basis depending on when each installment was due. In addition, according to some commenters, a legal action to collect a debt may be based on more than one legal theory or involve more than one cause of action, and each theory or cause of action may be subject to a different statute of limitations. Similarly, according to some commenters, certain secured debts may be subject to more than one method of suit and more than one statute of limitations. For example, these commenters asserted, in some States a mortgagee may choose whether to pursue a remedy at law on the note, a remedy in equity on the mortgage, or both, and the statute of limitations applicable to these claims may differ. Relatedly, one industry commenter asked the Bureau to clarify that debt collectors are not prohibited from taking legal action to enforce a lien even if a claim on the underlying obligation is time barred. Alternatively, the commenter asked the Bureau to clarify that the requirements of proposed § 1006.26 would apply only when all causes of action associated with the underlying note and with the security instrument are time barred.[99]

The Bureau is finalizing § 1006.26(a)(2) as proposed. As industry commenters confirmed, the definition of time-barred debt in § 1006.26(a)(2) is consistent with debt collectors'

[94] *Id.*

[95] *Young* v. *United States,* 535 U.S. 43, 47 (2002) (quoting *Rotella,* 528 U.S. at 555).

[96] *See* 84 FR 23274, 23328 (May 21, 2019).

[97] *See, e.g.,* Cal. Civ. Code sec. 1788.52(d)(3); Conn. Gen. Stat. sec. 36a–805(a)(14); Mass. Code Regs., tit. 940, § 7.07(24); N.M. Code. R. sec. 12.2.12.9(A); N.Y. Comp. Codes R. & Regs., tit. 23, sec. 1.3; New York City, N.Y., Rules, tit. 6, sec. 2–191(a); W. Va. Code sec. 46a–2–128(f).

[98] *See* Fed. Trade Comm'n, *The Structure and Practices of the Debt Buying Industry,* at 49 (Jan. 2013), *https://www.ftc.gov/sites/default/files/documents/reports/structure-and-practices-debt-buying-industry/debtbuyingreport.pdf* (FTC Debt Buying Report) (''The data the Commission received from debt buyers suggests that debt buyers usually are likely to know or be able to determine whether the debts on which they are collecting are beyond the statute of limitations.''). Similarly, the majority of respondents to the Bureau's Debt Collection Operations Study reported always or often receiving certain information and documentation that may be relevant to determining whether a debt is time barred, such as debt balance at charge off, account agreement documentation, and billing statements. *See* CFPB Debt Collection Operations Study, *supra* note 37, at 23.

[99] Another commenter seeking clarification on the scope of proposed § 1006.26(b) asserted that *in rem* enforcement of a security instrument is not inherently debt collection. The Bureau notes that § 1006.26, like the rest of this final rule, applies only to FDCPA debt collectors. The Supreme Court recently held that a business engaged in no more than nonjudicial foreclosure proceedings is not an FDCPA debt collector, except for the limited purpose of FDCPA section 808(6). *See Obduskey* v. *McCarthy & Holthus LLP,* 139 S. Ct. 1029 (2019). FDCPA section 808(6) specifically prohibits taking or threatening to take any nonjudicial action in certain circumstances, such as where there is no present right to possession through an enforceable security instrument.

understanding of the term. In response to commenters' concerns that the term time-barred debt might imply that a debt collector has no right to collect the debt, the Bureau notes that, in most jurisdictions, as commenters observed and as is discussed in the section-by-section analysis of § 1006.26(b), a debt is not extinguished when the statute of limitations expires. Rather, in these jurisdictions, a debt collector still may collect the debt using non-litigation means, such as telephone calls and letters, and the Bureau's use of the term time-barred debt neither changes that fact nor is meant to imply otherwise. With respect to industry commenters' concern about debts for which multiple statutes of limitation may be relevant, the Bureau notes that a debt is a time-barred debt under § 1006.26(a)(2) if the applicable statute of limitations has expired. The applicable statute of limitations depends on the specific legal action the debt collector takes or represents that it will take. For some debts, such as certain installment loans and secured debts, it may be the case that one claim associated with a debt is time barred while another claim associated with the debt is not. In such a case, the prohibitions in § 1006.26(b) apply to the time-barred claim only.

26(b) Legal Actions and Threats of Legal Actions Prohibited

The Bureau proposed § 1006.26(b) to prohibit a debt collector from bringing or threatening to bring a legal action against a consumer to collect a debt that the debt collector knows or should know is a time-barred debt.[100] In response to comments, the Bureau is finalizing proposed § 1006.26(b) with two principal changes. First, the Bureau is not adopting the proposed knows-or-should-know standard; instead, a debt collector may violate final § 1006.26(b) even if the debt collector neither knew nor should have known that a debt was time barred. Second, consistent with the Supreme Court's decision in *Midland Funding, LLC* v. *Johnson,* the final rule clarifies that the prohibitions in § 1006.26(b) do not apply to proofs of claim filed in bankruptcy proceedings.[101]

Prohibitions

As the Bureau explained in the May 2019 proposal, in most States the expiration of the applicable statute of limitations, if raised by the consumer as an affirmative defense, precludes the debt collector from recovering on the debt using judicial processes, but it does not extinguish the debt itself.[102] In other words, in most States a debt collector may use non-litigation means to collect a time-barred debt, as long as those means do not violate the FDCPA or other laws. If a debt collector does sue to collect a time-barred debt, and if the consumer proves the expiration of the statute of limitations as an affirmative defense, the court will dismiss the suit.

Suits and threats of suit on time-barred debts can harm consumers in multiple ways. A debt collector's threat to sue on a time-barred debt may prompt some consumers to pay or prioritize that debt over others in the mistaken belief that doing so is necessary to avoid litigation. In some jurisdictions, a consumer's payment on or acknowledgement of a debt can revive the debt collector's right to sue for the entire amount, opening the consumer to new legal liability.[103] Similarly, suits on time-barred debts may lead to judgments against consumers on claims for which those consumers had meritorious defenses, including defenses based on the statute of limitations. Few consumers who are sued for allegedly unpaid debts—whether time barred or not—actually defend themselves in court, and those who do often are unrepresented. As a result, the vast majority of judgments on unpaid debts, including on time-barred debts, are default judgments, entered solely on the representations contained in the debt collector's complaint.[104]

Consumer and consumer advocate commenters generally supported the prohibitions in proposed § 1006.26(b). Many of these commenters also argued that, to prevent deception, the Bureau should prohibit the collection of time-barred debt altogether, even though the Bureau did not propose such a prohibition in the May 2019 proposal or the February 2020 proposal. The Bureau certainly supports measures to prevent deception because of the harm it causes to consumers. However, the Bureau concludes that is not necessary to ban the collection of time-barred debt to prevent potential deception. As discussed in the February 2020 proposal, the Bureau's quantitative testing generally indicates that disclosures, in certain situations, can be effective in curing the potential deception associated with the collection of time-barred debt.[105] The Bureau concludes that a prohibition on the collection of time-barred debt would impose significant burden on debt collectors to identify such debts and would decrease the value of time-barred debts to little or nothing; a debt has little or no value if the owner cannot collect the debt either in litigation or outside of litigation. The Bureau declines to impose such extraordinarily large costs because much less costly measures—namely, disclosures—can be

[100] *See* 84 FR 23274, 23328–29 (May 21, 2019).

[101] 137 S. Ct. 1407 (2017).

[102] *See generally Midland Funding, LLC* v. *Johnson,* 137 S. Ct. 1407, 1411–12 (2017) (noting that under ''the law of many States . . . a creditor has the right to payment of a debt even after the limitations period expires,'' and collecting State laws). In Mississippi and Wisconsin, however, debts are extinguished when the applicable statute of limitations expires. *See* Miss. Code Ann. sec. 15–1–3 (''The completion of the period of limitation prescribed to bar any action, shall defeat and extinguish the right as well as the remedy.''); Wis. Stat. Ann. sec. 893.05 (''When the period within which an action may be commenced on a Wisconsin cause of action has expired, the right is extinguished as well as the remedy.'').

[103] Revival extinguishes the consumer's right to raise the expiration of the statute of limitations as an affirmative defense to litigation; that is, it revives the debt collector's right to sue to collect the debt. Although State revival laws vary, there are generally several circumstances in which revival occurs. First, in some States, a consumer's partial payment on a time-barred debt revives the debt collector's right to sue. Second, in some States, a consumer's written acknowledgement of a time-barred debt revives the debt collector's right to sue. Third, a consumer's oral acknowledgement of a time-barred debt may revive the debt collector's right to sue in some States. *See, e.g., Lima* v. *Schmidt,* 595 So. 2d 624, 631 (La. 1992) (''Our courts have consistently held that renunciation must be clear, direct, and absolute and manifested by words or actions of the party in whose favor prescription has run.'') (citations omitted); 22 Tenn. Pract. Contract Law and Practice § 12:88 (rev. Aug. 2020) (''[T]he defendant may revive a plaintiff's remedy that has been barred by the statute of limitations. This event can occur either when the defendant expressly promises to pay a debt or when the defendant acknowledges the debt *and* expresses a willingness to pay it . . . . The expression of a defendant's willingness to pay might be implied from the words or action of a debtor . . . . .'') (citations and internal quotation marks omitted).

[104] *See* FTC Debt Buying Report, *supra* note 98, at 45 (observing that ''90 percent or more of consumers sued in [debt collection actions] do not appear in court to defend,'' which ''creates a risk that consumer will be subject to a default judgment on a time-barred debt''); Peter A. Holland, *The One Hundred Billion Dollar Problem in Small Claims Court: Robo-Signing and Lack of Proof in Debt Buyer Cases,* 6 J. Bus. & Tech. L. 259, 265 (2011) (''In the majority of debt buyer cases, the courts grant the debt buyer a default judgment because the consumer has failed to appear for trial . . . . Debtors who do receive notice usually appear without legal representation.''); CFPB Debt Collection Operations Study, *supra* note 37, at 18 (observing that respondents reported obtaining default judgments in 60 to 90 percent of their filed suits); *cf. Kimber* v. *Fed. Fin. Corp.,* 668 F. Supp. 1480, 1478 (M.D. Ala. 1987) (''Because few unsophisticated consumers would be aware that a statute of limitations could be used to defend against lawsuits based on stale debts, such consumers would unwittingly acquiesce to such lawsuits. And, even if the consumer realizes that she can use time as a defense, she will more than likely still give in rather than fight the lawsuit because she must still expend energy and resources and subject herself to the embarrassment of going into court to present the defense; this is particularly true in light of the costs of attorneys today.'').

[105] *See* 85 FR 12672, 12677–79 (Mar. 3, 2020).

effective in preventing potential deception.

Moreover, the Bureau emphasizes that prohibiting the collection of time-barred debt when doing so is unnecessary to prevent potential deception is inconsistent with the First Amendment limitations on the Bureau's authority to ban commercial speech. Courts have held that a debt collector who asks a consumer to pay a debt is engaging in commercial speech.[106] Prohibiting the collection of time-barred debt therefore would restrict commercial speech. The Supreme Court has held that restrictions on commercial speech are permissible when they: (1) Are supported by a substantial government interest; (2) directly advance that interest; and (3) are no more extensive than necessary to serve that interest.[107] If the potential deception associated with the collection of time-barred debt can be cured by a disclosure, then prohibiting the collection of time-barred debt would impose a restriction that is more extensive than necessary.[108] As noted above, the Bureau's quantitative testing generally indicates that, in certain situations involving the collection of time-barred debt, disclosures can be effective in curing potential deception. Therefore, the Bureau declines to finalize a prohibition on the collection of time-barred debt.

In addition to consumers and consumer advocates, several industry commenters, Federal agency staff, and one local government commenter expressed support for the proposed prohibitions. Commenters who supported the proposed prohibitions asserted that suits and threats of suit on time-barred debts may induce consumers to make payments they otherwise would not make. Some consumer advocate commenters noted that these payments can revive the debt collector's right to sue in certain jurisdictions. Additionally, consumer advocate commenters asserted that consumers often assume that the mere filing of a lawsuit means that they owe the debt, that the amount owed is accurately stated, and that the debt collector has the legal right to collect the debt, whereas in fact the debt collector may lack support for its claims. These commenters also asserted that consumers generally lack the knowledge and resources to defend their rights in court, and, as a consequence, many claims result in default judgments on debts that were not legally enforceable. Consumer advocate commenters also provided anecdotes and pointed to recent enforcement actions to show that debt collectors continue to sue and threaten to sue on time-barred debt.[109] One industry commenter who supported elements of proposed § 1006.26(b) acknowledged that proposed § 1006.26(b) is consistent with long-standing FDCPA case law.

Several industry commenters who opposed proposed § 1006.26(b) argued that the Bureau should not prohibit suits and threats of suit on time-barred debt because, in most jurisdictions, expiration of the statute of limitations does not prohibit a debt collector from bringing suit but rather provides the consumer with an affirmative defense to liability. According to these commenters, proposed § 1006.26(b) would effectively preempt State affirmative defense laws by making expiration of the statute of limitations a total bar to suit, thereby interfering with debt collectors' right to legal recourse under State law. Relatedly, an industry commenter argued that State courts are capable of addressing situations in which a debt collector sues to collect a time-barred debt, including by dismissing the debt collector's claim and awarding sanctions if appropriate. Another industry commenter asserted that consumers should be responsible for tracking the legal obligations associated with their debts, and that it would be unduly burdensome to require debt collectors to determine whether a debt is time barred, particularly for debt collectors who are small businesses.

Some industry commenters argued that the Bureau lacks the authority to prohibit suits and threats of suit on time-barred debts. For example, several industry commenters argued that proposed § 1006.26(b) exceeds the Bureau's authority because, in their view, nothing in the FDCPA permits the Bureau to preempt State laws relating to debt collection or access to courts or establishes a Federal role in determining State law defenses. Similarly, one industry commenter asserted that proposed § 1006.26(b) contradicts the Federal Rules of Civil Procedure and State-law equivalents and abridges a debt collector's right to petition the courts. The commenter pointed to Federal Rule of Civil Procedure 11, pursuant to which an attorney's claims, defenses, and other legal contentions must be warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law. According to this commenter, the proposed prohibitions conflict with Rule 11 and its equivalents by discouraging debt collectors from filing legitimate lawsuits that argue in good faith for the modification or reversal of existing law.

Final § 1006.26(b) prohibits a debt collector from bringing or threatening to bring a legal action against a consumer to collect a time-barred debt. A debt collector who sues or threatens to sue a consumer to collect a time-barred debt explicitly or implicitly misrepresents to the consumer that the debt is legally enforceable, and that misrepresentation is material to consumers because it may affect their conduct with regard to the collection of that debt, including whether to pay it.[110] The Bureau's consumer testing suggests that consumers often are uncertain about their rights concerning time-barred debt.[111] Consumers sued or threatened with suit on a time-barred debt generally do not recognize that the debt is time barred, that time-barred debts are unenforceable in court, or that they must raise the expiration of the statute of limitations as an affirmative defense.

The prohibitions in final § 1006.26(b) generally are consistent with the current state of the law. Multiple courts have held that suits and threats of suit on time-barred debt violate the FDCPA, reasoning that such practices violate FDCPA section 807's prohibition on false or misleading representations, FDCPA section 808's prohibition on unfair practices, or both.[112] The FTC

[106] *See, e.g., ACA Int'l* v. *Healey,* 457 F. Supp. 3d 17, 25–26 (D. Mass. 2020); *Stover* v. *Fingerhut Direct Mktg.,* 709 F. Supp. 2d 473, 479 (S.D. W.Va. 2009).

[107] *See Cent. Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557, 566 (1980).

[108] *In re R.M.J.,* 455 U.S. 191, 203 (1982); *see also Pearson* v. *Shalala,* 164 F.3d 650 (D.C. Cir. 1999).

[109] *See, e.g.,* Consent Order ¶¶ 65–69, *In re Encore Capital Grp., Inc.,* No. 2015–CFPB–0022 (Sept. 9, 2015), *http://files.consumerfinance.gov/f/201509_cfpb_consent-order-encore-capital-group.pdf;* Consent Order ¶¶ 56–59, *In re Portfolio Recovery Assocs. LLC,* No. 2015–CFPB–0023 (Sept. 9, 2015), *http://files.consumerfinance.gov/f/201509_cfpb_consent-order-portfolio-recovery-associates-llc.pdf; see also* Complaint ¶¶ 30–35, *Bureau of Consumer Fin. Prot.* v. *Encore Capital Grp., Inc.,* No. 2020CV1750 (S.D. Cal. Sept. 8, 2020), *https://www.consumerfinance.gov/documents/9167/cfpb_encore-capital-group-et-al_complaint_2020-08.pdf.*

[110] *See, e.g., Kimber,* 668 F. Supp. at 1489 (''By threatening to sue Kimber on her alleged debt . . . FFC implicit[ly] represented that it could recover in a lawsuit, when in fact it cannot properly do so.'').

[111] *See* FMG Focus Group Report, *supra* note 26, at 9–10; FMG Cognitive Report, *supra* note 27, at 36–37; FMG Summary Report, *supra* note 29, at 35–36; *see also* Fed. Trade Comm'n, *Repairing a Broken System: Protecting Consumers in Debt Collection Litigation and Arbitration* at iii, 26 (July 2010), *https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-bureau-consumer-protection-staff-report-repairing-broken-system-protecting/debtcollectionreport.pdf* (FTC Litigation Report).

[112] *See, e.g., Pantoja* v. *Portfolio Recovery Assocs., LLC,* 852 F.3d 679, 683–84 (7th Cir. 2017); *McMahon* v. *LVNV Funding, LLC,* 744 F.3d 1010, 1020 (7th Cir. 2014); *Phillips* v. *Asset Acceptance, LLC,* 736 F.3d 1076, 1079 (7th Cir. 2013); *Huertas*

also has concluded that the FDCPA bars actual and threatened suits on time-barred debt.[113] In addition, the prohibitions in final § 1006.26(b) generally are consistent with current industry practice. For example, a number of industry commenters stated they do not sue or threaten to sue on time-barred debt as a matter of policy, and one trade group commenter stated that it requires its members to refrain from suing or threatening to sue on time-barred debts.

The Bureau recognizes that, in most jurisdictions, expiration of the statute of limitations provides the consumer with an affirmative defense to liability, but it does not bar a debt collector from bringing suit. The Bureau concludes, however, that consumers are unlikely to know whether the applicable statute of limitations has expired or that the expiration of the statute of limitations provides an affirmative defense. Suits and threats of suit on time-barred debts therefore imply to the least sophisticated consumer not simply that the debt collector may sue or has sued the consumer but also that the debt collector's claim is legally enforceable. For time-barred debts, this is misleading because expiration of the statute of limitations provides the consumer with a complete defense.[114] Accordingly, the Bureau concludes that bringing or threatening to bring a legal action to collect a time-barred debt is a deceptive practice under FDCPA section 807 even if expiration of the statute of limitations is an affirmative defense rather than a categorical bar to suit.

As explained below, the Bureau is finalizing § 1006.26(b) as an interpretation of FDCPA section 807's prohibition on deception; such an interpretation is squarely within the Bureau's authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors. Contrary to commenters' claims, § 1006.26(b) does not preempt State laws relating to when a debt collector may bring a lawsuit in State court. Rather, it provides that a debt collector who sues or threatens to sue a consumer to collect a time-barred debt violates the FDCPA even if applicable State law permits the suit. In addition, contrary to commenters' assertions, § 1006.26(b) does not exceed the Bureau's authority by regulating access to the courts or litigation activities. Debt collectors have repeatedly argued that they cannot be held liable under the FDCPA for actions taken in litigation because, for example, the United States Constitution allows debt collectors to petition the courts, or because the Federal Rules of Civil Procedure (or their State equivalents) allow debt collectors to argue for the modification or reversal of existing law. Many courts have rejected such arguments, generally reasoning that the FDCPA unquestionably applies to litigation activities.[115] The fact that expiration of a State's statute of limitations may not extinguish a debt under State law or bar a lawsuit in State court unless an affirmative defense is raised and proven does not render the FDCPA's prohibition on using deceptive or misleading representations or means in debt collection inapplicable. There is nothing unusual about the proposition that some behavior permitted by State law may nevertheless violate Federal law. Moreover, nothing in § 1006.26(b) prohibits a debt collector from bringing a legal action against a consumer in which the debt collector argues for an extension, modification, or reversal of existing law or the establishment of new law—including a legal action in which the debt collector argues that a debt is not time barred. Debt collectors remain free to do so. But a debt collector who brings such an action may violate § 1006.26(b) if a court ultimately determines that the debt was time barred.

Liability Standard

Proposed § 1006.26(b) would have prohibited a debt collector from bringing or threatening to bring a legal action against a consumer to collect a time-barred debt only if the debt collector knew or should have known the debt was time barred.

In proposing a knows-or-should-know standard, the Bureau explained that determining whether a debt is time barred may involve analyzing which State law applies, which statute of limitations applies, when the statute of limitations began to run, and whether the statute of limitations has been tolled or reset. In many cases, a debt collector will know, or will be able to readily determine, whether the statute of limitations has expired. In some instances, however, a debt collector may be genuinely uncertain even after undertaking a reasonable investigation, such as if the case law in a State is unclear as to which statute of limitations applies to a particular type of debt. The proposed knows-or-should-know standard was meant to address this concern by not imposing liability on a debt collector if it had no way of knowing that a particular debt was time barred. But the Bureau also acknowledged that it sometimes may be difficult to determine whether a knows-or-should-know standard has been met. Such uncertainty could increase litigation costs and make it difficult for consumers and government agencies to bring actions against debt collectors. To address this concern, the Bureau sought comment on an alternative strict liability standard pursuant to which a debt collector would be liable for suing or threatening to sue on a time-barred debt even if the debt collector neither knew nor should have known that the debt was time barred.

Industry commenters generally did not support a strict liability standard. These commenters generally agreed that it can be difficult for a debt collector to determine whether a debt is time barred and asserted that holding debt collectors strictly liable for good faith errors would be unduly harsh. These commenters stated, for example, that determining the applicable statute of limitations and whether it has expired may require analyzing a variety of factual and legal questions specific to the debt, and that, in many cases, a debt collector may reach the wrong conclusion even after undertaking a reasonable investigation and analysis. Industry commenters asserted that debt collectors may be unable to reliably determine the statute of limitations before filing suit because the law is unclear, because some information relevant to the analysis may be unavailable, or both. Some industry commenters also asserted that the analysis may change over time. For example, according to these commenters, a consumer's decision to move to a different State after signing a loan agreement could affect a debt collector's analysis of which State law applies and whether the statute of limitations has been tolled. As another example, an industry commenter stated that, in certain jurisdictions, the statute of limitations applicable to mortgage debt is in flux because of unprecedented access by consumers to loss mitigation and an increase in bankruptcy filings in

v. *Galaxy Asset Mgmt.,* 641 F.3d 28, 33 (3d Cir. 2011) (per curiam); *Goins* v. *JBC & Assocs., P.C.,* 352 F. Supp. 2d 262, 273 (D. Conn. 2005); *Kimber,* 668 F. Supp. at 1487–89.

[113] FTC Litigation Report, *supra* note 111, at 23.

[114] *See, e.g., Goins,* 352 F. Supp. 2d at 272 (holding that, although the statute of limitations is an affirmative defense, threatening to bring suit on time-barred debt ''can at best be described as a 'misleading' representation, in violation of § 1692e,'' because the statute of limitations is a complete defense to any suit).

[115] *See, e.g., Aguilar* v. *LVNV Funding LLC,* No. 2:19–cv–105, 2019 WL 3369706, at *3–4 (M.D. Fla. July 26, 2019); *Tobing* v. *Parker McCay, P.A.,* No. 3:17–cv–00474, 2018 WL 2002799, at *9 (D.N.J. Apr. 30, 2018); *Consumer Fin. Prot. Bureau* v. *Frederick J. Hanna & Assocs., P.C.,* 114 F. Supp. 3d 1342, 1359–61 (N.D. Ga. 2015); *Johnson* v. *Riddle,* 305 F.3d 1107, 1118 (10th Cir. 2002).

the wake of the foreclosure crisis. Several industry commenters also expressed concern that debt collectors who are not attorneys may have particular difficulty making an accurate time-barred debt determination. For these reasons, industry commenters asserted that a strict liability standard, which would leave no room for error, would expose debt collectors to liability even though it would be challenging or very costly in many circumstances to determine if a debt is time barred.

Some industry commenters supported the proposed knows-or-should-know standard. These commenters generally asserted that the proposed standard would help debt collectors avoid liability for good-faith mistakes in determining whether a debt is time barred—something industry commenters argued is important given the complexity and uncertainty of certain time-barred debt analyses. One industry commenter asserted that the proposed standard also would adequately protect consumers from harm. However, several industry commenters who expressed general support for the proposed standard also asked the Bureau to provide additional guidance, including examples of circumstances in which a debt collector neither knows nor should know that a debt is time barred.

Not all industry commenters supported the proposed knows-or-should-know standard. Some industry commenters argued that the proposed standard was vague and subjective and could increase litigation risk rather than mitigating it. Other industry commenters asked the Bureau to clarify that the knows-or-should-know standard depends on the specific understanding and sophistication of the particular debt collector. They asserted, for example, that what an attorney debt collector knows or should know about a debt's time-barred status may differ from what a non-attorney debt collector knows or should know.

Some industry commenters who opposed the proposed knows-or-should-know standard offered alternative standards. For example, several industry commenters recommended that the Bureau finalize a reasonable investigation standard such that a debt collector who sued or threatened to sue to collect a time-barred debt would not be liable if the debt collector undertook a reasonable investigation before doing so. Similarly, some industry commenters argued that a debt collector who acts in good faith should not be liable for suits and threats of suit on time-barred debts. Other industry commenters suggested that the Bureau finalize a liability standard akin to qualified immunity such that a debt collector who sued or threatened to sue to collect a time-barred debt would not be liable unless the applicable statute of limitations was clearly established. Other industry commenters suggested that the Bureau finalize an actual knowledge standard such that a debt collector who sued or threatened to sue on a time-barred debt would be liable only if the debt collector knew the debt was time barred.

Some commenters suggested that the Bureau finalize various safe harbors for debt collectors. For example, industry commenters recommended safe harbors for debt collectors collecting debts of a certain age and for debt collectors who rely on information provided by the creditor. Other industry commenters suggested that a debt collector who maintains and follows reasonable procedures for determining whether a debt is time barred should receive a safe harbor from liability in the event that the debt collector inadvertently sues or threatens to sue on a time-barred debt. One industry commenter requested that the Bureau specifically confirm that FDCPA section 813(c)'s bona fide error defense would apply to violations of § 1006.26(b).

Other commenters, including consumers, consumer advocates, academics, some members of Congress, a group of State Attorneys General, and several local governments, urged the Bureau to adopt a strict liability standard. Although some of these commenters acknowledged that determining whether a debt is time barred can be complicated,[116] others argued that determining whether a debt is time barred is relatively straightforward in most cases. One commenter suggested that, if the Bureau finalizes the proposed knows-or-should-know standard, the Bureau should clarify that in most cases a debt collector will know (or should know) whether the statute of limitations has run because in most cases debt collectors have the necessary information to make the determination.

Some consumer advocate commenters who argued for a strict liability standard stated that it would incentivize debt collectors to determine whether a debt is time barred before threatening or filing suit. Some consumer advocate commenters suggested that this would help reduce the consumer protection risks associated with the collection of time-barred debt, including the risk that consumers may be unable to adequately protect their rights in court and the risk that consumers may make a payment on the debt under the misimpression that the debt is legally enforceable, which could revive the debt collector's right to sue. Some commenters expressed concern that the proposed knows-or-should-know standard would not adequately incentivize debt collectors to determine the time-barred status of debts. Around two dozen members of Congress asserted that finalizing a knows-or-should-know standard without additional protections could encourage willful ignorance on the part of a debt collector about the time-barred status of a debt. A group of State Attorneys General and some consumer advocate commenters similarly argued that a knows-or-should-know standard would promote willful ignorance by debt collectors.

A number of commenters, including consumer advocate commenters and a group of State Attorneys General, advocated a strict liability standard because, in their view, debt collectors generally have more resources and expertise and better access to information than consumers. These commenters generally asserted that it would often be difficult for a consumer to establish that a debt was time barred and that the debt collector knew or should have known that fact.

Many of these commenters also argued that the proposed knows-or-should-know standard was inconsistent with the FDCPA (which some commenters described as a strict liability statute) and with FDCPA section 807's prohibition on deception (which does not include a knowledge element). Some commenters pointed out that, because FDCPA section 813(c) provides debt collectors with a bona fide error defense to liability in certain circumstances, a strict liability standard would not expose debt collectors to undue liability. Commenters also argued that the proposed knows-or-should-know standard was inconsistent with case law imposing or implying a strict liability standard when evaluating claims that a debt collector sued or threatened to sue to collect a time-barred debt. Several commenters agreed with the Bureau that a strict liability standard generally would reduce ambiguity and be easier to enforce than the proposed knows-or-should-know standard. Federal government agency staff encouraged the Bureau to consider

[116] A group of academic commenters challenged the Bureau's assertion that debt buyers generally receive enough information to determine whether a debt is time barred. These commenters noted that fewer than half of respondents to the Bureau's industry survey reported receiving account agreement documentation or billing statements, information that the commenters believed would help a debt collector calculate the applicable statute of limitations and whether it has expired.

further whether a knows-or-should-know standard would place an unnecessary burden on law enforcement agencies.

The Bureau is not finalizing the proposed knows-or-should-know standard and is instead finalizing a strict liability standard. Although determining whether a debt is time barred can be challenging or costly in certain circumstances, the Bureau concludes that the proposed knows-or-should-know standard is generally inconsistent with FDCPA section 807, which does not include an exception or exclusion for debt collectors whose deceptive statements are unintentional or for whom ensuring that a statement is not deceptive is burdensome.[117] The Bureau also concludes that a strict liability standard is more consistent with FDCPA section 807's prohibition on deception, as well as case law imposing or implying such a standard when evaluating claims under FDCPA section 807 generally and claims related to suits and threats of suit on time-barred debt specifically.[118]

Moreover, the Bureau notes that a knows-or-should-know standard could, in some circumstances, shift the risk that a claim is deceptive from debt collectors to consumers. As explained above, suits and threats of suit on time-barred debt can cause consumer harm. In a case in which it is difficult or costly to determine whether a debt is time barred, a knows-or-should-know standard could allow debt collectors to avoid liability for causing such harm. In other consumer protection contexts, courts and the FTC have recognized that an advertiser who makes an unsubstantiated claim may be liable for deception even if the cost of substantiating the claim is high or prohibitively expensive.[119] The Bureau's decision to finalize a strict liability standard is generally consistent with this principle.

The Bureau emphasizes that, although a strict liability standard might create some risk for debt collectors if a debt's time-barred status is unclear, debt collectors have multiple ways to manage such risk. In particular, a debt collector can avoid liability under § 1006.26(b) by confirming that the statute of limitations has not expired before bringing or threatening to bring a legal action. Similarly, a debt collector who is ultimately unable to determine with certainty whether a debt is time barred can avoid liability under § 1006.26(b) by refraining from bringing or threatening to bring a legal action while, in most States, continuing with non-litigation collection activities. Moreover, a debt collector who brings or threatens to bring a legal action against a consumer to collect a time-barred debt may, depending upon the reason for the debt collector's error, have a defense to civil liability under FDCPA section 813 if the debt collector shows by a preponderance of evidence that the violation was not intentional and resulted from a bona fide error notwithstanding the maintenance of procedures reasonably adapted to avoid any such error.[120] For these reasons, the Bureau concludes that finalizing a strict liability standard under § 1006.26(b) does not pose an undue risk of liability for debt collectors, even in cases in which a debt collector is unable to determine with certainty whether a debt is time barred.

Requests for Clarification

Several commenters asked the Bureau to clarify the scope of proposed § 1006.26(b)'s prohibitions.[121] Two industry commenters suggested that the term ''legal action'' is unclear and could be interpreted to encompass any action in any court of law or equity. These commenters suggested replacing ''legal action'' with ''lawsuit,'' asserting that, although ''legal action'' and ''lawsuit'' have overlapping meanings, ''lawsuit'' has a narrower connotation that excludes certain legal actions, such as bankruptcy proceedings. Alternatively, these commenters argued that, if the Bureau declines to change the term legal action, the prohibitions in proposed § 1006.26(b) should be adjusted to specifically exclude certain types of legal actions, such as garnishment actions, probate actions, and the filing of proofs of claim in bankruptcy proceedings.[122] Another commenter asked the Bureau to clarify that, for purposes of proposed § 1006.26(b), the term ''legal action'' does not include ''non-original complaints,'' such as amended complaints, supplemental complaints, complaints re-filed after a prior dismissal without prejudice, post-judgment court filings, or post-judgment communications (such as executions or garnishments).

Final § 1006.26(b) uses the term ''legal action.'' In *Midland Funding, LLC* v. *Johnson,* the Supreme Court held that filing a proof of claim on a time-barred debt in a bankruptcy proceeding does not violate the FDCPA sections 807 or 808.[123] Consistent with *Midland,* the final rule clarifies that § 1006.26(b) does not prohibit the filing of proofs of claim in a bankruptcy proceeding. The Bureau does not see a basis to categorically exclude other types of legal actions, such as garnishment and probate actions, from the prohibitions in § 1006.26(b). No other section of the FDCPA pertaining to legal actions contains a similar exclusion, and the commenters did not explain why they believe an exclusion is merited here.

At least one industry commenter asked the Bureau to clarify the types of actions and statements that qualify as a threat of legal action or that could be interpreted by a consumer as a threat of legal action. The Bureau declines to do so at this time. Whether a particular action or statement constitutes a threat of legal action depends on the facts and circumstances of the particular case. Nevertheless, the Bureau notes that § 1006.26(b) prohibits not only explicit

[117] For the same reasons, the Bureau concludes that the alternative standards proposed by industry commenters—including, for example, an actual knowledge standard, a reasonable-investigation standard, or a clearly-established-law standard—are generally inconsistent with FDCPA section 807.

[118] *See, e.g., Pantoja,* v. *Portfolio Recovery Assocs., LLC,* 852 F.3d 679, 683 (7th Cir. 2017); *Buchanan* v. *Northland Grp., Inc.,* 776 F.3d 393, 399 (6th Cir. 2015); *Phillips* v. *Asset Acceptance, LLC,* 736 F.3d 1076, 1083–84 (7th Cir. 2013); *Clark* v. *Capital Credit & Collection Servs.,* 460 F.3d 1162, 1176 (9th Cir. 2006); *Gearing* v. *Check Brokerage Corp.,* 233 F.3d 469, 472 (7th Cir. 2000).

[119] *See, e.g., POM Wonderful, LLC* v. *FTC,* 777 F.3d 478, 497 (D.C. Cir. 2015) (''We acknowledge that RCTs [*i.e.,* randomized clinical trials] may be costly. . . . Yet if the cost of an RCT proves prohibitive, petitioners can choose to specify a lower level of substantiation for their claims. As the Commission observed, the need for RCTs is driven by the claims petitioners have chosen to make.'') (internal brackets and quotation marks omitted); *In re POM Wonderful LLC,* 2013 WL 268926, at *50 (F.T.C. Jan. 16, 2013) (rejecting argument that an advertiser may ''make particular claims that go beyond the substantiation it possesses and then ask the Commission to excuse the inadequacy of its support by asserting that [the] advertiser did the best it could because the proper substantiation for the actual claim would be too expensive''); *In re Kroger Co.,* 98 F.T.C. 639, 737 (1981) (''Where the demands of the purse require such compromises, the advertiser must generally limit the claims it makes for its data or make appropriate disclosures to insure proper consumer understanding of the survey's results.'').

[120] *See Jerman* v. *Carlisle, McNellie, Rini, Kramer & Ulrich LPA,* 559 U.S. 573 (2010) (holding that bona fide error defense is not available when FDCPA violation arises from a debt collector's mistaken interpretation of FDCPA's legal requirements but noting that bona fide error defense is available when FDCPA violation arises from certain other types of errors).

[121] Commenters also asked the Bureau to adopt a number of interventions that the Bureau did not propose, such as a prohibition on revival and a prohibition on perpetual tolling, which commenters asserted prevents a statute of limitations from ever expiring in certain circumstances. The Bureau did not propose these interventions and it is not finalizing them.

[122] A consumer advocate commenter argued that the rule should expressly prohibit filing a bankruptcy proof of claim to recover a time-barred debt.

[123] 137 S. Ct. 1407 (2017).

threats of legal action but also implicit ones.

For the reasons discussed above, the Bureau is finalizing § 1006.26(b), which provides that a debt collector must not bring or threaten to bring a legal action against a consumer to collect a time-barred debt. Section 1006.26(b) also states that these prohibitions do not apply to proofs of claim filed in connection with a bankruptcy proceeding. The Bureau is finalizing § 1006.26(b) as an interpretation of FDCPA section 807. FDCPA section 807 generally prohibits debt collectors from using ''any false, deceptive, or misleading representation or means in connection with the collection of any debt,'' and FDCPA section 807(2)(A) specifically prohibits falsely representing ''the character, amount, or legal status of any debt.'' The Bureau interprets FDCPA section 807 and 807(2)(A) to prohibit debt collectors from suing or threatening to sue consumers on time-barred debts because such suits and threats of suit explicitly or implicitly misrepresent, and cause consumers to believe, that the debts are legally enforceable. In addition, threats to sue consumers on time-barred debts are similar to threats to take actions that cannot legally be taken, which FDCPA section 807(5) specifically prohibits, because both involve the threat of action to which the consumer has a complete legal defense.[124] The Bureau's interpretation of FDCPA section 807 is generally consistent with well-established case law holding that suits and threats of suits on time-barred debt violate FDCPA section 807.[125]

Proposed Provision Not Finalized

In the February 2020 proposal, the Bureau proposed to require a debt collector collecting a debt that the debt collector knows or should know is a time-barred debt to provide time-barred debt disclosures and, if applicable, revival disclosures (proposed § 1006.26(c)(1) and (2)).[126] The Bureau proposed to require these disclosures in the debt collector's initial communication with the consumer, on any validation notice, and in certain situations if the debt became time barred during collections. The February 2020 proposal also included, among other things, model forms and language a debt collector could have used to comply with the proposed disclosure requirements (proposed Model Forms B–4 through B–7), and it provided a safe harbor to a debt collector who used the model forms or language (proposed § 1006.26(c)(3)). In support of proposed § 1006.26(c), the Bureau cited, among other things, the results of its quantitative testing survey.[127]

Although some commenters expressed general support for the idea of addressing the risk of deception associated with the collection of time-barred debts by requiring time-barred debt and revival disclosures, many commenters opposed the Bureau's specific proposal. According to industry commenters, the proposal would have imposed a significant burden on debt collectors by requiring them to conduct time-barred debt and revival analyses for each debt in collection. These commenters also reported that they would face a significant risk of liability given uncertainty about the statute of limitations and revival law in at least some States. Industry commenters stated that most debt collectors lack the legal training to determine whether a debt is time barred or the circumstances in which it can be revived. To comply with the disclosure requirements, these commenters asserted that debt collectors would need to engage an attorney or otherwise incur substantial costs. Industry commenters particularly objected to imposing these costs on debt collectors who never sue to collect debts, or never sue to collect revived debts. Industry commenters also raised concerns about being required to respond to legal questions from consumers as a result of providing the disclosures.

Among consumer, consumer advocate, academic, and State Attorneys General commenters who opposed the Bureau's proposal, many doubted that disclosures can effectively convey information about topics as complicated and unfamiliar to consumers as time-barred debt and revival. These commenters also raised concerns about the Bureau's proposed model disclosures, characterizing them as confusing, vague, and ineffective—particularly for the least sophisticated consumer.[128] Some consumer advocate commenters also expressed concern about the accuracy of the proposed disclosures and the frequency with which the Bureau proposed to require them. These commenters urged the Bureau to reconsider or significantly revise the proposal.

Given industry commenters' concerns about the burden on debt collectors of the Bureau's specific proposal, and consumer advocate commenters' concerns about whether the Bureau's specific proposal would effectively cure consumer deception, the Bureau has decided not to finalize proposed § 1006.26(c). In deciding not to finalize proposed § 1006.26(c), the Bureau determines only that the specific disclosure requirements described in the February 2020 proposal may not sufficiently accommodate the concerns raised by different stakeholders. However, the Bureau concludes, as discussed in the February 2020 proposal, that, in many circumstances, disclosures can effectively cure the potential deception associated with the collection of time-barred debt.

Finally, the Bureau emphasizes that the FDCPA, the November 2020 Final Rule, and this final rule nevertheless apply to debt collectors' activities involving the collection of time-barred debts, including debt collectors' communications when collecting such debts. Accordingly, a debt collector may not use any false, deceptive, or misleading representation or means in connection with the collection of a time-barred debt. Nor may a debt collector use unfair or unconscionable means to collect or attempt to collect a time-barred debt. Depending on the circumstances associated with the collection of a specific time-barred debt, a debt collector may decide that, to avoid violating the FDCPA and the final

[124] A consumer advocate commenter requested that the Bureau clarify that a debt collector who brings or threatens to bring a legal action against a consumer to collect a time-barred debt also violates the Dodd-Frank Act. The Bureau is finalizing § 1006.26(b) as an interpretation of FDCPA section 807 only.

[125] *See, e.g., Pantoja,* 852 F.3d at 683; *McMahon,* 744 F.3d at 1020; *Phillips,* 736 F.3d at 1079; *Kimber,* 668 F. Supp. at 1488–89.

[126] Specifically, proposed § 1006.26(c)(1) would have required a debt collector collecting a debt that the debt collector knows or should know is a time-barred debt to disclose (i) that the law limits how long a consumer can be sued for a debt and that, because of the age of the debt, the debt collector will not sue the consumer to collect it; and (ii) if, under applicable law, the debt collector's right to bring a legal action against the consumer can be revived, then the fact that revival can occur and the circumstances in which it can occur. 85 FR 12672, 12696 (Mar. 3, 2020).

[127] *See id.* at 12678–79.

[128] Courts have applied an objective standard of an ''unsophisticated'' or ''least sophisticated'' consumer to claims brought under FDCPA section 807. *Jensen* v. *Pressler & Pressler,* 791 F.3d 413, 419 (3d Cir. 2015) (''The standard is an objective one, meaning that the specific plaintiff need not prove that *she* was actually confused or misled, only that the objective least sophisticated debtor would be.''); *Hartman* v. *Great Seneca Fin. Corp.,* 569 F.3d 606, 613 (6th Cir. 2009) (applying least sophisticated consumer standard to section 807 claim); *Bentley* v. *Great Lakes Collection Bureau,* 6 F.3d 60, 62 (2d Cir. 1993) (same); *Swanson* v. *S. Or. Credit Serv., Inc.,* 869 F.2d 1222, 1227 (9th Cir. 1988) (per curiam) (same). This standard ''protects the consumer who is uninformed, naive, or trusting, yet it admits an objective element of reasonableness.'' *Gammon* v. *GC Servs. Ltd. P'ship,* 27 F.3d 1254, 1257 (7th Cir. 1994). As discussed in part IV, the Bureau interprets FDCPA sections 807 to incorporate an objective, ''unsophisticated'' or ''least sophisticated'' consumer standard.

rule, the debt collector needs to disclose information to consumers about the debt collector's ability to sue and the possibility of revival and, in that case, the debt collector may do so.

Section 1006.30 Other Prohibited Practices

30(a) Required Actions Prior to Furnishing Information

The Bureau proposed in § 1006.30(a) to prohibit so-called passive collections, *i.e.,* the practice of a debt collector furnishing to a consumer reporting agency, as defined in section 603(f) of the Fair Credit Reporting Act (FCRA),[129] information regarding a debt before communicating with the consumer about the debt. The Bureau proposed § 1006.30(a) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors; pursuant to its authority to interpret FDCPA section 806, which prohibits a debt collector from engaging in any conduct the natural consequence of which is to harass, oppress, or abuse any person in connection with the collection of a debt; and pursuant to its authority to interpret FDCPA section 808, which prohibits a debt collector from using unfair or unconscionable means to collect or attempt to collect any debt. Courts have interpreted FDCPA sections 806 and 808 to prohibit certain coercive collection methods that may cause consumers to pay debts not actually owed.[130]

For the reasons discussed below, the Bureau is: (1) Finalizing § 1006.30(a) as § 1006.30(a)(1), with changes to specify the required actions that a debt collector generally must take before furnishing information to a consumer reporting agency; and (2) finalizing in § 1006.30(a)(2) a special rule for information furnished to certain specialty consumer reporting agencies.

30(a)(1) In General

The Bureau received comments on proposed § 1006.30(a) from consumer advocates and individuals, nonprofits, industry commenters, and government agencies. Many commenters supported the proposed prohibition on passive collections. A consumer group emphasized the consumer harms identified in the proposal and agreed that, because with passive collections a consumer does not know a debt is in collection, the practice can cause a consumer's credit score to decrease, increase the cost of future credit for the consumer, make it more difficult for a consumer to obtain affordable housing, and jeopardize some job opportunities, all without the consumer's knowledge. Three government commenters also supported the proposed prohibition; one of them reported receiving consumer complaints regarding passive collections. An industry commenter supporting the proposal noted that the commenter provides consumers with a 90-day grace period before furnishing information to consumer reporting agencies.

A number of comments, primarily from industry or industry trade groups, opposed the prohibition or suggested changes or clarifications. Two industry trade groups and a law firm commenter argued that proposed § 1006.30(a) should not be finalized because it conflicts with the FCRA, including section 623(a)(7), which requires certain financial institutions to provide written notice to customers if they furnish negative information to a consumer reporting agency, and section 623(a)(5), which requires furnishers to provide certain information about a reported delinquency to the consumer reporting agency no later than 90 days after furnishing information.[131] Other industry commenters argued that the proposal would encourage consumers to ignore communications, provide inaccurate forwarding information to the creditor, or falsely mark mail as undeliverable to avoid having collection items furnished to consumer reporting agencies. In addition, several industry commenters stated that locating consumers for certain debts, such as medical debt, telecommunications debt, or rental debt, is costly and may not be justified for small amounts. If debt collectors cannot passively collect these debts, the commenters argued, then the debts are effectively uncollectible. One industry trade group similarly argued that passive collections benefits consumers who otherwise cannot be located, rather than harming them, because the collection item on their credit report will provide them contact information for the debt collector, which the consumer can then use to make payment arrangements.

A number of commenters suggested changing or clarifying the proposed requirement to ''communicate'' before furnishing information to a consumer reporting agency. Some urged the Bureau to adopt a stricter requirement, such as by requiring written notice to the consumer before reporting, mandating specific disclosure language, imposing across-the-board waiting periods before reporting, or prohibiting indirect communications. Others expressed concern that the proposal would impose more stringent communication requirements than the FDCPA otherwise requires and asked the Bureau to relax the proposal, such as by clarifying that proof of receipt of a communication is not required, by allowing debt collectors to satisfy the proposed requirement by leaving limited-content messages (as defined in § 1006.2(j) of the November 2020 Final Rule), or by permitting debt collectors to presume receipt of a communication after a waiting period expires.

After considering all of the comments, the Bureau is finalizing proposed § 1006.30(a) and its related commentary with substantial revisions, as follows.

Subject to § 1006.30(a)(2) (discussed below), final § 1006.30(a)(1) requires a debt collector to take certain actions before furnishing information about a debt to a consumer reporting agency, as defined in section 603(f) of the FCRA. Specifically, the debt collector must either: (1) Speak to the consumer about the debt in person or by telephone, or (2) place a letter in the mail or send an electronic message to the consumer about the debt and wait a reasonable period of time to receive a notice of undeliverability. During the reasonable period, the debt collector must permit receipt of, and monitor for, notifications of undeliverability from communications providers. If the debt collector receives such a notification during the reasonable period, the debt collector must not furnish information about the debt to a consumer reporting agency until the debt collector otherwise satisfies § 1006.30(a)(1). The Bureau is finalizing commentary to clarify these requirements as discussed below.

The Bureau finalizes the requirements under § 1006.30(a)(1) to address consumer harms that may arise if a debt collector furnishes information about a debt to a consumer reporting agency without first informing the consumer about the debt. As discussed in the proposal, consumers who have not been informed about the debt are likely to be unaware that they have a debt in

[129] 15 U.S.C. 1681a(f).

[130] *See, e.g., Fox* v. *Citicorp Credit Servs., Inc.,* 15 F.3d 1507, 1517 (9th Cir. 1994) (reversing grant of summary judgment to debt collector in part because ''a jury could rationally find'' that filing writ of garnishment was unfair or unconscionable under section 808 when debt was not delinquent); *Ferrell* v. *Midland Funding, LLC,* No. 2:15–cv–00126–JHE, 2015 WL 2450615, at *3–4 (N.D. Ala. May 22, 2015) (denying debt collector's motion to dismiss section 806 claim where debt collector allegedly initiated collection lawsuit even though it knew plaintiff did not owe debt); *Pittman* v. *J.J. Mac Intyre Co. of Nev., Inc.,* 969 F. Supp. 609, 612–13 (D. Nev. 1997) (denying debt collector's motion to dismiss claims under sections 807 and 808 where debt collector allegedly attempted to collect fully satisfied debt).

[131] 15 U.S.C. 1681s–2(a)(5) and (7).

collection unless they obtain and review their consumer report. In turn, many consumers may not obtain their consumer reports until they apply for credit, housing, employment, or another product or service provided by an entity that reviews consumer reports during the application process. At that point, consumers may feel pressure to pay debts that they otherwise would dispute, including debts they do not owe, or may face the denial of an application, a higher interest rate, or other negative consequences.

In addition, as discussed in the proposal, debt collectors may attempt to collect debts passively if the expected return from that technique exceeds the cost of attempting to collect the debt by communicating with consumers.[132] The Bureau understands that imposing a requirement intended to inform the consumer about a debt before furnishing information about a debt to consumer reporting agencies will increase costs for debt collectors who do not currently attempt to do so. However, passive collection practices can harm consumers for the reasons discussed above. The Bureau has determined that the final rule best balances debt collectors' cost concerns with protections for consumers against the harms imposed by passive collection practices. Final § 1006.30(a)(1) gives a debt collector flexibility to contact consumers in a variety of ways, including in person, by telephone, by mail, or by electronic message.[133] This gives debt collectors flexibility to contact the consumer in a manner that works best for their operations, and debt collectors need not confirm receipt of mail or electronic messages.

Although proposed § 1006.30(a) used the term ''communicate,'' the proposal did not clearly specify a debt collector's obligations if the debt collector learned after furnishing information to a consumer reporting agency that no communication actually occurred (because, *e.g.,* the communication was sent by mail to the consumer's current address but the debt collector later received a notification that the letter was not delivered). Some commenters raised concerns that the proposal's use of the term ''communicate'' could be construed to require debt collectors to confirm a consumer's receipt of the information before furnishing information about a debt to a consumer reporting agency.

To respond to such comments, and because the proposal was designed to increase the likelihood that consumers would learn that a debt attributed to them is in collection but was not intended to be a broader limitation on furnishing valid information about debts to consumer reporting agencies, the Bureau finalizes specific requirements a debt collector must take before furnishing. The actions specified in the final rule are ones that increase the likelihood that a consumer will learn about a debt before a debt collector begins furnishing information about that debt to a consumer reporting agency. For this reason, after a debt collector has complied with § 1006.30(a)(1) and furnished information to a consumer reporting agency, the debt collector may furnish additional information with respect to that debt without having to repeat the actions specified in § 1006.30(a)(1). Accordingly, the Bureau does not incorporate a receipt requirement in final § 1006.30(a)(1) and, instead of using the term ''communicate,'' sets forth the specific actions that a debt collector must take before furnishing.

The Bureau has also determined that final § 1006.30(a)(1) does not conflict with FCRA section 623(a)(7) or (5) because those provisions have different requirements and goals than § 1006.30(a)(1). FCRA section 623(a)(7) applies only to ''financial institutions'' as defined in FCRA section 603(t), which will cover few, if any, FDCPA debt collectors. Final § 1006.30(a)(1) does not prevent debt collectors from complying with the FCRA, and the FCRA does not prevent debt collectors from complying with final § 1006.30(a)(1).[134] The FCRA also does not state that it is the exclusive Federal law governing credit reporting and, indeed, the FDCPA also references a debt collector's interactions with consumer reporting agencies.[135]

Because final § 1006.30(a)(1) clearly describes the specific actions that a debt collector must take before furnishing information about a debt to a consumer reporting agency, a debt collector may ensure compliance with the final rule based on the debt collector's own actions, such as by placing a letter about the debt in the mail to the consumer and waiting a reasonable period of time to receive a notice of undeliverability. Therefore, the final rule also resolves concerns about consumers avoiding a debt collector's communications to prevent the debt collector from furnishing information to a consumer reporting agency.

The final rule specifies in § 1006.30(a)(1)(i) and (ii) the methods by which a debt collector may meet its obligation to take certain actions before furnishing information about a debt to a consumer reporting agency. All of the methods require that information ''about the debt'' be conveyed to the consumer. Although the final rule does not specify the particular information required to meet the ''about the debt'' requirement, the final rule adds comment 30(a)(1)–1 to clarify that the validation information required by § 1006.34(c), including such information if provided in a validation notice, is information ''about the debt.''

Under § 1006.30(a)(1), information about a debt must be transmitted ''to the consumer'' as defined in § 1006.2(e). A debt collector who sends information about the debt that reaches a ''consumer'' as defined in § 1006.6(a), which includes additional persons,[136] may not have communicated with the consumer as defined in § 1006.2(e).

The Bureau notes that, in taking any of the actions specified in § 1006.30(a)(1), a debt collector must comply with the FDCPA and the November 2020 Final Rule, including the prohibition on communicating, in connection with the collection of any debt, with a third party.[137]

Proposed comment 30(a)–1 provided clarifications regarding the term ''communicate'' in proposed § 1006.30(a)(1). Because final § 1006.30(a)(1) does not use the term ''communicate'' and instead states the specific actions the debt collector must take before furnishing information about a debt to a consumer reporting agency, proposed comment 30(a)–1 is no longer

[132] 84 FR 23274, 23330 (May 21, 2019).

[133] Because medical offices, telecommunications companies, and rental offices typically have contact information for their customers, and because a variety of options to verify and forward mail to a consumer's new address exist, a debt collector of such debts should be able to satisfy § 1006.30(a)'s requirements without incurring significant costs.

[134] For example, FCRA section 623(a)(7) requires certain financial institutions that furnish negative information to a consumer reporting agency, as defined in FCRA section 603(p), to provide a written notice to consumers prior to, or no later than 30 days after, furnishing the negative information. A financial institution that is required to provide a written notice under FCRA section 623(a)(7) and that is also acting as an FDCPA debt collector could comply with both requirements by, for example, placing a letter in the mail to the consumer that contains sufficient information to satisfy both requirements before furnishing information to a consumer reporting agency.

[135] *See, e.g.,* 15 U.S.C. 1692c(b), 1692d(3).

[136] For purposes of § 1006.6(a), the term ''consumer'' also includes the consumer's spouse, parent (if the consumer is a minor), legal guardian, executor or administrator of the consumer's estate, if the consumer is deceased, and a confirmed successor in interest. *See* 85 FR 76734, 76889 (Nov. 30, 2020).

[137] A debt collector sending an email or text message who uses the procedures provided for in § 1006.6(d)(4) or (5) as finalized in the November 2020 Final Rule does not violate the prohibition on third-party disclosure under § 1006.6(d)(1).

necessary and the Bureau is not finalizing it.

The final rule specifies in § 1006.30(a)(1)(ii) that a debt collector who places a letter in the mail or sends an electronic message to the consumer about the debt to satisfy § 1006.30(a)(1) must wait a reasonable period of time to receive a notice of undeliverability before furnishing information about a debt to a consumer reporting agency. New comment 30(a)(1)–2 clarifies that the reasonable period of time begins on the date that the debt collector places the letter in the mail or sends the electronic message. Comment 30(a)(1)–2 also provides a safe harbor for waiting a reasonable period of time by clarifying that a period of 14 consecutive days after the date that the debt collector places a letter in the mail or sends an electronic message is a reasonable period of time.

Comment 30(a)(1)–3 clarifies that a debt collector who places a letter in the mail or sends an electronic message to the consumer about the debt to satisfy § 1006.30(a)(1) and does not receive a notice of undeliverability during the reasonable period of time, and who thereafter furnishes information about the debt to a consumer reporting agency, does not violate § 1006.30(a)(1) even if the debt collector subsequently receives a notice of undeliverability. Comment 30(a)(1)–3 also provides three examples illustrating this requirement.

The Bureau determines that these provisions clarify the proposal with respect to pre-furnishing outreach by mail or electronic message and provide protection for consumers.[138] The Bureau understands that the U.S. Postal Service typically notifies senders of most undeliverable-as-addressed mail within 14 days. The amount of time it takes a communications provider to return a notice of undeliverability with respect to electronic messages is less clear. While an undeliverability notice is typically received soon after sending an electronic message, the Bureau understands that the time for receiving a notice of undeliverability with respect to such electronic messages may vary by provider, and the Bureau does not have sufficient information to determine a uniform time period for electronic messages. Nevertheless, the Bureau has no reason to believe that notices of undeliverability are typically received more than 14 days after an electronic message is sent. Therefore, the Bureau is finalizing the same safe harbor time period (*i.e.,* 14 consecutive days) for electronic messages as for mailed letters.[139] The Bureau may consider revising the safe harbor for electronic messages in the future based on actual stakeholder experience with this provision.

The Bureau recognizes that the final rule may result in instances in which debt collectors furnish information about a debt to a consumer reporting agency even though the consumer has not been made aware of the collection item, either because the mail or electronic message is returned as undeliverable after the reasonable period has passed or is not received but is also not returned. These consumers will not have the same opportunity to receive a message about their debt as those consumers for whom the mail or electronic message is delivered. Nevertheless, the Bureau determines that establishing a requirement that debt collectors wait a reasonable period of time after placing a letter in the mail or sending an electronic message provides sufficient consumer protection without unduly prohibiting a debt collector from furnishing information about a valid debt to a consumer reporting agency.

The Bureau declines commenters' other suggestions, such as those to require communications in writing, dictate specific language, apply longer waiting periods (*e.g.,* 180 days), or establish other safe harbors because the suggestions are unnecessary to achieve the purpose of the passive collections ban. For example, requiring written communications and specific disclosure language is unnecessary to put the consumer on notice that a debt is in collections. Additional safe harbors are unnecessary and unwarranted at this time because the final rule clarifies the specific actions that must occur before furnishing information to a consumer reporting agency.

30(a)(2) Special Rule—Information Furnished to Certain Specialty Consumer Reporting Agencies

The Bureau did not propose a special rule regarding furnishing to specialty consumer reporting agencies. An industry commenter and a consumer reporting agency argued in a joint comment that the final rule should exempt from § 1006.30(a) information furnished to certain nationwide specialty consumer reporting agencies described in FCRA section 603(x)(3), *i.e.,* consumer reporting agencies that maintain and compile files on consumers on a nationwide basis relating to check writing history (''check verification consumer reporting agencies'').

The commenters explained that merchants use check verification consumer reporting agencies to determine whether they should accept a particular check. When a merchant seeks check verification information, the check verification consumer reporting agency issues a check verification report with a code that will indicate if the check appears acceptable, the check is potentially fraudulent, or the checking account is likely overdrawn. These inquiries are usually completed in real time, while a transaction is occurring in a checkout lane or in remote retailing. The commenters expressed concern that proposed § 1006.30(a) would degrade the timely content of check verification reports issued by check verification consumer reporting agencies because debt collectors would be required to delay or refrain from reporting altogether, which would undermine the accuracy of check verification reports and reduce the willingness of merchants to accept checks.

The commenters argued that the current system benefits consumers by alerting them to potential fraud or that their account may be overdrawn. Requiring contact before furnishing information would harm these consumers because the fraud or overdrawn status of the account may never be detected and, thus, consumers may not be alerted to potential fraud or may unknowingly continue writing checks on an overdrawn account. Further, the commenters stated that these requirements could harm consumers by decreasing the number of merchants that accept checks or increasing prices at merchants who continue to accept checks.

The commenters also expressly recognized the harm that can occur if a debt unexpectedly appears on a credit-related consumer reporting agency report if the consumer is applying for credit, a job, or rental housing, and cannot move forward with the transaction. However, they noted that check verification reporting does not present comparable risk of harm because (1) such reports are used to determine whether a particular check should be accepted, not to evaluate a consumer's creditworthiness for credit, a job, or rental housing; and (2) any harm caused by refusal to accept a

[138] The Bureau does not impose a similar period when a debt collector speaks to a consumer about the debt in person or by telephone because these scenarios do not have the potential for an equivalent undeliverable notice outcome.

[139] The Bureau notes that the 14-consecutive-day period is a safe harbor. To comply with the rule, a debt collector only needs to wait a ''reasonable period of time'' to receive a notice of undeliverability. Therefore, a debt collector who shows that the debt collector waited a reasonable time period to receive notices of undeliverability for electronic messages may be able to satisfy the requirements of the final rule without waiting 14 days.

check is outweighed by benefits, including alerting the consumer to potential fraud and preventing them from incurring additional overdraft or non-sufficient funds fees.

After carefully considering the comment, the Bureau has determined that § 1006.30(a) should not apply to a debt collector's furnishing of information about a debt to a check verification consumer reporting agency. The Bureau finds that a debt collector's furnishing of information about a debt to a check verification consumer reporting agency before engaging in outreach to the consumer about the debt is unlikely to undermine the ability of consumers to decide whether to pay debts in the same manner as the furnishing of information about debts to other consumer reporting agencies. As a result, the Bureau has not found that furnishing information about a debt to a check verification consumer reporting agency before engaging in outreach to the consumer about the debt constitutes conduct that may have the natural consequence of harassment, oppression, or abuse in violation of FDCPA section 806, or that is an unfair or unconscionable means to collect or attempt to collect a debt under FDCPA section 808.

Immediate and frequent reporting appears to be a critical aspect of check verification consumer reporting, and it appears that imposing a requirement that debt collectors inform consumers about debts before furnishing information to those check verification consumer reporting agencies would require significant operational changes and could significantly reduce the effectiveness of those reports. This is unlike credit-related reporting, which typically involves less immediate furnishing. The Bureau also finds that the consumer harm that § 1006.30(a)(1) is designed to address is not present for check verification consumer reporting because these reports are unlikely to be used in making credit, employment, or rental housing decisions. While consumers could also be harmed if they are unaware of checking account report items, the harm of reducing the effectiveness of the check verification system, including the potential harm to consumers if checks are accepted by fewer merchants, outweighs the benefits of requiring communication before furnishing. In addition, the immediacy of the current check verification system provides countervailing benefits to consumers who are alerted to potential fraud or to discontinue writing checks on an overdrawn account. Further, a special rule for check verification consumer reporting agencies is consistent with several State laws regulating passive collections.[140] For these reasons, the Bureau concludes that furnishing of information to a check verification consumer reporting agency before engaging in outreach to the consumer does not raise concerns under FDCPA sections 806 and 808 similar to furnishing to other types of consumer reporting agencies.

Therefore, the final rule adds § 1006.30(a)(2) to state that § 1006.30(a)(1) does not apply to a debt collector's furnishing of information about a debt to a nationwide specialty consumer reporting agency that compiles and maintains information on a consumer's check writing history, as described in FCRA section 603(x)(3).[141]

For the reasons discussed above, the Bureau is adopting final § 1006.30(a) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors. The Bureau is also adopting final § 1006.30(a) pursuant to its authority to interpret FDCPA section 806, which prohibits a debt collector from engaging in any conduct the natural consequence of which is to harass, oppress, or abuse any person in connection with the collection of a debt, and FDCPA section 808, which prohibits a debt collector from using unfair or unconscionable means to collect or attempt to collect any debt.

Section 1006.34 Notice for Validation of Debts

FDCPA section 809(a) generally requires a debt collector to provide certain information to a consumer either at the time that, or shortly after, the debt collector first communicates with the consumer in connection with the collection of a debt.[142] The required information—*i.e.,* the validation information—includes details about the debt and about consumer protections, such as the consumer's rights to dispute and receive verification of the debt and to request information about the original creditor. When this validation information is provided in writing, the document containing the information is commonly referred to as a ''validation notice.''

The requirement to provide validation information is an important component of the FDCPA and was intended to improve the debt collection process by helping consumers to recognize debts that they owe and raise concerns about debts that are unfamiliar. Congress in 1977 considered the requirement a ''significant feature'' of the FDCPA, explaining that it was designed to ''eliminate the recurring problem of debt collectors dunning the wrong person or attempting to collect debts which the consumer has already paid.'' [143] Congress provided the Bureau with rulemaking authority in 2010 apparently to address continuing inadequacies around validation information and verification, among other things.[144] In addition, debt collectors have sought clarification about how to provide information consistent with the FDCPA, noting, for instance, that a significant number of lawsuits are filed each year alleging deficiencies in their validation notices.

For these reasons, the Bureau proposed § 1006.34 to require debt collectors to provide certain validation information to consumers and to specify when and how the information must be provided. As discussed in more detail below, the Bureau is finalizing § 1006.34 with modifications in response to feedback and for clarity and consistency with other provisions in this final rule and the November 2020 Final Rule.

Final § 1006.34(a) sets forth the general requirement to provide validation information and describes how such information may be provided on a validation notice. Section 1006.34(b) sets forth definitions for purposes of § 1006.34. Section 1006.34(c) sets forth the validation information, and § 1006.34(d) sets forth a general requirement that such information be clear and conspicuous. Section 1006.34(d) also provides safe harbors for use of Model Form B–1 in appendix B to Regulation F, specified variations of the model notice, or a

[140] Colo. Rev. Stat. sec. 12–14–108 limits when ''debt collectors'' may furnish information to a consumer reporting agency, but exempts checks, negotiable instruments, or credit card drafts. California and Utah also limit when information can be furnished to a consumer reporting agency, but those laws only apply to ''creditors.'' Cal. Civ. Code sec. 1785.26; Utah Code sec. 70C–7–107.

[141] If and to the extent a check verification consumer reporting agency compiles and maintains other types of information specified in FCRA section 603(x) (*e.g.,* residential or tenant history), the special rule in § 1006.30(a)(2) does not apply with respect to a debt collector's furnishing of that information to the check verification consumer reporting agency.

[142] *See* 15 U.S.C. 1692g(a).

[143] S. Rep. No. 382, *supra* note 57; *see also Jacobson* v. *Healthcare Fin. Servs., Inc.,* 516 F.3d 85, 95 (2d Cir. 2008) (validation notices ''make the rights and obligations of a potentially hapless debtor as pellucid as possible''); *Wilson* v. *Quadramed Corp.,* 225 F.3d 350, 354 (3d Cir. 2000); *Miller* v. *Payco-Gen. Am. Credits, Inc.,* 943 F.2d 482, 484 (4th Cir. 1991); *Swanson* v. *S. Oregon Credit Serv., Inc.,* 869 F.2d 1222, 1225 (9th Cir. 1988).

[144] *See* S. Rep. No. 111–176, at 19 (''In addition to concerns about debt collection tactics, the Committee is concerned that consumers have little ability to dispute the validity of a debt that is being collected in error.'').

substantially similar form, and describes optional disclosures that debt collectors may, but are not required to, provide with the validation information.[145] Section 1006.34(e) affirmatively permits debt collectors to provide validation notices translated into other languages and requires debt collectors who offer to provide consumers translated notices to provide them to consumers who request them.

As discussed in further detail in the section-by-section analysis of § 1006.34(d), the Bureau proposed to require that validation notices must be the same as, or substantially similar to, the proposed model validation notice. The Bureau is not finalizing that requirement. Instead, the final rule provides certain safe harbors for compliance with the information and form requirements in § 1006.34(c) and (d)(1) for debt collectors who use the model validation notice, specified variations of the model notice, or a substantially similar notice.

34(a) Validation Information Required

34(a)(1) In General

FDCPA section 809(a) provides, in relevant part, that, within five days after the initial communication with a consumer in connection with the collection of any debt, a debt collector shall send the consumer a written notice containing the validation information, unless that information is contained in the initial communication or the consumer has paid the debt. The Bureau proposed § 1006.34(a)(1) to implement and interpret this general requirement.[146] Specifically, proposed § 1006.34(a)(1) provided that, subject to a limited exception for if a consumer has already paid a debt, a debt collector must provide a consumer the required validation information either: (1) By sending the consumer a validation notice (*i.e.,* a written or electronic notice)[147] in the manner permitted by § 1006.42[148] in the initial communication with the consumer in connection with the collection of the debt (proposed § 1006.34(a)(1)(i)(A)) or within five days of that initial communication (proposed § 1006.34(a)(1)(i)(B)); or (2) by providing the validation information orally in the initial communication (proposed § 1006.34(a)(1)(ii)).[149] As discussed below, the Bureau is adopting § 1006.34(a)(1) with certain minor revisions.

Some commenters recommended that the Bureau modify proposed § 1006.34(a)(1) generally. Some consumer advocate commenters stated that the Bureau should require debt collectors to provide non-electronic, written validation notices to all consumers. According to at least one commenter, the Bureau should require a written validation notice even if a debt collector also provides the validation information electronically. Another consumer advocate commenter asked the Bureau to require debt collectors to provide a consumer a validation notice in every communication.

The Bureau declines to require debt collectors to always provide written, non-electronic validation notices to consumers. For the reasons set forth in the November 2020 Final Rule, the Bureau interprets FDCPA section 809(a) as not requiring that the notice of debt be provided in writing when it is contained in the initial communication.[150] Moreover, if FDCPA section 809(a) does require that the notice of debt be provided in writing—*i.e.,* if the validation information is not contained within the initial communication—nothing in the FDCPA prohibits a debt collector from providing the required written validation notice electronically in accordance with the consumer-consent provisions of section 101(c) of the E–SIGN Act. In turn, if a statute (here, the FDCPA) requires a written disclosure, the E–SIGN Act's consumer-consent provisions specify requirements pursuant to which debt collectors may send the required written disclosures electronically. Accordingly, pursuant to § 1006.42, a debt collector may send the validation notice electronically under § 1006.34(a)(1)(i)(A) (*i.e.,* within the initial communication) if the debt collector complies with § 1006.42(a)(1), which requires that the debt collector send the notice in a manner that is reasonably expected to provide actual notice, and in a form that the consumer may keep and access later. A debt collector may send the validation notice electronically under § 1006.34(a)(1)(i)(B) (*i.e.,* not within the initial communication) if the debt collector complies with § 1006.42(a)(1) and also complies with § 1006.42(b), which requires that the debt collector send the notice in accordance with section 101(c) of the E–SIGN Act. The Bureau concludes that, if debt collectors send validation notices electronically as described above, there is a reasonable likelihood that consumers will receive and be able to retain the notices.

The Bureau determines, therefore, that it is unnecessary and unwarranted to impose the burden on debt collectors that would result from a requirement to always provide the validation notice in written, non-electronic form; to provide a validation notice in written form even if the debt collector also provides the validation notice electronically; or to provide a validation notice or validation information with every consumer communication.[151] Such requirements would go beyond the FDCPA's provisions and would be unduly burdensome on debt collectors, because, as stated above, the Bureau concludes that the Regulation F provisions that the Bureau is adopting provide sufficient consumer protection. Accordingly, the Bureau does not impose such requirements.

The Bureau received few comments specifically about proposed § 1006.34(a)(1)(i). Commenters who provided feedback supported the Bureau's proposal. Thus, the Bureau is adopting § 1006.34(a)(1)(i) largely as proposed.

A large number of commenters responded to the clarification in proposed § 1006.34(a)(1)(ii) that debt collectors may provide validation information orally in the initial communication. Commenters, including most consumer advocates who addressed the topic, urged the Bureau to

[145] The Bureau proposed a model validation notice as Model Form B–3. The Bureau is finalizing that form, with revisions, as Model Form B–1. This Notice refers to proposed Model Form B–3 as the ''proposed model validation notice'' or the ''proposed model notice'' and final Model Form B–1 as the ''model validation notice'' or ''model notice.'' This Notice uses the phrase ''specified variations of the model notice'' to refer to the specifically enumerated versions of the model notice that receive a safe harbor pursuant to § 1006.34(d)(2)(i) and (ii) (*i.e.,* notices that are the same as, or substantially similar to, the model notice but for: Omitting some or all of the optional disclosures that appear on the model notice; including optional disclosures that do not appear on the model notice; or including certain disclosures on a separate page as permitted by § 1006.34(c)(2)(viii) and (5)).

[146] *See* 84 FR 23274, 23333–34 (May 21, 2019).

[147] Proposed § 1006.34(b)(4) defined a validation notice as any written or electronic notice that provides the validation information described in § 1006.34(c).

[148] As finalized, § 1006.42 generally requires debt collectors to send written disclosures in a manner that is reasonably expected to provide actual notice, and in a form that the consumer may keep and access later. 85 FR 76734, 76893 (Nov. 30, 2020).

[149] Proposed § 1006.34(b)(2) provided that, with limited exceptions, initial communication means the first time that, in connection with the collection of a debt, a debt collector conveys information, directly or indirectly, to the consumer regarding the debt.

[150] 85 FR 76734, 76854 (Nov. 30, 2020).

[151] The Bureau additionally notes that, if a statute (here, FDCPA section 809(a)) requires a written disclosure, E–SIGN Act section 104(c)(1) states that Federal agencies' authority to interpret E–SIGN Act section 101 (including the consumer-consent provisions in E–SIGN Act section 101(c)) does not include the ''authority to impose or reimpose any requirement that a record be in a tangible printed or paper form.'' *See* 15 U.S.C. 7004(c)(1).

prohibit debt collectors from providing validation information orally. These commenters stated that debt collectors could not effectively convey orally to consumers the amount of validation information that the Bureau proposed.[152] Commenters argued that, if validation information were conveyed orally, a consumer would be unable to review the information at a later time, unless the consumer transcribed or recorded the communication with the debt collector. Commenters stated that this dynamic would place an unreasonable burden on consumers and would be atypical compared to other consumer law disclosure regimes, which mandate that required notices be provided in written form. At least one commenter stated that oral delivery would be incompatible with the formatting requirements in proposed § 1006.34(d).

On the other hand, some industry commenters supported the Bureau's clarification that debt collectors may provide validation information orally. These commenters asked the Bureau to provide additional guidance about oral delivery of validation information, including, for example, specific content for an oral notice, such as a script.

As proposed, the Bureau is finalizing the provision in § 1006.34(a)(1)(ii) that debt collectors may provide the required validation information orally in the initial communication. The Bureau agrees that there may be significant challenges to conveying the required validation information orally.[153] Nevertheless, FDCPA section 809(a) does not prohibit oral delivery. FDCPA section 809(a) states that the required validation information may be ''contained in the initial communication'' and that a written notice is mandatory only if that required information is *not* contained in the initial communication. Further, FDCPA section 807(11) indicates that the initial communication may be oral.[154] Accordingly, the Bureau concludes that the most reasonable interpretation of FDCPA sections 809(a) and 807(11) is that the FDCPA permits the required validation information to be conveyed orally if it is contained in the initial communication.

Moreover, debt collectors providing validation information orally will not be able to use the model validation notice and therefore will not receive a safe harbor for compliance under § 1006.34(d)(2). The Bureau declines to provide additional guidance about oral delivery of validation information. The Bureau is not aware of debt collectors providing validation information orally today, and, for the reasons discussed, the Bureau believes they will be unlikely to do so in the future. As a result, the Bureau concludes that such additional guidance is not necessary or warranted at this time.

The Bureau proposed comment 34(a)(1)–1 to clarify the provision of validation notices if the consumer is deceased. Proposed comment 34(a)(1)–1 explained that, if the debt collector knows or should know that the consumer is deceased, and if the debt collector has not previously provided the deceased consumer the validation information, a person who is authorized to act on behalf of the deceased consumer's estate operates as the consumer for purposes of providing validation information under § 1006.34(a)(1). Under proposed comment 34(a)(1)–1, a debt collector attempting to collect a debt from a deceased consumer's estate generally would provide the validation information to the named person who is authorized to act on behalf of the deceased consumer's estate, if the debt collector had not already provided that information to the consumer.

As discussed in the section-by-section analysis of § 1006.2(e), the Bureau is interpreting the term consumer to mean any natural person, whether living or deceased, who is obligated or allegedly obligated to pay any debt. And the Bureau is adopting commentary clarifying how this definition operates in the decedent debt context, including with respect to debt collectors' obligations to provide the validation information and respond to disputes and requests for original-creditor information. Accordingly, the Bureau is finalizing comment 34(a)(1)–1 as proposed.

For all of these reasons, and pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors, the Bureau is finalizing § 1006.34(a)(1) to implement and interpret the FDCPA section 809(a) requirement that debt collectors provide validation information to consumers.

34(a)(2) Exception

FDCPA section 809(a) contains a limited exception that provides that, if required validation information is not contained in the initial communication, a debt collector need not send the consumer a written validation notice within five days of that communication if the consumer has paid the debt prior to the time that the notice is required to be sent. The Bureau proposed in § 1006.34(a)(2) to implement this exception by providing that a debt collector who otherwise would be required to send a validation notice pursuant to § 1006.34(a)(1)(i)(B) is not required to do so if the consumer has paid the debt prior to the time that § 1006.34(a)(1)(i)(B) would require the validation notice to be sent. Proposed § 1006.34(a)(2) generally restated the statute, except for minor changes for organization and clarity.[155]

At least two consumer advocate commenters recommended that debt collectors be required to provide a validation notice even if a consumer has already paid the debt. According to these commenters, some consumers, including seniors, will pay a debt that they do not owe or recognize because they ''pay first and ask questions later.'' These commenters suggested that validation information would help such consumers assess after the fact whether they paid a debt that they owed. An industry trade group commenter stated that, for open-end credit, a debt collector should be permitted to satisfy § 1006.34(a)(1) by providing a periodic statement pursuant to Regulation Z, 12 CFR 1026.7, because periodic statements disclose sufficient account information to consumers.

The Bureau declines to require debt collectors to provide a validation notice if a consumer has already paid the debt. FDCPA section 809(a) explicitly provides that a debt collector is not required to send the validation notice if the consumer has paid the debt, and the Bureau has determined that it is neither necessary nor warranted to adopt a rule requiring otherwise.

The Bureau also declines to adopt recommendations to include an exception to § 1006.34(a)(1) for open-

[152] Proposed § 1006.34(c) described the validation information that proposed § 1006.34(a)(1) would have required debt collectors to provide. As discussed in the section-by-section analysis of § 1006.34(c), the final rule requires debt collectors to provide up to 18 items of validation information.

[153] Section 1006.34(c) requires a significant amount of validation information that debt collectors may not currently include in the validation information they provide to consumers. It might be difficult for a debt collector to convey all of the required information orally, particularly in an initial communication, which is the only context in which a debt collector could comply with its legal obligation by providing the validation information orally. Further, real-time communications with consumers are unpredictable. Accordingly, even if the required components of the validation information are contained in the oral communication, the debt collector might not convey them in a way that meets the requirements of the regulation; for example, as commenters noted the debt collector might not convey the required information clearly and conspicuously.

[154] *See* 15 U.S.C. 1692e(11).

[155] *See* 84 FR 23274, 23334–35 (May 21, 2019).

end credit, because a periodic statement provided in accordance with Regulation Z, 12 CFR 1026.7, is not an adequate substitute for the validation information. While such a periodic statement discloses some information about the debt, it typically does not disclose other information required under the final rule, such as the information about consumer protections required by FDCPA section 809(a)(3) through (5) and the corresponding provisions of final § 1006.34.

Accordingly, pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors, and to implement and interpret FDCPA section 809(a), the Bureau is finalizing § 1006.34(a)(2) as proposed.

34(b) Definitions

To facilitate compliance with § 1006.34, proposed § 1006.34(b) defined several terms that appear throughout the section. As discussed below, the Bureau is finalizing those definitions and related commentary with certain modifications in response to feedback. Consistent with the proposal, unless noted otherwise below, the Bureau is finalizing the definitions to implement and interpret FDCPA section 809(a) and pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors.

34(b)(1) Clear and Conspicuous

The Bureau proposed § 1006.34(b)(1) to define the term clear and conspicuous for purposes of Regulation F consistent with the standards used in other consumer financial services laws and their implementing regulations, including, for example, Regulation E, subpart B (Remittance Transfers).[156] Proposed § 1006.34(b)(1) thus provided that disclosures are clear and conspicuous if they are readily understandable. The proposal provided that, in the case of written and electronic disclosures, the location and type size also must be readily noticeable to consumers and that, in the case of oral disclosures, the disclosures must be given at a volume and speed sufficient for a consumer to hear and comprehend them.[157] For the reasons discussed below, the Bureau is adopting § 1006.34(b)(1) largely as proposed but with minor modifications for clarity and in response to feedback.

An industry commenter objected to the clear and conspicuous definition in proposed § 1006.34(b)(1). This commenter stated that a clear-and-conspicuous requirement is unnecessary in the debt collection context because consumers have an ongoing relationship with debt collectors, and a consumer therefore has the ability to ask a debt collector to explain a particular disclosure or communication if the consumer does not understand it.

Other commenters asked the Bureau to clarify the proposed definition. For instance, industry trade group and consumer advocate commenters offered various suggestions for specific font size or disclosure placement requirements. At least one industry commenter suggested that the Bureau explain how proposed § 1006.34(b)(1) would interact with State disclosure laws, which may have their own clear-and-conspicuous standards that dictate font size or disclosure placement. An industry trade group commenter asked the Bureau to provide additional guidance about oral delivery of the validation information because, in the commenter's view, the proposal that oral communications be ''given at a volume and speed sufficient for a consumer to hear and comprehend them'' was ambiguous.

The Bureau disagrees that ongoing relationships between debt collectors and consumers make a clear and conspicuous definition unnecessary or unwarranted in the debt collection context. Consumer financial services laws and their implementing regulations commonly include standards for clear and conspicuous disclosures provided in the context of ongoing customer and business relationships between consumers and consumer financial services providers.[158] Additionally, validation information is provided at the outset of collection communications. If a consumer chooses not to engage with the debt collector, no ongoing communications will be established.

The Bureau declines to further clarify the clear and conspicuous definition in § 1006.34(b)(1) by, for example, dictating font sizes or requirements regarding disclosure placement as requested by some commenters. Different debt collectors may design their communications in different ways, and the Bureau does not believe it is necessary or warranted to specify such details, as long as the disclosure satisfies the clear and conspicuous standard. In addition, the definition is consistent with, and provides the same level of specificity as, standards in some other consumer financial services laws and their implementing regulations, including but not limited to the Bureau's Remittance Transfers rule,[159] which do not specify font size or disclosure placement requirements. Moreover, the Bureau concludes that the lack of more prescriptive guidance will not impose material burden on debt collectors. As discussed in the section-by-section analysis of § 1006.34(d)(2), a debt collector who uses the model validation notice, specified variations of the model notice, or a substantially similar form, receives a safe harbor for the information requirements in § 1006.34(c) and for the clear-and-conspicuous requirement in § 1006.34(d)(1). Because debt collectors may use the model validation notice, specified variations of the model notice, or a substantially similar form if providing validation notices, debt collectors need not incur significant expenses ascertaining what meets the clear-and-conspicuous standard. Nevertheless, the final rule does clarify that, in the case of written and electronic disclosures, although no minimum font size is required, the location and type size must be both readily noticeable and legible to consumers.[160]

The Bureau declines to revise § 1006.34(b)(1) to clarify how the definition of clear and conspicuous interrelates with State disclosure laws. A debt collector can comply with both § 1006.34(b)(1) and State disclosure requirements that specify font size or disclosure placement. With respect to font size, the Bureau concludes, in general, that debt collectors satisfying State-law minimum-font-size requirements will also satisfy the standard in § 1006.34(b)(1) for a type size that is readily noticeable and legible to consumers. With respect to disclosure placement, as discussed in the section-by-section analysis of

[156] *See* 12 CFR 1005.31(a)(1), comment 31(a)(1)–1.

[157] *See* 84 FR 23274, 23335 (May 21, 2019).

[158] *See, e.g.,* 12 CFR 1026.5(a)(1)(i) (disclosures for open-end credit) and 12 CFR 1026.17(a)(1) (disclosures for closed-end credit). Moreover, a consumer does not typically get to choose which debt collector collects the consumer's debt, whereas a consumer does choose his or her financial services providers. Further, some customer relationships between consumers and debt collectors may be of shorter duration than customer relationships between consumers and other types of consumer financial services providers. These factors suggest that a standard for clear and conspicuous disclosures may be even more important in the debt collection context than in other consumer financial services contexts.

[159] *See* 12 CFR 1005.31(a)(1), comment 31(a)(1)–1. *See also, e.g.,* the general disclosure requirements for open-end and closed-end credit in, respectively, 12 CFR 1026.5(a)(1) and 1026.17(a)(1) and their commentary.

[160] The section-by-section analysis of § 1006.38(b)(2) discusses a new safe harbor from the overshadowing prohibition in § 1006.38(b)(1) for a debt collector who uses the model validation notice.

§ 1006.34(d)(3)(iv), a debt collector may place disclosures specifically required under other applicable law, which includes disclosures specifically required by State law, on the reverse (or, in certain specified circumstances, on the front) of the validation notice. The Bureau believes that § 1006.34(d)(3)(iv) will permit debt collectors to provide State law disclosures in a manner that is clear and conspicuous under applicable law.

The Bureau also declines to further clarify the meaning of clear and conspicuous in the context of oral delivery of validation information. The Bureau determines that the proposed and final regulatory text is sufficiently clear and that the final rule will not impose an undue burden on debt collectors, particularly in light of the Bureau's expectation that few, if any, oral disclosures will be provided.

For the reasons discussed above, the Bureau is finalizing § 1006.34(b)(1) to provide that clear and conspicuous means readily understandable and that, in the case of written and electronic disclosures, the location and type size also must be readily noticeable and legible to consumers, although no minimum type size is mandated. Final § 1006.34(b)(1) also provides that oral disclosures must be given at a volume and speed sufficient for the consumer to hear and comprehend them.

34(b)(2) Initial Communication

FDCPA section 809(a) requires debt collectors to provide consumers with certain validation information either in the debt collector's initial communication with the consumer in connection with the collection of the debt, or within five days after that initial communication. FDCPA section 803(2) defines the term communication broadly to mean the conveying of information regarding a debt directly or indirectly to any person through any medium.[161] FDCPA section 809(d) and (e) identifies particular communications that are not initial communications for purposes of FDCPA section 809(a) and that therefore do not trigger the validation notice requirement.[162] Pursuant to FDCPA section 809(d), an initial communication excludes a communication in the form of a formal pleading in a civil action. Pursuant to FDCPA section 809(e), an initial communication also excludes the sending or delivery of any form or notice that does not relate to the collection of the debt and is expressly required by the Internal Revenue Code of 1986, title V of the Gramm-Leach-Bliley Act, or any provision of Federal or State law relating to notice of a data security breach or privacy, or any regulation prescribed under any such provision of law.

The Bureau proposed § 1006.34(b)(2) to implement FDCPA section 809(a), (d), and (e) by defining the term initial communication. The proposed definition largely restated the FDCPA and defined initial communication as the first time that, in connection with the collection of a debt, a debt collector conveys information, directly or indirectly, regarding the debt to the consumer, other than a communication in the form of a formal pleading in a civil action, or a communication in any form or notice that does not relate to the collection of the debt and is expressly required by any of the laws referenced in FDCPA section 809(e).[163]

An industry trade group recommended a bankruptcy-specific exception to the definition of initial communication for debt collectors collecting debts owed by consumers in bankruptcy. The commenter expressed concern that certain actions by a debt collector in the context of a consumer's bankruptcy proceeding, in particular filing a proof of claim, may be construed to be an initial communication and therefore trigger the FDCPA section 809(a) validation notice requirement.[164] Additionally, according to the commenter, content on the validation notice, including the debt collection communication disclosure required by FDCPA section 807(11), could be construed as a demand for payment that violates the automatic stay provisions of the United States Bankruptcy Code (Bankruptcy Code)[165] or, if the consumer has been relieved of personal liability, the discharge injunction.[166] According to the commenter, some courts have opined that a debt collector would face an irreconcilable conflict between complying with the FDCPA and the Bankruptcy Code if the debt collector were required to provide a validation notice to a consumer in bankruptcy.[167]

The Bureau has determined to interpret the term initial communication not to include proofs of claim filed in bankruptcy proceedings. Courts have reached different conclusions about whether the FDCPA conflicts with the Bankruptcy Code.[168] The Bureau is unaware of any case definitively holding that a proof of claim is an initial communication and that a debt collector therefore must provide a validation notice after filing a proof of claim. On the other hand, some courts have held that proofs of claim are not initial communications because, under FDCPA section 809(d), they are communications in the form of a formal pleading in a civil action.[169] Further, the Bureau has decided to permit a debt collector to file a proof of claim in a bankruptcy proceeding as required by the Bankruptcy Code without thereby triggering the debt collector's obligation to provide a validation notice under the FDCPA, because the Bureau finds it unlikely that consumer harm will result if a consumer does not receive a validation notice subsequent to a proof of claim in bankruptcy. The bankruptcy proof-of-claim form is filed under penalty of perjury, and a person who files a fraudulent claim could be fined up to $500,000, imprisoned for up to 5 years, or both.[170] Thus, the Bureau concludes that bankruptcy proof-of-claim forms generally are likely to contain accurate information about the debt.

Accordingly, to provide clarity for debt collectors while maintaining protections for consumers, the Bureau is interpreting the term initial

[161] *See* 15 U.S.C. 1692a(2). The November 2020 Final Rule implemented this definition in § 1006.2(d). 85 FR 76734, 76888 (Nov. 30, 2020).

[162] *See* 15 U.S.C. 1692g(d), (e).

[163] *See* 84 FR 23274, 23335 (May 21, 2019).

[164] To receive a distribution from a bankruptcy estate, a creditor generally must file with the bankruptcy court a proof of claim, which includes details about an alleged debt or interest. *See* Fed. R. Bankr. P. 3002.

[165] *See* 11 U.S.C. 362.

[166] A debtor's bankruptcy petition operates as an automatic stay that, among other things, prohibits ''any act to collect, assess, or recover a claim against the debtor that arose before the commencement of the case.'' 11 U.S.C. 362(a)(6). When a debtor's liability is discharged through bankruptcy, the discharge ''operates as an injunction against the commencement or continuation of an action, the employment of process, or an act, to collect, recover or offset any such debt as a personal liability of the debtor, whether or not discharge of such debt is waived.'' 11 U.S.C. 524(a)(2).

[167] *See, e.g., In re Chaussee,* 399 B.R. 225, 238 (B.A.P. 9th Cir. 2008) (''In our opinion, the debt validation provisions required by the FDCPA clearly conflict with the claims processing procedures contemplated by the [Bankruptcy] Code and Rules.'').

[168] *See Walls* v. *Wells Fargo Bank,* 276 F.3d 502, 511 (9th Cir. 2002) (holding that the Bankruptcy Code precludes application of FDCPA requirements in bankruptcy cases); *Chaussee,* 399 B.R. at 239 (same); *contra Simon* v. *FIA Card Servs., N.A.,* 732 F.3d 259, 274 (3d Cir. 2013) (stating that when ''FDCPA claims arise from communications a debt collector sends a bankruptcy debtor in a pending bankruptcy proceeding, and the communications are alleged to violate the Bankruptcy Code or Rules, there is no categorical preclusion of the FDCPA claims'').

[169] *See Simon,* 732 F.3d at 273; *Townsend* v. *Quantum3 Grp., LLC,* 535 B.R. 415, 423 (M.D. Fla. 2015); *In re Brimmage,* 523 B.R. 134, 141–42 (Bankr. N.D. Ill. 2015).

[170] The official bankruptcy proof-of-claim form is available here: *https://www.uscourts.gov/forms/bankruptcy-forms/proof-claim-0.*

communication not to include proofs of claim filed in bankruptcy. Specifically, the Bureau is adopting new comment 34(b)(2)–1, which clarifies that a proof of claim that a debt collector files in a bankruptcy proceeding in accordance with the requirements of the Bankruptcy Code is a communication in the form of a formal pleading in a civil action and therefore is not an initial communication for purposes of § 1006.34. The Bureau adopts this comment as an interpretation of the phrase ''[a] communication in the form of a formal pleading in a civil action'' in FDCPA section 809(d). The Bureau interprets that phrase to include a proof of claim that a debt collector files in a bankruptcy proceeding in accordance with the requirements of the Bankruptcy Code.

The Bureau acknowledges that other scenarios may exist in which a debt collector communicates with a consumer in bankruptcy and subsequently may be required to provide a validation notice. To the extent that debt collectors do provide validation notices to consumers in bankruptcy, § 1006.34(a)(1) implements an existing FDCPA disclosure requirement and does not create a new tension between the FDCPA and the Bankruptcy Code. In addition, nothing in the final rule requires debt collectors to include payment requests in the validation information; instead, payment requests are optional disclosures that § 1006.34(d)(3)(iii) permits debt collectors to include along with the validation information. Consequently, a debt collector concerned that a payment request would violate the Bankruptcy Code's automatic stay or discharge injunction is not required to include a payment request and, additionally, could use the model validation notice, specified variations of the model notice, or a substantially similar form, without a payment request and receive a safe harbor under § 1006.34(d)(2).

An industry trade group recommended that the Bureau exclude from the § 1006.34(b)(2) definition of initial communication the notice of transfer of loan servicing required by Regulation X.[171] According to the commenter, after an FDCPA-covered mortgage debt is transferred and a consumer receives a servicing transfer notice, the transferee may not have received all the information necessary to send a validation notice within the five-day timeframe required by FDCPA section 809(a). For this reason, the commenter suggested that Regulation X servicing transfer notices should not trigger the validation information requirement.

The Bureau declines to interpret the term initial communication to exclude servicing transfer notices required by Regulation X. Section 1006.34(b)(2) largely mirrors existing language in FDCPA sections 803(2) and 809(a), (d), and (e) and does not impose new substantive requirements or obligations on covered entities. As discussed in the section-by-section analysis of § 1006.34(c), Regulation F will result in validation notices containing more information about the debt than they typically do today, but that information is, generally, either routine account information that owners of debts currently provide to debt collectors or that owners of debts can include without significant additional expense. Although the commenter argues that there may be timing considerations unique to mortgage servicing transfer notices, the Bureau determines that such timing concerns do not warrant an exception that would deem a mortgage servicing transfer notice, even one that does convey information, directly or indirectly, regarding the debt to the consumer to be excluded from the definition of an ''initial communication.''

Other commenters asked the Bureau to clarify whether a consumer-initiated communication, such as a consumer visiting a debt collector's website or a consumer leaving a voicemail with a debt collector, would constitute an initial communication under proposed § 1006.34(b)(2). The Bureau notes that, under § 1006.34(b)(2), for an initial communication to occur, a debt collector must ''convey[ ] information, directly or indirectly, regarding the debt. . . .'' Section 1006.34(b)(2) is clear that, if a debt collector conveys no information, directly or indirectly, regarding the debt, an initial communication has not occurred and, consequently, the validation notice requirement has not been triggered. Thus, a consumer's voicemail left with a debt collector generally would not qualify as an initial communication. Similarly, an initial communication generally would not include a consumer's visit to a debt collector's website, unless during that visit the debt collector conveyed information regarding the consumer's specific debt.[172]

For the reasons discussed above, the Bureau is finalizing § 1006.34(b)(2) largely as proposed but with a revision to clarify that proofs of claim filed in bankruptcy proceedings are not initial communications.

34(b)(3) Itemization Date

FDCPA section 809(a)(1) requires debt collectors to disclose to consumers, either in the debt collector's initial communication in connection with the collection of the debt, or within five days after that communication, the amount of the debt.[173] The Bureau proposed in § 1006.34(c)(2)(vii) through (ix) to interpret the phrase ''amount of the debt'' to mean that debt collectors must disclose the amount of the debt as of a particular ''itemization date.'' [174] To facilitate compliance with proposed § 1006.34(c)(2), the Bureau proposed § 1006.34(b)(3) to define itemization date as one of four reference dates for which a debt collector can ascertain the amount of the debt. The proposed reference dates were the last statement date, the charge-off date, the last payment date, and the transaction date.[175]

The proposed definition of itemization date was designed to allow the use of dates that debt collectors could identify with relative ease because they reflect routine and recurring events, and that correspond to notable events in the debt's history that consumers may recall or be able to verify with records. The proposed definition also was intended to include dates for which debt collectors typically may receive account information from debt owners and that, therefore, debt

[171] Generally, under Regulation X, each transferor servicer and transferee servicer of any mortgage loan shall provide to the borrower a notice of transfer for any assignment, sale, or transfer of the servicing of the mortgage loan. 12 CFR 1024.33(b)(1). Generally, the transferor servicer shall provide the notice of transfer to the borrower not less than 15 days before the effective date of the transfer of the servicing of the mortgage loan. The transferee servicer shall provide the notice of transfer to the borrower not more than 15 days after the effective date of the transfer. The transferor and transferee servicers may provide a single notice, in which case the notice shall be provided not less than 15 days before the effective date of the transfer of the servicing of the mortgage loan. 12 CFR 1024.33(b)(3)(i).

[172] For example, a debt collector potentially could convey information regarding the debt during a consumer's visit to a website through a website chat feature.

[173] *See* 15 U.S.C. 1692g(a)(1).

[174] Proposed § 1006.34(c)(2)(vii) and (viii) would have required debt collectors to disclose, respectively, the itemization date and the amount of the debt on the itemization date. Proposed § 1006.34(c)(2)(ix) would have required debt collectors to disclose an itemization of the debt reflecting interest, fees, payments, and credits since the itemization date. For additional discussion of these provisions, which have been renumbered in the final rule, see the section-by-section analysis of § 1006.34(c)(2)(vi) through (viii).

[175] *See* 84 FR 23274, 23335–37 (May 21, 2019). The reference dates were set forth in proposed § 1006.34(b)(3)(i) through (iv) and are discussed in the section-by-section analysis of those paragraphs below.

collectors would be able to use to provide the disclosures proposed in § 1006.34(c)(viii) and (ix).

Proposed comment 34(b)(3)–1 explained that a debt collector could select any of the four reference dates as the itemization date. Once a debt collector used one of the reference dates for a specific debt in a communication with a consumer, however, the debt collector would be required to use that reference date for that debt consistently when providing disclosures pursuant to § 1006.34 to that consumer.

For the reasons discussed below, the Bureau is adopting § 1006.34(b)(3) and its related commentary largely as proposed but with minor wording changes and to include an additional reference date in response to feedback: The judgment date. The Bureau also is adopting new comment 34(b)(3)–2, which provides that a debt collector may use a different reference date than a prior debt collector used for the same debt.

Some industry commenters supported the itemization date definition in proposed § 1006.34(b)(3). At least two industry commenters supported providing debt collectors with a choice of several reference dates because a debt collector might not be able ascertain the amount of the debt on a single reference date. According to an industry trade group commenter, the proposed reference dates would provide adequate flexibility, as a creditor's information systems will have recorded at least one of those dates for any given debt. Another industry trade group commenter stated that the proposal's standardization of account information would allow debt collectors to build better internal procedures and improve consumer communication practices. An industry commenter stated that proposed § 1006.34(b)(3) would require significant client education and information technology investment but ultimately concluded that the framework was feasible.

Other commenters objected to proposed § 1006.34(b)(3). An industry commenter stated that creditors may provide debt collectors information about multiple reference dates. According to this commenter, analyzing creditor records to identify and organize account information as of a single reference date would be complicated, costly, and increase the likelihood of validation notice errors. A group of consumer advocate commenters stated that, instead of permitting debt collectors to choose between reference dates, § 1006.34(b)(3) should define the itemization date as a single reference date supported by consumer testing.

The Bureau determines that § 1006.34(b)(3) will facilitate compliance with the itemization date-related requirements in final § 1006.34(c)(2)(vi) through (viii). Account information available to debt collectors may vary by debt type because some account information is not universally tracked or used across product markets. To facilitate the ability of debt collectors across debt markets to comply with Regulation F, the final rule permits debt collectors to determine the itemization date by selecting from one of five reference dates for which they can ascertain the amount of the debt.

The Bureau finds that this framework will not result in undue industry burden. Debt collectors today routinely analyze and organize account information included in files from creditors when creditors place accounts for collection. Debt collectors should be able to use or build on these existing functions to select an itemization date based on the definition in § 1006.34(b)(3). Therefore, even if creditors provide or retain account information based on multiple reference dates, debt collectors should not face substantial new costs or litigation risks from complying with § 1006.34(b)(3).

The Bureau declines consumer advocates' suggestion to specify a single reference date. As discussed in the proposal, the Bureau considered requiring debt collectors to provide an itemization of the debt based on a single reference date but rejected that approach because of the infeasibility of identifying a single reference date that applies to all debt types across all relevant markets.[176] The group of consumer advocate commenters that recommended a single reference date did not suggest or provide evidence that it would be feasible to identify a single date that would be appropriate for all types of debt. The Bureau also declines to exercise its discretion to conduct consumer testing to attempt to determine an optimal itemization date for debt collectors to use within each debt collection market (*e.g.,* mortgage debt, credit card debt, student loan debt, medical debt, and so on). The Bureau determines that such testing is not necessary or warranted, because the Bureau finds that debt collectors' use of any one of the five itemization dates set forth in § 1006.34(b)(3) should correspond, in most cases, to events in the debt's history that consumers may recall or be able to verify with records.

In the proposal, the Bureau requested comment on whether the itemization date should be structured as a prescriptive ordering of reference dates, such as a hierarchy that would permit a debt collector to use a date listed later in the hierarchy only if the debt collector did not have information about any dates earlier in the hierarchy. Industry and industry trade group commenters generally favored the proposed flexible approach. According to commenters, a prescriptive ordering would significantly increase costs and litigation risk for debt collectors. As noted above, consumer advocates expressed concern that the proposed approach would result in disclosure of itemization dates that are not meaningful to consumers and urged the Bureau to use consumer testing to determine a date that would be meaningful.

The Bureau agrees that a prescriptive ordering could impose undue costs and litigation risks for debt collectors. In addition, as discussed below in the section-by-section analysis of § 1006.34(b)(3)(i) through (v), each reference date may be meaningful to consumers because it corresponds to a notable event in the debt's history that consumers may recall or be able to verify with records. Because each reference date may be meaningful to a consumer, and because each reference date may be more or less meaningful to the consumer than one of the other reference dates depending on the circumstances surrounding the debt, there may not be a benefit to consumers if the Bureau were to structure the dates as a hierarchy. The Bureau therefore declines to adopt a prescriptive ordering of the reference dates.

Some commenters who did not object to the proposed itemization date framework in principle either raised concerns that the proposed reference dates would not accommodate debts in all product markets or recommended additional reference dates. At least one industry trade group commenter asked the Bureau to clarify what reference date debt collectors should use for debts in bankruptcy. An industry commenter stated that the proposal might not accommodate a debt a consumer owes to a government, such as a tax debt. According to this commenter, although the FDCPA does not cover many debts consumers owe to governments,[177] some debt collectors who collect debts on behalf of Federal government agencies are legally or contractually obliged to

[176] *See* 84 FR 23274, 23336 (May 21, 2019).

[177] FDCPA section 803(5) defines a ''debt'' as any obligation arising out of a transaction ''primarily for personal, family, or household purposes.'' 15 U.S.C. 1692a(5). According to the commenter, a debt a consumer owes to a government in many cases does not meet this definition.

abide by the FDCPA.[178] This commenter stated that the proposed reference dates might not accommodate tax debt because, in some instances, it will be the case that no previous statement was provided, no prior payment was made, and there was no transaction per se between the consumer and the government creditor.

According to another commenter, an additional reference date for student loan debt is necessary because debt collectors collecting Federal student loans do not receive any of the proposed reference dates at the time of placement. Some commenters suggested that the Bureau permit debt collectors to use the date of default as defined by the Higher Education Act of 1965; commenters argued that this date is a widely used reference date in the student loan market.[179] By contrast, an FTC commissioner urged the Bureau not to use the Higher Education Act's definition of default and instead to use the date a student loan borrower becomes 90 days past due.

In addition, an industry commenter recommended that § 1006.34(b)(3) incorporate: (1) The date a creditor places a debt with the debt collector, or (2) the date the debt collector provides validation information to the consumer. Another industry commenter suggested that § 1006.34(b)(3) incorporate the date of a previously obtained court judgment.

The Bureau determines that § 1006.34(b)(3)—in conjunction with the five reference dates described in § 1006.34(b)(3)(i) through (v)—provides adequate flexibility for debts in all product markets, including for debts in bankruptcy. A debt collector may choose which of the five reference dates to use based on the facts and circumstances surrounding the history of the debt—*e.g.,* whether a creditor provided statements, whether the consumer made payments—and the information available to the debt collector.

With respect to which reference date a debt collector should use to itemize a tax obligation a consumer owes to a government, the date the tax was assessed may be a transaction date for tax debt, as discussed in the section-by-section analysis of § 1006.34(b)(3)(iv). In addition, a date on which the government provided a written invoice or tax bill may constitute a last statement date for tax debt under § 1006.34(b)(3)(i).

The Bureau determines that a reference date specific to student loan debt is unnecessary and unwarranted because the reference dates in § 1006.34(b)(3) are sufficient. For virtually any student loan debt, there will be a last statement date as described in § 1006.34(b)(3)(i), a last payment date as described in § 1006.34(b)(3)(ii), or a transaction date as described in § 1006.34(b)(3)(iv). For many student loan debts, all three reference dates will exist.

The Bureau also declines to incorporate into § 1006.34(b)(3) the date of placement or the date the debt collector provides the validation notice. From a consumer's perspective, these dates do not correspond to notable events in a debt's history that the consumer may recall or be able to verify. As noted above, however, in response to feedback, the Bureau is adding a new reference date called the ''judgment date,'' which is the date of a final court judgment that determines the amount of the debt owed by the consumer. The judgment date is discussed in the section-by-section analysis of final § 1006.34(b)(3)(v).

With respect to the Bureau's request for comment about whether a subsequent debt collector should be permitted to use a different itemization date than a prior debt collector used for the same debt, industry and industry trade group commenters generally agreed that requiring debt collectors to use the same reference date as a prior collector would be burdensome and impractical. These commenters stated that debt collectors would be unable to ensure compliance with such a requirement because a creditor might not disclose the reference date that a prior debt collector used. By contrast, an academic and a consumer advocate commenter stated that a debt collector should be required to use the same itemization date the prior debt collector used because a consumer may not be able to assess the amount owed if the subsequent debt collector uses a different reference date.

The final rule permits a debt collector to use a different itemization date than a prior debt collector used for the same debt. The availability of account information, including about a prior debt collector's activities, to a subsequent debt collector depends on the creditor or debt buyer who places the debt with the subsequent debt collector. If the creditor or debt buyer does not provide the previously used itemization date, the subsequent debt collector may be unable to determine that date, and therefore fail to comply with a requirement to use it. It is conceivable that, were the rule to require use of the same itemization date previously used, debt collectors and creditors could begin to structure their contracts and processes to enable creditors and debt collectors to transfer a previously used itemization date. However, establishing such contracts and processes would likely impose costs on creditors and debt collectors,[180] and those costs would likely be passed on to consumers. Further, the Bureau finds that the costs are not warranted because permitting a subsequent debt collector to use a different itemization date will maintain protections for consumers, as long as the debt collector uses one of the five itemization dates specified in the rule. As stated above, the Bureau finds that the five itemization dates are all dates that should result in reasonably meaningful and recognizable debt amounts for consumers. Accordingly, the Bureau is adopting new comment 34(b)(3)–2 to clarify that, when selecting an itemization date pursuant to § 1006.34(b)(3), a debt collector may use a different reference date than a prior debt collector who attempted to collect the debt.

For the reasons set forth above, the Bureau is finalizing § 1006.34(b)(3) and its related commentary with minor wording changes and to include a new reference date, the judgment date, in § 1006.34(b)(3)(v). In addition, the Bureau is adopting new comment 34(b)(3)–2 to explain that a debt collector may use a different reference date than a prior debt collector. The Bureau is finalizing § 1006.34(b)(3) and § 1006.34(b)(3)(i) through (v), discussed below, pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors and pursuant to its

[178] For example, debt collectors who collect on behalf of the Internal Revenue Service under a ''qualified tax collection contract'' generally are required by statute to comply with the FDCPA. *See* 26 U.S.C. 6306(g) (''The provisions of the [FDCPA] shall apply to any qualified tax collection contract, except to the extent superseded by section 6304, section 7602(c), or by any other provision of this title.'').

[179] The Higher Education Act defines ''default'' as ''the failure of a borrower . . . to make an installment payment when due, or to meet other terms of the promissory note, the Act, or regulations as applicable, if the Secretary or guaranty agency finds it reasonable to conclude that the borrower and endorser, if any, no longer intend to honor the obligation to repay, provided that this failure persists for—(1) 270 days for a loan repayable in monthly installments; or (2) 330 days for a loan repayable in less frequent installments.'' 34 CFR 682.200(b).

[180] In order for the contractual framework and processes to achieve the desired result of a creditor passing the previously used itemization date to the current debt collector, creditors would have to structure contracts to require the previous debt collectors to pass back to the creditors the previously used itemization dates so that the creditors, in turn, can pass them on to the current debt collectors. Developing and implementing such contractual provisions and processes across the debt collection industry would likely impose potentially significant costs.

authority under Dodd-Frank Act section 1032(a) to prescribe rules to ensure that the features of consumer financial products and services are disclosed to consumers fully, accurately, and effectively.

34(b)(3)(i)

The Bureau proposed in § 1006.34(b)(3)(i) to permit debt collectors to use as the itemization date the date of the last periodic statement or written account statement or invoice provided to the consumer. Proposed comment 34(b)(3)(i)–1 explained that a statement provided by a creditor or a third party acting on the creditor's behalf, including a creditor's service provider, may constitute the last statement provided to the consumer for purposes of § 1006.34(b)(3)(i).

Commenters disagreed about whether the Bureau should adopt the last statement date as a permissible reference date. Several industry and industry trade group commenters supported the proposal, stating that, for some debts, the last statement date is readily available to debt collectors and recognizable to consumers. Some commenters stated that, even when creditors do not initially provide periodic statements to debt collectors, such statements are available upon request. However, some consumer advocate commenters stated that the last statement date may not be meaningful to some consumers and may not help them recognize a debt. For example, a commenter stated that a creditor may send duplicates of the same periodic statement or invoice to a consumer multiple times, even when the balance is changing due to interest or fees. In this scenario, the commenter said, the last statement a consumer received would not reflect the actual amount owed and would not be helpful to the consumer.

At least two commenters stated that a validation notice provided by a prior debt collector should not constitute a last statement for purposes of § 1006.34(b)(3)(i). According to a consumer advocate commenter, the date of a prior validation notice will not be meaningful to consumers and, consequently, an itemization as of that date will not help consumers recognize an alleged debt. An industry trade group commenter advised against relying on a validation notice provided by a prior debt collector because creditors generally do not provide previously sent validation notices to subsequent debt collectors.

The Bureau determines that the last statement date may be used as a reference date. Many creditors or third parties acting on a creditor's behalf routinely provide consumers with account statements, such as periodic statements or invoices. If a consumer has received an account statement from a creditor, the consumer either may recognize the date that they last received a statement or may be able to verify that date in their records.[181] Further, last statement information is often readily available to debt collectors, as debt collectors frequently receive, or have the ability to request, last statement information or records from creditors.

The Bureau determines that only a last statement or invoice provided to a consumer by a creditor, as opposed to a statement, such as a validation notice, provided by a debt collector, should serve as a basis for a last statement date as defined in § 1006.34(b)(3)(i) because consumers may be more likely to recall or be able to verify a statement sent by a creditor than by a debt collector. This may be true even if a creditor issues a statement after the debt has gone into collection. Under § 1006.34(b)(3)(i), such a new statement may serve as the last statement for purposes of the itemization date.

For these reasons, the Bureau is finalizing § 1006.34(b)(3)(i) and its related commentary with revisions to provide that only a statement or invoice provided by a creditor qualifies as a last statement for purposes of § 1006.34(b)(3)(i). Specifically, the Bureau is revising § 1006.34(b)(3)(i) to state that the last statement date is the date of the last periodic statement or written account statement or invoice provided to the consumer by a creditor. The Bureau also is revising comment 34(b)(3)(i)–1 to provide that a statement or invoice provided by a debt collector is not a last statement for purposes of § 1006.34(b)(3)(i), unless the debt collector is also a creditor.

34(b)(3)(ii)

The Bureau proposed in § 1006.34(b)(3)(ii) to permit debt collectors to use the date that the debt was charged off as the itemization date.

An industry trade group and an industry commenter supported the use of the charge-off date, particularly for debts associated with open-end credit, such as credit cards. The commenters stated that charge off is a regulated Federal standard for consumer credit[182] and would be a reliable reference date for itemization-related disclosures in some circumstances. An industry trade group commenter stated that creditors frequently provide debt collectors account information as of the charge-off date. Commenters stated that consumers may recognize the amount due as of the charge-off date because some creditors provide charge-off statements that reflect the charge-off balance and, they said, consumers have the ability to review these charge-off statements.

Other commenters objected to including the charge-off date as a permissible reference date. An industry commenter stated that not all creditors maintain account information as of the charge-off date or communicate that information to debt collectors at placement. Consumer advocates and at least two industry trade group commenters stated that, although the charge-off date may be widely used for some financial products, it may not resonate with consumers or help them recognize a debt because consumers might not know the charge-off date.[183]

The Bureau determines that the charge-off date may be used as a reference date. Creditors frequently provide account information as of the charge-off date for various types of debts, including credit card debt, to debt collectors. The Bureau acknowledges that not all creditors maintain account information as of the charge-off date or provide such information to debt collectors, but the charge-off date is only one of five reference dates specified in the final rule. Further, account information at charge off is readily available to a sufficiently large number of debt collectors—including collectors of credit card debt—to justify its adoption as a reference date. In addition, while consumers might not know the specific charge-off date, they may, in fact, recognize account information as of approximately the charge-off date because charge off often occurs at around the time the creditor provided a last account statement. Further, as noted by commenters, some creditors may provide consumers with charge-off statements that reflect the balance as of the charge-off date.

Accordingly, the Bureau is finalizing § 1006.34(b)(3)(ii) as proposed.

[181] This is likely to be true even if the consumer has received a duplicative statement as the last statement. In that scenario, under § 1006.34(c)(2)(vii), which requires a debt collector to disclose the amount of the debt on the itemization date, the debt amount that the debt collector discloses to the consumer must be the debt amount as of that last statement date.

[182] 65 FR 36903 (June 12, 2000); Off. of the Comptroller of the Currency, Bulletin 2000–20, *Uniform Retail Credit Classification and Account Management Policy* (June 20, 2000).

[183] An individual commenter requested clarification whether, for medical debt, the date of charge off is the date a creditor places the account for collection. The Bureau is not aware that such a definition is commonly used.

34(b)(3)(iii)

The Bureau proposed in § 1006.34(b)(3)(iii) to permit debt collectors to use the date the last payment was applied to the debt as the itemization date.

Industry and consumer advocate commenters generally supported proposed § 1006.34(b)(3)(iii). These commenters agreed that account information as of the last payment date is readily available to debt collectors and recognizable to consumers. According to one consumer advocate, a consumer may have a general idea of when a bill was last paid, especially if the consumer's delinquency was related to a significant life event, such as a job loss, a divorce, or an illness. Accordingly, the Bureau determines that the last payment date as defined in § 1006.34(b)(3)(iii) is an appropriate reference date.

Commenters asked the Bureau to clarify whether a third-party payment could serve as the basis for the last payment date. For example, several trade group commenters stated that, if a consumer's car is repossessed, the sale of the collateral may be applied to the consumer's balance after receipt of the consumer's last payment. Another commenter raised the possibility of third-party payments and insurance adjustments in the medical debt context. A group of consumer advocates recommended that only a payment from a consumer to a creditor should serve as the basis for a last payment date. According to this commenter, a last consumer payment to a prior debt collector may not be significant or recognizable to a consumer.

The Bureau determines that third-party payments may serve as the basis for the last payment date under § 1006.34(b)(3)(iii). The Bureau finds that the date of a third-party payment on the debt, such as a payment from an auto repossession agent or an insurance company, may be meaningful to a consumer because such payments may be accompanied by a notice to the consumer, and therefore the consumer could recognize or verify with records the date of such payments.

The Bureau also determines that a consumer's payment to a prior debt collector may serve as the last payment date. The Bureau finds that consumers are at least as likely to recognize or be able to verify with records the status of the debt as of the consumer's last payment to a prior debt collector as consumers are able to recognize or verify an earlier (perhaps much earlier) payment to the creditor, particularly if the debt has been outstanding for a long time.

For these reasons, the Bureau is finalizing § 1006.34(b)(3)(iii) as proposed to provide that the last payment date is the date the last payment was applied to the debt. The Bureau also is adopting new comment 34(b)(3)(iii)–1, which clarifies that a third-party payment applied to the debt, such as a payment from an auto repossession agent or an insurance company, can be a last payment for purposes of § 1006.34(b)(3)(iii).

34(b)(3)(iv)

The Bureau proposed in § 1006.34(b)(3)(iv) to permit debt collectors to use as the itemization date the date of the transaction that gave rise to the debt. Proposed comment 34(b)(3)(iv)–1 explained that the transaction date is the date that a creditor provided, or made available, a good or service to a consumer, and it included examples of transaction dates. The comment also explained that, if a debt has more than one potential transaction date, a debt collector may use any such date as the transaction date but must use whichever transaction date it selects consistently.

A number of commenters, including consumer advocates, industry trade groups, and at least one industry commenter, supported including the transaction date in the itemization date definition. According to several commenters, consumers likely would recognize the transaction date as defined by proposed § 1006.34(b)(3)(iv). At least one commenter stated that creditors provide account information as of the transaction date for some debt types.

With respect to proposed comment 34(b)(3)(iv)–1, a consumer advocate commenter stated that, if a debt has more than one potential transaction date, the debt collector should not be permitted to choose which date to use as the transaction date for purposes of § 1006.34(b)(3)(iv). The commenter urged the Bureau to develop a prescriptive standard for identifying the appropriate transaction date for scenarios where multiple transaction dates exist.

Several commenters also stated that determining the transaction date may be problematic in some circumstances. For example, a consumer advocate commenter explained that, while determining the transaction date is straightforward with one-time transactions, identifying the transaction date may be more difficult with respect to contracts for ongoing services, such as gym memberships, cellular telephone contracts, or lawn care service contracts. In addition, an industry commenter stated that medical providers may combine multiple dates of service into one account or use family billing that combines separate bills for family members into one account. The commenter suggested that, if an account in collection reflects services on multiple dates or for multiple individuals, identifying a transaction date may be difficult for the debt collector.

The Bureau finds that, for some debts, creditors may provide debt collectors with account information related to the transaction date. In addition, consumers may recognize the amount of a debt on the transaction date, which may be reflected on a copy of a contract or a bill provided by a creditor. For this reason, the Bureau is finalizing § 1006.34(b)(3)(iv) as proposed to provide that the transaction date, which is the date of the transaction that gave rise to the debt, can be the itemization date for purposes of § 1006.34(b)(3).

As commenters noted, various dates may serve as potential transaction dates under § 1006.34(b)(3)(iv). For example, potential transaction dates may include the date a service or good was provided to a consumer or the date that a consumer signed a contract for a service or good. In the case of a consumer's tax debt, the date a government assessed the tax may be a transaction date for purposes of § 1006.34(b)(3)(iv).[184] Nevertheless, the Bureau declines to adopt a prescriptive standard for identifying the only transaction date debt collectors may use. Both the contract date and the service date are significant dates that may resonate with a consumer. Because the consumer may recognize the amount of the debt on those dates, the Bureau finds that either date may serve as the transaction date. Further, the Bureau determines that developing a more prescriptive standard that would apply to all debt types is not feasible. For this reason, the Bureau is finalizing comment 34(b)(3)(iv)–1, with minor changes for clarity, to provide that, if a debt has more than one transaction date, a debt collector may use any such date as the transaction date, but the debt collector must use whichever date the debt collector selects consistently, as described in comment 34(b)(3)–1. Comment 34(b)(3)(iv)–1 also addresses concerns regarding identifying the transaction date for medical debt that includes services on

[184] See the discussion of tax debts in the introductory section-by-section analysis of § 1006.34(b)(3).

multiple dates or for multiple individuals.[185]

The Bureau recognizes that the transaction date may be difficult to determine in some circumstances. However, under the framework in § 1006.34(b)(3) for determining the itemization date, the transaction date is one of five reference dates from which a debt collector may choose. Section 1006.34(b)(3) does not require a debt collector to use the transaction date as the reference date for itemization-related disclosures. If a debt collector cannot determine the transaction date, the debt collector may use another reference date.

34(b)(3)(v)

As discussed above, the proposed definition of itemization date included four reference dates. In response to the proposed definition, an industry commenter suggested that the Bureau add a fifth date—the date of a court judgment. The Bureau has determined to adopt this recommendation. As a general matter, debt collectors will know if a court judgment against a consumer exists and consumers are likely to recognize the date of a court judgment against them or be able to verify the date with records. Further, the amount of the debt as of the date of a court judgment is verifiable as it will have been memorialized in court records. Accordingly, the Bureau is finalizing § 1006.34(b)(3)(v) to permit debt collectors to use as the itemization date the judgment date, which is the date of a final court judgment that determines the amount of the debt owed by the consumer.

34(b)(4) Validation Notice

FDCPA section 809(a) provides, in relevant part, that, within five days after the initial communication with a consumer in connection with the collection of any debt, a debt collector shall send the consumer a written notice containing specified information (*i.e.,* validation information), unless that information is contained in the initial communication or the consumer has paid the debt. Debt collectors and others commonly refer to the written notice required by FDCPA section 809(a) as a ''validation notice'' or a ''g notice.'' The Bureau proposed in § 1006.34(b)(4) to define validation notice to mean a written or electronic notice that provides the validation information described in § 1006.34(c).[186] The Bureau received no comments regarding proposed § 1006.34(b)(4) and is finalizing it with a minor wording change for consistency with final § 1006.34(c).

34(b)(5) Validation Period

FDCPA section 809(b) contains certain requirements that a debt collector must satisfy if a consumer disputes a debt or requests the name and address of the original creditor.[187] If a consumer disputes a debt in writing within 30 days of receiving the validation information, a debt collector must stop collection of the debt until the debt collector obtains verification of the debt or a copy of a judgment against the consumer and mails it to the consumer. Similarly, if a consumer requests the name and address of the original creditor in writing within 30 days of receiving the validation information, the debt collector must cease collection of the debt until the debt collector obtains and mails such information to the consumer. FDCPA section 809(b) also prohibits a debt collector, during the 30-day period for written disputes and original-creditor information requests, from engaging in collection activities and communications that overshadow, or are inconsistent with, the disclosure of the consumer's rights to dispute the debt and request original-creditor information, which are sometimes referred to as ''verification rights.''

As described in the section-by-section analysis of § 1006.34(c)(3)(i) through (iii), the Bureau proposed to require debt collectors to disclose to a consumer the date certain on which the consumer's verification rights under FDCPA section 809(b) expire. To facilitate compliance with that proposed requirement, proposed § 1006.34(b)(5) defined the term validation period to mean the period starting on the date that a debt collector provides the validation information described in § 1006.34(c) and ending 30 days after the consumer receives or is assumed to receive the validation information.[188] To clarify how to calculate the end of the validation period—including how debt collectors may disclose a period that provides consumers additional time beyond the required 30 days to exercise their validation rights—proposed § 1006.34(b)(5) provided that a debt collector may assume that a consumer receives the validation information on any day that is at least five days (excluding legal public holidays, Saturdays, and Sundays) after the debt collector provides it. Proposed comment 34(b)(5)–1 clarified that, if a debt collector sends an initial validation notice that was not received and then sends a subsequent validation notice, the validation period ends 30 days after the consumer receives or is assumed to receive the subsequent validation notice.

For the reasons discussed below, the Bureau is finalizing proposed § 1006.34(b)(5) and proposed comment 34(b)(5)–1 (which is renumbered as comment 34(b)(5)–2) with minor wording changes for clarity and consistency with other provisions of Regulation F. The Bureau is adopting new comment 34(b)(5)–1 to illustrate how a debt collector may calculate the end of the validation period before sending the validation notice.

A number of commenters, including industry commenters, supported proposed § 1006.34(b)(5). According to several commenters, the proposed definition is consistent with current industry practices. For example, with respect to the proposed five-day delivery timing assumption, industry commenters stated that debt collectors generally assume that a consumer receives a validation notice five to eight days after mailing. Consumer advocate commenters objected to the proposed definition, stating that debt collectors should be obligated to honor consumer verification requests at any time, not only during the validation period.

Some commenters recommended lengthening the proposed five-day delivery timing assumption. A consumer advocate commenter and an industry trade group commenter suggested that the validation period definition should assume that the consumer receives the validation notice seven days after the debt collector mails it to account for delays or bulk mail delivery.[189] Another trade group

[185] Because of differences between various debt types and the particular facts and circumstances of any given transaction, § 1006.34(b)(3)(iv) provides debt collectors flexibility when selecting a transaction date. However, if the total amount of a debt in collection includes amounts incurred on different dates of service, the Bureau believes that, even though § 1006.34(b)(3)(iv) does not require it, debt collectors generally will select the last date of service as the transaction date. This date may be most recognizable to consumers. Further, disclosing itemization-related information as of the last date, as opposed to an earlier date, likely would be easier for a debt collector.

[186] *See* 84 FR 23274, 23337 (May 21, 2019).

[187] 15 U.S.C. 1692g(b).

[188] 84 FR 23274, 23337–38 (May 21, 2019).

[189] United States Postal Service (USPS) delivery times for Standard Mail, commonly referred to as bulk mail, are typically longer than delivery times for first-class mail. For example, based on the USPS Originating Service Standards, bulk mail originated in Washington, DC takes six days to reach New York City, seven days to reach Denver, and nine days to reach Seattle. By contrast, first-class mail from Washington, DC reaches New York City in two days and Denver and Seattle in three days. *See* U.S. Postal Serv., *Service Standards Maps, https://postalpro.usps.com/ppro-tools/service-standards-maps* (last visited Nov. 16, 2020).

commenter recommended a fixed ten-day assumption that omits consideration of weekends and holidays.

Other commenters recommended shortening the delivery timing assumption. For example, an industry trade group commenter recommended that the Bureau eliminate the assumption entirely and clarify that the validation period commences upon mailing of a validation notice. Other industry commenters urged the Bureau to shorten the assumption for near-instantaneous communication methods, such as electronic or oral delivery. In contrast, at least two industry trade groups commenters and a consumer advocate commenter recommended a uniform validation period across delivery methods. According to an industry trade group commenter, if the validation period is not the same for all delivery methods, consumers may be confused if they receive validation notices through different delivery methods with different due dates.

After considering this feedback, the Bureau determines that a validation period definition will facilitate debt collectors' compliance with the requirement in § 1006.34(c)(3) to disclose to a consumer the date certain on which the consumer's FDCPA section 809(b) verification rights expire. The Bureau declines, as requested by consumer advocate commenters, to require a debt collector to comply with a verification request that a consumer submits after the 30-day period provided by the statute has expired. FDCPA section 809(b) establishes a 30-day period for consumers to exercise their verification rights.[190]

The Bureau also declines to modify the length of the five-day delivery timing assumption. The Bureau proposed § 1006.34(b)(5) on the basis that a consumer typically receives a validation notice no more than five days (excluding legal public holidays, Saturdays, and Sundays) after the debt collector provides the notice. Based on its market monitoring activities, the Bureau understands that debt collectors typically send consumer communications by first-class mail, which generally is delivered in three business days or less.[191] The Bureau is unaware that debt collectors typically use bulk mail to deliver validation notices, and commenters offered no evidence otherwise. For these reasons, the Bureau declines to extend the five-day delivery timing assumption.

The Bureau also declines to shorten the validation period's five-day delivery timing assumption. The FDCPA's 30-day validation period begins to run when the consumer receives the validation information.[192] If the 30-day clock began to run upon the debt collector's mailing of the validation notice, as some commenters suggested, the consumer would be deprived of the full 30-day period provided by the FDCPA to respond to the notice. Further, the Bureau declines to shorten the length of the validation period for validation information provided by communication methods such as electronic delivery. A delivery timing assumption that varied by delivery method could pose compliance challenges and incentivize use of one communication method over another. Therefore, as proposed, the five-day delivery timing assumption applies uniformly to all validation information delivery methods.

A group of consumer advocates asked the Bureau to define the validation period based solely on when the consumer is assumed to receive the validation information. In other words, this commenter requested that the rule not permit the date that a consumer actually received the validation notice to serve as the basis of the validation period. According to this commenter, relying solely on the date that the consumer is assumed to receive the information would prevent confusion if the date the consumer received the notice and the date the debt collector assumed the consumer received it are different.

The Bureau declines to adopt this suggestion. The FDCPA's 30-day validation period begins to run when the consumer receives the validation information. Nevertheless, the Bureau determines that, at least in certain contexts, the date that the consumer is assumed to receive the validation notice is the only date information that a debt collector will have at the time the validation information is generated. Specifically, a debt collector who sends a written or electronic validation notice will not know, at the time the notice is generated, the date on which the consumer will receive the notice and, therefore, must be able to use the date of assumed receipt to calculate the validation period end date. The Bureau is adding new comment 34(b)(5)–1 to clarify that, in such circumstances, debt collectors may rely on the date of assumed receipt, even if they learn after sending the notice that the consumer received the validation information on a different date.

Several industry and industry trade group commenters expressed concern about the use of the term ''legal public holiday'' in proposed § 1006.34(b)(5). According to these commenters, legal public holidays may include State and local holidays that the debt collector is not aware of and cannot reasonably ascertain. In response to these concerns, and consistent with § 1006.22(c)(1) in the November 2020 Final Rule,[193] the Bureau is revising § 1006.34(b)(5) to provide that a debt collector may assume that a consumer receives the validation information on any date that is at least five days (excluding legal public holidays identified in 5 U.S.C. 6103(a), Saturdays, and Sundays) after the debt collector provides it.

Several industry commenters asked the Bureau to clarify whether a debt collector must receive a consumer's verification request before the validation period end date, or whether the consumer need only send the request by the validation period end date for the request to be effective. The Bureau determines that a consumer's verification request—whether an original-creditor information request or a dispute—is effective if the consumer sends or submits the request within the 30-day period established in § 1006.34(b)(5), even if the debt collector does not receive the request until after the 30-day period. In specifying requirements for debt collectors' responses to consumers' verification requests, § 1006.38(c) and (d)(2) of the Bureau's November 2020 Final Rule implemented FDCPA section 809(b) by providing that, upon receipt of an original-creditor information request (§ 1006.38(c)) or a dispute (§ 1006.38(d)(2)) ''*submitted by the consumer* in writing within the validation period, a debt collector must cease collection of the debt . . . .'' (emphasis added). The Bureau determines that a consumer's original-

[190] Although the FDCPA and this implementing regulation do not require a debt collector to provide verification after the validation period expires, a debt collector nevertheless may choose to do so. The Bureau has received feedback from debt collectors and at least one industry trade group that many debt collectors respond to disputes with verification, and to original-creditor-information requests, after the validation period has expired.

[191] *See* U.S. Postal Serv., *Service Standards Maps, https://postalpro.usps.com/ppro-tools/service-standards-maps* (last visited Dec. 1, 2020).

[192] FDCPA section 809(a)(3) requires the validation notice to include ''a statement that unless the consumer, within thirty days *after receipt of the notice,* disputes the validity of the debt, or any portion thereof, the debt will be assumed to be valid by the debt collector.'' 15 U.S.C. 1692g(a)(3) (emphasis added).

[193] 85 FR 76734, 76833–34, 76892 (Nov. 30, 2020).

creditor information request or dispute has been ''submitted by the consumer'' for purposes of § 1006.38(c) and (d)(2) if the consumer sends or submits the request within the 30-day period established in § 1006.34(b)(5), even if the debt collector does not receive the request until after the 30-day period.

For the reasons discussed above, the Bureau is adopting § 1006.34(b)(5) to provide that validation period means the period starting on the date that a debt collector provides the validation information and ending 30 days after the consumer receives or is assumed to receive it. Section 1006.34(b)(5) also specifies that a debt collector may assume that a consumer receives the validation information on any date that is at least five days (excluding legal public holidays identified in 5 U.S.C. 6103(a) (*i.e.,* federally recognized public holidays), Saturdays, and Sundays) after the debt collector provides it.

Proposed comment 34(b)(5)–1 clarified that, if a debt collector sends a subsequent validation notice to a consumer because the consumer did not receive the original validation notice and the consumer has not otherwise received the validation information, the debt collector must calculate the end of the validation period based on the date the consumer receives or is assumed to receive the subsequent validation notice.

At least two industry trade group commenters stated that proposed comment 34(b)(5)–1 was consistent with current industry practice. According to these commenters, if a validation notice is returned as undeliverable, debt collectors typically send a new validation notice and provide a new period for consumers to exercise their verification rights. A law firm commenter asked the Bureau to provide additional guidance on a debt collector's duties if a validation notice is returned as undeliverable after the validation period has expired.

The Bureau concludes based on feedback received and its own market-monitoring, supervision, and enforcement experience that proposed comment 34(b)(5)–1 is consistent with existing industry practice and therefore is adopting it largely as proposed but renumbered as comment 34(b)(5)–2. If a validation notice is returned as undeliverable after the validation period has expired and the debt collector sends a subsequent notice, then, as stated in the comment, the debt collector must calculate the end of the validation period based on the date the consumer receives or is assumed to receive the subsequent validation notice.

34(c) Validation Information

Proposed § 1006.34(c) set forth the validation information that proposed § 1006.34(a)(1) would have required debt collectors to disclose. The validation information consisted of four general categories: Information to help consumers identify debts (including the information specifically referenced in FDCPA section 809(a)); information about consumers' protections in debt collection; information to facilitate consumers' ability to exercise their rights with respect to debt collection; and certain other statutorily required information. Each of those categories is addressed separately in the section-by-section analysis of § 1006.34(c)(1) through (4).

34(c)(1) Debt Collector Communication Disclosure

FDCPA section 807(11) requires a debt collector to disclose in its initial written communication with a consumer—and, if the initial communication is oral, in that oral communication as well—that the debt collector is attempting to collect a debt and that any information obtained will be used for that purpose.[194] A debt collector must also disclose in each subsequent communication that the communication is from a debt collector. If a debt collector provides validation information, the debt collector engages in a debt collection communication and must make an appropriate FDCPA section 807(11) disclosure.[195]

The Bureau proposed to implement the FDCPA section 807(11) disclosures in § 1006.18(e).[196] In turn, the Bureau proposed in § 1006.34(c)(1) that the § 1006.18(e) disclosure is required validation information. The Bureau finalized § 1006.18(e) in the November 2020 Final Rule.[197] Section 1006.18(e)(1) requires a debt collector to disclose in its initial communication that the debt collector is attempting to collect a debt and that any information obtained will be used for that purpose. Section 1006.18(e)(2) requires a debt collector to disclose in each subsequent communication that the communication is from a debt collector.

At least one industry trade group supported proposed § 1006.34(c)(1)'s cross-reference to the FDCPA section 807(11) requirement. A consumer advocate commenter asked the Bureau to clarify what version of the FDCPA section 807(11) disclosure should appear on the validation notice: The longer, initial disclosure described in § 1006.18(e)(1) or the shorter, subsequent disclosure described in § 1006.18(e)(2).

The Bureau is adopting new comment 34(c)(1)–1 to clarify that a debt collector who provides the validation notice required by § 1006.34(a)(1)(i)(A)—*i.e.,* a debt collector who provides the validation notice in the initial communication—complies with § 1006.34(c)(1) by providing the disclosure described in § 1006.18(e)(1). The disclosure described in § 1006.18(e)(1) is broader than, and incorporates the content of, the disclosure described in § 1006.18(e)(2). Accordingly, new comment 34(c)(1)–1 also clarifies that a debt collector who provides the validation notice required by § 1006.34(a)(1)(i)(B)—*i.e.,* a debt collector who provides the validation notice within five days of the initial communication—complies with § 1006.34(c)(1) by providing either the disclosure required by § 1006.18(e)(1) or the disclosure required by § 1006.18(e)(2).[198] The Bureau determines that this clarification will facilitate compliance, encourage use of the model validation notice, and protect consumers.

The consumer advocate commenter also recommended that the Bureau require every validation notice to include a Spanish translation of the FDCPA section 807(11) disclosure to assist Spanish-speaking consumers. The Bureau declines to do so. Mandating that every debt collector provide a Spanish translation of the disclosure is unnecessary for the majority of consumers, who are not Spanish speakers. Further, a mandatory translation could undermine the effectiveness of the other validation information disclosures. Moreover, the November 2020 Final Rule contained a targeted language access intervention on this topic. Pursuant to § 1006.18(e)(4) in that rule, debt collectors will be required to make the FDCPA section 807(11) disclosure in the same language or languages used for the rest of the communication in which the disclosures are conveyed. Thus, if a debt collector provides a consumer a

[194] *See* 15 U.S.C. 1692e(11).

[195] *See, e.g., Dorsey* v. *Morgan,* 760 F. Supp. 509 (D. Md. 1991).

[196] *See* 84 FR 23274, 23322–23, 23402 (May 21, 2019).

[197] *See* 85 FR 76734, 76830–31, 76891–92 (Nov. 30, 2020).

[198] The model validation notice includes the disclosure required by § 1006.18(e)(1). As explained in the section-by-section analysis of § 1006.34(d)(2), new comment 34(d)(2)(i)–1 clarifies that a debt collector who uses the model notice to provide a validation notice as described in § 1006.34(a)(1)(i)(B) may replace the disclosure required by § 1006.18(e)(1) with the disclosure required by § 1006.18(e)(2) without losing the safe harbor provided by use of the model notice.

validation notice in Spanish pursuant to § 1006.34(e), the debt collector must include on that notice a Spanish translation of the FDCPA section 807(11) disclosure.

Accordingly, the Bureau is finalizing § 1006.34(c)(1) as proposed and is finalizing new comment 34(c)(1)–1 as described above.

34(c)(2) Information About the Debt

Proposed § 1006.34(c)(2) specified that certain information about the debt and the parties related to the debt was required validation information.[199] The section-by-section analysis of proposed § 1006.34(c)(2)(i) through (x) discussed the specific items of information, which were designed to help consumers recognize debts and included existing disclosures. The Bureau addresses comments related to specific disclosures in the section-by-section analysis of § 1006.34(c)(2)(i) through (x). In this section-by-section analysis, the Bureau addresses comments related to § 1006.34(c)(2) more generally.

Some commenters supported proposed § 1006.34(c)(2). A consumer advocate and a municipal government commenter stated that the proposed validation information would help consumers determine whether they owe a debt. A group of State Attorneys General stated that consumers today do not consistently receive the information they need to identify debts. According to these commenters, consumers routinely submit complaints that they do not recognize the debts or creditors disclosed on validation notices. An industry trade group stated that it would be feasible for debt collectors to disclose the proposed information because debt buyers routinely obtain such information at purchase.

Other commenters objected to proposed § 1006.34(c)(2) and suggested that consumers do not need information beyond what the FDCPA expressly requires. An industry trade group stated, without providing verifiable evidence, that most debts are valid and asserted that less than one-half of 1 percent of debts lack a contractual basis or are miscalculated. According to this commenter, the small number of debts that are problematic can be resolved by consumers invoking their FDCPA verification rights.

Other commenters who objected to proposed § 1006.34(c)(2) cited industry burden. For example, one industry commenter stated that requiring debt collectors to disclose the proposed information about the debt and parties related to the debt would increase costs for debt collectors as well as for creditors. Another industry commenter suggested that proposed § 1006.34(c)(2) was not feasible because debt collectors rely on creditors for account information and records. According to this commenter, if creditors did not provide the information, debt collectors would be unable to comply with § 1006.34(c)(2).

Some commenters stated that the information proposed § 1006.34(c)(2) would require might confuse consumers and questioned whether it was supported by the Bureau's consumer testing.

Some commenters recommended that the Bureau revise proposed § 1006.34(c)(2) to require additional validation information. Federal government agency staff, a group of State Attorneys General, and a government commenter suggested that the name of the original creditor and the date of the original transaction should be required validation information. A group of State Attorneys General suggested that the Bureau require debt collectors to provide information about the debt as of the charge-off date. Two associations representing State regulatory agencies recommended that the Bureau require disclosure of a debt collector's State license or registration number, such as the Nationwide Multi-State Licensing System identification. According to these commenters, requiring debt collectors to disclose license or registration information would assist regulators examining for compliance with State debt collection laws. In addition, a consumer advocate, an industry trade group, and an industry commenter recommended that, for medical debt, validation information should include the facility name associated with the debt. According to these commenters, a consumer may be more likely to recognize a facility where treatment was provided than the name of the physician or healthcare provider to whom the consumer owes the debt.

After considering the feedback, the Bureau has determined to finalize § 1006.34(c)(2). The Bureau determines that validation notices in use today frequently lack sufficient information about the debt and the parties related to the debt, and this lack of information undermines the ability of consumers to determine whether they owe an alleged debt. This conclusion is consistent with feedback from Federal and State government commenters, including the FTC and a group of State Attorneys General. The Bureau's testing also supports this conclusion.[200]

The Bureau determines that requiring debt collectors to disclose the information about the debt and parties related to the debt in § 1006.34(c)(2) is necessary. Industry commenters did not support their claims about the relative infrequency of problematic debts with verifiable evidence.[201] In addition, a group of State Attorneys General stated that consumers routinely complain that they do not recognize debts being collected, and the Bureau's complaint statistics indicate similar concerns about debts among consumers.[202] Thus, the Bureau is finalizing § 1006.34(c)(2) to require information about the debt and parties related to the debt.

The Bureau also determines that § 1006.34(c)(2) will not impose undue industry burden. As discussed in part VII, while § 1006.34(c)(2) may increase some costs for debt collectors, as well as cause some indirect costs for creditors, the Bureau does not expect these costs to be substantial. The Bureau disagrees that a significant number of debt collectors will be unable to comply with § 1006.34(c)(2). The Bureau acknowledges that debt collectors depend on creditors to provide account information and that creditors will not be required by the final rule to provide the information that § 1006.34(c)(2) will require. Notwithstanding this fact, the Bureau has received feedback that many creditors today make available much of the information mandated by § 1006.34(c)(2). To the extent that creditors do not already provide debt collectors with this information, the Bureau determines that creditors will be incentivized to do so after § 1006.34(c)(2)'s effective date because the debt collectors they hire or sell debts to will be unable to legally collect without it.

[199] 84 FR 23274, 23338–42, 23404 (May 21, 2019). Proposed § 1006.34(c)(5) set forth a special rule for information about the debt for certain residential mortgage debt.

[200] Certain information that Bureau qualitative testing indicates helps consumers to recognize a debt—including a debt's original account number or an itemization of interest and fees—may not consistently appear on validation notices. *See* FMG Cognitive Report, *supra* note 27, at 8–11.

[201] Even assuming one commenter's claim that only one-half of 1 percent of debts lack a contractual basis or are miscalculated, this error rate would impact hundreds of thousands of consumers annually. As the proposal noted, 49 million consumers are contacted by debt collectors every year. *See* 84 FR 23274, 23382 n.656 (May 21, 2019). If one-half of 1 percent of these consumers received validation notices for debts they did not owe, 245,000 consumers could be impacted.

[202] The most common debt collection complaint received by the Bureau continues to be about attempts to collect a debt that the consumer reports is not owed. *See* 2020 FDCPA Annual Report, *supra* note 12, at 14. Consumers may report that a debt is not owed for a variety of reasons including, but not limited to, that the debt is being collected in error or that the consumer does not recognize the debt.

The Bureau determines that the information required by § 1006.34(c)(2) will not confuse consumers. As discussed in part III.C, the Bureau has validated the model validation notice and the validation information contained therein through four rounds of consumer testing.

The Bureau declines the recommendation to add certain disclosures to § 1006.34(c)(2). First, the Bureau declines to require the name of the original creditor and the date of the original transaction. Requiring this additional information on validation notices may overwhelm consumers, may be repetitive, or may otherwise not add to consumer understanding because the validation information already includes items such as the debt collector's name (§ 1006.34(c)(2)(i)), the name of the creditor to whom the debt was owed on the itemization date (§ 1006.34(c)(2)(iii)), and the name of the creditor to whom debt is currently owed (§ 1006.34(c)(2)(v)).

The Bureau also declines to tie information disclosure requirements to the date that a debt was charged off because charge off is not relevant to all debt types. However, as discussed in the section-by-section analysis of § 1006.34(b)(3)(ii), a debt collector may use the charge-off date as the itemization date, in which case consumers will receive information about the amount of the date as of the charge-off date, as well as information about interest, fees, payments, and credits since that date.[203]

The Bureau also declines to require a debt collector to disclose a State license or registration number. If a debt collector is specifically required by applicable law to disclose such information, a debt collector may do so as an optional disclosure under final § 1006.34(d)(3)(iv)(A).

The Bureau does agree that a facility name associated with a debt may be helpful to consumers in the medical debt context. The Bureau is not modifying § 1006.34(c)(2) to require this information, but final § 1006.34(d)(3)(vii) permits debt collectors to include facility name as an optional disclosure.

Accordingly, as noted above, the Bureau is finalizing § 1006.34(c)(2) to require debt collectors to provide certain information about the debt and the parties related to the debt. Except with respect to final § 1006.34(c)(2)(iii), the Bureau is finalizing § 1006.34(c)(2) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors and, as described more fully below, its authority to implement and interpret FDCPA section 809. In addition, except with respect to final § 1006.34(c)(2)(v) and (ix), the Bureau is finalizing § 1006.34(c)(2) pursuant to its authority under section 1032(a) of the Dodd-Frank Act, on the basis that the validation information describes the debt, which is a feature of debt collection.

34(c)(2)(i)

FDCPA section 809(b) provides that a consumer may notify a debt collector in writing, within 30 days after receipt of the information required by FDCPA section 809(a), that the consumer is exercising certain verification rights, including the right to dispute the debt.[204] FDCPA section 809(a)(3) through (5), in turn, requires debt collectors to disclose how consumers may exercise their verification rights. The proposal stated that to notify a debt collector in writing that the consumer is exercising the consumer's verification rights, the consumer must have the debt collector's name and address.[205] Proposed § 1006.34(c)(2)(i) therefore provided that the debt collector's name and mailing address are required validation information.

Industry and industry trade group commenters recommended various revisions to proposed § 1006.34(c)(2)(i). First, some industry trade group commenters suggested that the Bureau permit a debt collector to disclose a trade name or doing-business-as name (DBA), in lieu of the debt collector's legal name. According to these commenters, because a debt collector may not use its legal name when communicating with consumers, a consumer may be more likely to recognize the debt collector's trade name or DBA.

Next, one industry trade group commenter recommended that the Bureau permit a debt collector to disclose a vendor's mailing address because some debt collectors do not receive mail from consumers at their office locations and instead use letter vendors.

Finally, some industry and industry trade group commenters recommended that the Bureau permit debt collectors to disclose multiple addresses. Some of these commenters stated that debt collectors may use separate addresses for payments and other correspondence, including disputes. For example, an industry trade group stated that some clients of debt collectors, including the Department of Education, do not permit debt collectors to receive payments at their office locations and instead require debt collectors to direct payments to a ''lockbox,'' which is a post office box administered by a third party for the receipt of payments.

A consumer advocate asked the Bureau to modify proposed § 1006.34(c)(2)(i) to require debt collectors to also disclose a telephone number, an email address, and any other method the debt collector uses for consumer communications.

After considering the feedback, the Bureau is adopting § 1006.34(c)(2)(i) with a revision for clarity and is also adopting two new comments to incorporate certain suggestions made by commenters.

As noted, some commenters suggested that debt collectors who use multiple mailing addresses be permitted to include more than one mailing address as validation information. The Bureau declines to affirmatively permit the use of more than one mailing address as validation information. As discussed in the proposal, the purpose of validation information is to facilitate a consumer's exercise of their rights in debt collection, namely, the right to dispute the debt or to request original-creditor information. Accordingly, the mailing address included in the validation information must be an address at which the debt collector accepts disputes and original-creditor information requests. The Bureau is revising § 1006.34(c)(2)(i) to affirmatively state this requirement. If a debt collector only accepts payments at a different address than the address at which it accepts disputes and original-creditor information requests, the Bureau notes that the debt collector need not include payment disclosures with the validation information; they are optional disclosures under § 1006.34(d)(3)(iii).[206] Moreover, if a debt collector omits the optional payment disclosures, the validation

[203] *See* the section-by-section analysis of § 1006.34(c)(2)(vii) and (viii).

[204] 15 U.S.C. 1692g(b).

[205] 84 FR 23274, 23339, 23404 (May 21, 2019).

[206] The Bureau also notes that nothing in Regulation F prevents a debt collector from using a different mailing address in communications that do not contain the validation information. For example, if a debt collector accepts payments at a different address, the payment address may be included in a separate communication seeking payment. Additionally, as noted at the outset of the section-by-section analysis of § 1006.34, the Bureau is not finalizing the proposed requirement that all validation notices be substantially similar to the Bureau's model validation notice. Therefore, a debt collector may include a separate payment address on a validation notice, but a debt collector who does so will not receive safe harbors pursuant to §§ 1006.34(d)(2) and 1006.38(b)(2) and must otherwise comply with the FDCPA and Regulation F.

notice will continue to contain contact information for the debt collector, including, at the debt collector's option, the debt collector's telephone number pursuant to § 1006.34(d)(3)(i), should the consumer wish to reach out for payment information or to make a payment.

The Bureau is also adopting new comment 34(c)(2)(i)–1 to clarify that a debt collector may disclose the debt collector's trade name or DBA in lieu of the debt collector's legal name. The Bureau observes that, in some cases, a debt collector's trade name or DBA may be more recognizable to consumers than the debt collector's legal name. The Bureau therefore determines that a debt collector may use its trade name or DBA when communicating with consumers. However, when disclosing a trade name or DBA, the debt collector may not do so in a manner that violates the FDCPA section 807 prohibition on false or misleading representations. For example, a debt collector may violate the FDCPA and this final rule if the debt collector discloses a trade name or DBA that falsely represents or implies that the debt collector is an attorney, when that is not the case.[207]

Second, the Bureau is adopting new comment 34(c)(2)(i)–2 to clarify that a debt collector may disclose a vendor's mailing address, if that is an address at which the debt collector accepts disputes and requests for original-creditor information. As one commenter observed, some debt collectors may use a vendor to receive mail from consumers. The Bureau is finalizing comment 34(c)(2)(i)–2 to accommodate this business practice.

The Bureau declines to adopt the recommendation of some commenters to require debt collectors to disclose other contact methods, including a telephone number or an email address. The FDCPA does not require debt collectors to communicate by telephone or email. However, as noted, § 1006.34(d)(3)(i) permits a debt collector to disclose the debt collector's telephone number. Likewise, § 1006.34(d)(3)(v)(A), permits a debt collector to disclose the debt collector's website and email address.

34(c)(2)(ii)

FDCPA section 809(a) requires debt collectors to disclose information about the debt that helps consumers identify the debt and facilitates resolution of the debt. The proposal stated that, like the information FDCPA section 809(a) expressly requires, the consumer's name and address is essential information about the debt that may help a consumer determine whether the consumer owes a debt and is the intended recipient of a validation notice.[208] The Bureau therefore proposed § 1006.34(c)(2)(ii) to provide that the consumer's name and mailing address is required validation information. As discussed below, proposed comment 34(c)(2)(ii)–1 clarified the meaning of the term ''consumer's name.''

A consumer advocate and an industry trade group expressed overall support for the proposed provision. The consumer advocate stated that consumer name information would help a consumer identify an alleged debt. The consumer advocate also stated that complete name information—such as a first name, middle name, last name, and suffix—would help consumers determine whether a debt collector is seeking a different consumer with a similar name. According to the industry trade group, it would be unreasonable for a debt collector to omit known name information. For the reasons discussed in the proposal, the Bureau is finalizing § 1006.34(c)(2)(ii) as proposed.

Proposed comment 34(c)(2)(ii)–1 clarified that the consumer's name should reflect what the debt collector reasonably determines is the most complete version of the name information about which the debt collector has knowledge, whether obtained from the creditor or another source. Proposed comment 34(c)(2)(ii)–1 further explained that a debt collector would not be able to omit name information in a manner that would create a false, misleading, or confusing impression about the consumer's identity and provided an example.

Some commenters raised concerns about proposed comment 34(c)(2)(ii)–1. A number of industry and industry trade group commenters objected to the statement that debt collectors would be required to determine the most complete version of the name about which the debt collector has knowledge, whether obtained from the creditor or another source. These commenters stated that the reference to ''another source'' was ambiguous and would create litigation risk and compel debt collectors to conduct open-ended research about a consumer's name. Several commenters urged the Bureau to omit the reference to ''another source.''

The Bureau is finalizing comment 34(c)(2)–1 with revisions in response to feedback and for clarity. First, the Bureau is deleting the phrase ''whether obtained from the creditor or another source.'' This phrase is unnecessary as it does not alter the fundamental expectation that a debt collector will disclose the most complete and accurate name about which the debt collector has knowledge. In addition, the Bureau determines that the reference to ''another source'' is ambiguous and may create unjustified litigation risk and industry burden.

Second, the Bureau is revising the comment to clarify that a debt collector must reasonably determine ''the most complete and accurate version'' of a consumer's name. The Bureau intended that a debt collector would be required to disclose ''accurate'' consumer name information, but proposed comment 34(c)(2)–1 only referred to ''the most complete version'' of the consumer's name. Finally, the Bureau has elaborated on the example of a debt collector omitting a consumer's name information.

34(c)(2)(iii)[209]

FDCPA section 809(a)(2), which requires debt collectors to disclose to consumers the name of the creditor to whom the debt is owed, typically is understood to refer to the current creditor.[210] As the proposal stated, if the original creditor (or the creditor as of the itemization date) and the current creditor are the same, a consumer is more likely to recognize the creditor's name. If they are different, however, a consumer may be less likely to recognize the current creditor than the name of the creditor as of the itemization date. Proposed § 1006.34(c)(2)(iv) provided that, if a debt collector is collecting a consumer financial product or service debt (as that term was defined in proposed § 1006.2(f)), the name of the creditor to whom the debt was owed on the itemization date is required validation information.[211] For the reasons discussed below, the Bureau is finalizing proposed § 1006.34(c)(2)(iv) with minor wording changes and renumbered as § 1006.34(c)(2)(iii), and is adopting new comment 34(c)(2)(iii)–1 to clarify that a debt collector may disclose the trade name or DBA of the creditor to whom the debt was owed on the itemization date.

[207] *See* 15 U.S.C. 1692e(3).

[208] 84 FR 23274, 23339 (May 21, 2019).

[209] Proposed § 1006.34(c)(2)(iii) generally provided that the merchant brand, if any, associated with a credit card debt was required validation information. The Bureau is finalizing merchant brand information as an optional disclosure. *See* the section-by-section analysis of § 1006.34(d)(3)(vii). The Bureau therefore is finalizing proposed § 1006.34(c)(2)(iv) through (x) as § 1006.34(c)(2)(iii) through (ix).

[210] *See* 15 U.S.C. 1692g(a)(2). *See* the section-by-section analysis of § 1006.34(c)(2)(v).

[211] 84 FR 23274, 23404 (May 21, 2019).

An industry trade group commenter expressed support for requiring debt collectors to disclose the creditor to whom the debt was owed on the itemization date but asked the Bureau to clarify that a debt collector may disclose this creditor's trade name or DBA, as opposed to its legal name, which a consumer may not recognize.

A consumer advocate objected to the proposal because a consumer may not recognize the creditor to whom the debt was owed on the itemization date. According to the commenter, in some cases, the itemization date may have occurred years after the debt was incurred. And, particularly if the debt was transferred before the itemization date, the consumer may not recognize the creditor as of that date. As an alternative, the commenter suggested that a debt collector be required to disclose the name of the original creditor.

As discussed in the section-by-section analysis of § 1006.34(c)(2)(i), an entity's trade name or DBA may be more recognizable to consumers than an entity's legal name. It may be appropriate for a debt collector to disclose a creditor's trade name or DBA, in lieu of the creditor's legal name, when communicating with consumers. Thus, the Bureau is adopting new comment 34(c)(2)(iii)–1 to clarify that a debt collector may disclose as validation information the trade name or DBA of the creditor to whom the debt was owed on the itemization date.

The Bureau declines to require a debt collector to disclose the name of the original creditor as validation information under § 1006.34(c). FDCPA section 809(a)(5) and (b) require a debt collector to provide the name and address of the original creditor in response to a consumer request. While the Bureau acknowledges that, in some cases, a consumer may not recognize the creditor to whom the debt was owed on the itemization date, this information will still benefit some consumers. For an older debt or a debt that has been transferred, consumers may be more likely to recognize the creditor as of the itemization date than the current creditor.

Accordingly, the Bureau is finalizing § 1006.34(c)(2)(iii) to provide that, if the debt collector is collecting debt related to a consumer financial product or service as defined in § 1006.2(f), the name of the creditor to whom the debt was owed on the itemization date is required validation information. In addition, the Bureau is finalizing comment 34(c)(2)(iii)–1 to clarify that a debt collector may disclose the trade name or DBA of the creditor to whom the debt was owed on the itemization date.

34(c)(2)(iv)

The purpose of FDCPA section 809 is to ''eliminate the recurring problem of debt collectors dunning the wrong person or attempting to collect debts which the consumer has already paid.'' [212] Consistent with the FDCPA's purpose, FDCPA section 809(a) requires debt collectors to disclose to consumers certain information, such as the amount of the debt, to help consumers identify debts. According to the proposal, an account number associated with a debt on the itemization date may be integral information that a consumer uses to identify the debt.[213] The Bureau proposed § 1006.34(c)(2)(v) to provide that the account number, if any, associated with the debt on the itemization date, or a truncated version of that number, is required validation information. Proposed comment 34(c)(2)(v)–1 explained that a debt collector may truncate an account number provided that the account number remains recognizable. For the reasons discussed below, the Bureau is adopting proposed § 1006.34(c)(2)(v), renumbered as § 1006.34(c)(2)(iv), and its related commentary with minor wording changes.

Industry commenters, a consumer advocate, and a group of State Attorneys General, expressed overall support for proposed § 1006.34(c)(2)(v). However, one industry commenter recommended that the Bureau exempt debt collectors collecting residential mortgage debt from the requirement to disclose an account number. According to the commenter, the account number for a residential mortgage that has had a servicing transfer may not be the current account number, which might confuse consumers.

The Bureau concludes that an account number associated with a debt on the itemization date may help some consumers recognize the debt. The Bureau declines to adopt the recommendation to exempt debt collectors collecting residential mortgage debt from disclosing an account number. As discussed in the section-by-section analysis of § 1006.34(b)(3), the Bureau has determined that the reference dates that a debt collector may use to determine the itemization date may be meaningful to consumers because they correspond to a notable event in the debt's history that consumers may recall or be able to verify with records. By extension, the Bureau determines that an account number associated with a debt as of one of those dates will also likely resonate with a consumer, even if it is not the current account number.

Accordingly, the Bureau is finalizing § 1006.34(c)(2)(iv) and its related commentary largely as proposed, with only minor wording changes to the commentary for clarity. No substantive change is intended.

34(c)(2)(v)

FDCPA section 809(a)(2) requires debt collectors to disclose to consumers the name of the creditor to whom the debt is owed.[214] By using the present tense ''is owed,'' the statute appears to refer to the creditor to whom the debt is owed when the debt collector makes the disclosure.[215] The Bureau proposed § 1006.34(c)(2)(vi) to provide that the name of the current creditor is required validation information. For the reasons discussed below, the Bureau is finalizing the proposal, renumbered as § 1006.34(c)(2)(v), and is adopting new comment 34(c)(2)(v)–1 to clarify that a debt collector may disclose the trade name or DBA of the creditor to whom the debt is currently owed, instead of its legal name.

The Bureau received no comments specifically addressing proposed § 1006.34(c)(2)(vi) and is finalizing it as proposed but renumbered as § 1006.34(c)(2)(v). An industry trade group commenter recommended that the Bureau permit debt collectors to disclose, along with the required validation information, all current and past creditors associated with the debt. According to the commenter, some creditors, such as healthcare and financial services providers, may have multiple sub-entities with different corporate names. This commenter suggested that disclosing more names of creditors will increase the likelihood that a consumer will recognize one of them.

The Bureau declines to adopt this recommendation. Disclosing all current and past creditors along with the validation information could overwhelm and confuse consumers.[216] Thus, as discussed in the section-by-section analysis of § 1006.34(c), the Bureau is requiring debt collectors to

[212] S. Rep. No. 382, *supra* note 57, at 4.

[213] 84 FR 23274, 23340 (May 21, 2019).

[214] *See* 15 U.S.C. 1692g(a)(2).

[215] 84 FR 23274, 23341 (May 21, 2019).

[216] During one round of cognitive testing, participants were shown disclosure language that included a list of prior creditors. Confusion was observed when participants tried to explain the difference between prior and current creditors. The unclear relationship between creditors was highlighted when participants attempted to identify the creditor that currently owned the debt. *See* FMG Cognitive Report, *supra* note 27, at 3–4.

disclose as validation information only two creditors: The creditor to whom the debt was owed on the itemization date (§ 1006.34(c)(2)(iii)) and the creditor to whom the debt is currently owed (§ 1006.34(c)(2)(v)). Nothing in the final rule prohibits a debt collector from including the name of another creditor on a validation notice, but a debt collector who does so will not receive the § 1006.34(d)(2) safe harbor and will risk not complying with the requirements of § 1006.34, including the § 1006.34(b)(1) clear and conspicuous standard.

As discussed in the section-by-section analysis of § 1006.34(c)(2)(i) and (iii), the Bureau is finalizing new comments 34(c)(2)(i)–1 and 34(c)(2)(iii)–1 to clarify that a debt collector may disclose an entity's trade name or DBA, instead of its legal name. The Bureau concludes that it is also appropriate to permit a debt collector to disclose the trade name or DBA of a current creditor. Thus, the Bureau is adopting new comment 34(c)(2)(v)–1 to clarify that a debt collector may disclose the trade name or a DBA of the creditor to whom the debt is currently owed, instead of its legal name.

34(c)(2)(vi)

FDCPA section 809(a)(1) requires debt collectors to disclose to consumers the amount of the debt.[217] In § 1006.34(c)(2)(viii), the Bureau proposed to interpret FDCPA section 809(a)(1), and to use its authority under Dodd-Frank Act section 1032(a), to provide that the amount of the debt on the itemization date is required validation information.[218] Consistent with proposed § 1006.34(c)(2)(viii), the Bureau proposed § 1006.34(c)(2)(vii) to provide that the itemization date, as defined in § 1006.34(b)(3), also is required validation information. For the reasons discussed below, the Bureau is finalizing § 1006.34(c)(2)(vii) as proposed but renumbered as § 1006.34(c)(2)(vi).

Several commenters, including an industry commenter, an industry trade group commenter, and a group of consumer advocates, stated that the itemization date may not be meaningful to consumers or help them recognize debts, if disclosed without an explanation of its relevance. These commenters, along with Federal government agency staff, recommended requiring debt collectors to disclose with the itemization date a statement explaining which reference date the debt collector used to determine that date.[219]

The Bureau declines to adopt this recommendation. As discussed in the section-by-section analysis of § 1006.34(b)(3), the Bureau determines that the reference dates that a debt collector may use to determine the itemization date have a significant likelihood of being meaningful to consumers because they correspond to notable events in a debt's history that consumers may recall or be able to verify with records. Because each of the reference dates may be meaningful to consumers, the Bureau determines that no additional disclosure explaining their relevance is necessary. Moreover, the Bureau determines that an additional disclosure explaining the reference date may confuse or overwhelm some consumers. While a debt collector likely could describe some reference dates (*e.g.,* a last statement date) in a straightforward manner, other reference dates (*e.g.,* the charge-off date and the transaction date) do not lend themselves to a succinct explanation. That is because some reference dates reflect financial concepts that are inherently complex (*i.e.,* charge off) or that could vary by debt type and the facts and circumstances surrounding a particular debt (*i.e.,* transaction dates). For such reference dates, a statement explaining their relevance could distract or confuse consumers, thereby undermining the efficacy of the other validation information.

34(c)(2)(vii)

As noted, FDCPA section 809(a)(1) requires debt collectors to disclose to consumers the amount of the debt. As discussed in the proposal, the phrase ''the amount of the debt'' is ambiguous; it does not specify which debt amount is being referred to, even though the debt amount may change over time. As also discussed in the proposal, consumers may recognize the amount of the debt as of the itemization date (as the Bureau proposed to define that term in § 1006.34(b)(3)). Because the amount of the debt on the itemization date may help a consumer recognize a debt and determine whether the amount of a debt is accurate, the Bureau proposed to interpret FDCPA section 809(a)(1), and to use its authority under Dodd-Frank Act section 1032(a), to provide in proposed § 1006.34(c)(2)(viii) that the amount of the debt on the itemization date is required validation information.[220] Proposed comment 34(c)(2)(viii)–1 explained that this amount includes any fees, interest, or other charges owed as of the itemization date.

An industry commenter questioned whether proposed § 1006.34(c)(2)(viii) would significantly improve consumer understanding. According to the commenter, if a debt collector determines the itemization date based on the last statement date pursuant to § 1006.34(b)(3)(i), and if the debt is placed for collection shortly after the last statement was provided, the current amount of the debt (which the Bureau proposed as a separate item of required validation information) and the amount of the debt on the itemization date would be approximately the same. The commenter stated that, in this scenario, disclosing the amount of the debt on the itemization date would not benefit the consumer.

The Bureau acknowledges that, for a given debt, the amount owed on the itemization date and the current amount of the debt may be similar or even the same. However, as discussed below in the section-by-section analysis of final § 1006.34(c)(2)(viii), even in these cases, the itemization of the debt will still be required, and, as clarified in final comment 34(c)(2)(viii)–1, the itemization (if the amounts are the same) will show $0 in interest, fees, payments, and credits. As such, it should be clear to the consumer why the two amounts are the same. In many other cases, these amounts will differ, sometimes substantially. In these cases, the amount of the debt on the itemization date will help consumers recognize or evaluate the debt.

For these reasons, the Bureau is finalizing § 1006.34(c)(2)(viii) and its related commentary as proposed but renumbered as § 1006.34(c)(2)(vii).

34(c)(2)(viii)

As noted, FDCPA section 809(a)(1) requires a debt collector to disclose to consumers the amount of the debt. As discussed, the Bureau proposed to implement and interpret FDCPA section 809(a)(1) to provide that debt collectors must disclose to consumers both the amount of the debt on the itemization date and the current amount of the debt (*i.e.,* the amount of the debt on the date that the validation information is

[217] *See* 15 U.S.C. 1692g(a)(1).

[218] 84 FR 23274, 23341 (May 21, 2019).

[219] As discussed in the section-by-section analysis of § 1006.34(b)(3), the Bureau defines itemization date to mean one of five reference dates for which a debt collector can ascertain the amount of the debt.

[220] 84 FR 23274, 23341 (May 21, 2019). As proposed, the Bureau is finalizing § 1006.34(c)(2)(ix) (renumbered from proposed § 1006.34(c)(2)(x)) separately to provide that the current amount of the debt also is required validation information.

provided).[221] In conjunction with the amount of the debt on the itemization date and the current amount of the debt, the Bureau proposed § 1006.34(c)(2)(ix) to provide that an itemization of the current amount of the debt, in a tabular format reflecting interest, fees, payments, and credits since the itemization date, is required validation information. Proposed comment 34(c)(2)(ix)–1 clarified how debt collectors could disclose that no interest, fees, payments, or credits were assessed or applied to a debt.

For the reasons discussed below, the Bureau is finalizing the proposal, renumbered as § 1006.34(c)(2)(viii), with revisions to permit debt collectors to disclose the itemization on a separate page provided in the same communication with a validation notice, if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page. The Bureau also is finalizing comment 34(c)(2)(ix)–1 with a substantive modification and renumbered as comment 34(c)(2)(viii)–1, and is adopting new comments 34(c)(2)(viii)–2 through–4 to clarify other aspects of final § 1006.34(c)(2)(viii).

Commenters offered differing opinions regarding proposed § 1006.34(c)(2)(ix). A group of State Attorneys General, Federal government agency staff, consumer advocate commenters, some industry trade group commenters, and at least one industry commenter supported the proposed provision. These commenters generally agreed that an itemization of the debt would help consumers recognize an alleged debt and understand how the debt had evolved over time due to interest, fees, payments, and credits. Further, the Bureau received feedback that the proposal was consistent with some industry practice. For instance, a commenter noted an industry certification standard that, during the sales of certain debt types, requires debt buyers to obtain or provide the unpaid balance due on the account, with a breakdown of the post-charge-off balance, interest, fees, payments, and credits or adjustments.[222]

The majority of industry and industry trade group commenters objected to proposed § 1006.34(c)(2)(ix). Some such commenters stated that the proposed itemization requirement would be burdensome. According to several industry commenters, debt collectors would either have to manually access itemization information in creditor files or implement costly information technology solutions to comply with the proposed requirement. Some industry commenters, industry trade groups, and the SBA argued that the proposed requirement would impose burdens on creditors. Commenters stated that some creditors may not maintain all of the itemization information that the proposal would require or do not typically provide itemization information at placement and that to do so would involve significant expense. Some commenters speculated that, to avoid such costs, creditors might refer fewer accounts for collection or file more collections lawsuits against consumers. The SBA, an industry trade group, and industry commenters argued that compliance costs could be onerous for smaller creditors and debt collectors. For the most part, commenters offered qualitative assessments of industry burden, but one industry trade group did estimate that proposed § 1006.34(c)(2)(ix) would impose billions of dollars in compliance costs on industry.[223]

Some commenters stated that proposed § 1006.34(c)(2)(ix) is unnecessary or unhelpful. Multiple industry commenters asserted that an itemization is superfluous because consumers can exercise their FDCPA section 809 verification rights to receive more account information if desired. With respect to medical debt, an industry trade group stated that proposed § 1006.34(c)(2)(ix) is unnecessary because the Internal Revenue Service (IRS) requires non-profit hospitals to send letters with itemized information to consumers, and health insurance companies routinely mail to responsible parties ''Explanation of Benefits'' documents that provide details about coverage, payments, and co-pays. Some commenters expressed concern that proposed § 1006.34(c)(2)(ix) could increase legal risk for debt collectors if the itemization information confused consumers. At least one industry commenter stated that the Bureau's consumer testing did not support proposed § 1006.34(c)(2)(ix) because the testing did not involve actual consumers assessing debts in a real-world setting.

A few industry commenters objected to proposed § 1006.34(c)(2)(ix) because the FDCPA does not expressly require an itemization of the current amount of the debt.

Some industry and industry trade group commenters objected to proposed § 1006.34(c)(2)(ix) because the itemization that appears on the model validation notice is formatted for a single debt. According to commenters, the proposal would not accommodate debt collectors who combine multiple debts in a single validation notice. Several commenters stated that not permitting debt collectors to include multiple debts in one validation notice would dramatically increase the volume of mail sent to consumers and would require consumers to exercise their verification rights for each individual debt in the event that a consumer has a global dispute. Industry and industry trade group commenters stated that the inability to combine multiple debts would be particularly challenging for medical debt collectors. According to some commenters, healthcare providers routinely combine multiple debts, in part because they utilize family billing, which involves combining the separate bills for family members of a primary insured party. Commenters stated that itemizations for medical debt may be further complicated by the fact that healthcare providers typically do not maintain a rolling total of charges for a general service and instead individually bill for each good or service provided. At least one trade group stated that student loan debt presents comparable itemization-related challenges because student loan debt may be provided through multiple disbursements with separate account numbers.

An industry trade group suggested that proposed § 1006.34(c)(2)(ix) would not accommodate debts in bankruptcy. According to the commenter, the proposal did not have the specificity necessary to account for how the Bankruptcy Code permits a debtor to cure pre-bankruptcy defaults over the term of the bankruptcy plan while maintaining regular post-bankruptcy payments. In addition, the commenter argued, the proposal would not accommodate the nuances that arise in the context of certain bankruptcy scenarios, such as a cramdown plan or a lien strip.[224]

[221] 84 FR 23274, 23341 (May 21, 2019).

[222] *See* Receivables Mgmt. Ass'n Int'l, *Receivables Management Certification Program,* at 41–45 (Mar. 1, 2020), *https://rmaintl.org/RMCP* (last visited Dec. 9, 2020).

[223] One industry trade group estimated that an itemization requirement would cost $600 million in professional fees to conduct legal analyses of HIPAA compliance for medical debt, $30 million for one-time system reprogramming for debt collectors, and $3 billion for one-time system reprogramming for creditors. The proposal allegedly would also result in billions of dollars in ongoing support costs and uncompensated medical care because, according to the commenter, the proposed requirement, if adopted, would increase the risks that hospitals might be unable to use debt collectors.

[224] Pursuant to 11 U.S.C. 1322(b)(5), a bankruptcy court may change the underlying terms of a debt, which is referred to as a ''cramdown.'' Pursuant to

With regard to medical debt, industry commenters, an industry trade group, and the SBA stated that healthcare providers might violate the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[225] Privacy Rule if they provided the proposed itemization.[226] According to these commenters, proposed § 1006.34(c)(2)(ix) would require debt collectors to disclose more information than the minimum necessary for treatment of the patient, payment of the bill, or healthcare operations, in violation of HIPAA.

Commenters recommended various modifications to proposed § 1006.34(c)(2)(ix). Industry and industry trade group commenters suggested that debt collectors should not need to comply with proposed § 1006.34(c)(2)(ix) if interest and fees are not charged on an account.[227] An industry commenter stated that debt collectors should be permitted to indicate ''U'' for ''unknown'' or ''unavailable'' in fields for which a creditor did not provide the relevant information.

Several commenters asked the Bureau to clarify the proposal. An industry commenter asked how a debt collector could disclose third-party payments or insurance adjustments, particularly in the context of medical debt. An industry trade group sought additional guidance about how to disclose balance increases that are not caused by interest or fees, such as a balance increase caused by a returned payment. Noting the existence of validation notice itemization requirements imposed by other applicable law, such as New York State regulations, two industry trade groups requested guidance about how a debt collector should simultaneously comply with those requirements and proposed § 1006.34(c)(2)(ix).[228]

With respect to the Bureau's request for comment about whether the proposed itemization should be more detailed—for example, by reflecting each fee charged and each payment received—or whether certain itemization categories should be combined as proposed, industry commenters suggested that the Bureau not deviate from the proposal. For instance, a commenter stated that, in the context of medical debts, listing all payments and credits individually could result in multiple additional pages because of the number of third-party payments. In contrast, citing the Bureau's consumer testing, an academic commenter argued that the itemization should be more detailed because consumers prefer to see penalties and fees broken down into individual charges.[229]

After considering these comments, and for the reasons discussed below, the Bureau is adopting the proposed requirement, renumbered as § 1006.34(c)(2)(viii), with revisions to provide that validation information includes an itemization of the current amount of the debt reflecting interest, fees, payments, and credits since the itemization date. Final § 1006.34(c)(2)(viii) further provides that a debt collector may disclose the itemization on a separate page provided in the same communication with a validation notice, if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page.

The Bureau determines that an itemization of the debt will help a significant number of consumers recognize whether they owe a debt and evaluate whether the debt is accurate, because the itemization will disclose how the amount may have changed over time due, for example, to interest, fees, payments, and credits that have been assessed or applied to the debt.

The Bureau determines that § 1006.34(c)(2)(viii) will not create undue industry burden in light of modifications made in response to comments.[230] The Bureau acknowledges that complying with the itemization requirement may result in some additional costs to debt collectors, particularly if they do not currently provide itemization information at placement or on validation notices, as well as in some indirect costs to creditors. However, the Bureau concludes that these costs will not substantially impact companies' business operations because the final rule provides sufficient flexibility to debt collectors to tailor the itemization to specific business practices and types of debt. Accordingly, the Bureau does not conclude, as some commenters suggested, that the itemization requirement will result in creditors referring significantly fewer accounts for collections or filing more lawsuits against consumers.[231]

Although several commenters stated that the required itemization information may not be available for every debt, the Bureau notes that the itemization of the debt is based on the type of routine account information that debt collectors typically provide in response to consumer verification requests and that, as such, debt collectors should be able to obtain such information to comply with the final rule. While some debt collectors do not currently provide this itemized information at the outset of collection communications, providing such itemization information to consumers already is considered a best practice in some segments of the debt buying industry, including for credit card debt and student loan debt.[232] Further, debt collectors are already required to disclose an itemization for some types of debt in at least one jurisdiction, New York State.[233]

In addition, as discussed in the section-by-section analysis of § 1006.34(b)(3), the final rule's itemization date definition permits debt collectors to select an itemization date that is feasible for the type of debt in collection and the information debt collectors receive. And § 1006.34(c)(2)(viii) requires itemization of fees, interest, and credits only subsequent to the selected itemization date. Thus, for example, if a debt collector selects the last statement date as the itemization date under § 1006.34(b)(3), and if the creditor has

11 U.S.C. 1322(c)(2), a secured claim can be converted to an unsecured claim, which is referred to as a ''lien strip.''

[225] Public Law 104–191, 110 Stat. 1936 (1996).

[226] 45 CFR part 160 and part 164 subparts A and E.

[227] In addition, an industry trade group suggested that debt collectors should not be required to comply with the itemization requirement for pre-charge-off debts, particularly if periodic statements continue to be provided. The Bureau notes that, in many cases, a person collecting a debt that was not in default at the time it was obtained by such person will not be a debt collector subject to the FDCPA or Regulation F. *See* FDCPA section 803(6)(F)(iii), 15 U.S.C. 1692a(6)(F)(iii).

[228] *See* 23 NYCRR 1.2(b)(2).

[229] FMG Summary Report, *supra* note 29.

[230] For example, as noted in the section-by-section analysis of § 1006.34(b)(3)(i), a creditor or a third-party servicer acting on the creditor's behalf may issue a statement even after the debt has gone into collection. In that case, under § 1006.34(b)(3)(i), that new statement may serve as the last statement for purposes of the itemization date.

[231] An industry trade group cited an article to suggest that collection lawsuits nearly doubled in New York City since 2015 because of New York State's debt collection rules, which mandate an itemization. *See* Yuka Hayashi, *Debt Collectors Wage a Comeback,* Wall Street Journal (July 5, 2019). The Bureau notes that the article did not cite a connection between higher rates of lawsuits and the itemization requirement. Instead, the article discussed the phenomenon of increasing lawsuits nationwide, including in States like Texas, which had not recently introduced a significant debt collection rule.

[232] *See* Receivables Mgmt. Ass'n Int'l, *Receivables Management Certification Program,* at 41–45 (Mar. 1, 2020), *https://rmaintl.org/RMCP* (last visited Dec. 9, 2020).

[233] *See* 23 NYCRR 1.2(b) (requiring debt collectors to provide an itemized accounting of the debt within five days after the initial communication with a consumer in connection with the collection of certain types of charged-off debt, such as credit card debt).

recently issued a statement to the consumer, the debt collector need only obtain and provide to the consumer an itemization with fees, interest, and credits subsequent to that last statement date. And, as discussed in the section-by-section analysis of § 1006.34(d)(2), a debt collector may provide the itemization on a separate page and retain the safe harbor for the rest of the validation notice. For all of these reasons, the Bureau concludes that the final rule will not impose undue burdens on debt collectors and will provide consumers with useful information. The Bureau will monitor whether the itemization date definition, including the last statement date definition, meets these goals.

The Bureau disagrees that § 1006.34(c)(2)(viii) is unnecessary or unhelpful. The verification rights afforded by FDCPA section 809 are an important statutory protection; however, they do not serve the same purpose or provide an adequate substitute to the itemization of the debt that § 1006.34(c)(2)(viii) will require. The Bureau disagrees that an itemization of the current amount of the debt is unnecessary for medical debt, as some commenters argued. Although some non-profit hospitals or insurance companies may provide itemization information to some consumers, commenters did not suggest, and the Bureau is not aware of other evidence indicating, that all consumers with medical debt receive itemization information such that § 1006.34(c)(2)(viii) would be unnecessary. The Bureau also disagrees with comments that an itemization will confuse consumers. As the proposal noted, the Bureau's qualitative consumer testing indicates that an itemization improves consumer understanding about the debt.[234]

The Bureau also disagrees that the FDCPA's not expressly requiring an itemization is a sufficient reason for the Bureau not to require it by rule. The Bureau proposed and is finalizing the itemization requirement pursuant to its authority to interpret FDCPA section 809(a), as well as pursuant to its authority under Dodd-Frank Act section 1032(a) to prescribe rules to ensure that the features of debt collection are fully, accurately, and effectively disclosed to consumers.

The Bureau is revising § 1006.34(c)(2)(viii) to permit debt collectors to disclose the itemization on a separate page.[235] The itemization that appears on the model validation notice may not accommodate all debt types in every instance. Some debt collectors may have legitimate reasons to combine multiple debts on a single validation notice. This may be the case with respect to medical debt (for instance, owing to healthcare provider billing practices) and student loan debt (because consumers may receive loans through multiple disbursements with separate account numbers). As finalized, § 1006.34(c)(2)(viii) states that a debt collector may disclose the itemization on a separate page provided in the same communication with a validation notice, if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page.[236] New comment 34(c)(2)(viii)–3 clarifies that a debt collector may comply with the requirement to refer to the separate page by, for example, including on the validation notice the statement, ''See the enclosed separate page for an itemization of the debt,'' situated next to the information about the current amount of the debt required by § 1006.34(c)(2)(ix).[237]

The Bureau is making an additional change to § 1006.34(c)(2)(viii). As finalized, § 1006.34(c)(2)(viii) omits the proposed language that an itemization must be ''in a tabular format.'' The Bureau determined that it is unnecessary and unwarranted to mandate the use of a tabular format because, if the itemization information is provided on a separate page or orally, using a tabular format may be impractical or infeasible and, if the itemization information is provided on a validation notice, debt collectors likely will use the tabular format shown on the model notice such that they may receive a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1).

To accommodate debt collectors who wish to combine multiple debts on a single validation notice, the Bureau is adopting new comment 34(c)(2)(viii)–4 to clarify that a debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(viii) by disclosing either a single, cumulative itemization on the validation notice or a separate itemization of each debt on a separate page or pages provided in the same communication as the validation notice.[238]

The Bureau concludes that the itemization requirement will not cause healthcare providers or debt collectors to violate the HIPAA Privacy Rule. HHS staff has advised the Bureau that the HIPAA Privacy Rule generally permits covered entities to disclose protected health information required by applicable law.[239] Because disclosure of itemization information will be necessary to comply with § 1006.34(c)(2)(viii), this guidance indicates that the HIPAA Privacy Rule will permit its disclosure.

The Bureau declines to modify § 1006.34(c)(2)(viii) as commenters otherwise recommended. An itemization, even if no interest and fees have been assessed or charged on an account, remains relevant information about the debt. Further, complying with § 1006.34(c)(2)(viii) if no interest and fees have been assessed or charged is relatively straightforward, and comment 34(c)(2)(viii)–1 clarifies how debt collectors may do so.

However, the Bureau is finalizing proposed comment 34(c)(2)(viii)–1 with a modification to delete language stating that debt collectors may indicate ''N/A'' in a required field when no interest, fees, payments, or creditors have been

[234] *See* 84 FR 23274, 23341 (May 21, 2019); FMG Usability Report, *supra* note 28, at 16–19.

[235] Under § 1006.34(d)(2)(ii), a debt collector who otherwise uses the model validation notice or a substantially similar form, but who provides the itemization of the current amount of the debt on separate page, receives a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1) except with respect to the itemization that appears on the separate page.

[236] For example, when delivering a validation notice by mail, a debt collector may include the separate itemization in the same envelope as the validation notice. Similarly, when delivering a validation notice electronically, a debt collector may include the separate itemization in the same email as the validation notice.

[237] Section 1006.34(d)(2)(iii) establishes that a debt collector who uses the model validation notice and who provides an itemization on a separate page receives a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1), except with respect to the disclosures that appear on the separate page.

[238] Relatedly, as discussed in the section-by-section analysis of § 1006.34(c)(2)(ix), the Bureau is adopting new comment 34(c)(2)(ix)–2 to clarify that a debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(ix)'s requirement to disclose the ''current amount of the debt'' by disclosing on the validation notice a single, cumulative figure that is the sum of the current amount of all the debts.

[239] *See* 45 CFR 164.512(a)(1) (''A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.''); *see also* U.S. Dep't of Health & Human Servs., *Does the HIPAA Privacy Rule prevent health plans and providers from using debt collection agencies? Does the Privacy Rule conflict with the Fair Debt Collection Practices Act?, https://www.hhs.gov/hipaa/for-professionals/faq/268/does-the-hipaa-privacy-rule-prevent-health-care-providers-from-using-debt-collection-agencies/index.html* (last visited Dec. 1, 2020) (noting that the HIPAA Privacy Rule permits healthcare providers to provide the minimum necessary patient information to debt collectors for the purpose of receiving payment).

assessed or applied to the account because different consumers may interpret ''N/A'' differently. For example, some consumers might understand it as indicating ''not available,'' and others might construe it as meaning ''not applicable.'' To eliminate this potential ambiguity, the Bureau is revising comment 34(c)(2)(viii)–1 to provide that a debt collector may indicate that the value of a required field is ''0,'' ''none,'' or may state that no interest, fees, payments, or credits have been assessed or applied to the debt. The Bureau also is revising the comment to clarify, as was intended in the proposal, that a debt collector may not leave a required field blank.

The Bureau declines the recommendation that debt collectors be permitted to indicate ''U'' for ''unknown'' or ''unavailable'' in the itemization if a creditor did not provide the relevant information. Allowing debt collectors to omit specific itemization information in this manner could incentivize debt collectors to avoid receiving it, thereby undermining the effectiveness of § 1006.34(c)(2)(viii).

Debt collectors sought clarification as to how they should comply with § 1006.34(c)(2)(viii) in various scenarios. Depending on the facts and circumstances, a third-party payment or insurance adjustment may be disclosed as a ''payment'' or a ''credit'' in the itemization. Also depending on the facts and circumstances, a payment that is returned may be omitted from the itemization provided that the payment and the return offset each other, and provided that the amount of the debt owed on the itemization date pursuant to § 1006.34(c)(2)(vii) and the current amount of the debt pursuant to § 1006.34(c)(2)(ix) are accurately disclosed.

Regarding § 1006.34(c)(2)(viii)'s interaction with itemization requirements in other applicable law, the Bureau is finalizing new comment 34(c)(2)(viii)–2, which states that, if a debt collector is required by other applicable law to provide an itemization of the current amount of the debt with the validation information, the debt collector may comply with § 1006.34(c)(2)(viii) by disclosing the itemization required by other applicable law in lieu of the itemization described in § 1006.34(c)(2)(viii), if the itemization required by other applicable law is substantially similar to the itemization that appears on the model validation notice. The Bureau is aware of only one jurisdiction that requires debt collectors to provide an itemization with the validation information, and that itemization is substantially similar to the itemization required by § 1006.34(c)(2)(viii).[240] Further, consumers likely would not benefit—and, in fact, may be disadvantaged—by receiving multiple itemizations with the validation information. For instance, although a debt collector could include both the itemization required by § 1006.34(c)(2)(viii) on the front of a validation notice, and, on the reverse, an itemization specifically required by other applicable law (as an optional disclosure pursuant to § 1006.34(d)(3)(iv)), a consumer would be unlikely to benefit from receiving two itemizations. In addition, permitting debt collectors to simultaneously satisfy the Bureau's itemization requirement and a substantially similar requirement under other applicable law with one itemization avoids burdening debt collectors with the costs of creating redundant disclosures.

The Bureau determines that the itemization of the current amount of the debt should not be more detailed (*e.g.,* it should not include a detailed list of all payments). The itemization that appears on the model validation notice has been validated through four rounds of consumer testing and is effective, and the Bureau agrees with commenters who observed that a detailed disclosure of, for example, all payments could be overwhelming and not logistically feasible.

For all of these reasons, the Bureau is finalizing proposed § 1006.34(c)(2)(ix), renumbered as § 1006.34(c)(2)(viii), to provide that required validation information includes an itemization of the current amount of the debt reflecting interest, fees, payments, and credits since the itemization date. Final § 1006.34(c)(2)(viii) also provides that a debt collector may disclose the itemization on a separate page provided in the same communication with a validation notice if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page. The Bureau is finalizing comment 34(c)(2)(ix)–1 with revisions and renumbered as comment 34(c)(2)(viii)–1 and is adding comments 34(c)(2)(viii)–2 through –4 to clarify various aspects of final § 1006.34(c)(2)(viii), as discussed above. The Bureau is finalizing § 1006.34(c)(2)(viii) and its related commentary pursuant to its authority to interpret FDCPA section 809(a), as well as its authority under Dodd-Frank Act section 1032(a).

[240] *See* 23 NYCRR 1.2(b)(2).

34(c)(2)(ix)

FDCPA section 809(a)(1) requires debt collectors to disclose to consumers the amount of the debt. Proposed § 1006.34(c)(2)(x) provided that the current amount of the debt is required validation information.[241] Proposed comment 34(c)(2)(x)–1 explained that, for residential mortgage debt subject to Regulation Z, 12 CFR 1026.41, a debt collector could comply with § 1006.34(c)(2)(x) by including in the validation notice the total balance of the outstanding mortgage, including principal, interest, fees, and other charges.

Some commenters raised concerns about how proposed § 1006.34(c)(2)(x) would disclose the current amount of the debt. Industry and industry trade group commenters stated that, if interest and fees are increasing, the current amount of the debt that appears on a validation notice may no longer be accurate by the time the consumer receives the notice. Some commenters stated that some State laws and court decisions require debt collectors to disclose if the current amount of the debt may change due to interest and fees.[242] To address these concerns, industry and industry trade group commenters suggested that the Bureau should either develop a stand-alone increasing-interest-and-fee disclosure or structure § 1006.34(c)(2)(x) to permit debt collectors to disclose that the itemized current amount of the debt may increase or decrease.[243]

An industry trade group stated that disclosing the current amount of the debt as proposed would present challenges for some reverse mortgage debt because that amount might differ from the amount disclosed in monthly statements.[244] The commenter

[241] 84 FR 23274, 23342, 23415 (May 21, 2019).

[242] *See Avila* v. *Riexinger & Assocs., LLC,* 817 F.3d 72, 76 (2d Cir. 2016) (holding that 15 U.S.C. 1692e requires debt collectors to disclose if the amount of a debt may increase due to interest and fees).

[243] A trade group commenter recommended the following dynamic balance disclosure: ''As of the date of this letter, the balance due on the account is <current>. Because interest, fees, and/or other charges may change the total owed from day to day, the amount due on the day you pay may be greater. If you pay the amount shown above, an adjustment may be necessary after we receive your payment, in which event you may be informed of any other amount due.''

[244] The Bureau understands that, for some reverse mortgages, including Home Equity Conversion Mortgages insured by the FHA, when the reverse mortgage is due and payable, the amount due from the borrower may not be the amount of outstanding debt because these reverse mortgages are non-recourse loans and a borrower will never owe more than a portion of the appraised value of the home. *See* 24 CFR 206.125.

recommended that, to avoid potential confusion in the context of reverse mortgage debt, a debt collector should be permitted to provide the last monthly account statement in lieu of disclosing the current amount of the debt.

A group of consumer advocates recommended that, for residential mortgage debt, the Bureau should require debt collectors to disclose the current amount of the total unpaid balance owed as well as the arrearage owed. According to this commenter, the arrearage owed is important information because, in many jurisdictions, homeowners in default can pay the arrearage to stop a foreclosure and reinstate a mortgage.

After considering these comments, the Bureau is finalizing § 1006.34(c)(2)(x) as proposed but renumbered as § 1006.34(c)(2)(ix). In addition, the Bureau is finalizing comment 34(c)(2)(x)–1 as proposed and is adopting new comment 34(c)(2)(ix)–2 to clarify how a debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(ix).

With respect to interest and fee accrual when disclosing the current amount of the debt, the Bureau declines to incorporate an increasing-interest-or-fee disclosure or to structure the current amount of the debt as a dynamic balance in § 1006.34(c)(2)(ix). The Bureau notes, however, that comment 34(c)(2)(ix)–1 (proposed as comment 34(c)(2)(x)–1) clarifies that the current amount of the debt is the amount of the debt as of the date that the validation information is provided. Therefore, a debt collector satisfies the requirement in § 1006.34(c)(2)(ix) without providing a dynamic balance or increasing-interest-or-fee disclosure. Additionally, as discussed in the section-by-section analysis of § 1006.34(d)(3)(iv), the final rule affirmatively permits debt collectors to include along with the required validation information other disclosures specifically required by applicable law. As such, debt collectors may include a disclosure pursuant to a judicial decision or order that the current amount of the debt may increase or vary due to interest, fees, or other charges. This modification addresses the challenges debt collectors face related to interest and fee accrual in disclosing the current amount of the debt.

The Bureau declines to permit debt collectors collecting reverse mortgage debt to include a last monthly account statement in place of disclosing the current amount of the debt. Unlike the special rule for certain residential mortgage debt discussed in the section-by-section analysis of § 1006.34(c)(5), reverse mortgages are not generally subject to a separate disclosure requirement, such as 12 CFR 1026.41(b)'s periodic statement requirement, that is functionally equivalent to, or as useful to consumers as, certain disclosures required by § 1006.34(c)(2). Reverse mortgages generally are exempt from providing periodic statements under the Truth in Lending Act (TILA) [245] and its implementing Regulation Z.[246] While reverse mortgages may be subject to a monthly statement requirement that would require entities to disclose the ''total outstanding loan balance,'' this regulatory requirement is not as prescriptive as the Bureau's periodic statement requirement for other residential mortgage debt.[247] Thus, the Bureau determines that a last monthly statement for a reverse mortgage debt is not an adequate substitute for § 1006.34(c)(2)(ix).

The Bureau declines to require debt collectors to separately disclose an arrearage owed for residential mortgage debt. Because the Bureau did not propose this disclosure, it lacks the benefit of public comment and concludes that additional information, including through public comment, would be advisable before adopting any such interpretation. However, the Bureau notes that a debt collector who utilizes the special rule for certain residential mortgage debt described in § 1006.34(c)(5) to comply with § 1006.34(c)(2)(vi) through (viii) will provide a periodic statement that may disclose such information.[248] Although a mortgage servicer is not required to use the special rule for certain residential mortgage debt, a mortgage servicer who does so and who otherwise uses the model validation notice or a substantially similar form receives a safe harbor for compliance pursuant to § 1006.34(d)(2)(ii). The Bureau therefore expects that, in many circumstances, a debt collector who is also a mortgage servicer that is required to provide periodic statements under Regulation Z, 12 CFR 1026.41 will disclose arrearage information.

As noted in the section-by-section analysis of § 1006.34(c)(2)(viii), industry commenters requested further guidance about how to combine multiple debts on a single validation notice. The Bureau is adopting new comment 34(c)(2)(ix)–2 to clarify that a debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(ix) by disclosing on the validation notice a single, cumulative figure that is the sum of the current amount of all the debts.

Proposed Provision Not Finalized

As discussed in the section-by-section analysis of § 1006.26(c), in the February 2020 proposal, the Bureau proposed to require debt collectors collecting time-barred debt to include time-barred debt and revival disclosures on the validation notice.[249] Proposed § 1006.34(c)(2)(xi) provided that validation information included those disclosures, as applicable, if the debt collector determined after a reasonable investigation that such disclosures were required by § 1006.26(c).[250] For the reasons discussed in the section-by-section analysis of § 1006.26(c), the Bureau is not finalizing the proposed time-barred debt disclosure requirements and, accordingly, the Bureau is not finalizing proposed § 1006.34(c)(2)(xi). However, as discussed in the section-by-section analysis of § 1006.34(d)(3)(iv)(B), any disclosures relating to time-barred debt that are specifically required by applicable law or that provide safe harbors under applicable law are optional disclosures that the final rule affirmatively permits debt collectors to include on the validation notice.

34(c)(3) Information About Consumer Protections

The disclosures in FDCPA section 809(a) help consumers to determine if a particular debt is theirs and to facilitate action in response to the receipt of validation information. However, as the proposal stated, debt collectors typically disclose only the information that FDCPA section 809(a) specifically references and provide the FDCPA section 809 information using statutory

[245] 15 U.S.C. 1601 *et seq.*

[246] *See* 12 CFR 1026.41(e)(1).

[247] The regulation provides: ''The mortgagee shall provide to the borrower a monthly statement regarding the activity of the mortgage for each month, as well as for the calendar year. The statement shall summarize the total principal amount which has been paid to the borrower under the mortgage during that calendar year, the MIP paid to the Commissioner and charged to the borrower, the total amount of deferred interest added to the outstanding loan balance, the total outstanding loan balance, and the current principal limit. The mortgagee shall include an accounting of all payments for property charges. The statement shall be provided to the borrower monthly until the mortgage is paid in full by the borrower. The mortgagee shall provide the borrower with a new payment plan every time it recalculates monthly payments or the payment option is changed. The statements shall be in a format acceptable to the Commissioner.'' *See* 24 CFR 206.203(a).

[248] 12 CFR 1026.41(d)(8)(vi) requires a periodic statement to include, if the consumer is more than 45 days delinquent, the total payment amount needed to bring the account current.

[249] *See* 85 FR 12672 (Mar. 3, 2020).

[250] *Id.* at 12685, 12696.

language, rather than plain language that consumers can more easily comprehend.[251] To address these concerns, proposed § 1006.34(c)(3) provided that certain information about a consumer's rights with respect to debt collection is required validation information. This information, which is discussed in the section-by-section analysis of § 1006.34(c)(3)(i) through (vi) below, included disclosures specifically referenced in FDCPA section 809(a)(4) and (5), as well as additional disclosures intended to help consumers understand their debt collection rights.[252]

Commenters generally supported requiring debt collectors to disclose information about a consumer's rights with respect to debt collection. Federal government agency staff and a consumer advocate commenter stated that proposed § 1006.34(c)(3) would improve consumers' understanding of their rights in debt collection. Some industry and industry trade group commenters supported using plain language disclosures to explain consumer protections in debt collection.

Some commenters recommended that the Bureau require additional disclosures about consumers' rights with respect to debt collection. Federal government agency staff, a group of 28 State Attorneys General, and a number of consumer advocate commenters recommended that debt collectors be required to disclose the FDCPA section 805(c) cease communication right.[253] A State regulatory agency recommended that the Bureau require debt collectors to disclose that a consumer's failure to act or to dispute a debt may have credit reporting implications. This commenter also recommended that § 1006.34(c)(3) require debt collectors to disclose how consumers may obtain an annual credit report, which consumers are entitled to under the FCRA and its implementing Regulation V.[254]

The Bureau determines, as discussed in the proposal, that consumers will benefit from receiving additional information about their rights in debt collection and from plain language disclosures rather than disclosures that parrot the FDCPA's statutory text.[255] The Bureau therefore is adopting § 1006.34(c)(3). Specifically, as discussed further in the section-by-section analysis below, the Bureau is adopting § 1006.34(c)(3)(i) through (v) and its related commentary with minor modifications, but is not finalizing proposed § 1006.34(c)(3)(vi), which addressed the opt-out notice required by § 1006.6(e) for electronic communications or attempts to communicate.

The Bureau declines to require additional disclosures about consumer protections in debt collection, as some commenters suggested. In particular, the Bureau concludes that, although consumers may benefit from understanding the rights the commenters discussed, those rights are not sufficiently related to the purposes of FDCPA section 809—*i.e.,* helping consumers to determine if a debt is theirs and to facilitate action in response to the receipt of validation information—to require debt collectors to include them as validation information.[256] In addition, as discussed in the section-by-section analysis of § 1006.34(c)(3)(iv), the final rule generally requires debt collectors to include a statement that informs consumers that additional information regarding consumer protections in debt collection is available on the Bureau's website, with a link to the information.[257] The Bureau's website will disclose more information about consumer protections in debt collection, including about the cease communication right.

The Bureau is finalizing § 1006.34(c)(3)(i) through (iii) and (v) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors and, as described more fully below, its authority to implement and interpret FDCPA section 809. The Bureau also is finalizing § 1006.34(c)(3) pursuant to its authority under section 1032(a) of the Dodd-Frank Act, on the basis that a consumer's rights are a feature of debt collection.

34(c)(3)(i)

FDCPA section 809(a)(4) requires debt collectors to disclose to consumers their right under FDCPA section 809(b) to dispute the validity of the debt within 30 days after receipt of the validation information (*i.e.,* during the validation period).[258] If a consumer disputes a debt in accordance with FDCPA section 809(b), a debt collector must cease collecting the debt until the debt collector provides verification to the consumer; this is sometimes referred to as the collections pause. FDCPA section 809(a)(4) does not expressly indicate that a debt collector must disclose to consumers that a dispute triggers FDCPA section 809(b)'s collections pause, or whether a debt collector must disclose the end date of the validation period.

The Bureau proposed § 1006.34(c)(3)(i) to provide that validation information includes a statement that specifies the end date of the validation period and states that, if the consumer notifies the debt collector in writing before the end of the validation period that the debt, or any portion of the debt, is disputed, the debt collector must cease collection of the debt until the debt collector sends the consumer either the verification of the debt or a copy of a judgment.[259]

The Bureau received a variety of comments in response to proposed § 1006.34(c)(3)(i)'s incorporation of the validation period end date.[260] On the one hand, an industry trade group and a group of consumer advocate commenters supported the inclusion, asserting the validation period end date would provide certainty to consumers about the timeframe within which to exercise their verification rights.

However, other commenters opposed the inclusion because, if delivery of a validation notice is delayed and the consumer receives the notice later than the debt collector presumed, the validation period end date would be inaccurate. Commenters suggested this could pose legal risk to debt collectors. To address this concern, an industry commenter recommended that the Bureau modify proposed § 1006.34(c)(3)(i) to replace the validation period end date with a generic statement that a consumer may request verification within 30 days after receiving the validation notice.

[251] 84 FR 23274, 23342 (May 21, 2019).

[252] *See* 15 U.S.C. 1692g(a)(4) and (5).

[253] In the November 2020 Final Rule, the Bureau finalized § 1006.6(c)(1) to implement FDCPA section 805(c) and to provide that, ''if a consumer notifies a debt collector in writing that the consumer refuses to pay a debt or that the consumer wants the debt collector to cease further communication with the consumer, the debt collector must not communicate or attempt to communicate further with the consumer with respect to such debt.'' 85 FR 76734, 78889 (Nov. 30, 2020).

[254] *See* 15 U.S.C. 1681j(a); 12 CFR 1022.136.

[255] 84 FR 23274, 23342 (May 21, 2019).

[256] For example, when Congress established the cease communication right pursuant to FDCPA section 805(c), Congress did not require its disclosure pursuant to FDCPA section 809. The Bureau concludes that was intentional. Thus, the Bureau declines to include the cease communication right as validation information that debt collectors must disclose.

[257] Section 1006.34(c)(3)(iv) requires debt collectors to include the disclosure if they are collecting debt related to a consumer financial product or service, as defined in § 1006.2(f). Otherwise, debt collectors can optionally include the disclosure under § 1006.34(d)(3)(viii).

[258] *See* 15 U.S.C. 1692g(a)(4).

[259] 84 FR 23274, 23343, 23404 (May 21, 2019).

[260] The discussion under the ''Model Validation Notice'' heading in the section-by-section analysis of § 1006.34(d)(2) provides details about how the statement required by § 1006.34(c)(3)(i) is disclosed on the model validation notice.

Some commenters, including consumer advocate commenters and an industry trade group, stated that disclosing the validation period end date might leave consumers with the false impression that they could not raise concerns about a debt after the validation period expires. A group of academic commenters argued that a study suggested that a significant number of consumers believed that, if they did not dispute a debt during the validation period, they would be unable to assert later that they did not owe the debt.[261] Similarly, an industry commenter stated that disclosing the validation period end date might dissuade consumers from making verification requests after that date even though debt collectors sometimes honor such requests. To address this potential misunderstanding, some commenters recommended that the final rule require debt collectors to inform consumers that they can raise concerns about a debt after the validation period end date.

Commenters also addressed the Bureau's proposal to require debt collectors to disclose FDCPA section 809(b)'s collections pause. Federal government agency staff and a group of consumer advocate commenters supported the collections pause disclosure. However, industry commenters stated that the disclosure would be burdensome because it would encourage consumers to dispute the debt for the purpose of delaying or avoiding debt collection. According to an industry commenter, consumers do not need to be informed about FDCPA section 809(b)'s collections pause because debt collectors are aware of it and observe it.

The Bureau determines that consumers will benefit from § 1006.34(c)(3)(i)'s disclosure of the validation period end date. As discussed in the proposal, the validation period end date is an integral feature of consumers' dispute right. Among other things, the validation period end date will provide certainty to consumers about the timeframe provided by the FDCPA to exercise their verification rights.

The Bureau disagrees that a validation period end date that is inaccurate because a validation notice was delayed will present significant legal risk to debt collectors. Final § 1006.34(b)(5) and comment 34(b)(5)–1 provide that, for purposes of determining the end of the validation period, a debt collector who provides the validation information in writing or electronically may assume that a consumer receives the validation information on any date that is at least five business days after the debt collector provides it. If a debt collector calculates the validation period end date in accordance with this presumption, the debt collector will not violate the FDCPA or its implementing Regulation F, even if, as final comment 34(b)(5)–1 clarifies, the consumer receives the validation notice later than the debt collector assumed. Further, the Bureau determines that a generic statement that a consumer may request verification within 30 days after receiving the validation notice is not an adequate substitute for disclosing the validation period end date. Such a generic statement could leave many consumers unsure about when the validation period ends. For example, consumers might receive a validation notice in the mail but not open it immediately, or they might open it and return to it later without keeping track of how much time has passed. In these and similar scenarios, consumers would not be able to determine the validation period end date.

Regarding commenters' suggestion that the Bureau require debt collectors to inform consumers that they can raise concerns about a debt after the validation period end date, the Bureau concludes that it is not necessary to require such a disclosure. FDCPA section 809(a) requires specific consumer disclosures, including statements about the consumer's rights within 30 days of receipt of the notice, but does not require any additional statement addressing consumer actions after the expiration of that period. The Bureau determines that a specific end date will not increase consumer confusion more than general language such as ''within 30 days.'' The Bureau's testing shows that, while some confusion does occur, about 40 percent of participants said they could still dispute the debt after the validation period end date.[262] Of the remaining 60 percent of participants, about 40 percent were unclear what would happen if they wrote to dispute the debt, and only about 20 percent specifically said that they could not write to dispute the debt.[263] When asked whether the debt collector would be required to send information saying they owe the debt if they wrote to dispute after the validation period end date, a small majority of consumers assumed that the debt collector would be required to do so.[264] Thus, although consumers may not be certain of the effect of writing to dispute the debt after the validation period end date, the Bureau's testing indicates that a sizeable majority of consumers would not be inhibited about raising general concerns about the debt after the validation notice end date. As discussed above, the final rule's enhanced and plain-language disclosures should improve overall consumer understanding and empower consumers to respond, should they choose, to debt collectors. The Bureau therefore declines to require as part of the validation information an explicit statement informing consumers that they may continue to raise concerns about the debt after the validation period end date.

The Bureau also determines that § 1006.34(c)(3)(i) should not omit the collections pause disclosure. As the proposal noted, consumer testing indicates that knowing about the collections pause was important to consumers and would encourage them to exercise their dispute right if they questioned a debt's validity.[265] Debt collectors have not provided evidence to support the premise that a significant number of consumers exercise their FDCPA section 809 verification rights solely to evade or delay paying debts that they owe. Absent such evidence, the Bureau declines to conclude that consumers will exercise their rights for such purposes. Further, regardless of whether debt collectors are aware of and comply with FDCPA section 809(b)'s collections pause requirement, the Bureau concludes that consumers will benefit from this disclosure because it will provide them with more complete information about the actions that debt collectors must take if consumers notify them that the debt is disputed.

For all of these reasons, the Bureau is finalizing § 1006.34(c)(3)(i) as proposed, with minor wording changes to clarify the content of the required disclosure, including by specifying that the consumer must notify the debt collector in writing ''on or before'' the end of the validation period, as opposed to

[261] Jeff Sovern & Kate Walton, *Are Validation Notices Valid? An Empirical Evaluation of Consumer Understanding of Debt Collection Validation Notices,* 70 SMU L. Rev. 63, 128 (2017) (''Our study indicated that more than a third of the respondents believed that if they failed to meet the thirty-day deadline, they would either have to pay a debt they did not owe or would not be able to argue in court that they didn't owe the debt.'').

[262] *See* November 2020 Qualitative Testing Report, *supra* note 34, at 13. Similarly, the Bureau's prior testing suggested that ''[o]verall, participants' comments suggest that they understood the difference between writing before the specified date [and] writing after that date.'' FMG Usability Report, *supra* note 28, at 56.

[263] *Id.*

[264] *Id.* at 13–14.

[265] FMG Cognitive Report, *supra* note 27, at 30; *see also* FMG Summary Report, *supra* note 29, at 25.

''before'' the end of the validation period, as proposed.[266]

34(c)(3)(ii)

FDCPA section 809(a)(5) requires debt collectors to disclose to consumers their right under FDCPA section 809(b) to request, within 30 days after receipt of the validation information, the name and address of the original creditor, if different from the current creditor.[267] FDCPA section 809(a)(5) does not expressly indicate that a debt collector must disclose to consumers that an original-creditor information request invokes FDCPA section 809(b)'s collections pause, or whether a debt collector must disclose the end date of the validation period. The Bureau proposed § 1006.34(c)(3)(ii) to provide that validation information includes a statement that specifies the end date of the validation period and states that, if the consumer requests in writing before the end of the validation period the name and address of the original creditor, the debt collector must cease collection of the debt until the debt collector sends the consumer the name and address of the original creditor, if different from the current creditor.[268]

Some industry and industry trade group commenters recommended that the Bureau not finalize proposed § 1006.34(c)(3)(ii).[269] Some commenters stated that the validation information need not include a statement informing consumers of their right to request original-creditor information because, under the Bureau's rule, the validation information will include the creditor as of the itemization date and, according to the commenters, that creditor and the original creditor often will be the same. Relatedly, some commenters suggested that, because the validation information will include the names of the itemization-date creditor and the current creditor, debt collectors should be permitted to omit the statement informing consumers of their right to request original-creditor information if the original creditor is the same as either of those creditors.[270]

Some commenters recommended that the Bureau modify proposed § 1006.34(c)(3)(ii) to omit the validation period end date and the collections pause disclosures. These comments were substantially similar to comments discussed in the section-by-section analysis of § 1006.34(c)(3)(i).

After considering the feedback, the Bureau has determined to finalize § 1006.34(c)(3)(ii). FDCPA section 809(a)(5) expressly requires debt collectors to include in the validation information a statement that, upon the consumer's written request within 30 days after receipt of the validation information, the debt collector will provide the consumer with the name and address of the original creditor, if different from the current creditor. The Bureau proposed § 1006.34(c)(3)(ii) to implement that requirement and to clarify the content of the disclosures for debt collectors. The Bureau did not propose an exception to this disclosure requirement if the original creditor and the current creditor are the same and therefore does not have information regarding the costs or benefits of finalizing such an exception. To the extent that commenters were concerned about the burden of responding to original-creditor information requests when the original creditor and the current creditor are the same, the Bureau is finalizing a special rule for that scenario in § 1006.38(c)(2).[271] For these reasons, the Bureau is finalizing § 1006.34(c)(3)(ii) as proposed, with minor wording changes to clarify the content of the required disclosure, including by specifying that the consumer must notify the debt collector in writing ''on or before'' the end date of the validation period, as opposed to ''before'' the end of the validation period, as proposed.[272]

The Bureau declines to omit the validation period end date and the collections pause disclosures from § 1006.34(c)(3)(ii) for the same reasons discussed in the section-by-section analysis of § 1006.34(c)(3)(i).

34(c)(3)(iii)

FDCPA section 809(a)(3) requires a debt collector to disclose to a consumer that, unless the consumer disputes the validity of the debt within 30 days of receipt of the validation information, the debt collector will assume the debt to be valid.[273] The Bureau proposed § 1006.34(c)(3)(iii) to provide that validation information includes a statement that specifies the end date of the validation period and states that, unless the consumer contacts the debt collector to dispute the validity of the debt, or any portion of the debt, before the end of the validation period, the debt collector will assume that the debt is valid.[274]

At the time of the proposal, courts in various jurisdictions had reached different conclusions about whether FDCPA section 809(a)(3) requires debt collectors to recognize oral disputes about the validity of a debt.[275] These differing decisions principally arose from the fact that, whereas FDCPA section 809(a)(4) and (5) explicitly state that a consumer must notify a debt collector in writing, FDCPA section 809(a)(3) does not refer to a writing requirement. In the absence of an express writing requirement in FDCPA section 809(a)(3), the majority of circuit courts that considered the issue had determined that a consumer's oral dispute triggers certain FDCPA protections, including, for example, FDCPA section 810's payment application requirement.[276] Consistent with this majority position, and pursuant to its authority to implement and interpret FDCPA section 809(a)(3) as well as its authority under Dodd-Frank Act section 1032(a), the Bureau proposed to interpret FDCPA section 809(a)(3) to allow oral disputes.[277]

Industry commenters, industry trade group commenters, and a group of academic commenters supported the Bureau's proposed interpretation that FDCPA section 809(a)(3) permits

[266] The model validation notice uses the term ''by'' instead of ''on or before'' for plain language purposes.

[267] *See* 15 U.S.C. 1692g(a)(5).

[268] 84 FR 23274, 23343, 23404 (May 21, 2019).

[269] See the ''Model Validation Notice'' discussion in the section-by-section analysis of § 1006.34(d)(2) for additional details about how the statement required by § 1006.34(c)(3)(ii) is disclosed on the model validation notice.

[270] As an alternative to complying with § 1006.34(c)(3)(ii), an industry trade group commenter recommended that debt collectors be permitted to proactively disclose the original-creditor information that a consumer would receive in response to an FDCPA section 809(b) request. This comment is addressed in the section-by-section analysis of § 1006.38.

[271] *See* the section-by-section analysis of § 1006.38(c)(2).

[272] The model validation notice uses the term ''by'' instead of ''on or before'' for plain language purposes.

[273] 15 U.S.C. 1692g(a)(3).

[274] 84 FR 23274, 23343–44, 23404 (May 21, 2019).

[275] *Compare Clark* v. *Absolute Collection Serv., Inc.,* 741 F.3d 487, 490 (4th Cir. 2014) (per curiam) (holding that oral disputes trigger certain FDCPA protections, including under FDCPA section 809(a)(3)), *Hooks* v. *Forman, Holt, Eliades & Ravin, LLC,* 717 F.3d 282, 286 (2d Cir. 2013) (same), and *Camacho* v. *Bridgeport Fin. Inc.,* 430 F.3d 1078, 1082 (9th Cir. 2005) (same), *with Graziano* v. *Harrison,* 950 F.2d 107, 112 (3d Cir. 1991) (''[A] dispute, to be effective, must be in writing.'').

[276] FDCPA section 810 is implemented by § 1006.30(c). *See* 85 FR 76734, 76843 (Nov. 30, 2020); *see also Camacho,* 430 F.3d at 1081–82 (holding that oral disputes trigger certain FDCPA protections, including under FDCPA sections 807(8) and 810).

[277] After the proposal was published, the circuit split was resolved. In *Riccio* v. *Sentry Credit, Inc.,* the Third Circuit sitting en banc overruled its prior decision and determined that FDCPA section 809(a)(3) does not require a dispute to be in writing. *Riccio* v. *Sentry Credit, Inc.,* 954 F.3d 582, 594 (3d Cir. 2020) (en banc) (''In short, we conclude that debt collection notices sent under § 1692g need not require that disputes be expressed in writing. In doing so, we overrule *Graziano*'s contrary holding.'').

consumers to dispute the validity of a debt orally or in writing.

Several industry and industry trade group commenters expressed concerns about how proposed § 1006.34(c)(3)(iii) was disclosed on the proposed model validation notice, perceiving a tension between the regulatory text and the proposed model notice text. Specifically, whereas the proposed model validation notice stated that a consumer may ''call or write'' to dispute all or part of the debt, proposed § 1006.34(c)(3)(iii) did not specify the manner in which a consumer must contact the debt collector and instead used the general term ''contact.''

As proposed, the Bureau determines that FDCPA section 809(a)(3) permits both oral and written disputes. The Bureau agrees with every circuit court that has addressed this issue and interprets the absence of a reference to a writing requirement in FDCPA section 809(a)(3) to mean that a writing is not required. Further, commenters overall supported this interpretation.

The Bureau declines to modify how § 1006.34(c)(3)(iii) is phrased on the model validation notice. The Bureau developed the phrase ''call or write'' for comprehension purposes. The model notice's language is intended to be plain language and consumer-friendly and was validated through multiple rounds of qualitative and quantitative consumer testing.[278] Regulatory text and the model notice language reflecting that regulatory text need not be identical in every case. For instance, if consumers may not understand a requirement as described in regulatory text, it is appropriate to express that requirement in plain language in consumer disclosures.[279]

For these reasons, the Bureau is finalizing § 1006.34(c)(3)(iii) as proposed, with minor wording changes to clarify the content of the required disclosure, including by specifying that the consumer must notify the debt collector in writing ''on or before'' the end of the validation period, rather than ''before'' the end of the validation period, as proposed.[280]

34(c)(3)(iv)

Dodd-Frank Act section 1032(a) permits the Bureau to prescribe rules to ensure that the features of any consumer financial product or service, both initially and over the term of the product or service, are fully, accurately, and effectively disclosed to consumers in a manner that permits consumers to understand the costs, benefits, and risks associated with the product or service, in light of the facts and circumstances. To enhance consumer understanding of protections available during the debt collection process, and pursuant to its authority under Dodd-Frank Act section 1032(a), the Bureau proposed § 1006.34(c)(3)(iv) to provide that, if a debt collector is collecting a consumer financial product or service debt, as defined in § 1006.2(f), then validation information includes a statement that informs the consumer that additional information regarding consumer rights in debt collection is available on the Bureau's website at *https://www.consumerfinance.gov.*

Commenters generally agreed that consumers would benefit from information about additional protections available to consumers experiencing debt collection. However, commenters disagreed about the best way to provide that information.

A large number of consumer advocate and academic commenters recommended that, rather than a statement that additional information is available on the Bureau's website, the Bureau should require debt collectors to provide consumers, along with the validation notice, a reference document describing consumer protections in debt collection, similar to the document that the Bureau developed prior to the SBREFA process.[281] Commenters stated that a reference document would be more useful to consumers than a statement appearing on a validation notice. Further, some such commenters stated that proposed § 1006.34(c)(3)(iv) would not help consumers without internet access who are unable to visit the Bureau's website.

Consumer advocate commenters and a group of academics also stated that, if the Bureau does not require a reference document, the Bureau should revise proposed § 1006.34(c)(3)(iv) to require debt collectors to include a web address that directs consumers to a Bureau page dedicated to consumer protections in debt collection, instead of to the Bureau's general website landing page.[282] Other commenters stated that requiring consumers to click on a hyperlink if the validation notice is delivered electronically would create procedural hurdles that reduce consumer follow through and would pose security risks to consumers.

At least one industry trade group commenter disagreed and supported proposed § 1006.34(c)(3)(iv) on the grounds that including a reference document with the validation notice would overwhelm consumers.

For the reasons discussed below, the Bureau is finalizing § 1006.34(c)(3)(iv) as proposed with a revision in response to feedback.

The Bureau declines to require debt collectors to provide consumers a reference document describing consumer protections in debt collection. Because the Bureau did not propose such a requirement, the Bureau did not receive robust feedback in response to the proposal about what such a required form should look like and how a requirement to provide it might operate. Further, the Bureau expects that most consumers will receive the disclosure referring to the Bureau's website and will be able to access the website; most consumers use the internet and have experience navigating to websites.[283]

The Bureau determines that consumers would benefit from being directed to a page dedicated to consumer protections in debt collection instead of the Bureau's website landing page. Accordingly, the Bureau is modifying § 1006.34(c)(3)(iv) to specifically reference the web page *www.cfpb.gov/debt-collection* instead of the Bureau's general landing page. The Bureau is also making a conforming change to how the statement described in § 1006.34(c)(3)(iv) is disclosed on the model validation notice.

The Bureau determines that consumers will not face significant security risks when accessing the Bureau's website. The vast majority of validation notices today are delivered by mail, so an active hyperlink is not possible. In the case of electronic communications, the Bureau recognizes that active hyperlinks can present security concerns to consumers, including, among other things, phishing

[278] *See* part III.C.

[279] See the ''Model Validation Notice'' discussion in the section-by-section analysis of § 1006.34(d)(2) for additional details about how the statement required by § 1006.34(c)(3)(iii) is disclosed on the model validation notice.

[280] The model validation notice uses the term ''by'' instead of ''on or before'' for plain language purposes.

[281] For additional detail about information that the Bureau considered including in the reference document, see appendix G of the Small Business Review Panel Outline, *supra* note 39.

[282] Also, in response to proposed § 1006.34(d)(4)(ii), a consumer advocate commenter recommended that the Bureau permit debt collectors to embed a hyperlink that directs consumers to the Bureau's website address described in proposed § 1006.34(c)(3)(iv). As discussed in the section-by-section analysis of § 1006.34(d)(4)(ii), the Bureau is adopting this recommendation to permit debt collectors to include a hyperlink without losing the safe harbor in § 1006.34(d)(2).

[283] For example, a Pew Research Center study in 2019 found that 90 percent of U.S. adults use the internet. *See* Pew Research Ctr., *Internet/Broadband Fact Sheet, https://www.pewresearch.org/internet/fact-sheet/internet-broadband/#who-uses-the-internet* (last visited Dec. 1, 2020).

risks.[284] But the Bureau is not requiring debt collectors to include an active hyperlink to the Bureau's website in validation notices. In other words, even if the validation information is provided electronically, § 1006.34(c)(3)(iv) only requires that the text ''*www.cfpb.gov/debt-collection*'' be displayed in the information. As discussed in the section-by-section analysis of § 1006.34(d)(4)(ii), a debt collector is permitted, but not required, to include an active hyperlink to the Bureau's website. This is because hyperlinks are a common feature of electronic commercial communications. A validation notice that includes a hyperlink to the Bureau's website may be safe and convenient for a consumer. This would particularly be the case if the debt collector had prior contact with the consumer and the consumer recognizes that the validation notice was sent by a familiar source. If a consumer is unfamiliar with the debt collector or otherwise has concerns about clicking on an active hyperlink, the consumer could choose, rather than clicking on the hyperlink, to navigate independently to the Bureau's website to obtain more information about consumer protections in debt collection.

Accordingly, the Bureau is finalizing § 1006.34(c)(3)(iv) to provide that, if a debt collector is collecting debt related to a consumer financial product or service as defined in § 1006.2(f), validation information includes a statement that informs the consumer that additional information regarding consumer protections in debt collection is available on the Bureau's website at *www.cfpb.gov/debt-collection.*

34(c)(3)(v)

Proposed § 1006.34(c)(4) provided that validation information includes information that a consumer can use to take certain actions, including disputing a debt or requesting original-creditor information.[285] As discussed in the section-by-section analysis of § 1006.34(c)(3)(i) and (ii), FDCPA section 809(b) provides that consumers must notify a debt collector ''in writing'' to dispute a debt or request original-creditor information. Under § 1006.38, this writing requirement is satisfied if a consumer provides a dispute or request for original-creditor information to the debt collector using a medium of electronic communication through which a debt collector accepts electronic communications from consumers, such as an email address or a website portal.[286] Thus, debt collectors are required to give legal effect to consumer disputes or requests for original-creditor information submitted electronically only if a debt collector chooses to accept electronic communications from consumers. The Bureau proposed § 1006.34(c)(3)(v) to provide that validation information includes a statement explaining how a consumer can take the actions described in proposed § 1006.34(c)(4) and (d)(3), as applicable, electronically, if the debt collector sends a validation notice electronically.

Proposed comment 34(c)(3)(v)–1 explained that a debt collector may provide the information described in § 1006.34(c)(3)(v) by including the statements, ''We accept disputes electronically,'' using that phrase or a substantially similar phrase, followed by an email address or website portal that a consumer can use to take the action described in § 1006.34(c)(4)(i), and ''We accept original-creditor information requests electronically,'' using that phrase or a substantially similar phrase, followed by an email address or website portal that a consumer can use to take the action described in § 1006.34(c)(4)(ii).[287] Proposed comment 34(c)(3)(v)–1 also clarified that, if a debt collector accepts electronic communications from consumers through more than one medium, such as by email and through a website portal, the debt collector is only required to provide information regarding one of these media but may provide information about additional media.

An industry commenter and an industry trade group commenter supported proposed § 1006.34(c)(3)(v) because it would inform consumers about alternative methods to contact debt collectors and would increase the likelihood that consumers would engage with debt collectors. However, another industry commenter objected to the proposal because, the commenter argued, allowing consumers to exercise verification rights electronically would encourage consumers to submit verification requests for the purpose of delaying or avoiding paying a debt.

The Bureau determines that requiring debt collectors who provide validation notices electronically to include statements on the validation notice explaining how consumers can dispute the debt or request original-creditor information electronically will benefit consumers by facilitating their ability to exercise those verification rights electronically. The Bureau agrees that such disclosures will increase the likelihood of engagement between consumers and debt collectors but does not agree that they will encourage consumers to submit disputes or original-creditor-information requests to delay or avoid paying the debt. As discussed in the section-by-section analysis of § 1006.34(c)(3)(i), commenters have not provided evidence demonstrating that a significant number of consumers exercise their verification rights with the principal purpose of avoiding paying debts that they owe. Absent such evidence, the Bureau declines to conclude that consumers will exercise verification rights for this purpose.

Accordingly, the Bureau is finalizing § 1006.34(c)(3)(v) and its related commentary largely as proposed, except that the final rule does not require debt collectors who provide validation notices electronically to include statements stating how consumers can take the actions described in § 1006.34(d)(3) (*i.e.,* responding to a payment prompt (§ 1006.34(d)(3)(iii)) or requesting a Spanish-language translation (§ 1006.34(d)(3)(vi))) electronically.

The Bureau notes that § 1006.34(d)(3)(vi)(A) affirmatively permits a debt collector to include supplemental information in Spanish specifying how a consumer may request a Spanish-language validation notice, and such information could include how the consumer may do so electronically. In addition, as discussed at the outset of the section-by-section analysis of § 1006.34, the Bureau is not finalizing the proposed requirement that all validation notices must be substantially similar to the model validation notice in order to avoid violating the rule. Therefore, under the final rule, a debt collector who chooses to include either or both of the optional payment disclosures in § 1006.34(d)(3)(iii) is not prohibited by Regulation F from including a statement about how the consumer can make a payment electronically (although including such a statement will take the debt collector out of the safe harbor in § 1006.34(d)(2)). The Bureau is

[284] *See, e.g.,* Fed. Trade Comm'n, *How to Recognize and Avoid Phishing Scams* (May 2019), *https://www.consumer.ftc.gov/articles/how-recognize-and-avoid-phishing-scams* (last visited Dec. 1, 2020).

[285] Proposed § 1006.34(c)(4) set forth required consumer-response information. Proposed § 1006.34(d)(3)(iii)(B) and (vi)(B) set forth certain other consumer-response information related to payment requests and requests for Spanish-language validation notices.

[286] *See* the section-by-section analysis of § 1006.38 and comment 38–1.

[287] On the model validation notice, this phrase appears as ''We accept such requests electronically.'' This wording deviates from the regulatory text due to space considerations and the context of surrounding disclosures.

finalizing § 1006.34(c)(3)(v) pursuant to its authority to interpret FDCPA section 809(a) and (b), as well as its authority under Dodd-Frank Act section 1032(a).

34(c)(3)(vi)

The Bureau proposed § 1006.34(c)(3)(vi) to provide that, for a validation notice delivered in the body of an email pursuant to procedures set forth in the proposal, validation information includes the opt-out statement required by § 1006.6(e).[288] Proposed comment 34(c)(3)(vi)–1 clarified certain details, including that the requirement would not apply in the case of validation notices delivered by hyperlink and that electronic delivery of a validation notice is not rendered ineffective if a consumer opts out of future electronic communications pursuant to § 1006.6(e).

Although no commenters objected to proposed § 1006.34(c)(3)(vi), the Bureau is not finalizing it. The Bureau has determined that it is not necessary to require debt collectors to include the § 1006.6(e) opt-out instructions on validation notices sent electronically because § 1006.6(e) itself already requires those instructions in every electronic communication or communication attempt, which will includes every electronic communication transmitting a validation notice. Thus, § 1006.34(c)(3)(vi) would be redundant.

A debt collector who sends a validation notice electronically may provide the § 1006.6(e) disclosure in the electronic communication outside of the validation notice. A debt collector who provides the model validation notice electronically will not lose the safe harbor described in § 1006.34(d)(2) by including the § 1006.6(e) disclosure in the electronic communication outside the model notice. Accordingly, the Bureau determines that the § 1006.6(e) opt-out disclosure is not necessary to include as validation information. Although the Bureau is not finalizing proposed § 1006.34(c)(3)(vi), the Bureau reaffirms the clarification in proposed comment 34(c)(3)(vi)–1 that electronic delivery of a validation notice is not rendered ineffective merely because a consumer opts out of future electronic communications pursuant to the instructions in § 1006.6(e).

34(c)(4) Consumer-Response Information

FDCPA section 809(b) contains certain requirements that a debt collector must satisfy if a consumer exercises the consumer's right to dispute the validity of the debt or request the name and address of the original creditor. If a consumer disputes a debt in writing within 30 days of receiving the validation information, a debt collector must stop collection of the debt until the debt collector obtains verification of the debt or a copy of a judgment against the consumer and mails it to the consumer. Similarly, if a consumer requests the name and address of the original creditor in writing within 30 days of receiving the validation information, FDCPA section 809(b) requires the debt collector to cease collection of the debt until the debt collector obtains and mails such information to the consumer. FDCPA section 809(b) also prohibits a debt collector, during the 30-day period consumers have to dispute a debt or request information about the original creditor, from engaging in collection activities and communications that overshadow, or are inconsistent with, the disclosure of the right to dispute the debt or request original-creditor information, which the Bureau collectively refers to as ''verification rights.''

The Bureau proposed § 1006.34(c)(4) to require a consumer-response information section to help consumers exercise their FDCPA section 809(b) verification rights.[289] Specifically, proposed § 1006.34(c)(4) provided that required validation information includes certain consumer-response information situated next to prompts that consumers could use to indicate that they want to take action or make a request. The proposed information, which is discussed in the section-by-section analysis of § 1006.34(c)(4)(i) through (iii), included statements describing certain actions that a consumer could take, including submitting a dispute, identifying the reason for the dispute, providing additional detail about the dispute, and requesting original-creditor information.[290] Proposed § 1006.34(c)(4) provided that the consumer-response information section must be segregated from the validation information described in § 1006.34(c)(1) through (3) and from any optional information included pursuant to proposed § 1006.34(d)(3)(i), (ii), (iv), or (v) and, if the validation information is provided in writing or electronically, located at the bottom of the notice and under the headings, ''How do you want to respond?'' and ''Check all that apply:''. As shown on the proposed model validation notice, the consumer-response information section appeared as a tear-off portion of the form. Proposed comment 34(c)(4)–1 clarified that, if the validation information is provided in writing or electronically, a prompt described in § 1006.34(c)(4) may be formatted as a checkbox, as shown on the model validation notice.

A group of academic commenters expressed general support for proposed § 1006.34(c)(4). However, some industry commenters objected to the proposed consumer-response information section. According to a depository institution, the proposed consumer- response information formatted as a tear-off is an obsolete approach because physical mail is increasingly less relevant as consumers prefer electronic communications. An industry commenter stated that the proposed consumer-response information section would encourage consumers to communicate through mail, which is more expensive and time-intensive than other communication methods, such as email.

Several commenters raised concerns about proposed § 1006.34(c)(4)'s use of the heading ''How do you want to respond?'' A group of State Attorneys General and at least one industry commenter stated that consumers may incorrectly infer from this phrase that they must use the consumer-response information section to respond to a debt collector. Some commenters suggested that this phrase created the false impression that consumers must engage with the debt collector, even if they prefer not to. To address this concern, consumer advocate commenters and a group of State Attorneys General recommended that the consumer-response information section include ''Do Nothing'' as a response option.

Some industry trade group commenters objected to proposed § 1006.34(c)(4) being formatted for use with a return envelope. According to these commenters, some debt collectors do not include return envelopes with

[288] As finalized in the November 2020 Final Rule, § 1006.6(e) requires a debt collector who communicates or attempts to communicate with a consumer electronically in connection with the collection of a debt using a specific email address, telephone number for text messages, or other electronic-medium address to include in such communication or attempt to communicate a clear and conspicuous statement describing a reasonable and simple method by which the consumer can opt out of further electronic communications or attempts to communicate by the debt collector to that address or telephone number. *See* 85 FR 76734, 76890 (Nov. 30, 2020).

[289] 84 FR 23275, 23404 (May 21, 2019).

[290] As discussed in the section-by-section analysis of § 1006.34(d)(3), proposed § 1006.34(d)(3)(iii)(B) and (vi)(B) provided that a debt collector also could include a payment disclosure and Spanish-language validation notice request disclosure as consumer-response information.

validation notices and instituting such a practice would entail significant costs. However, a consumer group commenter disagreed and stated that the Bureau should require debt collectors to include a return envelope with prepaid postage to facilitate use of the proposed consumer-response information section.

After considering comments, the Bureau is adopting § 1006.34(c)(4) with minor wording changes to conform to changes in § 1006.34(d).

The Bureau acknowledges that electronic communications are increasingly prevalent in society at large; however, most debt collectors do not presently communicate with consumers electronically, particularly to provide validation notices.[291] Further, many consumers still prefer to communicate with debt collectors via mail instead of email or other electronic media.[292] Given communication practices in the debt collection industry and consumer preferences, the Bureau determines that formatting the model validation notice consumer-response information section as a tear-off so that a consumer can return that portion of the form by mail if the consumer so chooses will benefit both debt collectors and consumers. Thus, if debt collectors opt not to format the consumer-response information section as a tear-off, the § 1006.34(d)(2) safe harbor will not apply to their validation notices.

The Bureau concludes that the heading ''How do you want to respond?'' likely will not lead consumers to believe that they must respond to the debt collector or use the consumer-response information section to do so. Consumer testing indicated that consumers paid relatively little attention to this heading.[293] Further, consumers generally grasped the consequences of not responding to a validation notice.[294] These findings suggest that the heading will not induce otherwise unwilling consumers to engage with debt collectors. This conclusion is bolstered by findings from the Bureau's most recent qualitative consumer testing. The Bureau's consumer testing suggests that consumers understand that they have the option of not engaging with a debt collector in response to a validation notice.[295] This testing also indicates that consumers understand that, if they choose to communicate with a debt collector, they do not have to use the consumer-response information section to do so.[296] The Bureau therefore determines that it is unnecessary to include a ''Do Nothing'' response option, as some commenters suggested.

The consumer-response information section should be formatted for use with a return envelope. The fact that the consumer-response information established by § 1006.34(c)(4) is formatted on the model validation notice for use with a return envelope does not require debt collectors to include return envelopes with validation notices, even if they use the model notice.

Accordingly, the Bureau is finalizing § 1006.34(c)(4) with minor wording changes to conform to changes in § 1006.34(d). The Bureau also is finalizing § 1006.34(c)(4)(i) through (iii) and their related commentary with certain modifications that are discussed in the section-by-section analysis below.

The Bureau is finalizing § 1006.34(c)(4) pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors and, as described more fully below, its authority to implement and interpret FDCPA section 809. The Bureau is also finalizing § 1006.34(c)(4) pursuant to its authority under section 1032(a) of the Dodd-Frank Act, on the basis that the information in § 1006.34(c)(4)(i) through (iii) informs consumers how to exercise their rights under FDCPA section 809(b) and therefore is a feature of debt collection. Requiring disclosure of consumer-response information will help to ensure that the features of debt collection are fully, accurately, and effectively disclosed to consumers, such that consumers may better understand the costs, benefits and risks associated with debt collection.

34(c)(4)(i) Dispute Prompts

FDCPA section 809(a)(4) requires a debt collector to disclose to consumers their right under FDCPA section 809(b) to dispute the validity of the debt within 30 days after receipt of the validation notice.[297] Proposed § 1006.34(c)(4)(i) provided that consumer-response information includes statements, situated next to prompts, that the consumer can use to dispute the validity of a debt and to specify a reason for that dispute.[298] Proposed § 1006.34(c)(4)(i), which was designed to work in tandem with § 1006.34(c)(3)(i),[299] provided that consumer-response information includes the following four statements, listed in the following order, using the following phrasing or substantially similar phrasing, each next to a prompt: ''I want to dispute the debt because I think:''; ''This is not my debt.''; ''The amount is wrong.''; and ''Other: (please describe on reverse or attach additional information).''

A group of academic commenters and some consumer advocate commenters supported the dispute prompts described in proposed § 1006.34(c)(4)(i). The academic commenters stated that the prompts would facilitate consumer disputes because consumers are accustomed to using forms with prompts, such as drop-down menus in online transactions. According to these commenters, the Bureau should facilitate consumer disputes given the low consumer literacy levels in the United States—particularly among consumers with limited English proficiency (LEP consumers)—and the FDCPA's least-sophisticated-consumer standard.[300] These commenters stated

[291] *See* 85 FR 76734, 76852 (Nov. 30, 2020).

[292] According to the CFPB Debt Collection Consumer Survey, 71 percent of consumers preferred to be contacted by a debt collector by mail. Only 12 percent of consumers preferred email. Bureau of Consumer Fin. Prot., *Consumer Experience with Debt Collection: Findings from CFPB's Survey of Consumer Views on Debt,* at 29–30 (Jan. 12, 2017), *http://files.consumerfinance.gov/f/documents/201701_cfpb_Debt-Collection-Survey-Report.pdf* (CFPB Debt Collection Consumer Survey).

[293] ''The 'You Have Rights' and 'How do you want to respond to this notice?' sections had a comparatively low number of fixations (*i.e.,* a testing participant's eyes resting on a piece of information) compared to other parts of the notice. These two sections were often discussed during the interview as being important so the fewer number of fixations suggests that this information might have been easy to read and comprehend. Participants also commented that these sections only needed to be scanned, further suggesting that fewer fixations on this section might have been due to ease of processing the information rather than a disinterest in the information. *See* FMG Usability Report, *supra* note 28, at 7.

[294] *See id.* at 83–84.

[295] When asked about whether they were legally required respond to the model validation notice, approximately 90 percent of participants reported that they were not. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 11.

[296] During testing, participants generally understood that they could dispute the debt by telephone, electronically, or writing with or without the ''tear-off.'' *See id.* at 15.

[297] 15 U.S.C. 1692g(a)(4).

[298] 84 FR 23274, 23404–05 (May 21, 2019).

[299] As finalized, § 1006.34(c)(3)(i) provides that validation information includes the date the debt collector will consider the end date of the validation period and a statement that, if the consumer notifies the debt collector in writing on or before that date that the debt, or any portion of the debt, is disputed, the debt collector must cease collection of the debt, or the disputed portion of the debt, until the debt collector sends the consumer either the verification of the debt or a copy of a judgment.

[300] *See, e.g., Rosenau* v. *Unifund Corp.,* 539 F.3d 218, 221 (3d Cir. 2008) (''We use the 'least sophisticated debtor' standard in order to effectuate the basic purpose of the FDCPA: to protect all consumers, the gullible as well as the shrewd.'') (citations and some internal quotation marks omitted); *Clomon* v. *Jackson,* 988 F.2d 1314, 1319 (2d Cir. 1993) (''To serve the purposes of the consumer-protection laws, courts have attempted to articulate a standard for evaluating deceptiveness

Continued

that facilitating disputes will also benefit industry because consumer disputes may lead to questionable or invalid debts being removed from the market.

Other commenters objected to proposed § 1006.34(c)(4)(i). Industry trade group commenters stated that the proposed dispute prompts would increase dispute volume and, consequently, debt collectors would incur additional costs responding to disputes. Industry commenters stated that higher dispute volumes would overwhelm debt collectors, making it difficult to identify and process valid disputes. Industry and industry trade group commenters stated that the proposed dispute prompts would lead consumers to believe that they had to dispute the debt, even if they recognized the debt as valid. Industry and industry trade groups argued that streamlining the dispute process would encourage frivolous disputes. One industry trade group stated that requiring a lawyer engaged in debt collection to include the proposed dispute prompts on a validation notice would constitute providing legal advice to unrepresented persons, which is a violation of attorney rules of professional conduct.

Industry and industry trade group commenters stated the proposed dispute prompts would not solicit enough information for debt collectors to evaluate disputes. According to commenters, the proposed dispute prompts are too general and would result in generic disputes that would increase compliance costs, frustrate dispute investigation, undermine consumer communication, and increase litigation risk. To address these concerns, commenters recommended modifications to proposed § 1006.34(c)(4)(i). Some commenters suggested that the validation notice provide additional space where a consumer could include additional dispute detail, update contact information, or provide communication preferences. Other commenters recommended replacing the proposed dispute prompts with narrative instructions that solicit dispute detail and supporting documentation.

As discussed in the section-by-section analysis of § 1006.34(c)(2)(i), commenters stated that some debt collectors receive payments and other correspondence, including disputes, at separate addresses. Industry commenters stated that proposed § 1006.34(c)(4)(i) would effectively combine a dispute form with a payment coupon. According to commenters, a consumer's dispute may not be processed in a timely fashion if a consumer returns a consumer-response information form with a dispute to a dedicated payment address.

Several consumer advocate commenters recommended combining the proposed dispute prompts into a single prompt. According to these commenters, a single dispute prompt would be appropriate because the FDCPA does not require a consumer to specify a reason for a dispute and a consumer may make unintentional admissions against their interest by providing details.

Some commenters suggested additional dispute-related prompts. Consumer advocate commenters recommended prompts for debts discharged in bankruptcy, debts resulting from identity theft, and debts that were previously paid or settled. Industry commenters urged the Bureau to add a general account inquiry prompt. According to one industry commenter, consumers with an account inquiry may perceive that they have no alternative but to select a dispute prompt if proposed § 1006.34(c)(4)(i) does not include a general account inquiry prompt.

An industry commenter asked for additional guidance about how the proposed dispute prompts should be formatted when validation information is provided on a website.

Consistent with the rationale discussed in the proposal and for the following reasons, the Bureau is adopting proposed § 1006.34(c)(4)(i).

The Bureau determines that § 1006.34(c)(4)(i) will help consumers exercise their FDCPA section 809 dispute rights, in part because prompts are a common feature in written and electronic communications and most consumers are familiar with the concept. The Bureau determines that facilitating consumer disputes under FDCPA section 809 is beneficial, particularly for less sophisticated consumers. Further, to the extent consumer disputes help remove invalid debts from circulation, § 1006.34(c)(4)(i) will improve the efficiency of debt markets.

It is also not clear that finalizing the dispute prompts will result in a significant increase in consumer disputes compared to current dispute rates. Section 1006.34(c)(2) will require debt collectors to disclose more information about the debt and will help consumers recognize debts they owe. Thus, § 1006.34(c)(2) may reduce the number of disputes arising from lack of consumer recognition.

The Bureau disagrees that § 1006.34(c)(4)(i) will make it more difficult for debt collectors to identify and process valid disputes. As noted above, § 1006.34(c)(2) should reduce the number of disputes arising from lack of consumer recognition. Therefore, the disputes debt collectors receive will be more likely to reflect problems with the underlying debt. Further, § 1006.34(c)(4)(i)'s dispute prompts—including § 1006.34(c)(4)(i)(D)'s free-form dispute prompt—may help consumers articulate and provide more detailed information about the nature of their disputes. Thus, debt collectors may better understand the nature of a consumer's dispute and be able to respond more efficiently than if consumers had provided generic disputes.

Further, dispute prompts likely will not lead consumers to believe that they must dispute the debt. The Bureau's consumer testing indicates that consumers who receive a validation notice understand that they are not required to dispute a debt.[301] Further, the Bureau disagrees that streamlining the dispute process will significantly increase the frequency of frivolous disputes. As discussed in the section-by-section analysis of § 1006.34(c)(3)(i) and (v), debt collectors have not provided evidence that supports the premise that a significant number of consumers exercise their FDCPA section 809 verification rights solely to evade or avoid paying debts that they owe. Absent such evidence, the Bureau declines to conclude that consumers will dispute for such purposes.

The Bureau determines that requiring debt collectors who are attorneys to include dispute prompts in the consumer-response information will not cause those debt collectors to violate the professional rule of conduct against providing legal advice to an unrepresented person.[302] The FDCPA

that does not rely on assumptions about the 'average' or 'normal' consumer. This effort is grounded, quite sensibly, in the assumption that consumers of below-average sophistication or intelligence are especially vulnerable to fraudulent schemes. The least-sophisticated-consumer standard protects these consumers in a variety of ways.'').

[301] During one round of testing, approximately 50 percent of participants stated that they would attempt to ''confirm'' a debt in response to receiving a validation notice. Participants stated that they would do so by, for example, contacting either the creditor or the debt collector. Participants did not report that they would dispute solely for the purposes of confirming the details of the debt. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 11.

[302] *See* Am. Bar Ass'n, *Model Rules of Professional Conduct, Rule 4.3: Dealing with Unrepresented Person https://www.americanbar.org/groups/professional_responsibility/publications/model_*

requires all debt collectors, including debt collectors who are attorneys, to include in the validation information statements relating to the consumer's right to dispute the debt. The dispute prompt merely provides consumers a simple way to exercise that right if the consumer so chooses; it does not advise the consumer whether to do so. In addition, the commenter that raised this concern cited no case law, legal interpretation, or comparable evidence to support the proposition that including the dispute prompt will be problematic.

The Bureau is not modifying § 1006.34(c)(4)(i) to provide additional space for consumers to provide dispute details or to replace the dispute prompts with narrative instructions. As discussed above, the Bureau finds that it is unlikely that § 1006.34(c)(4)(i) will increase generic dispute volume. On the contrary, the dispute prompts—including the free-form dispute prompt in § 1006.34(c)(4)(i)(D)—will provide debt collectors with more detailed dispute information than they receive in many cases today. Further, the free-form dispute prompt informs consumers that they can provide additional information on the reverse of the consumer-response-information section (which is formatted as a tear-off on the model validation notice) or on a separate page. Thus, there is no need to provide additional space for dispute detail on the validation notice itself.

Section 1006.34(c)(4)(i) will not lead to disputes being misdirected to dedicated payment addresses. As discussed in the section-by-section analysis of § 1006.34(c)(4)(iii), the debt collector must disclose in the consumer-response information section the same mailing address disclosed pursuant to § 1006.34(c)(2)(i), which is the mailing address where the debt collector accepts disputes and requests for original-creditor information.

The Bureau declines to structure § 1006.34(c)(4)(i) as a single dispute prompt. As discussed above, the dispute prompts are designed to help consumers articulate, and debt collectors better understand, the nature of a consumer's dispute and respond more efficiently than if consumers had provided generic disputes. Reformulating § 1006.34(c)(4)(i) as a single prompt would undermine this goal. Meanwhile, the dispute prompts described in § 1006.34(c)(4)(i) do not contain individualized information that could reasonably result in a consumer making an unintentional admission against their interest.

The Bureau declines to adopt additional dispute-related prompts. Additional prompts for debts discharged in bankruptcy, debts resulting from identity theft, and debts that were previously paid or settled are, in the aggregate, not feasible and would likely overwhelm consumers. Further, the Bureau believes the dispute prompts in § 1006.34(c)(4)(i)(B) (this is not my debt) and (C) (the amount is wrong) essentially capture these scenarios.

The Bureau also declines to add a general account inquiry prompt distinct from the dispute prompt, as suggested by some commenters who argued that consumers would use the dispute prompts to obtain general information. The Bureau's testing has shown that consumers generally understand that their response options are not limited to selecting a dispute prompt and that disputing the debt is not the appropriate method to raise a general question about the account.[303]

The Bureau declines to provide additional guidance about formatting the dispute prompts if validation information is provided on a website. As discussed in the November 2020 Final Rule, the Bureau did not finalize several proposed interventions related to electronic delivery of required notices, including proposed alternative procedures for providing the validation information on a secure website (proposed § 1006.42(c)(2)(ii)).[304] Because the Bureau is not addressing electronic delivery more broadly, the Bureau declines here to provide guidance about disclosing validation information on websites. However, as discussed in the section-by-section analysis of § 1006.34(d)(2), in contrast to the proposal, debt collectors are not required to use the model validation notice or a substantially similar form.

Accordingly, the Bureau is finalizing proposed § 1006.34(c)(4)(i) pursuant to its authority to implement and interpret FDCPA section 809, as well as its authority under Dodd-Frank Act section 1032(a).

34(c)(4)(ii) Original-Creditor Information Prompt

FDCPA section 809(a)(5) requires a debt collector to disclose to consumers their right under FDCPA section 809(b) to request the name and address of the original creditor, if different from the current creditor.[305] Proposed § 1006.34(c)(4)(ii) provided that consumer-response information includes the statement, ''I want you to send me the name and address of the original creditor,'' using that phrase or a substantially similar phrase, next to a prompt the consumer could use to request original-creditor information.[306] Proposed § 1006.34(c)(4)(ii) was intended to work in tandem with proposed § 1006.34(c)(3)(ii).[307] The Bureau received no comments specifically addressing proposed § 1006.34(c)(4)(ii) and is finalizing it as proposed.

34(c)(4)(iii)

FDCPA section 809(b) assumes that a consumer has the ability to write to a debt collector to exercise the consumer's verification rights.[308] Requiring a debt collector to include mailing addresses for the consumer and the debt collector, along with the consumer-response information described in § 1006.34(c)(4)(i) and (ii), may facilitate a consumer's ability to exercise the consumer's verification rights. The Bureau proposed § 1006.34(c)(4)(iii) to provide that consumer-response information includes mailing addresses for the consumer and the debt collector.[309]

An industry trade group stated that some debt collectors use vendors to receive and process mail from consumers. According to this commenter, the Bureau should permit a debt collector to disclose the address at which a debt collector receives mail, even if that address is not the debt collector's physical address.

The Bureau is finalizing § 1006.34(c)(4)(iii) with a clarifying revision that addresses the commenter's request regarding letter vendor mailing addresses. The Bureau is revising § 1006.34(c)(4)(iii) to provide that the mailing addresses disclosed for the consumer and the debt collector in the consumer-response information must include the debt collector's and the

of_professional_conduct/rule_4_3_dealing_with_unrepresented_person/ (last visited Dec. 2, 2020).

[303] During usability testing, when participants were asked what they could do if they did not think they owed the debt, ''all participants understood that they had options for contacting the debt collector to dispute the debt,'' which included calling and writing. FMG Usability Report, *supra* note 28, at 48. *See also* November 2020 Qualitative Testing Report, *supra* note 34, at 11 (discussion in ''Response to the model validation notice'' section).

[304] 85 FR 76734, 76850–55 (Nov. 30, 2020).

[305] 15 U.S.C. 1692g(a)(5).

[306] 84 FR 23274, 23405 (May 21, 2019).

[307] As finalized, § 1006.34(c)(3)(ii) provides that validation information includes the date that the debt collector will consider the end date of the validation period and a statement that, if the consumer requests in writing on or before that date the name and address of the original creditor, the debt collector must cease collection of the debt until the debt collector sends the consumer the name and address of the original creditor, if different from the current creditor.

[308] *See* 15 U.S.C. 1692g(b).

[309] 84 FR 23274, 23405 (May 21, 2019).

consumer's names and mailing addresses as disclosed pursuant to § 1006.34(c)(2)(i) and (ii). In turn, the Bureau notes that final § 1006.34(c)(2)(i) and comment 34(c)(2)(i)–2 permit debt collectors to disclose a vendor's mailing address, if that is an address at which the debt collector accepts disputes and requests for original-creditor information. Thus, under the final rule, a debt collector may include a vendor's address in the consumer-response information if that is the address that the debt collector discloses pursuant to § 1006.34(c)(2)(i).

The Bureau notes that final § 1006.34(c)(2)(i) and comment 34(c)(2)(i)–1 permit a debt collector to disclose its trade name or DBA, instead of its legal name. Thus, under the final rule, a debt collector must disclose its trade name or DBA in the consumer-response information if that is the name that the debt collector discloses pursuant to § 1006.34(c)(2)(i).

34(c)(5) Special Rule for Certain Residential Mortgage Debt

FDCPA section 809(a)(1) requires a debt collector to disclose to consumers the amount of the debt.[310] As discussed in the section-by-section analysis of § 1006.34(c)(2)(vi) through (viii), the Bureau interprets FDCPA section 809(a)(1) to require debt collectors to disclose three pieces of itemization-related information: The itemization date; the amount of the debt on the itemization date; and an itemization of the debt reflecting interest, fees, payments, and credits since the itemization date.

For certain residential mortgage debt covered by TILA, as implemented by Regulation Z, 12 CFR 1026, 12 CFR 1026.41(b) generally requires that a periodic statement be delivered or placed in the mail within a reasonably prompt time after the payment due date or the end of any courtesy period provided for the previous billing cycle. The Bureau understands that most residential mortgage debt is subject to this requirement, although exceptions exist.[311] The Bureau further understands that a consumer is provided with such a periodic statement every billing cycle, even if a loan is transferred between servicers. Pursuant to 12 CFR 1026.41(d)(3), such a periodic statement must include a past payment breakdown, which shows the total of all payments received since the last statement, including a breakdown showing the amount, if any, that was applied to principal, interest, escrow, fees, and charges, and the amount, if any, sent to any suspense or unapplied funds account. The proposal stated that these periodic statement disclosures may be functionally equivalent to, and as useful for the consumer as, the information described in proposed § 1006.34(c)(2)(vii) through (ix).[312]

Proposed § 1006.34(c)(5) therefore provided that, for debts subject to Regulation Z, 12 CFR 1026.41, a debt collector need not provide the validation information described in § 1006.34(c)(2)(vii) through (ix) if the debt collector provided the consumer, at the same time as the validation notice, a copy of the most recent periodic statement provided to the consumer under 12 CFR 1026.41(b), and referred to that periodic statement in the validation notice. Proposed comment 34(c)(5)–1 provided examples clarifying how debt collectors could comply with § 1006.34(c)(5). Consistent with the proposal's rationale, and for the reasons discussed below, the Bureau is adopting § 1006.34(c)(5) and its related commentary with a substantive modification and a clarification.

Some commenters recommended that the Bureau expand proposed § 1006.34(c)(5) to cover additional debt types. An industry trade group commenter stated that the Bureau should revise proposed § 1006.34(c)(5) to apply to all residential mortgage debt, including to transactions that are exempt from § 1026.41(b)'s periodic statement requirement, such as mortgage loans with certain consumers in bankruptcy. As discussed in detail in the section-by-section analysis of § 1006.34(c)(2)(viii), the Bureau received feedback that its proposed itemization would be incompatible with the account characteristics of debts in bankruptcy. Thus, this commenter suggested that the Bureau should revise proposed § 1006.34(c)(5) to permit a debt collector to reference the consumer's bankruptcy case and the filed or pending proof of claim instead of providing the itemization-related disclosures required by § 1006.34(c)(2). Other industry trade group commenters variously recommended that the special rule extend to reverse mortgages structured as open-end credit, home-equity lines of credit, and credit cards.

A consumer advocate commenter recommended that the Bureau revise proposed § 1006.34(c)(5) to apply only to debts that are currently subject to Regulation Z, 12 CFR 1026.41, to reduce the likelihood that a debt collector provides an outdated periodic statement. According to the commenter, TILA coverage is fluid and a significant amount of time can elapse between when the creditor provides a last periodic statement and when the debt collector provides a validation notice. This commenter recommended that the Bureau revise proposed § 1006.34(c)(5) to provide that the previous periodic statement must have been provided no more than 31 days before the validation notice is sent. The commenter also recommended that, if any entity other than the current servicer provided the most recent periodic statement, the debt collector must conduct a reasonable investigation to verify the accuracy of the prior entity's periodic statement or prepare its own periodic statement.

The Bureau declines to expand § 1006.34(c)(5) to cover additional debt types. For certain residential mortgage debt, the final rule permits debt collectors to provide a periodic statement that was provided under 12 CFR 1026.41(d)(3) in lieu of the information described in final § 1006.34(c)(2)(vi) through (viii) because those periodic statement disclosures are functionally equivalent to, and as useful for the consumer as, that itemization information. This special rule is not appropriate for the additional debt types recommended by commenters because those debt types are not subject to prescriptive disclosure regimes, such as Regulation Z. The Bureau doubts that disclosures used for those other debt types relate to information that is functionally equivalent to, or as useful as, the information § 1006.34(c)(2)(vi) through (viii) requires. For instance, mortgage loans with certain consumers in bankruptcy are exempt from § 1026.41(b)'s periodic statement requirement.[313] With respect to debts in bankruptcy in general, the Bankruptcy Code does not prescribe disclosure requirements for proofs of claim that are comparable to Regulation Z, 12 CFR 1026.41(d)(3). As discussed in the section-by-section analysis of § 1006.34(c)(2)(ix), reverse mortgages are not subject to prescriptive regulatory requirements for periodic statements. The periodic statement requirement in 12 CFR 1026.41(b) does not cover open-end consumer credit transactions,

[310] 15 U.S.C. 1692g(a)(1).

[311] The periodic statement requirement pursuant to 12 CFR 1026.41(b) does not apply to open-end consumer credit transactions, such as a home equity line of credit. *See* 12 CFR 1026.41(a)(1). Pursuant to 12 CFR 1026.41(e), certain types of transactions are exempt from § 1026.41(b)'s periodic statement requirement, including reverse mortgages, timeshare plans, certain charged-off mortgage loans, mortgage loans with certain consumers in bankruptcy, and fixed-rate mortgage loans where a servicer provides the consumer with a coupon book for payment. Further, small servicers as defined by 12 CFR 1026.41(e)(4)(ii) are exempt from the periodic statement requirement.

[312] 84 FR 23274, 23348 (May 21, 2019).

[313] *See* 12 CFR 1026.41(e).

including home-equity lines of credit.[314] With respect to credit card debt, no special accommodation is necessary as debt collectors can readily disclose the itemization information pursuant to § 1006.34(c)(2)(vi) through (viii).

The Bureau determines that § 1006.34(c)(5) should apply only to debts that are currently subject to Regulation Z, 12 CFR 1026.41. Modifying the proposal to this effect is appropriate to reduce the likelihood that a debt collector provides an outdated periodic statement, which may not provide information that is functionally equivalent to, or as useful as, the information described in § 1006.34(c)(2)(vi) through (viii). The Bureau therefore is revising proposed § 1006.34(c)(5) and its related commentary to provide that the special rule only applies to residential mortgage debt if a periodic statement is required under Regulation Z, 12 CFR 1026.41, at the time a debt collector provides the validation notice.[315]

Accordingly, the Bureau is finalizing § 1006.34(c)(5) as described above and is finalizing comment 34(c)(5)–1 with minor revisions for clarity and consistency with provisions of the final rule.

34(d) Form of Validation Information

34(d)(1) In General

The Bureau proposed § 1006.34(d)(1)(i) to require that the validation information described in § 1006.34(c) be conveyed in a clear and conspicuous manner. The Bureau reasoned that FDCPA section 809(a)'s required disclosures would be ineffective unless a debt collector disclosed them in a manner that was readily understandable to consumers.[316] The Bureau received no comments specifically addressing proposed § 1006.34(d)(1)(i). The Bureau therefore is finalizing it largely as proposed but renumbered as § 1006.34(d)(1)[317] and with a wording change solely for consistency with final § 1006.34(c). The Bureau adopts § 1006.34(d)(1) to implement and interpret FDCPA section 809(a) and pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors. The Bureau also adopts § 1006.34(d)(1) pursuant to its authority under section 1032(a) of the Dodd-Frank Act to prescribe rules to ensure that the features of consumer financial products and services are disclosed fully, accurately, and effectively. The Bureau finalizes this requirement on the basis that validation information is a feature of debt collection and this information must be readily understandable to be effectively and accurately disclosed.

Proposed Provision Not Finalized

As noted at the outset of the section-by-section analysis of § 1006.34, the Bureau proposed that debt collectors could use the model validation notice to comply with the disclosure requirements proposed in § 1006.34(a)(1)(i) and (d)(1).[318] In turn, the Bureau proposed § 1006.34(d)(1)(ii) to require that, if provided in a validation notice, the content, format, and placement of the validation information in § 1006.34(c) and the optional disclosures in § 1006.34(d)(3) must be substantially similar to the model validation notice. Proposed comment 34(d)(1)(ii)–1 explained that a debt collector could make certain changes as long as the resulting disclosures were substantially similar to the model validation notice, and it provided an example of a change that debt collectors may make to the validation notice if the consumer is deceased.

While some industry, industry trade group, and consumer advocate commenters supported proposed § 1006.34(d)(1)(ii), other industry and industry trade group commenters raised concerns that the proposed model validation notice would not accommodate all debt types and debt collection practices, suggesting that some debt collectors therefore would be unable to comply with proposed § 1006.34(d)(1)(ii). At least two commenters, including a debt buyer specializing in medical debt, stated that the proposed model validation notice was not well-suited for non-financial debts, such as medical debts. A number of commenters objected to the proposal because it would not allow debt collectors to combine multiple debts in a single validation notice or place multiple validation notices in one envelope. Commenters asked the Bureau to modify proposed § 1006.34(d)(1)(ii) to provide debt collectors more flexibility to customize validation notices to accommodate their business practices and the types of debts they collect.

As discussed in the section-by-section analysis of § 1006.34(d)(2), the Bureau has determined that a model validation notice will benefit consumers and industry. However, based in part on feedback from commenters, the Bureau also has determined that proposed § 1006.34(d)(1)(ii) was overly prescriptive. Proposed § 1006.34(d)(1)(ii) would have required any validation notice provided by a debt collector to be substantially similar to the model validation notice. Such a requirement could cause some debt collectors to face undue compliance challenges depending on their business practices and the types of debts they collect.

For this reason, the Bureau is not finalizing proposed § 1006.34(d)(1)(ii) and its related commentary. Instead, as discussed in the section-by-section analysis of § 1006.34(d)(2), the Bureau is adopting a more flexible framework in which debt collectors need not use either the model validation notice, specified variations of the model notice, or a substantially similar form, but debt collectors who do so will receive a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1).[319] This flexible framework is more consistent with model form safe harbors in other consumer financial regulations.[320] The Bureau determines that this new framework will accommodate industry without significantly increasing risks to consumers because the Bureau believes it is likely that, if possible, debt collectors will use the model validation notice, specified variations of the model notice, or a substantially similar form to receive the compliance safe harbor. The Bureau notes that a debt collector who provides the validation information in a form that is not substantially similar either to the model validation notice or to a specified variation of the model notice also is subject to the FDCPA section 807 prohibition on false or misleading representations and the FDCPA section 809(b) prohibition on overshadowing.

[314] *See* 12 CFR 1026.41(a)(1).

[315] Under § 1006.34(d)(2)(ii), a debt collector who uses the model validation notice and who also uses the special rule for certain residential mortgage debt under § 1006.34(c)(5) receives a safe harbor for use of the model notice except with respect to the disclosures that appear on the separate page.

[316] 84 FR 23274, 23348 (May 21, 2019). Section 1006.34(b)(1) defines clear and conspicuous, and the Bureau responded to comments on that definition in the section-by-section analysis of § 1006.34(b)(1).

[317] As discussed under the heading *Proposed Provision Not Finalized* in this section-by-section analysis, the Bureau is not finalizing proposed § 1006.34(d)(1)(ii) and therefore is finalizing proposed § 1006.34(d)(1)(i) as § 1006.34(d)(1).

[318] As discussed in the section-by-section analysis of § 1006.34(d)(1), the Bureau proposed § 1006.34(d)(1)(i) to require that required validation information be provided in a clear and conspicuous manner.

[319] The Bureau is relocating and repurposing some of the proposed text of § 1006.34(d)(1)(ii) and comment 34(d)(1)(ii)–1 to § 1006.34(d)(2). *See* the section-by-section analysis of § 1006.34(d)(2).

[320] 15 U.S.C. 1601 *et seq.*

34(d)(2) Safe Harbor

As discussed, the Bureau proposed § 1006.34(d)(2) to provide, pursuant to its authority under Dodd-Frank Act section 1032(b), that a debt collector who uses the model validation complies with the disclosure requirements of § 1006.34(a)(1)(i) and (d)(1).[321] Proposed comment 34(d)(2)–1 provided certain details regarding use of the model validation notice. Under proposed § 1006.34(d)(2) and as explained in proposed comment 34(d)(2)–1, although use of the model validation notice was not required, debt collectors would have received a safe harbor for compliance only if they used the model validation notice. Under proposed § 1006.34(d)(2), debt collectors would not have received a safe harbor if they used a form that was substantially similar to the model validation notice.

As discussed below, the Bureau is finalizing proposed § 1006.34(d)(2) and comment 34(d)(2)–1 with significant revisions to, among other things, provide that debt collectors may obtain a safe harbor for compliance with the validation information disclosure requirements by using either the model validation notice, specified variations of the model notice, or a substantially similar form. The Bureau is finalizing new commentary to provide additional details regarding the revised safe harbor framework.

Industry and industry trade group commenters overall supported providing a safe harbor to debt collectors who use the model validation notice. An industry and an industry trade group commenter stated that a safe harbor would reduce frivolous litigation and compliance costs. An industry commenter stated that not requiring debt collectors to use the model validation notice would help to ensure that debt collectors can provide validation notices in a manner consistent with their business practices and the debt types they collect.

Some industry commenters asked the Bureau to specify what optional disclosures could be added to the model notice. A number of industry and industry trade group commenters also asked the Bureau to further clarify what changes debt collectors could make to the model validation notice and still receive the safe harbor.

Relatedly, some industry and industry trade group commenters asked the Bureau to clarify the meaning of ''substantially similar,'' and two industry trade group commenters recommended that the Bureau adopt Regulation Z's definition of substantially similar. Some industry and industry trade group commenters recommended that the Bureau expand § 1006.34(d)(2) to provide that debt collectors who use the model validation notice comply with FDCPA section 807's prohibition on false or misleading statements and FDCPA section 809(b)'s overshadowing prohibition.[322]

A group of consumer advocate commenters stated that proposed § 1006.34(d)(2) was too broad. Specifically, according to the commenter, the safe harbor's cross-reference to § 1006.34(a)(1)(i) was overbroad because simply using the model validation notice does not mean that the debt collector sent the validation notice in an initial communication or within five days of the initial communication as required by § 1006.34(a)(1)(i). This commenter recommended that the Bureau remove the reference to § 1006.34(a)(1)(i) from § 1006.34(d)(2).

After considering this feedback, and to clarify each of the ways in which a debt collector may receive a safe harbor for compliance with the final rule's validation information disclosure requirements, the Bureau is finalizing § 1006.34(d)(2) and its related commentary with significant revisions, as follows.

34(d)(2)(i) In General

First, the Bureau is finalizing § 1006.34(d)(2)(i) to provide that, as proposed, a debt collector who uses the model validation notice receives a safe harbor for compliance with the final rule's validation information disclosure requirements. The Bureau determines that a safe harbor is appropriate because the model validation notice will effectively disclose information required by § 1006.34(c), and the safe harbor will incentivize debt collectors to use the model notice.

The Bureau agrees that the § 1006.34(d)(2) safe harbor should not cover delivery of the validation notice. The Bureau recognizes the risk that a debt collector could deliver the model validation notice in an ineffective manner and that, as a result, the notice would be delayed or never received by the consumer. The Bureau does not intend § 1006.34(d)(2) to provide a safe harbor in such a scenario. For this reason, the Bureau is finalizing § 1006.34(d)(2)(i) to specify that the safe harbor for use of the model notice covers only compliance with the information and form requirements of final § 1006.34(c) and (d)(1).

In response to comments requesting clarity about the use of optional disclosures on the model notice, the Bureau is finalizing § 1006.34(d)(2)(i) to squarely address how the safe harbor applies with respect to the § 1006.34(d)(3) optional disclosures.[323] First, the Bureau clarifies, as was intended in the proposal, that a debt collector may include any or all of the § 1006.34(d)(3) optional disclosures without losing the safe harbor pursuant to § 1006.34(d)(2). Specifically, final § 1006.34(d)(2)(i) provides that the model validation notice contains the validation information required by § 1006.34(c) and certain optional disclosures permitted by § 1006.34(d)(3). Section 1006.34(d)(2)(i) further provides that a debt collector who uses the model validation notice complies with the information and form requirements of § 1006.34(c) and (d)(1), including if the debt collector: Omits any or all of the optional disclosures shown on the model notice (*see* § 1006.34(d)(2)(i)(A)); or adds any or all of the optional disclosures described in § 1006.34(d)(3) that are not shown on the model notice (*see* § 1006.34(d)(2)(i)(B)), provided that any such optional disclosures are no more prominent than any of the required validation information.[324]

[321] 84 FR 23274, 23405 (May 21, 2019). As discussed elsewhere in part V, proposed § 1006.34(a)(1)(i) provided that debt collectors must send validation notices containing the information described in proposed § 1006.34(c) to consumers in a manner permitted by § 1006.42 (*i.e.,* in a manner reasonably expected to provide actual notice and in a form that the consumer may keep and access later). And proposed § 1006.34(d)(1) provided that debt collectors must provide such validation information clearly and conspicuously.

[322] *See* 15 U.S.C. 1692e; *see also* 15 U.S.C. 1692g(b) (''Any collection activities and communication during the 30-day period may not overshadow or be inconsistent with the disclosure of the consumer's right to dispute the debt or request the name and address of the original creditor.'').

[323] Proposed § 1006.34(d)(3) specified that a debt collector who used the model validation notice could include any of the optional disclosures along with the validation information without losing the § 1006.34(d)(2) safe harbor for compliance.

[324] The model validation notice includes the following optional disclosures permitted by § 1006.34(d)(3), each of which is described in more detail in the section-by-section analysis below: (1) Debt collector telephone contact information (*see* § 1006.34(d)(3)(i)); (2) reference code (*see* § 1006.34(d)(3)(ii)); (3) payment disclosures (*see* § 1006.34(d)(3)(iii)); (4) a statement referring to disclosures made under applicable law on the reverse of the validation notice (*see* § 1006.34(d)(3)(iv)(A)); (5) debt collector's website (*see* § 1006.34(d)(3)(v)(A)); (6) statement explaining how a consumer can dispute the debt or request original-creditor information electronically (*see* § 1006.34(d)(3)(v)(B)); (7) Spanish-language translation disclosures (*see* § 1006.34(d)(3)(vi)); (8) merchant brand information (*see* § 1006.34(d)(3)(vii)); and (9) for debt not related to a consumer financial product or service, the information specified in § 1006.34(c)(2)(iii) or

The requirement that any § 1006.34(d)(3) optional disclosures that are added to the model validation notice be no more prominent than any of the validation information is designed to ensure that any such optional disclosures do not overload consumers with information or distract them from the required validation information. A debt collector who chooses to include one or more of the § 1006.34(d)(3) optional disclosures that do not appear on the model validation notice, but who violates the no-more-prominent requirement, loses the safe harbor under § 1006.34(d)(2) and may violate § 1006.34 depending on the facts and circumstances.

As discussed in the section-by-section analysis of § 1006.34(c)(1), a consumer advocate commenter asked the Bureau to clarify what version of the FDCPA section 807(11) disclosure should appear on the validation notice: The longer, initial disclosure described in § 1006.18(e)(1) or the shorter, subsequent disclosure described in § 1006.18(e)(2). The model validation notice includes the disclosure required by § 1006.18(e)(1). The Bureau is adopting new comment 34(d)(2)(i)–1 to clarify that a debt collector who uses the model notice to provide a validation notice as described in § 1006.34(a)(1)(i)(B)—*i.e.,* a debt collector who provides the validation notice within five days of the initial communication—may replace the disclosure required by § 1006.18(e)(1) with the disclosure required by § 1006.18(e)(2) without losing the safe harbor provided by use of the model notice. Comment 34(d)(2)(i)–1 also refers to comment 34(c)(1)–1 for further guidance related to providing the disclosure required by § 1006.18(e) on a validation notice.

The Bureau declines to extend the § 1006.34(d)(2) safe harbor to cover compliance with FDCPA section 807's prohibition on false or misleading statements. A debt collector who uses the model validation notice is still capable of making false or misleading statements to consumers in the notice. For example, a debt collector using the model validation notice could include false or misleading information about the debt, such as an inflated current amount of the debt.

However, the Bureau agrees that debt collectors who use the model validation notice should have a safe harbor for compliance with FDCPA section 809(b)'s overshadowing prohibition. The Bureau provides a safe harbor to that effect in § 1006.38(b). The section-by-section analysis of § 1006.38(b) discusses this change in further detail.

34(d)(2)(ii) Certain Disclosures on a Separate Page

To conform with modifications in other sections of the Rule that permit debt collectors to make certain itemization-related disclosures on separate pages, the Bureau is finalizing new § 1006.34(d)(2)(ii). As discussed in the section-by-section analysis of § 1006.34(c)(2)(viii), when disclosing the itemization of the current amount of the debt, a debt collector has the option of disclosing that itemization on a separate page. As discussed in the section-by-section analysis of § 1006.34(c)(5), the final rule establishes a special rule for certain residential mortgage debt that permits a debt collector, subject to certain conditions, to provide a periodic statement under Regulation Z, 12 CFR 1026.41, instead of the itemization-related validation information required by § 1006.34(c)(2)(vi) through (viii).

Section 1006.34(d)(2)(ii) establishes how these provisions interact with the safe harbor provided by use of the model notice. Specifically, § 1006.34(d)(2)(ii) establishes that a debt collector who uses the model validation notice and makes certain disclosures on a separate page pursuant to § 1006.34(c)(2)(viii) or (5) may still receive a safe harbor for use of the model notice except with respect to the disclosures that appear on the separate page.

34(d)(2)(iii) Substantially Similar Form

As discussed in the section-by-section analysis of § 1006.34(d)(1), the Bureau has determined that debt collectors should receive a safe harbor for the information and form requirements of § 1006.34(c) and (d)(1) if they use a form that is substantially similar to the model validation notice. The Bureau determines that, so long as a form is substantially similar to the model notice, the validation information disclosures will remain effective; the Bureau therefore is finalizing § 1006.34(d)(2) to provide this flexibility for debt collectors.

For this reason, final § 1006.34(d)(2)(iii) provides that a debt collector who uses the model validation notice as described in § 1006.34(d)(2)(i) or (ii) may make changes to the form and retain a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1), provided that the form remains substantially similar to the model notice. (As discussed elsewhere in this Notice, a debt collector may comply with the requirements in § 1006.34(c) and (d)(1) without using the model validation notice.)

Final comment 34(d)(2)(iii)–1 provides details regarding the meaning of substantially similar, as requested by commenters, including examples of permissible changes. The Bureau believes that these are differences that may be useful to debt collectors and consumers and will not increase the risk of consumer harm.

One permissible change relates to deceased consumers. Comment 34(d)(2)(iii)–1 incorporates proposed comment 34(d)(1)(ii)–1, which discussed changes that debt collectors could make if the consumer were deceased. The Bureau proposed comment 34(d)(1)(ii)–1 to explain that a debt collector may make certain changes to the content, format, and placement of the validation information described in § 1006.34(c) as long as the resulting disclosures are substantially similar to the model notice. Proposed comment 34(d)(1)(ii)–1 also provided an example of a change that debt collectors may make to the model validation notice if the consumer is deceased.

The Bureau explained that, although the model validation notice will contain the name of the deceased consumer, some persons who are authorized to act on behalf of the deceased consumer's estate may be misled by the use of second person pronouns such as ''you'' in the validation notice. For example, the proposed model validation notice stated that ''you owe'' the debt collector. While nothing in the proposal would have prohibited a debt collector from including a cover letter to explain the nature of the validation notice, proposed comment 34(d)(1)(ii)–1 also clarified that a debt collector could modify inapplicable language in the validation notice that could suggest that the recipient of the notice was liable for the debt. For example, if a debt collector sent a validation notice to a person authorized to act on behalf of the deceased consumer's estate, and if that person was not liable for the debt, the debt collector could use the deceased consumer's name instead of ''you.''

(c)(3)(iv) (*i.e.,* name of the creditor to whom the debt was owed on the itemization date and Bureau's debt collection website, respectively) (*see* § 1006.34(d)(3)(viii)). The model validation notice does not include the following optional disclosures permitted by § 1006.34(d)(3): (1) Time-barred debt disclosures made under applicable law on the front of the validation notice (*see* § 1006.34(d)(3)(iv)(B)); (2) debt collector email address (*see* § 1006.34(d)(3)(v)(A)); and (3) affinity brand or facility name information (but, as noted above, merchant brand information is shown on the model notice in the same location) (*see* § 1006.34(d)(3)(vii)).

The Bureau received a few comments on proposed comment 34(d)(1)(ii)–1. One trade group commenter recommended that the Bureau allow debt collectors to replace second-person pronouns with references to the estate, such as ''the estate's bill.'' A group of consumer advocates stated that, although the comment's example would be appropriate in certain circumstances, the Bureau should provide an entirely separate model validation notice for decedent debt because, these commenters believed, debt collectors would be unlikely to diverge from the model notice. Two trade group commenters also asked the Bureau to create a second model validation notice for decedent debt.

The Bureau is incorporating proposed comment 34(d)(1)(ii)–1 into comment 34(d)(2)(iii)–1, which clarifies that a debt collector may make changes to the model validation notice and retain the safe harbor provided by use of the model notice. Because the example regarding decedent debt is illustrative, nothing in comment 34(d)(2)(iii)–1 prohibits a debt collector from making other substantially similar modifications, such as referring to the estate rather than ''you,'' while still retaining the safe harbor. As explained elsewhere in this section-by-section analysis, the Bureau declines to create separate model forms for certain types of debt. The Bureau has modified the model-form-safe-harbor framework under § 1006.34(d)(2) to afford debt collectors more flexibility to customize validation information to accommodate their business practices and the types of debts they collect. Within identified limits, debt collectors may make changes to the model validation notice and still meet the standard for a safe harbor under § 1006.34(d)(2).

Comment 34(d)(2)(iii)–1 also includes four new examples of other permissible changes: Relocating the consumer-response information required by § 1006.34(c)(4) to facilitate mailing; adding barcodes or QR codes, as long as the inclusion of such items does not violate § 1006.38(b); adding the date the form is generated; and embedding hyperlinks, if delivering the form electronically, which was proposed in comment 34(d)(2)–1.

The Bureau clarifies that, if a debt collector includes disclosures other than (1) the required validation information, (2) any optional disclosures described in § 1006.34(d)(3), or (3) any disclosures that, if included, still leave the form substantially similar in substance, clarity, and meaningful sequence to the model notice, then the safe harbor does not apply with respect to the entirety of the validation notice. Except as described in § 1006.34(d)(2)(ii), the Bureau has determined not to apply the safe harbor on a partial (*i.e.,* disclosure-by-disclosure) basis because it is not clear how disclosures other than those referenced above would interact with the validation information.[325] Final comment 34(d)(2)–1 clarifies that a debt collector who provides a validation notice that is neither a notice described in § 1006.34(d)(2)(i) or (ii), nor a substantially similar notice as described in § 1006.34(d)(2)(iii), does not receive a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1). The Bureau notes that a debt collector who adds disclosures to the model validation notice that are not referenced above nevertheless may be able to comply with the requirements in § 1006.34(c) and (d)(1), § 1006.38(b)(1), and other requirements of the FDCPA and this final rule.

Model Validation Notice

While the majority of industry commenters who commented on the topic supported the idea of a model form, some criticized the design of the proposed model validation notice. At least two industry commenters stated that the proposed model notice contained too much content and would overwhelm consumers. One commenter criticized the proposed model notice for departing from the prevailing industry design for validation notices. A number of identical or nearly identical comments suggested that consumers would confuse the proposed model notice for a government document, such as an IRS notice, but did not explain what in particular about the model notice they believed would cause such consumer confusion.

The Bureau's findings do not support the conclusions that the model notice contains too much content or will overwhelm consumers. The model validation notice was developed and validated over multiple rounds of consumer testing that support its efficacy and comprehensibility. The fact that the model validation notice departs from prevailing industry design is intended. As the proposal noted, many validation notices used today are confusing and lack sufficient information to help consumers recognize their debts or exercise their FDCPA verification rights.[326] With the model validation notice, the Bureau has developed an improved validation notice that benefits both consumers and debt collectors. In quantitative testing, the model validation notice consistently performed better than or equal to a ''status quo'' notice designed to resemble validation notices that some debt collectors use today.[327] The Bureau also disagrees that the model validation notice resembles a government document; the form clearly discloses that it is from a debt collector, not the government.

A number of consumer advocate and academic commenters asserted that the proposed model notice was not adequately tested. Some of these commenters stated that the Bureau's testing included too few participants to generate valid conclusions about the proposed model notice's efficacy or to evaluate the comprehension of consumers, particularly of the least sophisticated consumers. For instance, a consumer advocate commenter expressed concern that only 60 consumers were included in the cognitive and usability testing rounds.[328] Likewise, an academic commenter stated that the Bureau's consumer testing focused too heavily on observing what testing participants looked at on the model notice (based on the use of eye tracking techniques) at the expense of testing participants' comprehension of the notice. Another commenter stated that the Bureau should have tested more diverse groups, including consumers with limited English proficiency, students, older consumers, and consumers from more diverse socioeconomic backgrounds. Some consumer advocate and academic commenters recommended that the Bureau field test the proposed model notice with consumers with real debts. A consumer advocate expressed concern about the performance of certain aspects of the proposed model notice in quantitative testing, noting in particular that approximately 40 percent of respondents who received the model notice failed to identify the correct entity the consumer should pay.[329]

[325] As described in § 1006.34(d)(2)(ii), a debt collector who includes certain itemization-related disclosures on a separate page in the same communication with the validation notice, and who includes on the front of the notice the required statement referring to those disclosures, receives a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1) except with respect to the disclosures that appear on the separate page.

[326] *See* 84 FR 23274, 23338 (May 21, 2019).

[327] CFPB Quantitative Testing Report, *supra* note 31, at 13–16.

[328] *See* FMG Summary Report, *supra* note 29, at 5–7.

[329] Several comments in response to the May 2019 proposal also criticized the consumer testing as being outdated because, when that proposal was published, the most recent testing had occurred in 2016. However, the Bureau does not find any reason to believe that consumer understanding of the

The Bureau disagrees that the model notice was not adequately tested. The model validation notice was developed and validated over multiple rounds of testing between 2014 and 2020, and the Bureau determines that these multiple rounds of testing were sufficient to assess the model validation notice's efficacy and comprehensibility. Further, the Bureau disagrees that its testing focused on eye-tracking at the expense of comprehension testing as consumer comprehension of the model validation notice was assessed in three rounds of testing. The Bureau's testing used eye-tracking in conjunction with consumer responses to inform its conclusions.

The Bureau disagrees that it did not sample sufficiently diverse groups. The Bureau selected respondents with the goal of developing diverse testing pools that would serve as a proxy for the population at large. For example, in one round of usability testing, participants reflected a range of demographic characteristics broken down by race and ethnicity, household income, education level, and employment status.[330] With respect to criticism that the Bureau did not ''field test'' the model validation notice, testing the form with consumers with real debts would have been impractical. Regarding comments that the model validation notice did not perform well during the quantitative testing round, the Bureau disagrees. As noted above, in that testing round, the model validation notice consistently performed better than or equal to the status quo notice, including on the question of to whom the consumer should send a payment.[331]

Commenters provided feedback on specific aspects of the proposed validation notice, including the notice's disclosure of the FDCPA section 809(a)(4) dispute right. As discussed, § 1006.34(c)(3)(i), which implements FDCPA section 809(a)(4), requires debt collectors to: (1) Disclose the date the debt collector will consider the end date of the validation period; and (2) state that, if the consumer notifies the debt collector in writing on or before that date that the debt, or any portion of the debt, is disputed, the debt collector must cease collection of the debt, or the disputed portion of the debt, until the debt collector sends the consumer either verification of the debt or a copy of a judgment. The proposed model notice showed this disclosure as: ''Call or write to us by November 12, 2019, to dispute all or part of the debt . . . . If you write to us by November 12, 2019, we must stop collection on any amount you dispute until we send you information that shows you owe the debt.''

Some commenters criticized the phrase ''shows you owe the debt.'' Industry and industry trade group commenters stated that ''shows you owe the debt'' would require debt collectors to prove that consumers owe the debt. According to these commenters, this would modify the verification standard established by FDCPA section 809 and expose debt collectors to increased litigation risk.[332] Thus, these commenters recommended that the Bureau revise the proposed model notice to mirror the FDCPA's statutory text.[333] In contrast, a group of academic commenters stated that the verification standard established by case law is more robust than the phrase ''shows you owe the debt'' suggests.[334] These commenters expressed concerns that the proposed model notice would diminish the FDCPA's verification standard.

The Bureau is not changing the final model validation notice's disclosure of the FDCPA section 809(a)(4) dispute right. The Bureau does not intend to modify FDCPA section 809's verification standard and disagrees that the phrase ''shows you owe the debt'' has that effect. ''Shows you owe the debt'' is a plain-language phrase that the Bureau is adopting to improve consumer understanding. This rulemaking does not interpret what constitutes verification under FDCPA section 809.

The Bureau received comments on the model notice's description of the dispute rights under FDCPA section 809(a)(3) and (4). Under FDCPA section 809(a)(3), disputes can be made orally or in writing, which the proposed model notice showed in part as: ''Call or write to us by November 12, 2019, to dispute all or part of the debt.'' However, under FDCPA section 809(a)(4) and (b), requests for verification must be made in writing to have effect under the statute.[335] An academic commenter and at least two consumer advocates expressed concern that the proposed model notice's description of these dispute rights was too nuanced, and consumers would not understand that they must write to request verification. To address this concern, a commenter recommended that the Bureau revise the model notice to state, ''Call us to dispute. But if you do call, we may not be required to send information that shows you owe the debt.'' [336] An industry trade group expressed uncertainty about why the proposed model notice used the phrase ''call or write'' as opposed to ''write'' in different sentences.

The Bureau acknowledges that the dispute rights under FDCPA section 809(a)(3) and (4) may not be intuitive to some consumers. Nevertheless, the Bureau settled on the current phrasing in the model validation notice to emphasize the validation period end date as opposed to the actions—*i.e.,* calling or writing—that a consumer may take. In general, the model validation notice has tested well. The Bureau is concerned that revising or adding content to clarify the consequences of writing versus calling may undermine the overall efficacy of the form. Further, this clarification would be unnecessary in many cases. The Bureau expects that many consumers will visit the Bureau's website for more detailed information

model notice has changed since 2016, and the commenters did not provide any evidence to support such a claim. Moreover, since the May 2019 proposal, the Bureau has conducted two additional testing rounds.

[330] FMG Usability Report, *supra* note 28, at 85–87.

[331] In response to the question ''According to the notice, if Person A wanted to make a payment on the debt, who should he or she sent the payment to?'' approximately 60 percent of consumers who received the model validation notice answered correctly compared to approximately 40 percent of consumers who received a status quo notice. CFPB Quantitative Testing Report, *supra* note 31, at 14.

[332] An industry commenter stated that courts define verification narrowly and have not imposed a duty upon debt collectors to establish that a debt is owed. *See Walton* v. *EOS CCA,* 885 F.3d 1024, 1027–28 (7th Cir. 2018) (''The verification assures the consumer that the creditor actually made the demand the debt collector said it did and equips the consumer to evaluate the validity of the creditor's claim. It would be both burdensome and significantly beyond the Act's purpose to interpret § 1692g as requiring a debt collector to undertake an investigation into whether the creditor is actually entitled to the money it seeks.''); *Haddad* v. *Alexander, Zelmanski, Danner & Fioritto,* 758 F.3d 777 (6th Cir. 2014); *Dunham* v. *Portfolio Recovery Assocs.,* 663 F.3d 997, 1003 (8th Cir. 2001) (citing *Chaudhry* v. *Gallerizzo,* 174 F.3d 394 (4th Cir. 1999)).

[333] For instance, one commenter recommended that the model notice should state ''verifies the amount of the debt claimed'' instead of ''shows you owe the debt.''

[334] In *Haddad,* the court wrote that a verifying debt collector ''should provide the date and nature of the transaction that led to the debt, such as a purchase on a particular date, a missed rental payment for a specific month, a fee for a particular service provided at a specified time, or a fine for a particular offense assessed on a certain date.'' 758 F.3d at 786.

[335] While FDCPA section 809 requires a debt collector to honor only written verification requests, the Bureau understands that some debt collectors honor both written and non-written verification requests. Nothing in the FDCPA, the November 2020 Final Rule, or this rule prevents such debt collectors from continuing to do so.

[336] This recommendation is based on phrasing that the Bureau adopted for usability testing. As noted in the usability testing report, consumers who reviewed validation notices using this phrasing ''exhibited less confusion'' about the distinction between how a debt collector would be required to respond when receiving a dispute in writing or by telephone. *See* FMG Usability Report, *supra* note 28, at 55–56.

regarding consumer protections in debt collection.[337] However, to provide further clarity, the Bureau has reformatted how these dispute rights appear on the model validation notice. Specifically, the dispute rights now appear in separate bullets with bolded text for comprehension purposes.

Commenters provided feedback on the proposed model validation notice's original-creditor-information request disclosure pursuant to FDCPA section 809(a)(5). Section 1006.34(c)(3)(ii), which implements this provision, requires debt collectors to disclose the date the debt collector will consider the end date of the validation period and a statement that, if the consumer requests in writing on or before that date the name and address of the original creditor, the debt collector must cease collection of the debt until the debt collector sends the consumer the name and address of the original creditor, if different from the current creditor. The proposed model notice showed this disclosure as: ''Write to ask for the name and address of the original creditor. If you write by November 12, 2019, we will stop collection until we send you that information.'' An industry commenter stated that, by omitting the phrase ''if different from the current creditor,'' the proposed model notice would compel debt collectors to respond to original-creditor-information requests, even if the current creditor is the original creditor. A consumer advocate supported the omission, arguing that debt collectors should be required to respond to all original-creditor-information requests, even if the current creditor and the original creditor are the same.

The Bureau concludes that the model validation notice should include the statutory phrase ''if different from the current creditor'' when disclosing the original-creditor-information request right. Thus, as finalized, the model validation notice includes the phrase ''if different from the current creditor.'' Further, as discussed below, the Bureau is finalizing new § 1006.38(c)(2), which sets forth an alternative procedure that a debt collector may use to respond to a consumer's request for original-creditor information when the original creditor is the same as the current creditor.

Commenters recommended two other modifications to the proposed model notice. To emphasize the distinction between the debt collector and the creditor, an industry trade group commenter suggested that the Bureau revise the proposed model notice to emphasize that ''North South Group is a debt collector, *not a creditor.*'' Another industry trade group stated that the model notice should incorporate account information into the mini-*Miranda* disclosure, which would frontload information that would help consumers recognize alleged debts and thereby reduce the number of disputes debt collectors receive. An industry trade group commenter stated that the proposed model notice is not properly formatted for standard mailing envelopes. According to the commenter, § 1006.34(c)(4)'s consumer-response information section will not fit a standard glassine window return envelope.

The Bureau declines other recommendations to modify the model validation notice. The Bureau declines to specify that North South Group is ''not a creditor,'' as consumer testing indicates that consumers generally have a functional understanding that North South Group is a debt collector.[338] The Bureau declines to modify the debt collection disclosure required by FDCPA section 807(11) and § 1006.18(e) as finalized in the November 2020 Final Rule. The Bureau concludes that combining this statutory disclosure with account information would undermine its clarity and purpose. The Bureau declines to modify the model notice in response to feedback that the form is not properly formatted for standard mailing envelopes. Comment 34(d)(2)(iii)–1 clarifies that debt collectors may relocate the consumer-response information required by § 1006.34(c)(4) to facilitate mailing without losing the safe harbor provided by § 1006.34(d)(2). Thus, the Bureau determines that debt collectors will be able to format the form for mailing.

Various commenters requested that the Bureau publish additional model validation notices to address specific scenarios. Several consumer advocate commenters urged the Bureau to translate the model notice into other languages, including Spanish. An industry trade group commenter recommended that the Bureau develop a model notice that debt collectors could use with consumers who are not obligated on the debt, such as heirs, successors in interest, and consumers whose debts were discharged in bankruptcy. An industry commenter recommended that the Bureau create a model notice that omits all optional disclosures.

The Bureau declines to create additional model validation notice forms. As discussed earlier in this section-by-section analysis, the Bureau has modified the model-form-safe-harbor framework under § 1006.34(d)(2) to afford debt collectors more flexibility to customize validation information to accommodate their business practices and the types of debts they collect. Within identified limits, debt collectors may make changes to the model validation notice and still meet the standard for a safe harbor under § 1006.34(d)(2).

The Bureau is making an additional change to the model validation notice in response to testing. The statement required by § 1006.34(c)(3)(iv) informs the consumer that additional information regarding consumer protections in debt collection is available on the Bureau's website. The Bureau's most recent consumer testing indicated that a small number of participants who used the model validation notice were uncertain about where to find more information about consumers' protections in debt collection.[339] In response to this finding, the Bureau is modifying how the statement required by § 1006.34(c)(3)(iv) appears on the model validation notice to further emphasize this disclosure and the Bureau's website address.

34(d)(3) Optional Disclosures

Proposed § 1006.34(d)(3) provided that a debt collector could include the optional information described in § 1006.34(d)(3)(i) through (vi) when providing the validation information. The Bureau received no comments specifically addressing the language in proposed § 1006.34(d)(3). Commenters did suggest a variety of optional disclosures to add to § 1006.34(d)(3), such as barcodes or QR codes, the date a validation notice was created and sent, disclosures required by government creditors, and a disclosure notifying the consumer if the debt collector will

[337] If the debt collector is collecting debt related to a consumer financial product or service as defined in § 1006.34.2(f), a statement that informs the consumer that additional information regarding consumer protections in debt collection is available on the Bureau's website is required under § 1006.34(c)(3)(iv). If the debt collector is collecting debt other than debt related to a consumer financial product or service, such a statement is optional under § 1006.34(d)(3)(viii).

[338] During November 2020 usability testing, 98 percent of participants correctly identified North South Group as the correct party to send payments to. Further, participants generally understood that they could dispute the debt with North South Group. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 15.

[339] During the most recent round of qualitative testing, a few participants stated that they were unsure how to learn more about debt collection in general. For example, one participant was unable to find the statement required by § 1006.34(c)(3)(iv) on the model notice. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 13.

record telephone calls. Some of these suggested disclosures are permissible changes to the model notice under § 1006.34(d)(2)(iii) [340] or optional disclosures under § 1006.34(d)(3), and debt collectors can choose to make other suggested disclosures without safe harbor protection.

The Bureau is finalizing § 1006.34(d)(3) largely as proposed but with minor technical revisions for clarity and with one substantive revision to clarify that a debt collector who includes any of the optional disclosures receives the safe harbor described in § 1006.34(d)(2), provided that the debt collector otherwise uses the model validation notice or a variation of the model notice as described in § 1006.34(d)(2). This revision harmonizes § 1006.34(d)(3) with certain revisions to § 1006.34(d)(2) in the final rule.[341]

The Bureau is finalizing § 1006.34(d)(3) and the related provisions of § 1006.34(d)(2), including each of the optional disclosures that § 1006.34(d)(3) permits debt collectors to provide, to implement and interpret FDCPA section 809(a) and (b) and pursuant to its FDCPA section 814(d) authority to prescribe rules with respect to the collection of debts by debt collectors. The Bureau also is finalizing § 1006.34(d)(3) and the optional disclosures pursuant to its authority under section 1032(a) of the Dodd-Frank Act to prescribe rules to ensure that the features of consumer financial products and services are disclosed fully, accurately, and effectively.

34(d)(3)(i) Telephone Contact Information

Proposed § 1006.34(d)(3)(i) provided that a debt collector could include, along with the validation information, the debt collector's telephone contact information, including telephone number and the times that the debt collector accepts consumer telephone calls.

Two industry trade group commenters supported permitting debt collectors to disclose telephone contact information, with one such commenter noting that it would facilitate communication with consumers, and the other noting that some State laws require debt collectors to disclose telephone contact information. A group of consumer advocate commenters recommended that the Bureau make telephone contact information a mandatory disclosure.

The Bureau determines that debt collectors should be permitted to include their telephone contact information along with the validation information. Section 1006.34(d)(3)(i) will accommodate debt collectors who choose to communicate with consumers by telephone or who are required to disclose telephone contact information by applicable State law. The Bureau declines to make telephone contact information a mandatory disclosure because, while many debt collectors likely will provide telephone contact information, either by choice or because of a State-law requirement, some debt collectors may not need or want to do so. In such cases, consumers can use other contact information required in the validation information to contact the debt collector. For these reasons, the Bureau is finalizing § 1006.34(d)(3)(i) largely as proposed, except that the Bureau is finalizing the clarification that telephone contact information may include, for example, a telephone number as well as the times that the debt collector accepts consumer telephone calls, as new comment 34(d)(3)(i)–1, rather than in the regulation text as proposed.

34(d)(3)(ii) Reference Code

Many debt collectors include reference codes on validation notices for administrative purposes. The Bureau proposed § 1006.34(d)(3)(ii) to accommodate this practice by permitting a debt collector to include, along with the validation information, a number or code that the debt collector uses to identify the debt or the consumer. One industry commenter asked the Bureau to create a safe harbor for debt collectors to use an account number as a reference code, if that number is labeled as a reference code. The Bureau determines that creating such a safe harbor is unnecessary because debt collectors may use any number they choose as a reference code.[342] The Bureau therefore is finalizing § 1006.34(d)(3)(ii) as proposed.

34(d)(3)(iii) Payment Disclosures

The Bureau proposed in § 1006.34(d)(3)(iii) to allow debt collectors to include certain payment disclosures along with the validation information, provided that such disclosures were no more prominent than any of the validation information. Proposed § 1006.34(d)(3)(iii)(A) provided that a debt collector could include in the validation notice the statement ''Contact us about your payment options,'' using that phrase or a substantially similar phrase. Proposed § 1006.34(d)(3)(iii)(B) provided that a debt collector could include in the consumer-response information section described in proposed § 1006.34(c)(4) the statement, ''I enclosed this amount,'' using that phrase or a substantially similar phrase, payment instructions after that statement, and a prompt for a consumer to write in a payment amount. As discussed below, the Bureau is finalizing § 1006.34(d)(3)(iii) largely as proposed, but with certain revisions for clarity and consistency with other provisions in the final rule.

Industry and industry trade group commenters supported permitting debt collectors to include optional payment disclosures. One industry trade group stated that the proposed optional payment disclosures were appropriate because they would not violate FDCPA section 809(b)'s overshadowing prohibition.

Consumer advocate commenters generally objected to proposed § 1006.34(d)(3)(iii). A number of these commenters stated that consumers may perceive the payment disclosures as threatening, may misconstrue the disclosures as stating that consumers must make a payment to exercise their FDCPA dispute right, or may be confused about whether a payment is in their interest. Some commenters stated that the proposed disclosures could lead consumers to make payments that they might not otherwise have made, which some commenters noted could cause consumers to inadvertently revive previously time-barred debts. These commenters asked the Bureau not to finalize proposed § 1006.34(d)(3)(iii).

Some commenters suggested revisions to the proposed optional payment disclosures. Industry and industry trade group commenters recommended that the Bureau make the proposed optional payment disclosures more prominent. For example, some commenters suggested that the proposed optional payment disclosures be placed at the top of the consumer-response information section. An industry commenter recommended that the model validation notice include additional optional payment disclosures. Industry trade group commenters recommended that the Bureau permit debt collectors to include

[340] *See* comment 34(d)(2)(iii)–1 (examples of permissible changes to the model notice include (1) adding barcodes or QR codes as long as their inclusion does not violate § 1006.38(b), and (2) adding the date the form is generated).

[341] See the section-by-section analysis of § 1006.34(d)(2)(i), particularly the discussion of new § 1006.34(d)(2)(i)(A) and (B), which refers to the optional disclosures.

[342] Although § 1006.34(d)(3)(ii) permits debt collectors to use any number they choose as a reference code, debt collectors may be prohibited from using certain numbers by other applicable laws, such as privacy or data security rules or regulations.

instructions about how a consumer could make a payment by telephone, website, or alternative payment methods, such as debit card or ACH. Based on the concerns noted above about potential consumer misunderstanding of the payment disclosures, a group of consumer advocate commenters urged the Bureau to amend the validation notice to segregate the payment disclosures from the other disclosures and to eliminate the payment prompt on the consumer response form.

For the reasons discussed in the proposal, the Bureau determines that the proposed optional payment disclosures facilitate payments that may benefit both consumers and debt collectors. For consumers who recognize and choose to repay all or part of a debt, payment disclosures may make the transaction more efficient and convenient. In addition, for consumers who determine that they owe a debt but may not be ready to repay all of it at that time, payment disclosures may facilitate a discussion that can lead to repayment, settlement, or a payment plan.[343] The Bureau also has determined that the optional payment disclosures do not overshadow, and are not inconsistent with, consumers' verification rights pursuant to FDCPA section 809(b).[344]

Further, the Bureau's testing found that the model validation notice, which was tested with the optional payment disclosures, was not threatening or intimidating.[345] The Bureau disagrees that consumers will believe mistakenly that they must make a payment to exercise their verification rights. As the proposal noted, consumer testing indicates that consumers who encounter a payment disclosure on a validation notice understand that a payment is not required to dispute a debt.[346] The Bureau determines that inclusion of the neutral, non-threatening optional payment disclosures will not confuse consumers about whether making a payment is in their best interest. For the same reasons, the Bureau declines the suggestion to segregate the payment disclosures from the other disclosures and to eliminate the payment prompt on the consumer response form.

The Bureau declines recommendations to permit debt collectors to emphasize or highlight the payment option disclosures. Making the payment disclosures more prominent, as some industry commenters suggested, would reduce the efficacy of the model validation notice and risk overshadowing the validation information in violation of FDCPA section 809(b). The Bureau also determines that the optional payment disclosures in § 1006.34(d)(3)(iii)(A) and (B) are sufficient to facilitate payments[347] and that additional prominence for the payment disclosures is not justified. The Bureau also declines to permit debt collectors to include specific instructions about other payment methods. Section 1006.34(d)(3)(iii)(A) permits debt collectors to invite consumers to contact them about payment options, and debt collectors have the ability to provide information about alternative payment methods in subsequent communications.

For these reasons, this Bureau is finalizing § 1006.34(d)(3)(iii) largely as proposed but with several revisions for clarity and for consistency with other provisions in the final rule. First, the Bureau is deleting the sentences that specified that the optional payment disclosures in both § 1006.34(d)(3)(iii)(A) and (B) must be no more prominent than any of the validation information. These deleted sentences are unnecessary in view of revisions to the final rule in § 1006.34(d)(2) that apply to all of the optional disclosures, which makes the deleted sentences redundant.[348] In addition, the Bureau is adding language to clarify that a debt collector may choose to include either of the optional payment disclosures, or both of them. Lastly, the Bureau is finalizing § 1006.34(d)(3)(iii)(B) to clarify that the optional payment disclosure must appear ''below'' (rather than merely ''with'') the consumer-response information required by § 1006.34(c)(4)(i) and (ii).

Accordingly, final § 1006.34(d)(3)(iii) provides that debt collectors may include either or both of the following payment disclosures: (1) The statement, ''Contact us about your payment options,'' using that phrase or a substantially similar phrase; and (2) below the consumer-response information required by § 1006.34(c)(4)(i) and (ii), the statement, ''I enclosed this amount,'' using that phrase or a substantially similar phrase, payment instructions after that statement, and a prompt.

34(d)(3)(iv) Disclosures Under Applicable Law

Some States require specific disclosures to appear on validation notices. To enable debt collectors to comply with both § 1006.34(a)(1) and disclosure requirements under other applicable law, the Bureau proposed § 1006.34(d)(3)(iv) to permit a debt collector to include, on the front of the validation notice, a statement that other disclosures required by applicable law appear on the reverse of the form and, on the reverse of the validation notice, any such legally required disclosures. Proposed comment 34(d)(3)(iv)–1 provided examples of disclosure requirements that proposed § 1006.34(d)(3)(iv) would cover, including disclosures required by State statutes or regulations and disclosures required by judicial opinions or orders. For the reasons discussed below, the Bureau is adopting proposed § 1006.34(d)(3)(iv) with revisions, including the addition of new regulatory text subsections and commentary.

A number of industry and industry trade group commenters stated that the Bureau's proposal regarding disclosures required by other applicable law would either conflict with or not accommodate such disclosures. Commenters stated that some States require disclosures to appear on the front of a validation notice.[349] To address such concerns,

[343] *See* 84 FR 23274, 23350 (May 21, 2019).

[344] For example, during consumer testing, participants reported a variety of actions they thought they could take, and approximately 50 percent of respondents said they would confirm the debt is accurate before responding. Similarly, participants who received the model validation notice, which included the optional payment disclosures, generally understood from the notice how they could dispute the debt. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 11, 15.

[345] Participants with prior debt collection experience observed that the model notice was ''different'' than other validation notices they had received because the notice did not include threatening or intimidating language. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 10.

[346] FMG Usability Report, *supra* note 28, at 59–61.

[347] During usability testing, participants expressed an understanding that one purpose of the model validation notice was to solicit payment on a debt. When asked about their payment options based on the model validation notice, approximately 80 percent of participants stated that they would contact the debt collector by telephone, website, email, or write to explore payment options. *See* November 2020 Qualitative Testing Report, *supra* note 34, at 10,12.

[348] Final § 1006.34(d)(2)(i) states that certain optional disclosures permitted by § 1006.34(d)(3) are contained on the model notice; those optional disclosures satisfy the requirement to be no more prominent than any validation information. Final § 1006.34(d)(2)(i)(B) also permits inclusion of the optional disclosures described by § 1006.34(d)(3) that are not included on the model notice so long as they are no more prominent than any validation information; see the section-by-section analysis of § 1006.34(d)(2)(i) for more detail.

[349] Although these commenters cited various State laws requiring disclosures, they primarily referred to State laws requiring time-barred debt disclosures and revival disclosures. For example, one industry trade group commenter noted that Massachusetts, New Mexico, and New York State and City require disclosures about time-barred debt and revival that specifically or practically must appear on the front page of the validation notice.

commenters recommended that the Bureau allow debt collectors to include required State law disclosures on the front of the validation notice. One commenter, an industry trade group, urged the Bureau to allow for formatting flexibility for such State law disclosures while still affording safe harbor protection. At least one commenter suggested that the Bureau preempt State laws that require disclosures on the front of a validation notice.

The Bureau determines that, particularly with the changes to the model validation notice discussed in the section-by-section analysis, final § 1006.34(d)(3)(iv) generally will accommodate disclosures required by other applicable law.[350] As noted above, a few States require time-barred debt disclosures to appear on the front of a validation notice; time-barred debt disclosures are discussed further below. The Bureau is not aware that States specifically require any other disclosures to appear on the front of the validation notice; as such, the Bureau concludes that disclosures specifically required by applicable law, other than in those few instances relating to time-barred debt, can be accommodated on the reverse of the validation notice. The Bureau also is not aware of font size, prominence, or placement requirements established by State or other applicable law that final § 1006.34(d)(3)(iv) will not accommodate, as discussed further below. Further, the statement that § 1006.34(d)(3)(iv) permits on the front of a validation notice is consistent with State laws that require statements on the front of the notice.[351] The Bureau will continue to monitor whether disclosures required by other applicable law are inconsistent or conflict with § 1006.34 or Regulation F generally, and if such an inconsistency or conflict is identified, the Bureau will endeavor to take action to address it. The Bureau also reiterates that, unlike the proposal, the final rule does not require the validation notice to be substantially similar to the model validation notice; thus, if § 1006.34(d)(3)(iv) does not accommodate a disclosure required under State or other applicable law, then debt collectors can provide such a disclosure without necessarily violating the rule, but they would lose the § 1006.34(d)(2) safe harbor.

The Bureau has revised § 1006.34(d)(3)(iv) in response to feedback and for clarity. Final § 1006.34(d)(3)(iv)(A) provides that the debt collector may include, on the reverse of the validation notice, any disclosures that are specifically required by, or that provide safe harbors under, applicable law and, if any such disclosures are included, a statement on the front of the validation notice referring to those disclosures. Final comment 34(d)(3)(iv)(A)–1 clarifies that disclosures permitted by § 1006.34(d)(3)(iv)(A) include, for example, specific disclosures required by Federal, State, or municipal statutes or regulations, and specific disclosures required by judicial or administrative decisions or orders, including administrative consent orders. The comment also describes how such disclosures could include, for example, time-barred debt disclosures and disclosures that the current amount of the debt may increase or vary due to interest, fees, or other charges, provided that such disclosures are specifically required by applicable law.

The Bureau has revised § 1006.34(d)(3)(iv) and its accompanying commentary from the proposal to clarify the disclosures that are permitted by § 1006.34(d)(3)(iv). Specifically, the revisions clarify that the provision applies if a debt collector must comply with a specific disclosure requirement under Federal, State, or local law, or under a judicial or administrative decision or order. As such, the Bureau emphasizes that this provision is not intended to capture circumstances in which a debt collector is not providing a disclosure that is required under a specific law, decision, or order, but rather the debt collector is providing a disclosure to try to comply with a more general legal requirement. For example, if the debt collector were to add language to the validation notice to try to avoid a finding of an unfair, deceptive, or abusive practice under Dodd-Frank Act section 1031 or the FDCPA, that is not an optional disclosure covered by § 1006.34(d)(3)(iv). Debt collectors are not precluded from making such disclosures, but they will not receive the safe harbor under § 1006.34(d)(2).

The Bureau has made modifications to the final rule, moreover, to provide additional flexibility with respect to time-barred debt disclosures, in response to feedback to the proposal. Under new § 1006.34(d)(3)(iv)(B),[352] if a debt collector is collecting time-barred debt, the debt collector may include on the front of the validation notice any time-barred debt disclosure that is specifically required by, or that provides a safe harbor under, applicable law, provided that applicable law specifies the content of the disclosure.[353] New comment 34(d)(3)(iv)(B)–1 clarifies that, for example, if applicable State law requires a debt collector who is collecting time-barred debt to disclose to the consumer that the law limits how long a consumer can be sued on a debt and that the debt collector cannot or will not sue the consumer to collect it, the debt collector may include that disclosure on the front of the validation notice. New comment 34(d)(3)(iv)(B)–1 also includes a cross-reference to the definition of time-barred debt under § 1006.26(a)(2) and clarifies that, for purposes of § 1006.34(d)(3)(iv)(B), time-barred debt disclosures may include disclosures about revival of debt collectors' right to bring a legal action to enforce the debt. The Bureau concludes that providing additional flexibility to debt collectors to make these optional disclosures either on the front or reverse of the validation notice is warranted in view of circumstances in which it may be difficult to discern under applicable State or local law whether time-barred debt disclosures must appear on the front of a validation notice. Moreover, the Bureau is finalizing § 1006.34(d)(3)(iv)(B) in view of the

[350] As discussed in the section-by-section analysis of § 1006.34(d)(2), the final rule permits a debt collector who uses the model validation notice, specified variations of the model notice, or a substantially similar form to receive a safe harbor. Moreover, as discussed below in this section-by-section analysis of § 1006.34(d)(3)(iv), the Bureau is modifying how the statement required by § 1006.34(d)(3)(iv) is disclosed on the model validation notice to mirror language on a disclosure required under Wisconsin law.

[351] *See, e.g.,* Colo. Rev. Stat. sec. 12–14–105(3)(c) (''In its initial written communication to a consumer, a collection agency shall include the following statement: 'For information about the Colorado Fair Debt Collection Practices Act, see *www.ago.state.co.us/cadc/cadcmain.cfm*.' If the notification is placed on the back of the written communication, there shall be a statement on the front notifying the consumer of such fact.''); Wis. Admin. Code DFI-Bkg sec. 74.13 (''Unless the initial communication is written and contains the following notice or the debtor has paid the debt, a licensee shall send the debtor the following notice within 5 days after the initial communication with a debtor: 'This collection agency is licensed by the Division of Banking in the Wisconsin Department of Financial Institutions, *www.wdfi.org*.' . . . here the notice required by sub. (1) is printed on the reverse side of any collection notice or validation sent by the licensee, the front of such notice shall bear the following statement in not less than 8 point type: ''Notice: See Reverse Side for Important Information.'').

[352] To permit this additional flexibility for time-barred debt disclosures as distinguished from other disclosures made under applicable law, the final rule has re-numbered proposed § 1006.34(d)(3)(iv), which would have specified that the applicable law disclosures are placed on the reverse side of the validation notice only, as § 1006.34(d)(3)(iv)(A).

[353] As with other disclosures required by or providing safe harbors under applicable law, debt collectors can also make the time-barred debt disclosures on the reverse of the validation notice pursuant to § 1006.34(d)(3)(iv)(A). See comment 34(d)(3)(iv)(A)–1, which gives an example of a time-barred debt disclosure as a disclosure permitted by § 1006.34(d)(3)(iv)(A).

Bureau's decision not to finalize a requirement for debt collectors to provide disclosures relating to time-barred debt or revival laws, described in more detail in the section-by-section analysis of § 1006.26.

The Bureau received feedback about modifying the scope of proposed § 1006.34(d)(3)(iv). An industry trade group commenter stated that the Bureau should limit § 1006.34(d)(3)(iv) to State laws and exclude disclosures required by judicial decisions or orders. According to the commenter, courts should not be permitted to dictate non-standard disclosures that would limit the efficacy of the model validation notice and result in validation notices that vary by jurisdiction. This commenter asserted that permitting courts to vary the model validation notice would be inconsistent with the framework in other consumer financial laws and regulations, such as TILA and Regulation Z, which do not permit courts to add disclosures to model forms. A group of consumer advocate commenters asked the Bureau to prohibit debt collectors from including disclosures that are permitted, but not required, by applicable law, because including all possible disclosures would overwhelm consumers. On the other hand, an industry trade group commenter asked the Bureau to allow debt collectors to include such disclosures.

The Bureau determines that § 1006.34(d)(3)(iv) should cover disclosures required pursuant to judicial or administrative decisions or orders, including administrative consent orders. Permitting disclosures required by judicial or administrative decisions or orders to appear, like any State-law-required disclosures, on the reverse of a validation notice will neither undermine the efficacy of the model validation notice nor create validation notices that significantly vary by jurisdiction, other than on the reverse of the notice. Further, the Bureau concludes that permitting judicially mandated disclosures to appear on validation notices is not inconsistent with other consumer financial laws, as some commenters suggested. For instance, the Bureau understands that nothing in TILA and its implementing Regulation Z prohibit, as those commenters appeared to believe, creditors from making disclosures required pursuant to judicial orders or decisions. As noted above, final comment 34(d)(3)(iv)(A)–1 clarifies that the disclosures permitted by § 1006.34(d)(3)(iv) include specific disclosures required by judicial decisions or orders.

In response to feedback, the Bureau also is finalizing § 1006.34(d)(3)(iv)(A) and comment 34(d)(3)(iv)(A)–1 to permit debt collectors to include disclosures that provide safe harbors under applicable law without losing the safe harbor for compliance under § 1006.34(d)(2). Such disclosures can mitigate legal risks for debt collectors and reduce the potential for consumer harm.[354] On the other hand, the Bureau declines to allow debt collectors to include disclosures on the validation notice that are merely permitted by other applicable law and still retain the safe harbor.[355] Such disclosures may be irrelevant to consumers, and their inclusion on the validation notice may overwhelm consumers or overshadow more relevant disclosures. Nevertheless, as noted elsewhere, a debt collector who included such a disclosure would not necessarily violate Regulation F; that debt collector would, however, be outside the safe harbor for compliance.

Some commenters suggested that the Bureau revise the text and placement of the § 1006.34(d)(3)(iv) disclosure that appeared on the model validation notice. An industry trade group commenter noted that Wisconsin law allows disclosures on the reverse of the notice but requires the statement, ''Notice: See Reverse Side for Important Information.'' A group of consumer advocate commenters suggested that disclosures required by applicable law should be separately labeled as ''Disclosures Required by Your State'' and ''Disclosures Required by Local Federal Courts.''

Relatedly, some commenters noted that some State laws include specific prominence or font size requirements for validation notice disclosures. A comment letter from two associations of State regulatory agencies expressed concerns that proposed § 1006.34(d)(3)(iv), as disclosed on the model validation notice, was not sufficiently prominent. In particular, these commenters objected that the statement about disclosures required by applicable law appeared below the § 1006.34(d)(3)(iii)(A) payment disclosure.

In response to feedback, the Bureau is including a new comment 34(d)(3)(iv)(A)–2 to clarify how the disclosure described in § 1006.34(d)(3)(iv)(A) may appear depending on the delivery mechanism. The comment clarifies that, if a debt collector includes disclosures pursuant to § 1006.34(d)(3)(iv)(A), the debt collector must include a statement on the front of the validation notice referring to those disclosures; and a debt collector may comply with the requirement to refer to the disclosures by including on the front of the validation notice the statement, ''Notice: See reverse side for important information,'' or a substantially similar statement. The comment further notes that if, as permitted by comment 34(d)(3)(iv)(A)–1, a debt collector places the disclosures below the content of the validation notice, the debt collector may comply with the requirement to refer to the disclosures by stating, ''Notice: See below for important information,'' or a substantially similar statement.

In response to feedback, the Bureau is also modifying how the statement required by § 1006.34(d)(3)(iv) is disclosed on the model validation notice. Specifically, the § 1006.34(d)(3)(iv) statement appears on the final model notice as: ''Notice: See Reverse Side for Important Information.'' [356] The Bureau finds that this phrase is clearer, more conspicuous, and more likely to encourage consumer action than the proposed phrase, ''Review state law disclosures on reverse side, if applicable.'' Finally, the Bureau declines the suggestion to require debt collectors to label which disclosures are included pursuant to State law and which are included pursuant to judicial orders and decisions. That distinction likely makes little practical difference to consumers.

The Bureau also determines that the § 1006.34(d)(3)(iv) disclosure should be more prominent than in the proposed model validation notice, in part to account for the fact noted by some commenters that disclosures required by other applicable law may have prominence requirements, including clear and conspicuous requirements. The Bureau therefore has modified the model validation notice to further emphasize the § 1006.34(d)(3)(iv) disclosure. Specifically, in contrast to the proposed model validation notice, on which the disclosure appeared in regular font in the middle of a list of other disclosures, the disclosure appears on the final model validation notice

[354] *Avila,* 817 F.3d at 76 (adopting the safe harbor approach for debt collectors disclosing the amount of the debt when the balance may increase due to interest and fees adopted in *Miller* v. *McCalla, Raymer, Padrick, Cobb, Nichols, & Clark, LLC,* 214 F.3d 872, 876 (7th Cir. 2000)).

[355] As discussed earlier in this section-by-section analysis, § 1006.34(d)(3)(iv) has been revised in the final rule to clarify that the optional disclosures are those that are ''specifically'' required by applicable law or that provide a safe harbor under applicable law.

[356] The Bureau based this statement on a Wisconsin disclosure requirement. *See* Wis. Admin. Code DFI-Bkg sec. 74.13.

underlined and in bold font and separated from other disclosures.

Commenters sought additional guidance about what constitutes the ''reverse side'' of the validation notice. Two industry trade group commenters recommended that the Bureau interpret ''reverse side'' as synonymous with ''next page'' to allow debt collectors to use a second page to provide disclosures required by other applicable law. Relatedly, one commenter stated that requiring a debt collector to print on both sides of a validation notice would increase costs. Two associations of State regulatory agencies asked the Bureau to clarify where State law disclosures should be placed on validation notices delivered electronically, since disclosures delivered electronically will not have a reverse side.

The Bureau recognizes that the meaning of ''on the reverse'' may vary by delivery method and format and that clarification is warranted, particularly as to validation notices delivered electronically. As such, the Bureau is adopting new comment 34(d)(3)(iv)(A)–1, which clarifies, in relevant part, that if a debt collector provides a validation notice in the body of an email, the debt collector may, in lieu of including the disclosures permitted by § 1006.34(d)(3)(iv)(A) on the reverse of the validation notice, include them in the same communication below the content of the validation notice. Furthermore, as discussed above, comment 34(d)(3)(iv)(A)–2 notes that, if a debt collector places the disclosures below the content of the validation notice, the debt collector may comply with the requirement to refer to the disclosures by including the statement, ''Notice: See below for important information,'' or a substantially similar statement. These commentary provisions, therefore, address circumstances in which the validation notice is delivered in the body of an email.

The Bureau declines to permit debt collectors to place disclosures required by other applicable law on a second page while maintaining the § 1006.34(d)(2) safe harbor, as some commenters requested. In § 1006.34(d)(2)(ii), the Bureau specifies two narrow circumstances in which debt collectors are permitted to include validation information on a second page because such information, presented on a second page, is likely to benefit consumers.[357] And, in both cases, if a debt collector includes the disclosures on a second page, the debt collector loses the § 1006.34(d)(2) safe harbor with respect to the second page. The Bureau determines that it is unwarranted to provide a safe harbor that would be more expansive both in scope and protection than the other targeted exceptions to debt collectors providing other applicable law disclosures on a second page. The Bureau notes that debt collectors may include such disclosures on a second page without necessarily violating the rule.

The Bureau is making one additional change not in response to comments. Section 1006.34(d)(3)(iv)(A) provides, in relevant part, that disclosures made under § 1006.34(d)(3)(iv) must not appear directly on the reverse of the consumer-response information required by § 1006.34(c)(4), which appears on the front of the notice. This revision is included to ensure that debt collectors who choose to make the optional disclosures under § 1006.34(d)(3)(iv) do not provide the disclosures in a place where the disclosures would be returned with the consumer-response information.

The Bureau notes that if, as permitted by § 1006.34(d)(3)(iv), a debt collector includes on the front of a validation notice the required statement regarding disclosures under other applicable law (*i.e.,* ''Notice: See reverse side for important information''), the debt collector must actually place such disclosures on the reverse. Conversely, a debt collector may not include disclosures under other applicable law on the reverse of a validation notice without including the statement about those disclosures on the front of the validation notice. The Bureau intended this effect when it proposed § 1006.34(d)(3)(iv) and notes it here for clarity.

Accordingly, the Bureau is finalizing § 1006.34(d)(3)(iv) and its related commentary with both substantive revisions and minor wording changes.

34(d)(3)(v) Information About Electronic Communications

Proposed § 1006.34(d)(3)(v) provided that debt collectors could include certain information about electronic communications along with the validation information. First, proposed § 1006.34(d)(3)(v)(A) provided that a debt collector could include the debt collector's website and email address. Second, proposed § 1006.34(d)(3)(v)(B) provided that a debt collector could include, for validation information not provided electronically, the statement described in § 1006.34(c)(3)(v) explaining how a consumer could take the actions described in § 1006.34(c)(4) and § 1006.34(d)(3) electronically.[358] One industry commenter supported proposed § 1006.34(d)(3)(v), and the Bureau is finalizing it as proposed, with technical revisions to reflect conforming changes to final § 1006.34(c)(3)(v). For example, final § 1006.34(d)(3)(v)(B) no longer contains a reference to § 1006.34(d)(3) because final § 1006.34(c)(3)(v) itself no longer refers to § 1006.34(d)(3).[359]

34(d)(3)(vi) Spanish-Language Translation Disclosures

Proposed § 1006.34(d)(3)(vi) provided that a debt collector could include, along with the validation information, optional Spanish-language disclosures that consumers could use to request a Spanish-language validation notice. The proposal stated that Spanish-speaking LEP consumers may benefit from a Spanish-language disclosure informing them of their ability to request a Spanish-language translation, if a debt collector chooses to make such a translation available.[360] The proposal stated that debt collectors may wish to provide validation information in Spanish, as doing so may facilitate their communications with consumers.

Consumer advocate commenters generally supported permitting debt collectors to provide certain Spanish-language disclosures along with the validation information. Some consumer advocate commenters recommended that the Bureau also require debt collectors to provide the disclosures described in proposed § 1006.34(d)(3)(vi). A group of consumer advocate commenters urged the Bureau to require a debt collector to send a translated validation notice if the debt collector receives a request from a consumer seeking information in the

[357] Final § 1006.34(d)(2)(ii) allows a second page for debt collectors to provide information that would otherwise be provided in a relatively abbreviated itemization of the debt (*i.e.,* itemization on a second page and for the special rule regarding certain residential mortgage debt). This narrow exception allows the debt collector to potentially provide significantly more information to the consumer on a second page.

[358] Proposed § 1006.34(c)(3)(v) provided that such a statement was required validation information for validation notices provided electronically.

[359] As discussed in the section-by-section analysis of § 1006.34(c)(3)(v), the final rule does not require debt collectors who provide validation notices electronically to include statements explaining how consumers can take the actions described in § 1006.34(d)(3) electronically.

[360] Spanish speakers represent the second-largest language group in the United States after English speakers. As of 2016, 40 million residents in the United States ages five and older spoke Spanish at home. *See* U.S. Census Bureau, *Profile America for Facts for Features CB17–FF.17: Hispanic Heritage Month 2017,* at 4 (Oct. 17, 2017), *https://www.census.gov/newsroom/facts-for-features/2017/hispanic-heritage.html.*

consumer's preferred language, including a request received using the proposed tear off portion of the validation notice.

An industry commenter supported proposed § 1006.34(d)(3)(vi) on the understanding that the Spanish-language disclosures would be optional. According to the commenter, requiring debt collectors to provide foreign language disclosures would entail significant costs. An industry commenter and an industry trade group commenter asked the Bureau to clarify whether providing the proposed § 1006.34(d)(3)(vi) disclosures would obligate a debt collector to provide future communications in Spanish to the consumer. Some commenters raised questions about whether the validation period would be paused when a consumer requests a Spanish-language translation of the validation notice and then restart when it is received, with a local government commenter supporting such a revision in the final rule.

The Bureau declines to make the Spanish-language disclosures described in § 1006.34(d)(3)(vi) mandatory. A requirement to provide the § 1006.34(d)(3)(vi) disclosures, standing alone, would not be overly burdensome because the translation language is precisely described in the regulation and is also included on the model validation notice. However, the content of those disclosures means that mandating them would effectively compel debt collectors to provide translated validation notices to certain consumers (*i.e.,* consumers who respond to the § 1006.34(d)(3)(vi) disclosures by requesting a Spanish-language validation notice).[361] As discussed in the proposal, the Bureau did not propose to require debt collectors to provide translated validation notices because of the associated costs of such a requirement,[362] and the Bureau is declining to finalize such a requirement in this final rule.[363]

A debt collector who provides the optional disclosure described in § 1006.34(d)(3)(vi) must honor a consumer's request for a translated validation notice or risk violating FDCPA section 807. However, the proposal did not expressly state that the debt collector would be obligated to provide the Spanish-language translation of the validation notice in this circumstance. The proposal only implied such an obligation. To make the rule clearer, the Bureau is finalizing a new § 1006.34(e)(2), which provides that a debt collector who includes in the validation information either or both of the optional disclosures described in § 1006.34(d)(3)(vi), and who thereafter receives a request from the consumer for a Spanish-language validation notice, must provide the consumer a validation notice completely and accurately translated into Spanish.[364] The Bureau clarifies that, other than with respect to § 1006.34(e)(2), nothing in the rule obligates a debt collector to provide future communications in Spanish solely because the debt collector provided a disclosure described in § 1006.34(d)(3)(vi) in Spanish.

Regarding the commenters who asked for clarification about, or supported, restarting the validation period when the consumer requests a Spanish-language validation notice, the Bureau declines to mandate such a change but notes that debt collectors who voluntarily restart the validation period after providing a copy of the Spanish-language validation notice following the consumer's request do not violate the FDCPA or Regulation F.

For these reasons, the Bureau is finalizing § 1006.34(d)(3)(vi) largely as proposed but with a revision to clarify that a debt collector may include either of the optional Spanish-language translation disclosures, or both of them.

34(d)(3)(vi)(A)

Proposed § 1006.34(d)(3)(vi)(A) provided that a debt collector could include a statement in Spanish informing a consumer that the consumer could request a Spanish-language validation notice. Specifically, the Bureau proposed in § 1006.34(d)(3)(vi)(A) to permit the statement, ''Póngase en contacto con nosotros para solicitar una copia de este formulario en español,'' using that phrase or a substantially similar phrase in Spanish. In English, this phrase means, ''You may contact us to request a copy of this form in Spanish.'' The proposal clarified that a debt collector who provided this optional disclosure could also include supplemental information in Spanish specifying how a consumer could request a Spanish-language validation notice. Proposed comment 34(d)(3)(vi)(A)–1 explained that, for example, a debt collector could provide a statement in Spanish that a consumer could request a Spanish-language validation notice by telephone or email.

Consumer advocate commenters supported the Spanish-language disclosure described in proposed § 1006.34(d)(3)(vi)(A). The Bureau received no other comments specifically addressing the disclosure. Accordingly, the Bureau is finalizing § 1006.34(d)(3)(vi)(A) and its related commentary as proposed, with only minor wording changes.

34(d)(3)(vi)(B)

Proposed § 1006.34(d)(3)(vi)(B) provided that debt collectors could include in the consumer-response information section of the validation notice a statement in Spanish that a consumer could use to request a Spanish-language validation notice. Specifically, the Bureau proposed in § 1006.34(d)(3)(vi)(B) to permit debt collectors to include the statement, ''Quiero esta forma en español,'' using that phrase or a substantially similar phrase in Spanish. In English, this phrase means, ''I want this form in Spanish.'' Proposed § 1006.34(d)(3)(vi)(B) would have required this statement to be next to a prompt that the consumer could use to request a Spanish-language validation notice.

Consumer advocate commenters generally supported the Spanish-language disclosure described in proposed § 1006.34(d)(3)(vi)(B). However, a group of consumer advocate commenters stated that the Spanish translation in proposed § 1006.34(d)(3)(vi)(B) was inaccurate. Specifically, the commenters stated that the correct Spanish translation of ''form'' is ''formulario,'' not ''forma.'' The word ''forma'' appeared in both proposed § 1006.34(d)(3)(vi)(B) and in the sample disclosure on the proposed model validation notice. The Bureau finds that ''formulario,'' not ''forma,'' is the correct Spanish translation of ''form.'' The Bureau also finds that, for gender agreement, § 1006.34(d)(3)(vi)(B) should read ''este formulario,'' not ''esta formulario.''

The Bureau is finalizing § 1006.34(d)(3)(vi)(B), its related commentary, and the disclosure on the model validation notice as proposed, but with revisions to correct the translation errors and with other, minor wording changes for consistency with other provisions of the final rule.

34(d)(3)(vii)

The Bureau proposed § 1006.34(c)(2)(iii) to provide that the merchant brand, if any, associated with a credit card debt, to the extent available to the debt collector, is validation information that must be provided to the consumer. Proposed comment 34(c)(2)(iii)–1 provided an example of

[361] 15 U.S.C. 1692e.

[362] 84 FR 23274, 23352 (May 21, 2019).

[363] *See* the section-by-section analysis of § 1006.34(e).

[364] *Id.*

merchant brand information that the Bureau initially determined would be available to a debt collector and that, therefore, would be required on a validation notice.

For the reasons discussed below, the Bureau is not finalizing § 1006.34(c)(2)(iii) and its related commentary. Instead, the Bureau is restructuring and renumbering proposed § 1006.34(c)(2)(iii) as a new optional disclosure under § 1006.34(d)(3)(vii), which permits, but does not require, debt collectors to disclose the merchant brand, affinity brand, or facility name, if any, associated with the debt (and does not limit the optional disclosure to credit card debt).

Industry, industry trade group, and consumer advocate commenters uniformly agreed that, if available, merchant brand information may help consumers recognize debts. For example, consumer advocate commenters stated that, in the case of a store-branded credit card, a consumer may not associate the debt with the original creditor (often a bank) and may be more likely to recognize the merchant, whose name appears on the credit card. A group of consumer advocate commenters asserted that such information was important, impliedly suggesting that the Bureau require its disclosure as part of the validation information.

Although supportive of the proposed disclosure in principle, some industry trade group commenters asked the Bureau to clarify the circumstances in which merchant brand information would be deemed available. According to these commenters, whether merchant brand information is available may be unclear because it is not always identifiable in a consumer's file or a creditor may not have provided it. One industry trade group commenter stated that the proposed provision requiring disclosure of merchant brand information for credit cards as part of the validation information would better serve consumers and reduce compliance costs if the provision included broader categories than merchant brand names and was an optional, rather than mandatory, disclosure.

The Bureau received other comments about expanding the scope of proposed § 1006.34(c)(2)(iii). An industry trade group commenter recommended that § 1006.34(c)(2)(iii) also encompass affinity brand information (*e.g.,* the name of a college). Other commenters recommended that debt collectors be permitted or required to disclose the facility name associated with a medical debt (*e.g.,* the name of a hospital). According to commenters, a consumer may be more likely to recognize a facility where treatment was provided than the healthcare service provider that is the creditor. A group of consumer advocate commenters noted that increasingly a hospital name may act as a brand for an umbrella of service providers and thus should be treated in the same manner as a merchant brand.

The Bureau determines that merchant brand information may help consumers recognize debts. However, the Bureau agrees with the feedback that whether merchant brand information is available may not always be clear to a debt collector. This ambiguity is particularly likely with respect to debts that have been sold or transferred multiple times. Furthermore, not all creditors will have an associated merchant brand, at least one that is distinct from the creditor name.

Accordingly, in lieu of finalizing the requirement in proposed § 1006.34(c)(2)(iii), the Bureau is adopting new § 1006.34(d)(3)(vii), which permits, rather than requires, debt collectors to disclose the merchant brand information, if any, associated with a debt. By making merchant brand an optional disclosure, the Bureau eliminates a source of potential ambiguity that could expose debt collectors to legal risk. In addition, notwithstanding this modification, the Bureau concludes that debt collectors will be incentivized to provide merchant brand information if it is available. Commenters uniformly agreed that merchant brand information helps consumers recognize debts.[365] Thus, debt collectors likely will benefit from including merchant brand information if possible. Providing merchant brand information will also benefit consumers by allowing them to more easily identify debts, determine whether they owe them, and avoid the confusion resulting from seeing a validation notice with an unfamiliar name (which potentially leads to the consumer ignoring the notice).

The Bureau finds that affinity brand information and facility name information also may help consumers recognize debts they owe. Whereas a merchant brand can be generally understood as the labelling or branding of a commercial entity, such as a retail store, an affinity brand may reflect the labelling or branding of an entity that is not necessarily commercial but one with which the consumer has a relationship. For example, a higher education institution (*e.g.,* ''College of Columbia'') or a charity may be associated with a consumer financial product (*e.g.,* a credit card provided by ''ABC Bank'') as an affinity brand. *See* comment 34(d)(3)(vii)–2. Moreover, facility name information (*e.g.,* ''ABC Hospital'') may prove more recognizable to consumers with respect to a medical debt than the name of, for example, the physicians group or laboratory that is the actual creditor (particularly if the consumer has one appointment or procedure at one facility that results in multiple bills from multiple providers). *See* comment 34(d)(3)(vii)–3. Thus, § 1006.34(d)(3)(vii) also permits debt collectors to disclose an affinity brand or a facility name, if any, associated with a debt.[366]

For these reasons, the Bureau is finalizing § 1006.34(d)(3)(vii) to provide that, along with the validation information, debt collectors may disclose the merchant brand, affinity brand, or facility name, if any, associated with a debt. The Bureau also is adopting new comments 34(d)(3)(vii)–1 through –3 to provide examples of a merchant brand, an affinity brand, and a facility name, respectively.

34(d)(3)(viii)

The Bureau is finalizing § 1006.34(d)(3)(viii) to provide that, although it is not required, a debt collector who is collecting debt not related to a consumer financial product or service may disclose certain additional information without losing the safe harbor provided by § 1006.34(d)(2) (assuming the debt collector otherwise satisfies the conditions for the safe harbor). Specifically, § 1006.34(d)(3)(viii) provides that, if a debt collector is collecting debt other than debt related to a consumer financial product or service as defined in § 1006.2(f), the debt collector may disclose: (1) The name of the creditor to whom the debt was owed on the itemization date (*i.e.,* the information specified in § 1006.34(c)(2)(iii)); or (2) a statement that informs the consumer that additional information regarding consumer protections in debt collection is available on the Bureau's website at *www.cfpb.gov/debt-collection* (*i.e.,* the information specified in § 1006.34(c)(3)(iv)). The Bureau determines that receipt of this

[365] *See* 84 FR 23274, 23340 (May 21, 2019) (citing the Bureau's consumer focus group findings that indicate consumers use merchant brands to recognize credit card debts).

[366] Although § 1006.34(d)(3)(vii) permits debt collectors to disclose the facility name associated with a medical debt along with the validation information, debt collectors may be prohibited from doing so by other applicable laws, such as healthcare privacy rules or regulations.

information may be helpful for consumers.

34(d)(4) Validation Notices Delivered Electronically

As discussed in the proposal and in the November 2020 Final Rule, promoting electronic communications may benefit consumers and debt collectors.[367] As also discussed in the proposal, allowing debt collectors to make certain formatting modifications to validation notices delivered electronically may help consumers exercise their verification rights under FDCPA section 809 and may facilitate a debt collector's ability to process and understand a consumer's response to such an electronically delivered validation notice. Proposed § 1006.34(d)(4) therefore provided several modifications, discussed in the section-by-section analysis of § 1006.34(d)(4)(i) and (ii) below, that a debt collector could make, at its option, to the formatting of a validation notice delivered electronically.

An industry trade group commenter expressed support for proposed § 1006.34(d)(4)'s facilitation of validation notices delivered electronically. The Bureau received no other comments specifically addressing proposed § 1006.34(d). Accordingly, the Bureau is finalizing § 1006.34(d)(4) with only minor wording changes.

The Bureau is finalizing § 1006.34(d)(4) to implement and interpret FDCPA section 809(b) by establishing formatting requirements that facilitate the consumer's right to dispute a debt and request original-creditor information, and pursuant to its FDCPA section 814(d) authority to prescribe rules with respect to the collection of debts by debt collectors. The Bureau also is finalizing § 1006.34(d)(4) pursuant to its authority under section 1032(a) of the Dodd-Frank Act to prescribe rules to ensure that the features of consumer financial products and services are disclosed fully, accurately, and effectively.

34(d)(4)(i) Prompts

Proposed § 1006.34(d)(4)(i) provided that a debt collector delivering a validation notice electronically pursuant to § 1006.42 could display any prompt required by § 1006.34(c)(4)(i) or (ii) or (d)(3)(iii)(B) or (vi)(B) as a fillable field.[368]

One industry trade group commenter supported proposed § 1006.34(d)(4)(i). According to the commenter, if a validation notice is delivered by email, a debt collector should be permitted to format the prompts in the consumer-response information section so that the debt collector receives an email if a consumer selects them. Another industry trade group commenter asked the Bureau to clarify whether a fillable field includes a checkbox.

A consumer advocate commenter raised concerns about permitting a debt collector to format the payment prompt described in § 1006.34(d)(3)(iii)(B) as a fillable field. According to the commenter, scammers could impersonate legitimate debt collectors and attempt to convince consumers to make payments on fraudulent debts using the payment prompts. The commenter urged the Bureau to evaluate the security risks associated with fillable payment prompts and consider other approaches.

The Bureau determines that allowing a debt collector to design a validation notice delivered electronically to include fillable prompts will benefit consumers and industry by making it easier for consumers to exercise their verification rights, make a payment, or request a Spanish-language translation of the notice. The Bureau does not find that permitting a debt collector to format the payment prompt described in § 1006.34(d)(3)(iii)(B) as a fillable field entails substantial security risks. The Bureau acknowledges that, in general, electronic communications present certain security risks to consumers. However, the Bureau finds that these general risks do not justify preventing debt collectors from including in electronic communications common design modifications, such as prompts, that are convenient to consumers. Thus, the Bureau declines to limit the ability of legitimate debt collectors to include on validation notices a common design modification that will benefit consumers.[369]

Accordingly, the Bureau is finalizing § 1006.34(d)(4)(i) largely as proposed, with only minor wording changes for consistency with other provisions in the final rule.

34(d)(4)(ii) Hyperlinks

Proposed § 1006.34(d)(4)(ii) provided that a debt collector delivering a validation notice electronically could embed hyperlinks in the validation notice that, when clicked, would connect consumers to the debt collector's website or permit consumers to dispute a debt or request original-creditor information.

Industry trade group commenters supported proposed § 1006.34(d)(4)(ii). For example, a commenter stated that hyperlinks are an important feature used to reduce the complexity of email and text messages while allowing readers to access important information. A consumer advocate commenter recommended that the Bureau also permit debt collectors to embed a hyperlink that connects consumers to the Bureau's website address described in § 1006.34(c)(3)(iv).

The Bureau determines that hyperlinks are a formatting modification that may benefit consumers and debt collectors if included in validation notices that are delivered electronically. And the Bureau agrees that debt collectors should be permitted to include a hyperlink that connects consumers to the Bureau's website address described in § 1006.34(c)(3)(iv). Accordingly, the Bureau is finalizing § 1006.34(d)(4)(ii) to provide that debt collectors may embed hyperlinks that, when clicked, connect consumers to the debt collector's website, connect consumers to the Bureau's debt collection website as disclosed pursuant to § 1006.34(c)(3)(iv), or permit consumers to dispute the debt or request original-creditor information.

34(e) Translation Into Other Languages

The Bureau proposed § 1006.34(e) to provide that a debt collector could send a consumer a validation notice completely and accurately translated into any language if the debt collector also sent an English-language validation notice that satisfied § 1006.34(a)(1). Proposed § 1006.34(e) also provided that, if a debt collector already provided a consumer an English-language validation notice that satisfied § 1006.34(a)(1) and subsequently provided the consumer a validation notice translated into any other language, the debt collector would not need to provide an additional copy of the English-language notice. Proposed comment 34(e)–1 clarified that the language of a validation notice obtained from the Bureau's website would be considered a complete and accurate translation, although debt collectors would be permitted to use other validation notice translations if they were accurate and complete.

Industry and industry trade group commenters supported proposed § 1006.34(e) and its optional approach to providing validation notices translated into other languages. An industry trade group commenter stated that this approach was appropriate

[367] *See* 84 FR 23274, 23351 (May 21, 2019); 85 FR 76734, 76755 (Nov. 30, 2020).

[368] 84 FR 23274, 23405 (May 21, 2019).

[369] With respect to the comment about whether a fillable field includes a checkbox, the Bureau confirms that a fillable field may appear as an unmarked checkbox that a consumer can select.

because some debt collectors may not have the resources to conduct collections activities in languages other than English. Other industry trade group commenters stated that requiring debt collectors to provide validation notices in other languages would be burdensome and costly. An industry trade group commenter stated that, if a debt collector provided a validation notice in another language, a consumer would expect the debt collector to communicate in that language. According to this commenter, if the debt collector was unable to do so, this unfulfilled expectation would frustrate consumers and expose debt collectors to litigation risk.

Other commenters, including consumer advocates, legal aid providers, and faith groups, recommended that debt collectors be required to provide non-English validation notices to LEP consumers. According to these commenters, LEP consumers tend to experience poverty at much greater rates, face significant challenges navigating the debt collection process, and are often subject to harassment and deception. Commenters stated that English-language validation notices would not enable LEP consumers to understand their rights in debt collection or to take appropriate action if they did not believe that they owed a debt. Commenters cited demographic statistics showing the growing population of LEP consumers, particularly in certain localities. A consumer advocate commenter stated that case law suggests that a debt collector's failure to provide a non-English validation notice to an LEP consumer may violate the FDCPA.[370]

To address these concerns, these commenters suggested various mandatory frameworks that would require debt collectors to provide translated validation notices to consumers. These suggested alternative frameworks included requiring debt collectors to provide a translated validation notice: (1) In Spanish and located on the back of every English-language validation notice; (2) with every English-language validation notice if the debt collector knows or should know the consumer has another language preference; (3) if the original transaction or the debt collector's prior communication was conducted in a foreign language; (4) upon a consumer's request; (5) if the debt collector received information in the file from the creditor or a prior debt collector indicating the consumer's non-English language preference; or (6) if and when the debt collector at a later point communicates with the consumer in a foreign language. In some cases, commenters framed these interventions as narrow or measured. A group of consumer advocates also urged the Bureau to make available on its website Spanish-translated validation notices as well as translations in the next seven most common languages spoken by LEP consumers in the United States.

The Bureau determines that LEP consumers may benefit from translated validation notices. Further, some debt collectors may want to provide translated validation notices to LEP consumers, if doing so is consistent with their business practices.

The Bureau, however, declines commenters' requests to require debt collectors to provide a Spanish-language translation to all consumers on the back of every English-language validation notice or a translated notice to consumers in other languages if the debt collector knows or should know the consumer has a different language preference. As discussed in the proposal,[371] these types of mandatory approaches would result in significant, industry-wide costs on both an upfront (implementation) basis and an ongoing basis, especially for smaller debt collectors and in connection with translations of the validation notice in languages whose use is not prevalent in the United States.[372] The Bureau acknowledges that some LEP consumers may experience particular challenges in the debt collection process. However, commenters did not provide information about the costs and benefits of requiring debt collectors to provide translated validation notices to all consumers, regardless of whether the consumer requests the translation, that persuades the Bureau that such mandatory requirements are justified. The Bureau, as stated above, recognizes the benefits of providing translated disclosures to consumers. However, the Bureau concludes that the approach in the proposal, supplemented by certain changes in the final rule, strikes a better balance than a mandatory requirement. The final rule permits debt collectors to provide disclosures carrying safe harbor protection that notify and encourage consumers to request a Spanish-language translation of the validation notice or additional information in Spanish, which can assist the largest group of LEP consumers in the United States by a wide margin compared to other languages. At the same time, the final rule does not require debt collectors to provide all consumers with translated validation notices, whether in Spanish or other languages, and irrespective of whether the consumers request it or speak a language that is uncommon among LEP consumers in the United States.

Regarding the request by a group of consumer advocate commenters that the Bureau translate the validation notice into Spanish and seven other languages and deem the Bureau translations as complete and accurate, the Bureau plans to make available on its website, prior to the effective date of the final rule, a Spanish-language translation of the validation notice, and it will consider taking such action in the future with respect to one or more of the other languages cited by these commenters following implementation of the final rule.

The Bureau also declines to implement the other mandatory approaches suggested by consumer advocate, faith group, and legal aid provider commenters. As discussed above, these commenters suggested a variety of interventions, such as requiring the debt collector provide the translated notice in circumstances in which the consumer had expressed a language preference to a prior debt collector or the creditor and that preference is noted in the file for the debt, or in which, at a later point in the process, the consumer communicates in a foreign language.

The Bureau disagrees with some commenters' characterization of these interventions as targeted or narrow in scope, as each suggestion would entail a mandatory requirement with associated upfront and ongoing costs and complexity (which would be compounded if more than one or even all of these interventions were adopted collectively). In some cases, these suggested interventions are beyond the scope of the proposal. As to others, the Bureau concludes that the costs of such interventions to debt collectors, particularly smaller entities, would not outweigh the benefits to consumers because they would add undue complexity to the rule from an

[370] The commenter cited, for example, *Evory* v. *RJM Acquisitions Funding LLC,* 505 F.3d 769, 774 (7th Cir. 2007). However, the Bureau disagrees with the commenter's premise that this opinion and the others it cited imply a general requirement under the FDCPA to provide translated notices to all Spanish-speaking LEP consumers. The Bureau believes, instead, that those holdings were dependent on the facts of those cases. For example, *Evory* discussed in *dicta* a hypothetical in which a debt collector targeted vulnerable Spanish-speaking LEP consumers with English-language validation notices, 505 F.3d at 774, but that particular scenario involved targeting, which is beyond the scope of § 1006.34(e).

[371] *See also* the section-by-section analysis of § 1006.34(d)(3)(vi).

[372] *See* 84 FR 23274, 23352 (May 21, 2019).

operational, compliance, and supervisory perspective.

For these reasons, the Bureau declines to adopt a final rule that requires debt collectors to provide translated validation notices. Nevertheless, because the Bureau determines that, as discussed in the proposal, LEP consumers may benefit from receiving translated validation notices, the Bureau is finalizing § 1006.34(e) to clarify how debt collectors may provide such notices if they choose. The Bureau is finalizing proposed § 1006.34(e) as § 1006.34(e)(1), with certain revisions and organizational changes for clarity; no substantive change is intended. Furthermore, as discussed in the section-by-section analysis of § 1006.34(d)(3)(vi), the Bureau is finalizing new § 1006.34(e)(2) to provide that, if a debt collector includes in the validation information either or both of the optional disclosures notifying a consumer that the consumer can request a copy of the validation notice in Spanish, the debt collector must provide the consumer a Spanish-language validation notice if the consumer requests one. The Bureau intended this result in the proposal and is including § 1006.34(e)(2) for clarity and in response to feedback. Finally, the Bureau is finalizing comment 34(e)–1 with revisions to conform to the revisions and organizational changes made to § 1006.34(e); no substantive change is intended.

Section 1006.38 Disputes and Requests for Original-Creditor Information

FDCPA section 809(b) requires debt collectors both to refrain from taking certain actions during the 30 days after the consumer receives the validation information or notice described in FDCPA section 809(a) (*i.e.,* during the validation period) and to take certain actions if a consumer either disputes the debt in writing, or requests the name and address of the original creditor in writing, during the validation period. The Bureau proposed § 1006.38 to implement and interpret FDCPA section 809(b) and (c), and the Bureau finalized the majority of proposed § 1006.38 in the November 2020 Final Rule.[373] The Bureau now is finalizing the remainder of proposed § 1006.38 as follows.

Comment 38–1

The Bureau proposed comment 38–2 (renumbered in the November 2020 Final Rule as comment 38–1) to set forth examples of written and electronic communications consumers can use in disputing the debt or requesting the name and address of the original creditor.[374] The second proposed example, proposed comment 38–2.ii, would have clarified that a consumer could return to the debt collector the consumer-response form that proposed § 1006.34(c)(4)(i) would have required to appear on the validation notice and indicate on the form a dispute or request. The Bureau received no comments on proposed comment 38–2.ii.[375] The Bureau did not finalize proposed comment 38–2.ii in the November 2020 Final Rule because the Bureau did not finalize § 1006.34 as part of that final rule. The Bureau now is finalizing comment 38–2.ii as proposed, renumbered as comment 38–1.ii, except that the Bureau is correcting a typographical error in the proposed comment such that the final comment cross references § 1006.34(c)(4) rather than § 1006.34(c)(4)(i).

Comment 38–3

The Bureau proposed comment 38–1 (renumbered in this final rule as comment 38–3) to clarify the applicability of § 1006.38 in the decedent debt context. Proposed comment 38–1 would have clarified that, if the consumer has not previously disputed the debt or requested the name and address of the original creditor, then a person who is authorized to act on behalf of the deceased consumer's estate operates as the consumer for purposes of § 1006.38. Proposed comment 38–1 also would have clarified that, if a person who is authorized to act on behalf of the deceased consumer's estate submits either a written request for original-creditor information or a written dispute to the debt collector during the validation period, then § 1006.38(c) or (d)(2), respectively, would require the debt collector to cease collection of the debt until the debt collector has responded to that request or dispute.

For the reasons discussed in the section-by-section analysis of § 1006.2(e), the Bureau is interpreting the term consumer to mean any natural person, whether living or deceased, who is obligated or allegedly obligated to pay any debt. And, pursuant to its authority under FDCPA section 814(d) to prescribe rules with respect to the collection of debts by debt collectors, the Bureau is adopting commentary clarifying how this definition operates in the decedent debt context, including debt collectors' obligations for providing the validation information and responding to disputes and requests for original-creditor information. Accordingly, the Bureau is finalizing comment 38–1 as proposed, renumbered as comment 38–3 in this final rule.

38(a) Definitions

38(a)(2) Validation Period

The Bureau proposed in § 1006.38(a)(2) to provide that the term validation period as used in § 1006.38 has the same meaning given to it in proposed § 1006.34(b)(5).[376] Because the Bureau did not finalize § 1006.34 in the November 2020 Final Rule, the Bureau finalized the definition in § 1006.38(a)(2) with revised wording to refer to the 30-day period described in FDCPA section 809 as defined by Regulation F.[377] The Bureau noted that it might, as part of this final rule, revise the definition of validation period as finalized in the November 2020 Final Rule to cross-reference any definition of that term that the Bureau adopts in this final rule. As discussed in the section-by-section analysis of § 1006.34(b)(5), the Bureau is finalizing the definition of validation period.[378] Therefore, the Bureau is making a technical change revising § 1006.38(a)(2), as finalized in the November 2020 Final Rule, to provide that the term validation period as used in § 1006.38 has the same meaning given to it in § 1006.34(b)(5).

38(b) Overshadowing of Rights To Dispute or Request Original-Creditor Information

FDCPA section 809(b) provides that, for 30 days after the consumer receives the validation information described in FDCPA section 809(a), a debt collector must not engage in collection activities or communications that overshadow or are inconsistent with the disclosure of the consumer's right to dispute the debt or request information about the original creditor.[379] The Bureau proposed in

[373] 85 FR 76734, 74843–48, 76893 (Nov. 30, 2020).

[374] 84 FR 23274, 23353 (May 21, 2019).

[375] The Bureau addressed comments received on other aspects of proposed comment 38–2 in the November 2020 Final Rule. 85 FR 76734, 76843–44 (Nov. 30, 2020).

[376] 84 FR 23274, 23353 (May 21, 2019).

[377] 85 FR 76734, 76844, 76893 (Nov. 30, 2020).

[378] The Bureau addresses comments received regarding the definition of validation period in the section-by-section analysis of § 1006.34(b)(5).

[379] This language was added to the FDCPA by the Financial Services Regulatory Relief Act of 2006, Public Law 109–351, sec. 802(c), 120 Stat. 1966, 2006 (2006), after an FTC advisory opinion on the same subject. *See* Fed. Trade Comm'n, *Advisory Opinion to American Collector's Ass'n* (Mar. 31, 2000) (opining that the 30-day period set forth in FDCPA section 809(a) ''is a *dispute* period within which the consumer may insist that the debt collector verify the debt, and not a *grace* period within which collection efforts are prohibited'' but that ''[t]he collection agency must ensure, however, that its collection activity does not overshadow and is not inconsistent with the disclosure of the

§ 1006.38(b) to implement this prohibition and generally restate the relevant statutory language, with only minor changes for style and clarity.[380]

As the Bureau discussed in the November 2020 Final Rule,[381] the Bureau received a few substantive comments addressing proposed § 1006.38(b). Two industry commenters requested that the final rule define the term ''overshadowing.'' These commenters observed that debt collectors' communications of validation information almost always expressly advise the consumer of the right to dispute the debt and to request the name and address of the original creditor. These commenters asserted that overshadowing claims are nonetheless some of the most common allegations in FDCPA lawsuits. These commenters also requested clarity as to whether the safe harbor in proposed § 1006.34(d)(2) for debt collectors who use the model validation notice also would provide a safe harbor for compliance with the overshadowing prohibition in proposed § 1006.38(b). One industry commenter requested that the final rule clarify that credit reporting during the validation period does not constitute overshadowing.[382]

In the November 2020 Final Rule, the Bureau finalized proposed § 1006.38(b) as § 1006.38(b)(1) and reserved § 1006.38(b)(2).[383] As noted above, proposed § 1006.38(b) generally restated the relevant statutory language, with only minor changes for style and clarity, and § 1006.38(b)(1) in the November 2020 Final Rule did the same. In the November 2020 Final Rule, the Bureau stated that it expected to address, as part of this final rule, the comments it received requesting further clarity about the safe harbor provided by § 1006.34(d)(2), and the Bureau reserved § 1006.38(b)(2) for that purpose.[384]

After considering the comments, the Bureau is finalizing in § 1006.38(b)(2) a safe harbor from the prohibition in § 1006.38(b)(1) against overshadowing.[385] Section 1006.38(b)(2) provides that a debt collector who uses Model Form B–1 in appendix B of this part in a manner described in § 1006.34(d)(2) has not thereby violated § 1006.38(b)(1). Therefore, a debt collector who uses Model Form B–1 in appendix B to Regulation F, specified variations of the model notice, or a substantially similar form, has not thereby violated § 1006.38(b)(1). The safe harbor protects only the use of the model validation notice to comply with the information and form requirements of § 1006.34(c) and (d)(1). If a debt collector uses the model validation notice as described in § 1006.34(d)(2) and conducts other collection activities during the validation period, the debt collector does not receive a safe harbor for those other collection activities. A debt collector also does not receive a safe harbor for the manner in which a model validation notice is provided, such as the envelope in which a model validation notice is provided.

The Bureau declines to otherwise define the term ''overshadow'' or to clarify whether other collection activities during the validation period either violate or comply with the prohibition in final § 1006.38(b)(1). The Bureau finds that the safe harbor in § 1006.38(b)(2) provides sufficient clarity for debt collectors.

38(c) Requests for Original-Creditor Information

FDCPA section 809(a)(5) states that the validation information a debt collector provides to a consumer must include a statement that, upon the consumer's written request within the 30-day validation period, the debt collector will provide the consumer with the name and address of the original creditor, if different from the current creditor. FDCPA section 809(b) provides that, if a consumer requests the name and address of the original creditor in writing within 30 days of receiving the validation information described in FDCPA section 809(a), the debt collector must cease collection of the debt until the debt collector obtains and mails that information to the consumer. The Bureau proposed in § 1006.38(c) to implement this prohibition and generally restate the relevant statutory language.

As the Bureau discussed in the November 2020 Final Rule, the Bureau received a number of comments addressing proposed § 1006.38(c).[386] Three industry commenters requested that the final rule provide that, if a debt collector's communication of the validation information to a consumer identifies the original creditor, the debt collector need not give the consumer the option of requesting original-creditor information from the debt collector. These commenters stated that, if the original creditor has already been identified to a consumer, it would be confusing to the consumer to provide the option to request the name and address of the original creditor. Further, they stated, consumers could use unnecessary requests for original-creditor information as a tactic to delay or avoid collection. One industry commenter requested that the final rule clarify that a debt collector is not required to include original-creditor information in its communication of validation information to a consumer. This commenter stated that lawsuits are often filed alleging that a debt collector has violated the FDCPA by not identifying the original creditor in the validation information.

Several commenters recommended that the Bureau define ''original creditor'' to mean the creditor at the time of charge off. According to an industry trade group, this definition would be consistent with other laws, including the Uniform Rules for New York State Trial Courts.[387] Other industry and industry trade group commenters stated that this definition would be appropriate for older debts because a consumer may no longer recognize the original creditor, particularly if an account has been sold. An industry trade group suggested that defining ''original creditor'' as the creditor at the time of charge off may resolve some compliance challenges in the retail installment sales context. According to the commenter, in retail installment sales, the original creditor is the retail seller, not the entity that ultimately buys the contract, and retail-seller information may not be readily available to the debt collector or helpful to the consumer.

A group of consumer advocate commenters who addressed proposed § 1006.38(c) generally noted the importance of original-creditor information to consumers in helping them recognize the debt in question. One commenter stated that the rule

consumer's right to dispute the debt specified by [s]ection 809(a)'').

[380] 84 FR 23274, 23353–54 (May 21, 2019).

[381] 85 FR 76734, 76844 (Nov. 30, 2020).

[382] In addition, one industry commenter stated that it generally agreed with proposed § 1006.38, and a group of consumer advocates that addressed proposed § 1006.38(b) did not object to the proposal.

[383] 85 FR 76734, 76844, 76893 (Nov. 30, 2020).

[384] *Id.*

[385] Accordingly, the heading for final § 1006.38(b)(2) refers to the safe harbor, and the Bureau is revising: (1) The heading for § 1006.38(b)(1) as finalized in the November 2020 Final Rule to clarify that that paragraph relates to the overshadowing prohibition; and (2) § 1006.38(b)(1) to omit a reference to the fact that the Bureau may provide in this part a safe harbor for debt collectors when they use certain Bureau-approved disclosures because the Bureau is providing that safe harbor in this final rule.

[386] 85 FR 76734, 76844–45 (Nov. 30, 2020).

[387] ''*Original creditor* means the financial institution that owned the consumer credit account at the time the account was charged off, even if that financial institution did not originate the account. *Charged-off consumer debt* means a consumer debt that has been removed from an original creditor's books as an asset and treated as a loss or expense.'' 22 NYCRR 208.14–a(a)(2).

should require debt collectors to identify the original creditor in the validation information.[388]

In the November 2020 Final Rule, the Bureau finalized proposed § 1006.38(c) as § 1006.38(c)(1) and reserved § 1006.38(c)(2).[389] As noted above, proposed § 1006.38(c) generally restated the relevant statutory language, and § 1006.38(c)(1) in the November 2020 Final Rule did the same.[390] In the November 2020 Final Rule, the Bureau stated that it expected to address, as part of this final rule, how a debt collector may respond to a request for original-creditor information if the original creditor is the same as the current creditor, and the Bureau reserved § 1006.38(c)(2) for that purpose.[391] The Bureau also noted that it would respond in this final rule to the comments asking the Bureau to define the term original creditor.

The Bureau has determined that a debt collector's communication of the validation information must include disclosure of the option to request original-creditor information. As noted above, FDCPA section 809(a)(5) states that the validation information must include ''a statement that, upon the consumer's written request within the thirty-day period, the debt collector will provide the consumer with the name and address of the original creditor, if different from the current creditor.'' [392] Because FDCPA section 809(a) requires the validation information to include disclosure of the consumer's right to request original-creditor information, the Bureau finds that consumer confusion would result if the final rule were to permit a debt collector not to respond to a consumer's timely request for that information if the original creditor is the same as the current creditor. Further, FDCPA section 809(b) states that ''[a]ny collection activities and communication during the 30-day period may not overshadow or be inconsistent with the disclosure of *the consumer's right to* dispute the debt or *request the name and address of the original creditor.*'' [393] The Bureau therefore has determined to require a debt collector to respond to a consumer's request for original-creditor information if the original creditor is the same as the current creditor.

However, the Bureau also has determined that FDCPA section 809(a)(5) and (b) permits a debt collector to respond differently to the consumer's request for original-creditor information when the original creditor is the same as the current creditor. Specifically, the Bureau has determined that FDCPA section 809(b), when read together with FDCPA section 809(a)(5), requires the debt collector to provide the name and address of the original creditor to the consumer only if the original creditor is different from the current creditor. Accordingly, the Bureau is finalizing new § 1006.38(c)(2) to set forth an alternative procedure that a debt collector may use to respond to a consumer's request for original-creditor information if the original creditor is the same as the current creditor. Specifically, if a debt collector receives a request for the name and address of the original creditor submitted by the consumer in writing within the validation period, the special rule set forth in § 1006.38(c)(2) provides that the debt collector must cease collection of the debt until the debt collector reasonably determines that the original creditor is the same as the current creditor and either (i) notifies the consumer in writing or electronically in the manner required by § 1006.42 that the original creditor is the same as the current creditor and refers the consumer to the debt collector's earlier provision of the validation information or (ii) satisfies § 1006.38(c)(1).

Under the final rule, a debt collector is not required to use the alternative procedure in § 1006.38(c)(2); a debt collector can always comply with the rule by complying with § 1006.38(c)(1). By adopting the § 1006.38(c)(2) alternative procedure, the Bureau strikes the best balance between providing debt collectors with a less burdensome method of responding to consumer requests for original-creditor information and protecting consumers.

The Bureau adopts the alternative procedure in § 1006.38(c)(2) as an interpretation of FDCPA section 809(a)(5) and (b), and pursuant to its authority under FDCPA section 814(d). In particular, § 1006.38(c)(2) is an interpretation of what it means for a debt collector, pursuant to FDCPA section 809(b), to ''obtain[ ] . . . the name and address of the original creditor'' and send that information to the consumer when, pursuant to FDCPA section 809(a)(5), the debt collector already provided the name of the current creditor to the consumer within the validation information (as required by FDCPA section 809(a)(2) and § 1006.34(c)(2)(v)) and the original creditor is not different from the current creditor. If the original creditor is the same as the current creditor, the Bureau interprets FDCPA section 809(b)'s requirement to provide original-creditor information to the consumer to mean that a debt collector must cease collection of the debt until the debt collector either provides the name and address of the original creditor to the consumer in compliance with § 1006.38(c)(1) or, in compliance with § 1006.38(c)(2), notifies the consumer in writing or electronically in the manner required by § 1006.42 that the original creditor is the same as the current creditor and refers the consumer to the debt collector's earlier provision of the validation information.

The Bureau declines to require all debt collectors to include the name of the original creditor in the validation information because the Bureau believes such a requirement is not necessary or warranted. The statute prescribes a method for a consumer to obtain this information upon request. Further, the Bureau interprets FDCPA section 809(a)(2) as requiring debt collectors to disclose in the validation information the name of the current creditor; *i.e.,* ''the name of the creditor to whom the debt is owed.''

The Bureau declines to define ''original creditor'' in the manner commenters suggested. Although the definition suggested by commenters might be accurate for some debts, it is not clear to the Bureau that the suggested definition would be accurate for all debts. The Bureau did not propose such a definition and the Bureau does not have sufficient information to develop and include a definition of ''original creditor'' in the rule.

Taking into consideration the provisions of FDCPA section 809(a) and (b), the final rule provides debt collectors an alternative response procedure, described above, when the original creditor—which in many cases will be the creditor as of the itemization date—is the same as the current creditor. The alternative procedure permits debt collectors to respond to some consumer requests for original-creditor information in a less burdensome way, while also protecting consumers. Therefore, the Bureau believes that defining original creditor in the final rule is unnecessary and unwarranted.

[388] Consumer advocates also addressed the proposal's provisions regarding electronic delivery of original-creditor information (and other information) in proposed § 1006.42. These comments regarding electronic delivery were addressed in the November 2020 Final Rule. *Id.* at 76848.

[389] *Id.* at 76893.

[390] While this final rule republishes in § 1006.38(c) some of the text of § 1006.38(c)(1) as finalized in the November 2020 Final Rule, this final rule makes no change to the substance of § 1006.38(c)(1) from what the Bureau finalized in the November 2020 Final Rule.

[391] 85 FR 76734, 76845 n.557 (Nov. 30, 2020).

[392] 15 U.S.C. 1692g(a)(5).

[393] 15 U.S.C. 1692g(b) (emphasis added).

Section 1006.42 Sending Required Disclosures

42(a) Sending Required Disclosures

42(a)(2) Exceptions

The Bureau proposed in § 1006.42(a)(2) to provide that a debt collector need not comply with § 1006.42(a)(1) when providing the disclosure required by § 1006.6(e) or § 1006.18(e) in writing or electronically, unless the disclosure was included on a notice required by § 1006.34(a)(1)(i) or § 1006.38(c) or (d)(2).[394] Because the Bureau did not finalize § 1006.34 in the November 2020 Final Rule, the Bureau finalized § 1006.42(a)(2) with a reference to the notice required by FDCPA section 809(a), as implemented by Regulation F, in lieu of a reference to the notice required by § 1006.34(a)(1)(i).[395] Because the Bureau is now finalizing § 1006.34, the Bureau is making a technical change revising § 1006.42(a)(2) to refer to the notice required by § 1006.34(a)(1)(i), as originally proposed. The Bureau addressed comments received regarding proposed § 1006.42(a)(2) in the section-by-section analysis of § 1006.42(a)(2) in the November 2020 Final Rule.[396]

42(b) Requirements for Certain Disclosures Sent Electronically

Proposed § 1006.42(b)(1) generally would have required a debt collector who provided the validation notice described in § 1006.34(a)(1)(i)(B) electronically to do so in accordance with section 101(c) of the E–SIGN Act.[397] Because the Bureau did not finalize § 1006.34 in the November 2020 Final Rule, the Bureau finalized § 1006.42(b) with a reference to the notice required by FDCPA section 809(a), as implemented by Regulation F, in lieu of a reference to the validation notice described in § 1006.34(a)(1)(i)(B).[398] Because the Bureau is now finalizing § 1006.34, the Bureau is making a technical change revising § 1006.42(b) to refer to the validation notice required by § 1006.34(a)(1)(i)(B), as originally proposed. The Bureau addressed comments received regarding proposed § 1006.42(b)(1) in the section-by-section analysis of § 1006.42(b) in the November 2020 Final Rule.[399]

Subpart C—Reserved

Subpart D—Miscellaneous

Section 1006.100 Record Retention

100(a) In General

Section 1006.100(a), as finalized in the November 2020 Final Rule, requires a debt collector to retain records that are evidence of compliance or non-compliance with the FDCPA and Regulation F. The Bureau proposed comment 100–1 to clarify that, for purposes of § 1006.100(a), evidence of compliance includes, among other things, copies of documents provided by the debt collector to the consumer in accordance with the requirements of proposed § 1006.34.[400] Because the Bureau did not finalize § 1006.34 in the November 2020 Final Rule, the Bureau finalized comment 100(a)–1 to include, as an example of evidence of compliance, copies of documents provided by the debt collector to the consumer in accordance with FDCPA section 809(a), as implemented by Bureau regulation.[401] Because the Bureau now is finalizing § 1006.34, the Bureau is making a technical change revising comment 100(a)–1 to include, as an example of evidence of compliance, copies of documents provided by the debt collector to the consumer in accordance with § 1006.34, as originally proposed. The Bureau addressed comments received regarding proposed comment 100–1 in the section-by-section analysis of § 1006.100(a) and comment 100(a)–1 in the November 2020 Final Rule.[402]

Section 1006.104 Relation to State Laws

FDCPA section 816 provides that the FDCPA does not annul, alter, or affect, or exempt any person subject to the provisions of the FDCPA from complying with the laws of any State with respect to debt collection practices, except to the extent that those laws are inconsistent with any provision of the FDCPA, and then only to the extent of the inconsistency. FDCPA section 816 also provides that, for purposes of that section, a State law is not inconsistent with the FDCPA if the protection such law affords any consumer is greater than the protection provided by the FDCPA.[403] The November 2020 Final Rule finalized § 1006.104 to implement FDCPA section 816.[404]

Proposed comment 104–1 clarified that a disclosure required by applicable State law that describes additional protections under State law does not contradict the requirements of the FDCPA or the corresponding provisions of Regulation F.[405] In the November 2020 Final Rule, the Bureau indicated that it was not finalizing proposed comment 104–1 as part of that rule and would determine whether and how to finalize the comment as part of this final rule.[406]

As discussed in the November 2020 Final Rule, some commenters asked the Bureau to clarify how proposed comment 104–1 would interact with State law disclosure requirements.[407] According to these commenters, the proposed commentary did not track FDCPA section 816's statutory language and therefore would be susceptible to competing interpretations. These commenters expressed concern that proposed comment 104–1 could be interpreted to mean that § 1006.104 would preempt State law disclosure requirements that afford the same protections as the FDCPA and the corresponding provisions of Regulation F. These commenters opposed such an interpretation as inconsistent with FDCPA section 816.

With proposed comment 104–1, the Bureau did not intend to communicate that § 1006.104 would preempt disclosures required by State law that describe State laws that afford the same protections as the FDCPA and the corresponding provisions of Regulation F. To mitigate the risk that the proposed commentary could be interpreted in this manner, the Bureau is modifying proposed comment 104–1 to more closely track FDCPA section 816's statutory language.

Accordingly, the Bureau is finalizing comment 104–1 to clarify that the FDCPA and the corresponding provisions of Regulation F do not annul, alter, or affect, or exempt any person subject to these requirements from complying with a disclosure requirement under applicable State law that describes additional protections under State law that are not inconsistent with the FDCPA and Regulation F. In addition, comment 104–1 clarifies that a disclosure required by State law is not inconsistent with the FDCPA or Regulation F if the disclosure describes a protection such law affords any consumer that is greater than the protection provided by the FDCPA or Regulation F.

[394] 84 FR 23274, 23357–59 (May 21, 2019).
[395] 85 FR 76734, 76893 (Nov. 30, 2020).
[396] *Id.* at 76850–51.
[397] 84 FR 23274, 23356–57 (May 21, 2019).
[398] 85 FR 76734, 76893 (Nov. 30, 2020).
[399] *Id.* at 76850–51.
[400] 84 FR 23274, 23367 (May 21, 2019).
[401] 85 FR 76734, 76907 (Nov. 30, 2020).
[402] *Id.* at 76858 n.600.
[403] 15 U.S.C. 1692n.
[404] 85 FR 76734 at 76860 (Nov. 30, 2020).
[405] 84 FR 23274, 23368 (May 21, 2019).
[406] 85 FR 76734, 76860 (Nov. 30, 2020).
[407] *Id.*

VI. Effective Date

As discussed in the November 2020 Final Rule, the Bureau proposed an implementation period of one year after publication of the final rule in the **Federal Register**.[408] The Bureau received several comments on the proposed effective date. As noted in the November 2020 Final Rule, a few industry commenters supported the proposed effective date, stating that a one-year implementation period would provide debt collectors with enough time to comply with the rule. Two other industry commenters supported an 18-month and a 24-month implementation period, respectively, arguing that it would take longer than one year to update policies and procedures, train employees, and make programming changes necessary to come into compliance. A government commenter encouraged the Bureau to provide small entities more than one year to comply, if such entities were not exempted from the rule altogether. Several industry commenters asked the Bureau to clarify that a debt collector is permitted to comply with all or part of the final rule before the effective date.

The Bureau considered those comments in finalizing the November 2020 Final Rule and determined that that final rule would take effect one year after publication in the **Federal Register**. The Bureau determined that the revisions made to the proposal and discussed in that Final Rule would permit debt collectors to meet that effective date. The Bureau also recognized that all stakeholders might benefit if the November 2020 Final Rule and this final rule had the same effective date.

As noted in part III, the November 2020 Final Rule was published in the **Federal Register** on November 30, 2020 and will take effect on November 30, 2021. The Bureau concludes that all stakeholders will benefit if the November 2020 Final Rule and this final rule have the same effective date. The Bureau also determines that setting the effective date for this final rule as November 30, 2021, consistent with the effective date of the November 2020 Final Rule, will provide debt collectors nearly one year, and therefore sufficient time, to come into compliance with this final rule.

The Bureau notes that debt collectors may, but are not required to, comply with the final rule's requirements and prohibitions before the effective date. Until that date, the FDCPA and other applicable law continue to govern the conduct of FDCPA debt collectors. Similarly, to the extent the final rule establishes a safe harbor from liability for certain conduct or a presumption that certain conduct complies with or violates the rule, those safe harbors and presumptions are not effective until the final rule's effective date.

VII. Dodd-Frank Act Section 1022(b) Analysis

A. Overview

In developing the final rule, the Bureau has considered the potential benefits, costs, and impacts as required by section 1022(b)(2)(A) of the Dodd-Frank Act.[409]

Debt collectors play a critical role in markets for consumer financial products and services. Credit markets function because lenders expect that borrowers will pay them back. In consumer credit markets, if borrowers fail to repay what they owe per the terms of their loan agreement, creditors often engage debt collectors to attempt to recover amounts owed, whether through the court system or through less formal demands for repayment.

In general, third-party debt collection creates the potential for market failures. Consumers do not choose their debt collectors, and, as a result, debt collectors do not have the same incentives that creditors have to treat consumers fairly.[410] Certain provisions of the FDCPA may help mitigate such market failures in debt collection, for example by prohibiting unfair, deceptive, or abusive debt collection practices by third-party debt collectors.

Any restriction on debt collection may reduce repayment of debts, providing a benefit to some consumers who owe debts and an offsetting cost to creditors and debt collectors. A decrease in repayment will in turn lower the expected return to lending. This can lead lenders to increase interest rates and other borrowing costs and to restrict availability of credit, particularly to higher-risk borrowers.[411] Because of this, policies that increase protections for consumers with debts in collection involve a tradeoff between the benefits of protections for those consumers and the possibility of increased costs of credit and reduced availability of credit for all consumers. Whether there is a net benefit from such protections depends on whether consumers value the protections enough to outweigh any associated increase in the cost of credit or reduction in availability of credit.

The final rule will further the FDCPA's goals of eliminating abusive debt collection practices and ensuring that debt collectors who refrain from such practices are not competitively disadvantaged.[412] However, as discussed below, it is not clear based on the information available to the Bureau whether the net effect of the final rule will be to make it more costly or less costly for debt collectors to recover unpaid amounts, and therefore not clear whether the rule will tend to increase or decrease the supply of credit. The final rule will benefit both consumers and debt collectors by increasing clarity and certainty about what the FDCPA prohibits and requires. When a law is unclear, it is more likely that parties will disagree about what the law requires, that legal disputes will arise, and that litigation will be required to resolve disputes. Since 2010, consumers have filed approximately 8,000 to 12,000 lawsuits under the FDCPA each year, some of which involve issues on

[408] 85 FR 76734, 76863 (Nov. 30, 2020); *see also* 84 FR 23274, 23276 (May 21, 2019).

[409] Specifically, section 1022(b)(2)(A) of the Dodd-Frank Act (12 U.S.C. 5512(b)(2)(A)) requires the Bureau to consider the potential benefits and costs of the regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products and services; the impact of the rule on insured depository institutions and insured credit unions with less than $10 billion in total assets as described in section 1026 of the Dodd-Frank Act (12 U.S.C. 5516); and the impact on consumers in rural areas.

[410] Consumers do choose their lenders, and, in principle, consumer loan contracts could specify which debt collector would be used or what debt collection practices would be in the event a loan is not repaid. Some economists have identified potential market failures that prevent loan contracts from including such terms even when they could make both borrowers and lenders better off. For example, terms related to debt collection may not be salient to consumers at the time a loan is made. Alternatively, if such terms are salient, a contract that provides for more lenient collection practices may lead to adverse selection, attracting a disproportionate share of borrowers who know they are more likely to default. *See* Thomas A. Durkin *et al., Consumer Credit and the American Economy* 521–25 (Oxford U. Press 2014) (discussing potential sources of market failure and potential problems with some of those arguments). *See also* Erik Durbin & Charles Romeo, *The Economics of Debt Collection: With attention to the issue of salience of collections at the time credit is granted,* Journal of Credit Risk (Sept. 4, 2020) (discussing how rules that limit debt collection affect consumer welfare when debt collection is not salient to consumers when they borrow).

[411] *See* Thomas A. Durkin *et al., Consumer Credit and the American Economy* 521–25 (Oxford U. Press 2014) (discussing theory and evidence on how restrictions on creditor remedies affect the supply of credit). Empirical evidence on the impact of State laws restricting debt collection is discussed in section G below. The provisions in this final rule could also affect consumer demand for credit, to the extent that consumers contemplate collection practices when making borrowing decisions. However, there is evidence suggesting that consumer demand for credit is generally not responsive to differences in creditor remedies. *See* James Barth *et al., Benefits and Costs of Legal Restrictions on Personal Loan Markets,* Journal of Law & Economics, 29(2) (1986).

[411] *See* 15 U.S.C. 1692(e).

[412] *See id.*

which the law is unclear.[413] The number of disputes settled without litigation has likely been much greater.[414] Perhaps more important than the costs of resolving legal disputes are the steps that debt collectors take to prevent legal disputes from arising in the first place. This includes direct costs of legal compliance, such as auditing and legal advice, as well as indirect costs from avoiding collection practices that might be both effective and legal but that raise potential legal risks. In some cases, debt collectors seeking to follow the law and avoid litigation have adopted practices that appear to be economically inefficient, with costs that exceed the benefits to consumers or even impose net costs on consumers.[415]

This final rule relating to disclosures could make debt collection either more or less costly in ways that are difficult to predict. For example, the validation notice requirements will provide consumers with more information than they currently receive about debts, which could reduce costs to consumers and debt collectors from disputes that arise when consumers do not recognize the debt or do not understand the basis for the alleged amount due. At the same time, the final rule's clearer explanation of dispute rights could make consumers more likely to dispute, which could provide benefits to consumers while increasing costs for debt collectors. Disputes are costly for debt collectors to process, so these requirements could either increase or decrease debt collector and consumer costs depending on the net effect on dispute rates.

In developing the final rule, the Bureau has consulted, or offered to consult with, the appropriate prudential regulators and other Federal agencies, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

B. Provisions To Be Analyzed

The analysis below considers the potential benefits, costs, and impacts to consumers and covered persons of key provisions of the final rule (provisions), which include:

1. Time-barred debt: Prohibiting suits and threats of suit.
2. Notice for validation of debts.
3. Required actions prior to furnishing information.

C. Data Limitations and Quantification of Benefits, Costs, and Impacts

The discussion in this part VII relies on publicly available information as well as information the Bureau has obtained. To better understand consumer experiences with debt collection, the Bureau developed its 2015 Survey of Consumer Views on Debt, which provided the first comprehensive and nationally representative data on consumers' experiences and preferences related to debt collection.[416] In addition, the Bureau relies on its Consumer Credit Panel (CCP) to understand potential benefits and costs to consumers of the rule.[417] To better understand potential effects of the rule on industry, the Bureau has engaged in significant outreach to industry, including through the CFPB Debt Collection Operations Study.[418] In July 2016, the Bureau consulted with small entities as part of the SBREFA process and obtained important information on the potential impacts of proposals that the Bureau was considering at the time for the topics covered by the final rule; many of those proposals are included in the final rule.[419]

The sources described above, together with other sources of information and the Bureau's market knowledge, form the basis for the Bureau's consideration of the likely impacts of the final rule. The Bureau makes every attempt to provide reasonable estimates of the potential benefits and costs to consumers and covered persons of this final rule given available data. However, available data sources generally do not permit the Bureau to quantify, in dollar terms, how particular provisions will affect consumers. With respect to industry impacts, much of the Bureau's existing data come from qualitative input from debt collectors and other entities that operate in the debt collection market rather than from representative sampling that would allow the Bureau to estimate total benefits and costs.

General economic principles and the Bureau's expertise in consumer financial markets, together with the data and findings that are available, provide insight into the potential benefits, costs, and impacts of the final rule. Where possible, the Bureau has made quantitative estimates based on these principles and the data available. Some benefits and costs, however, are not amenable to quantification, or are not quantifiable given the data available to the Bureau. The Bureau provides a qualitative discussion of those benefits, costs, and impacts. The Bureau requested additional data or studies that could help quantify the benefits and costs to consumers and covered persons of the May 2019 Proposed Rule and the February 2020 Proposed Rule. The Bureau summarizes comments on this subject below, but few comments explicitly addressed quantifying the costs and benefits of the rule or provided additional data or studies. Comments on the benefits and costs of the rule are also discussed in part V above.

D. Baseline for Analysis

In evaluating the potential benefits, costs, and impacts of the final rule, the Bureau takes as a baseline the current legal framework governing debt collection. This includes debt collector practices as they currently exist, responding to the requirements of the FDCPA as currently interpreted by courts and law enforcement agencies, other Federal laws, and the rules and statutory requirements promulgated by the States.[420] In the consideration of potential benefits, costs, and impacts below, the Bureau discusses its understanding of practices in the debt collection market under this baseline and how those practices are likely to change under the final rule.

Until the creation of the Bureau, no Federal agency was given the authority to write substantive regulations implementing the FDCPA, meaning that

[413] *See* WebRecon LLC, *WebRecon Stats for Dec 2019 & Year in Review, https://webrecon.com/webrecon-stats-for-dec-2019-and-year-in-review-how-did-your-favorite-statutes-fare/* (last visited Dec. 1, 2020). Greater clarity about legal requirements could reduce unintentional violations and could also reduce lawsuits because, when parties can better predict the outcome of a lawsuit, they may be more likely to settle claims out of court.

[414] Some debt collectors have reported that they receive approximately 10 demand letters from attorneys asserting a violation of the FDCPA for each lawsuit filed. *See* Small Business Review Panel Outline, *supra* note 39, at 69 n.105.

[415] For example, as discussed further below, debt collectors typically may disclose only the information that FDCPA section 809(a) specifically references and may provide the FDCPA section 809 information using statutory language, rather than plain language that consumers can more easily comprehend.

[416] *See* CFPB Debt Collection Consumer Survey, *supra* note 292.

[417] For more information about Bureau data sources, see Bureau of Consumer Fin. Prot., *Sources and uses of data at the Bureau of Consumer Financial Protection* (Sept. 26, 2018), *https://www.consumerfinance.gov/data-research/research-reports/sources-and-uses-data-bureau-consumer-financial-protection/.*

[418] *See* CFPB Debt Collection Operations Study, *supra* note 37.

[419] *See* Small Business Review Panel Report, *supra* note 40.

[420] These requirements, and the specificity of the requirements, may vary depending upon the jurisdiction in which the collection occurs. This baseline does not include any potential impacts of the November 2020 Final Rule, however. The November 2020 Final Rule included a separate Dodd-Frank Act Section 1022(b) analysis, and that rule's provisions do not go into effect until November 30, 2021.

many of the FDCPA's requirements are subject to interpretations in court decisions that are not always consistent or do not always definitely resolve an issue, such as a single district court opinion on an issue. Debt collectors' practices reflect their interpretations of the FDCPA and their decisions about how to balance effective collection practices against litigation risk. Many of the impacts of the final rule relative to the baseline would arise from changes that debt collectors would make in response to additional clarity about the most appropriate interpretation of what conduct is permissible and not permissible under the FDCPA's provisions.

The Bureau received no comments regarding its choice of baseline for its section 1022(b) analysis.

E. Goals of the Rule

The final rule is intended to further the FDCPA's goals of eliminating abusive debt collection practices and ensuring that debt collectors who refrain from such practices are not competitively disadvantaged. To these ends, an important goal of the rule is to benefit both consumers and debt collectors by increasing clarity and certainty about what the FDCPA prohibits and requires, which could improve compliance with the FDCPA while reducing unnecessary litigation regarding the FDCPA's requirements.

As discussed in part V and in this part VII, other goals of the rule's provisions regarding validation information include providing more information to consumers about their debts, which may help consumers determine whether a debt is theirs and whether the reported amount owed is accurate and may reduce unnecessary disputes. The validation information is also intended to help consumers to know their rights and be able to exercise them, including by disputing a debt. In addition, the model validation notice is intended to provide information to consumers in a more appealing and easy-to-read format, making it more likely that consumers read and comprehend the information than with the validation notices currently in use.

The rule's provision requiring debt collectors to take certain actions prior to furnishing information about a debt to a consumer reporting agency is intended to increase the likelihood that consumers learn about an alleged debt before furnishing occurs, giving them an opportunity to resolve the debt or dispute it if appropriate.

The rule's provision prohibiting debt collectors from suing or threatening to sue on time-barred debts is intended to mitigate the consumer harms that can result from such actions, including causing some consumers to pay or prioritize time-barred debts over other debts in the mistaken belief that doing so is necessary to avoid litigation or adverse judgments, when in fact consumers have meritorious defenses based on the statute of limitations.

F. Coverage of the Rule

The final rule applies to debt collectors as defined in the FDCPA and § 1006.2(i) of the November 2020 Final Rule. Creditors that collect on debts they own generally will not be affected directly by the final rule because they typically are not debt collectors for purposes of the FDCPA. Creditors, however, may experience indirect effects if debt collectors' costs increase and if those costs are passed on to creditors.

G. Potential Benefits and Costs to Consumers and Covered Persons

The Bureau discusses the benefits and costs of the rule to consumers and covered persons (generally FDCPA debt collectors) in detail below.[421] The Bureau believes that an important benefit of many of the provisions to both consumers and covered persons—compared to the baseline of the FDCPA as currently interpreted by courts and law enforcement agencies—is an increase in clarity and precision of the law governing debt collection. Greater certainty about legal requirements can benefit both consumers and debt collectors, making it easier for consumers to understand and assert their rights and easier for firms to ensure they are in compliance. The Bureau discusses these benefits in more detail with respect to certain provisions below but believes that they generally apply, in varying degrees, to all of the provisions discussed below.

1. Time-Barred Debt: Prohibiting Suits and Threats of Suit

Section 1006.26(b) prohibits a debt collector from suing or threatening to sue a consumer to collect a time-barred debt.

As discussed in part V above, multiple courts have held that the FDCPA prohibits suits and threats of suit on time-barred debt. The Bureau understands that most debt collectors do not knowingly sue or threaten to sue consumers to collect time-barred debts. Although the final rule applies a strict liability standard to this prohibition, under which debt collectors may be liable for suits or threats of suit even if they do not know that the debt is time-barred, the Bureau believes that debt collectors have multiple ways of managing such risk including, but not limited to, confirming that the statute of limitations has not expired before bringing or threatening to bring a legal action or, if a debt collector is unable to make such a determination, refraining from bringing or threatening to bring a legal action while, in most States, continuing with non-litigation collection activities. Therefore, the Bureau does not expect this provision of the rule to have a significant effect on most debt collectors.

To the extent that there are costs to covered persons or benefits to consumers from this provision, they will most likely come from reduced payments on time-barred debts, to the extent that some debt collectors currently sue or threaten to sue on time-barred debts as a strategy to elicit payment.[422] If it is currently true that (1) suing or threatening to sue on debts is an important means of collection for debts for which the statute of limitations is close to expiring, and (2) most debt collectors stop suing or threatening to sue once the statute of limitations for a debt expires, then one would expect repayment rates to drop after the statute of limitations expires, and that drop might be made more significant by the provision. Such a reduction in payments would benefit consumers who owe the debts while imposing costs on debt collectors and creditors and potentially increasing the cost of credit generally.

The Bureau therefore attempted to indirectly measure the potential effect of the provision by examining the behavior of consumers who owe debts that either recently expired or are close to expiring under their State's statute of limitations. To do so, the Bureau used data from its Consumer Credit Panel (CCP), which contains information from one of the

[421] For purposes of the section 1022(b)(2) analysis, the Bureau considers any consequences that consumers perceive as harmful to be a cost to consumers. In considering whether consumers might perceive certain activities as harmful, the Bureau is not analyzing whether those activities would be unlawful under the FDCPA or the Dodd-Frank Act.

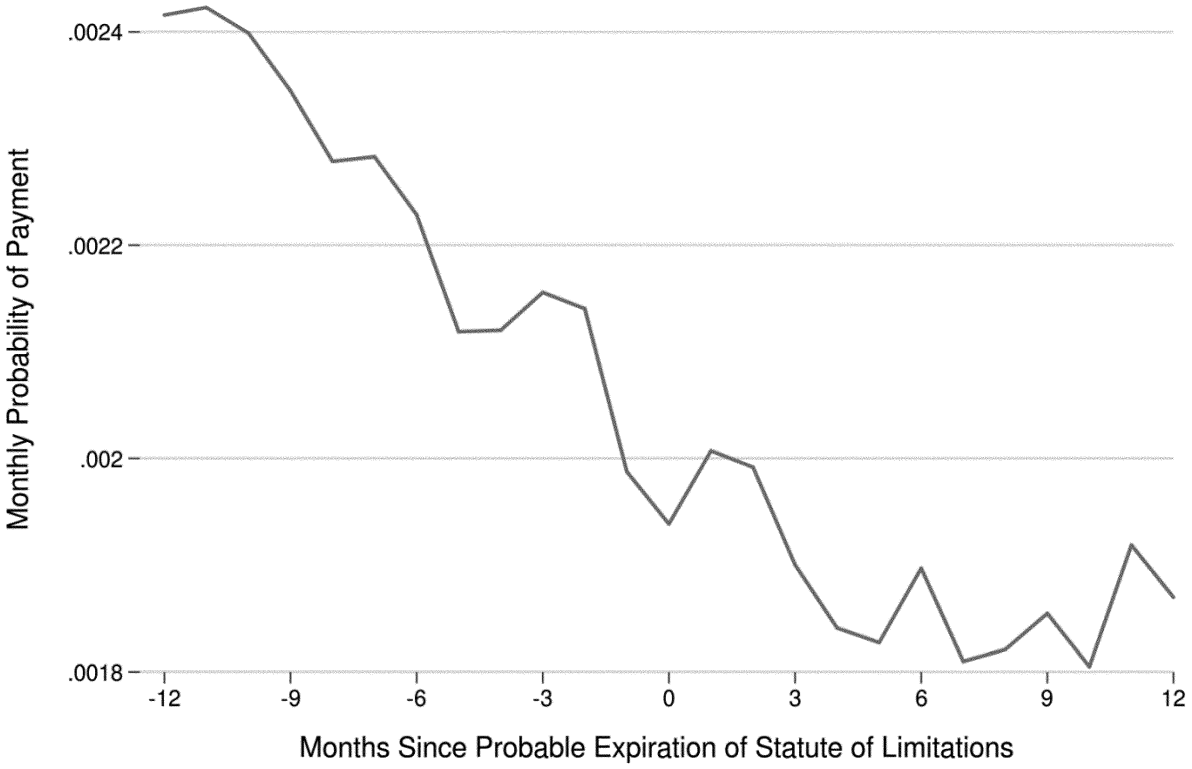
[422] The final rule may also increase costs to covered persons to the extent that debt collectors who currently sue or threaten to sue to collect time-barred debt increase their efforts to determine whether or not a debt is time barred. As discussed above in part V, The Bureau recognizes that, in most jurisdictions, expiration of the statute of limitations provides the consumer with an affirmative defense to liability, but it does not bar a debt collector from bringing suit. As such, some debt collectors who sue or threaten to sue on older debts may currently expend less time and effort verifying the time-barred status of a debt than they will under the final rule.

three nationwide CRAs. The Bureau used data from the CCP to attempt to estimate the current effect of State statutes of limitation on the propensity of consumers to pay old debts in collection.

The CCP contains information on collections tradelines—records that were furnished to this nationwide CRA by third-party debt collectors or debt buyers. The Bureau analyzed these data to determine whether the probability of payment declines around the expiration of the statute of limitations in the consumer's State. Specifically, the Bureau followed debts reported in the CCP from the time they were first reported on a consumer's credit record until they either showed some record of payment or disappeared from the credit record. In this analysis, the Bureau assumed that the applicable statute of limitations is the one applicable to written contracts in the consumer's State of residence and that the statute of limitations begins for a debt on the date that the debt first appears on the consumer's credit report. The Bureau assumed this starting date because there was no other date in the available data on which to reasonably base the beginning of the statute of limitations. There is likely to be some inaccuracy in this assumption due to a variety of factors, including delays between the beginning of the period defined by the statute of limitations and the first report of information to the CRA and cases in which the applicable statute of limitations is not the one in the consumer's State. However, if the estimated expiration of the statute of limitations is at least approximately correct in most cases, then one would expect to observe whether the expiration of the statute of limitations has an effect on the likelihood that a debt is reported to have been paid.

The Bureau calculated the probability of payment occurring after a given number of days, conditional on no payment occurring before—in technical terms, the ''hazard rate'' for payments—for all collections tradelines in the CCP. The Bureau then calculated the average hazard rate based on the number of months before or after the estimated expiration of the applicable statute of limitations. This calculation is plotted in Figure 1, below. The figure shows that the probability of a collections tradeline showing evidence of payment declines steadily for at least a year leading up to the estimated expiration of the statute of limitations and continues to decline at roughly the same rate afterwards. Thus, while the probability of payment declines over time, the reduced ability of debt collectors to pursue litigation does not seem to materially affect payments on collections tradelines. Combined with the Bureau's understanding that debt collectors generally do not knowingly sue or threaten to sue on time-barred debt, this suggests that the provision would be unlikely to cause any further reduction in the rate of repayment on time-barred debt.

Figure 1: Probability of Payment



Because the available data do not permit the Bureau to identify the expiration of the statute of limitations precisely, the analysis above may fail to identify some effects.

2. Notice for Validation of Debts

Section 1006.34 implements and interprets FDCPA section 809(a), (b), (d), and (e). Specifically, § 1006.34(a) provides that, subject to certain exceptions, a debt collector must provide a consumer the validation information described in § 1006.34(c). Section 1006.34(c) implements FDCPA section 809(a)'s content requirements

and specifies that validation information includes certain information about the debt and the consumer's protections with respect to debt collection that debt collectors do not currently provide to consumers. Section 1006.34(d) sets forth a general requirement that such information be clear and conspicuous. Section 1006.34(d) also provides safe harbors for using the model validation notice, specified variations of the model notice, or a substantially similar form, and permits the inclusion of certain optional information. Section 1006.34(e) affirmatively permits debt collectors to provide validation notices translated into other languages and requires debt collectors who offer to provide consumers translated notices to provide them to consumers who request them.

Potential benefits and costs to consumers. The required validation information may benefit consumers in four ways. First, the disclosures will provide more information about the debt, which may help consumers determine whether the debt is theirs and whether the reported amount owed is accurate. Second, the notice will provide a plain-language disclosure of the consumer's rights in debt collection, in particular the right to dispute, which should help consumers to know their rights and be able to exercise them. Third, the validation information will include consumer-response information that should make it easier for consumers to take certain actions, including disputing a debt. Finally, the model validation notice form is intended to provide information to consumers in a more plain-language and visually appealing format, making it more likely that consumers will read and comprehend the information than with the validation notices currently in use.

To quantify the benefit of providing more and clearer validation information, the Bureau would need to estimate the impact of this additional information on consumers' ability to recognize their debts compared to what is currently provided on validation notices, as well as how consumers would respond to that additional information. Although the Bureau is not aware of data that would permit a full accounting of these benefits, below is a summary of information the Bureau is aware of that is relevant to assessing these benefits.

The Bureau understands that, in general, validation notices currently include little or no information about the debt beyond the information specifically listed in section 809(a) of the FDCPA (*e.g.,* the current amount of the debt and the name of the current creditor). This information may not be sufficient for the consumer to recognize the debt, particularly if: (1) The amount owed has changed over time due to interest, fees, payments, or credits; (2) the debt collector has changed since an original collection attempt; or (3) the creditor's name is not one the consumer associates with the debt (as with some store-branded credit cards issued by third-party financial institutions). Consumers who do not recognize a debt because the information on a validation notice is insufficient may incur costs if they mistakenly dispute a debt they owe, make a payment on a debt they do not owe, or ignore a debt on the assumption that the collection attempt is in error.

Relative to current validation notices, the validation information under the final rule will include more specific details about the debt, such as the debt's account number and an itemization of the debt. The Bureau has determined that this information will benefit consumers by making it easier for them to determine whether they owe a debt and, therefore, reducing the likelihood of incurring costs due to mistakes like those noted above. The consumer can also use the consumer-response information to request the name and address of the original creditor, which may further help the consumer to recognize the debt.

To fully evaluate the benefits to consumers of disclosing this additional information, the Bureau would need representative data to estimate how often consumers would read and understand the additional information on the notice and the extent to which that information increases consumer recognition and understanding compared to a notice without it. For example, the Bureau could further quantify some of the consumer benefits of the additional information if the Bureau were able to estimate: (1) How many consumers ignore notices out of a mistaken conclusion that the debt is not theirs; (2) how many consumers dispute correct debts, and subsequently, how much time the validation notice saves by obviating later interactions that result from improper disputes; and (3) how many consumers fail to dispute or make payments on incorrect debts. The Bureau is not aware of a source of information on the number of consumers in these categories or the possible time savings that could result from the validation information. The Bureau's Debt Collection Consumer Survey suggests that the required validation information would likely be helpful in recognizing a debt. Specifically, when asked how helpful various pieces of information would be in figuring out whether they owed a debt, consumers were most likely to indicate that the creditor name, type of debt, and an itemization of the amount owed (such as principal, interest, and fees) were especially valuable.[423] These opinions were echoed in focus groups in which consumers noted that, after a debt is sold, it is more difficult to recognize, and that they wanted as much information as possible to help them recognize the debt as theirs (especially the account number, creditor, and amount due) with the exception of sensitive information like social security numbers.[424]

To quantify the benefits of the provision requiring a clear and conspicuous disclosure of a consumer's right to dispute a debt, the Bureau would need to estimate the number of consumers who fail to dispute debts that they do not owe because they are unaware of, or do not comprehend, their right to dispute. The Bureau cannot precisely quantify this benefit; however, the discussion below identifies several applicable considerations and estimates.

The Bureau estimates that at least 49 million consumers are contacted by debt collectors each year.[425] Twenty-eight percent of consumers who said they had been contacted about one or more debts in collection reported that the contacts included attempts to collect at least one debt that the consumers believed they did not owe.[426] One-third of consumers who had been contacted said the amount the creditor or debt collector was trying to collect was wrong for at least one of these debts, and 16 percent said the contacts included at least one contact about a debt that was instead owed by a family member. (Some consumers reported more than one of these issues). Taken together, more than half of consumers (53 percent) who said they had been contacted about one or more debts in collection reported that they thought at least one of the debts they were contacted about was in error. This suggests that there are many consumers who receive the validation notices in use today who might be likely

[423] CFPB Debt Collection Consumer Survey, *supra* note 292.

[424] FMG Focus Group Report, *supra* note 26, at 15–16.

[425] *See* CFPB Debt Collection Consumer Survey, *supra* note 292, at 13, 40–41.

[426] The survey questions concerning consumer beliefs about errors in collections did not ask respondents to distinguish between debts owed to a debt collector and debts owed to a creditor. If consumers are more or less likely to believe there is an error for collection attempts by debt collectors, then this percentage and those below may over- or under-estimate the likelihood that a consumer believes a debt is in error when the consumer is contacted by a debt collector.

to dispute based on their perception that either the debt is not theirs or is wrong.

Among the 53 percent of consumers who cited one of the issues noted above, 42 percent reported that they disputed a collection in the prior year, and 11 percent of consumers who had not cited one of those issues indicated that they had disputed a debt. The fact that less than half of consumers who questioned a debt about which the creditor or debt collector contacted them reported disputing a debt is consistent with the possibility that some consumers do not dispute in response to a collection effort because they are not aware of the option to dispute or do not understand the steps required to do so. The required clear-and-conspicuous statement of the dispute right could benefit these consumers by making them aware of their right to dispute and informing them how to dispute.

The survey's finding that only 42 percent of consumers who thought they experienced an error with a debt in collection disputed the error suggests consumers are uncertain about how to dispute a debt in collection or that they believe that disputes require too much time and effort relative to the expected benefit. The required consumer-response information could reduce these impediments to disputing debts that consumers believe are in error. Specifically, the consumer-response information will provide a clear means of disputing a debt in a way that triggers the protections provided by the FDCPA and this rule. Furthermore, the convenience of the consumer-response information, which is formatted on the model validation notice as a tear-off with prompts for various actions, could reduce barriers to responding by eliminating or reducing the burden of, for example, deciding what information is relevant and how to phrase the response.[427] This could allow some consumers to save time and avoid other negative consequences, such as lower credit scores due to a debt they may not owe being listed as unpaid on their credit reports.

Additionally, the consumer-response information includes an option to request information about the original creditor. Original-creditor information may help consumers in determining whether the debt is theirs.

The Bureau has tested a model validation notice. Several considerations went into the content and design of the model validation notice. First, consumers must have relevant and accurate information to make informed decisions about how to act with regard to the debt. The Bureau therefore conducted consumer testing to identify what pieces of information consumers considered to be important to help them identify whether a debt was theirs, whether the amount stated was correct, and how the amount the debt collector was attempting to collect has changed over time (*e.g.,* due to fees, interest, and payments).[428] However, there is some indication that consumers tend to not read certain types of standard-form disclosures.[429] To try to avoid this result, the Bureau conducted consumer testing exploring how consumers interacted and engaged with the notice and the pieces of information contained therein.[430] This helped the Bureau understand whether consumers were inclined to engage with the document in general and which pieces of the validation notice received more or less consumer attention.

The Bureau incorporated the findings from this consumer testing in its design of the model validation notice. To increase both consumer engagement with and comprehension of the validation information, the Bureau designed the model notice to be visually engaging. The notice uses plain language wherever possible and conforms to recommendations the Securities and Exchange Commission (SEC) set forth in its plain English handbook.[431] To reduce the perceived complexity of the information, the form uses a clear hierarchy of information through positioning in a columnar format, varying type size, and bold-faced type for subsection headings. It uses shading to highlight the amount due and plain language rather than technical terms. Usability testing analyzing eye-tracking suggests that participants were able to locate relevant information on the form, with most participants able to quickly locate their account number and the contact information of the creditor.[432] The information presented in the form is also concise, presenting consumers with a manageable amount of information about the debt and what they can do in response to the information. This is important, as the perceived and actual cost to a consumer of reading a disclosure increases with the amount of information provided.[433]

A number of consumer advocate and academic commenters asserted that the proposed model notice was not adequately tested. Some of these commenters stated that the Bureau's testing included too few participants to generate valid conclusions about the proposed model notice's efficacy or to evaluate the comprehension of consumers, particularly of the least sophisticated consumers. For instance, a consumer advocate expressed concern that only 60 consumers were included in the cognitive and usability testing rounds.[434] Likewise, an academic commenter stated that the Bureau's consumer testing focused too heavily on observing what testing participants looked at on the model notice (based on the use of eye tracking techniques) at the expense of testing participants' comprehension of the notice. Another commenter stated that the Bureau should have tested more diverse groups, including consumers with limited English proficiency, students, older consumers, and consumers from more diverse socioeconomic backgrounds. Some consumer advocate and academic commenters recommended that the Bureau field test the proposed model notice with consumers with real debts. A consumer advocate expressed concern about the performance of certain aspects of the proposed model notice in quantitative testing, noting in particular that approximately 40 percent of respondents who received the model

[427] A 2016 research report by the United Kingdom's Financial Conduct Authority showed that, in a large randomized control trial, a tear-off form (with a text or email reminder) led to more consumers switching from a current savings account to one with a better interest rate relative to getting only an informational text or email reminder and relative to an informational box with instructions on how to switch. Paul Adams *et al., Attention, Search and Switching: Evidence on Mandated Disclosure from the Savings Market* (UK Fin. Conduct Authority, Occasional Paper No. 19 2016), *https://www.fca.org.uk/publication/occasional-papers/occasional-paper-19.pdf.*

[428] FMG Summary Report, *supra* note 29.

[429] *See, e.g.,* Ian Ayres & Alan Schwartz, *The No-Reading Problem in Consumer Contract Law,* 66 Stan. L. Rev. 545 (2014); Yannis Bakos *et al., Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts,* 43 J. Legal Studies 1, 1–35 (2014); George R. Milne & Mary J. Culnan, *Strategies for Reducing Online Privacy Risks: Why Consumers Read (or Don't Read) Online Privacy Notices,* 18 J. Interactive Mktg. 3, 15–29 (2004); Jonathan A. Obar & Anne Oeldorf-Hirsch, *The Biggest Lie on the internet: Ignoring the Privacy Policies and Terms of Service Policies of Social Networking Services* (York U., draft version, 2018), *http://dx.doi.org/10.2139/ssrn.2757465.*

[430] FMG Cognitive Report, *supra* note 27.

[431] *See* Sec. & Exchange Comm'n, *A Plain English Handbook* (Aug. 1998), *https://www.sec.gov/pdf/handbook.pdf.*

[432] FMG Summary Report, *supra* note 29.

[433] The idea that consumers may decrease their engagement with information when more information is provided is somewhat supported by research on ''choice overload.'' This work indicates that, if choice sets are large, some people opt to make no choice at all. *See, e.g.,* Sheena Iyengar *et al., How Much Choice is Too Much? Contributions to 401(k) Retirement Plans, in Pension Design and Structure: New Lessons from Behavioral Finance,* at 83 (Oxford U. Press 2004).

[434] *See* FMG Summary Report, *supra* note 29, at 5–7.

notice failed to identify the correct entity the consumer should pay.[435]

The Bureau disagrees that the model validation notice was not adequately tested. The model validation notice was developed and validated over multiple rounds of testing between 2014 and 2020, and the Bureau determines that these multiple rounds of testing were sufficient to assess the model validation notice's efficacy and comprehensibility. Further, the Bureau disagrees that its testing focused on eye-tracking at the expense of comprehension testing as consumer comprehension of the model validation notice was assessed in three rounds of testing. The Bureau's testing used eye-tracking in conjunction with consumer responses to inform its conclusions.

The Bureau disagrees that it did not sample sufficiently diverse groups. The Bureau selected respondents with the goal of developing diverse testing pools that would serve as a proxy for the population at large. For example, in one round of usability testing, participants reflected a range of demographic characteristics broken down by race and ethnicity, household income, education level, and employment status.[436] With respect to the criticism that the Bureau did not ''field test'' the model validation notice, testing the form with consumers with real debts would have been impractical.

Regarding comments that the model validation notice did not perform well during the quantitative testing round, the Bureau disagrees. As noted above, in that testing round, the model validation notice consistently performed better than or equal to the status quo notice, including on the question of to whom the consumer should send a payment.[437] Additionally, the Bureau conducted qualitative follow-up testing of the model notice in October 2020. In this testing 88 percent of respondents reported that the notice was either ''very easy'' or ''easy'' to understand.[438] Between 71 percent and 100 percent of participants responded correctly to 14 different comprehension questions. Although some participants expressed confusion about a few aspects of the notice, the initial reactions to the notice were that information was clear and the available actions were obvious.

In summary, the Bureau's testing establishes that consumers will benefit from the use of the model notice compared to the baseline of status quo validation notices.

The Bureau expects consumers to experience few costs as a result of the provision.

Potential benefits to covered persons. The provision provides debt collectors with a safe harbor if they use the model validation notice, specified variations of the model notice, or a substantially similar form to meet the requirements in § 1006.34(c). The Bureau understands that debt collectors currently face litigation risk associated with the validation notices they send, reflecting, in part, conflicting court decisions about what language is required and what language is permitted in the notices.[439] The Bureau expects a significant number of debt collectors will use the model notice, specified variations of the model notice, or a substantially similar form and, therefore, will face significantly reduced litigation risk when providing validation notices because they will receive the safe harbor. This will benefit debt collectors directly, by reducing litigation costs related to validation notices. The provision's requirements to provide specific information about the debt and about a consumer's protections in debt collection could also indirectly benefit debt collectors by adding information to validation notices that would be helpful to consumers but that debt collectors currently do not include for fear that it would increase litigation risk. The validation information may also make consumers more likely to dispute, which could increase costs for debt collectors, as discussed under ''Potential costs to covered persons'' below.

The validation information includes specific information about the debt intended to help consumers identify the debt and understand the amount the debt collector claims is owed. The Bureau's qualitative consumer research and the Bureau's complaint data suggest that the information currently included in validation notices is often not sufficient for consumers to identify a debt or whether the amount owed is correct. If consumers are better able to identify debts, they may be less likely to dispute or ignore a debt that they in fact owe, and at the same time may be better able to articulate the basis for a dispute of a debt that they do not owe. These effects could benefit debt collectors by reducing the costs associated with consumer disputes. Although it is possible that debt collectors could currently provide such information on validation notices, the Bureau understands that some debt collectors who would like to provide additional information do not do so largely due to the legal risks associated with including information in the validation notice beyond what is expressly required by the FDCPA.[440] The form will significantly reduce this legal risk. To quantify the benefits of this provision to covered persons, the Bureau would need data on how frequently consumers do not recognize the debt or the amount owed as identified on a validation notice, how many consumers would better recognize the debt if they received the required validation information, and how consumers would act in response to that information. While the Bureau is not aware of available data that would permit it to estimate these numbers, the Debt Collection Consumer Survey does provide some basis for concluding that the required validation information will be helpful to consumers and, therefore, beneficial for debt collectors.

The validation information could reduce debt collector costs associated with disputes by preventing some disputes from consumers who are more likely to recognize that they owe a debt and by making the disputes that debt collectors receive clearer and easier to resolve.

Debt collectors report that processing disputes is a costly activity and that it can be especially difficult to process disputes if the consumer provides little or no detail about the basis for a dispute. Debt collectors surveyed by the Bureau indicated that most disputes took between five minutes and one hour of staff time to resolve, with 15 to 30 minutes being the most common amount of time.[441] Respondents said that disputes took the longest amount of time to resolve if the basis of the dispute

[435] Several comments in response to the May 2019 proposal also criticized the consumer testing as being outdated because, when that proposal was published, the most recent testing had occurred in 2016. However, the Bureau does not find any reason to believe that consumer understanding of the model notice has changed since 2016, and the commenters did not provide any evidence to support such a claim. Moreover, since the May 2019 proposal, the Bureau has conducted two additional testing rounds.

[436] FMG Usability Report, *supra* note 28, at 85–87.

[437] In response to the question ''According to the notice, if Person A wanted to make a payment on the debt, who should he or she sent the payment to?'' approximately 60 percent of consumers who received the model validation notice answered correctly compared to approximately 40 percent of consumers who received a status quo notice. CFPB Quantitative Testing Report, *supra* note 31, at 14.

[438] *See id.* at 16.

[439] *See* Small Business Review Panel Report, *supra* note 40, at 22.

[440] *See* Small Business Review Panel Report, *supra* note 40, at 22 (finding that small entities would benefit from a model notice that reduced litigation risk arising from conflicting court decisions about what information is permitted on a validation notice).

[441] CFPB Debt Collection Operations Study, *supra* note 37, at 31.

was unclear or if the consumer said the debt was not theirs.[442]

One commenter noted that 40 percent of disputes at their debt collection agency are non-generic and generally resolvable. This commenter asserted that the tear offs on the model validation notice will make these non-generic disputes less informative. An industry commenter noted that 99.4 percent of accounts it received were not disputed. Of the 0.6 percent that are disputed, 80 percent are accurate once more information is gathered. Given this, the commenter argued that providing consumers itemized statements for medical bills, which can run into many pages, is unnecessary.

The Bureau does not have a basis to estimate how much the validation information might affect dispute rates. As an illustration of potential cost savings if dispute rates fall, if the information were to reduce the number of consumers who dispute by 1 percent of all validation notices sent, and assuming that there are 140 million validation notices sent per year,[443] the overall number of annual disputes would fall by 1.4 million. Assuming time to process each dispute of 0.375 hours, the overall savings to industry would be estimated at 525,000 person-hours, or approximately 250 full-time equivalents. Assuming labor costs for debt collectors of $22 per hour,[444] this would represent industry cost savings of about $11.5 million.

The validation notice could also reduce the cost of processing disputes by making it easier for consumers who dispute to provide at least some information about the basis of their disputes. This could reduce the costs to covered persons of processing disputes by making it easier for debt collectors to investigate disputed debts in order to verify the debt.

Potential costs to covered persons. Debt collectors already send validation notices to consumers to comply with the FDCPA, so the validation information will generally affect the content of existing disclosures debt collectors are sending rather than require debt collectors to send entirely new disclosures. Nonetheless, debt collectors will incur certain costs to comply with the form. These include one-time compliance costs, the ongoing costs of obtaining the required validation information, and potentially ongoing costs of responding to a potential increase in the number of disputes.

The provision will require debt collectors to reformat their validation notices to accommodate the validation information requirements. The Bureau expects that any one-time costs to debt collectors of reformatting the validation notice will be relatively small, particularly for debt collectors who rely on vendors, because the Bureau expects that most vendors will provide an updated notice at no additional cost.[445] The Bureau understands from its outreach that many covered persons currently use vendors to provide validation notices.[446] Surveyed firms, and their vendors, told the Bureau that vendors do not typically charge an additional cost to modify an existing template (although this practice might not apply given that the final rule likely will require more extensive changes to validation notices than vendors typically make today).[447] Debt collectors and vendors will bear costs to understand the requirements of the provision and to ensure that their systems generate notices that comply with the requirements, although these costs will be mitigated somewhat by the availability of a model notice.

The validation information will require debt collectors to provide certain additional information about the debt, which will require that debt collectors receive and maintain certain data fields and incorporate them into the notices. The Bureau believes that the large majority of debt collectors already receive and maintain most data fields included in the final validation information. However, some respondents to the Debt Collection Operations Study reported that they do not receive from creditors information about post-default interest, fees, payments, and credits.[448] These debt collectors will have to update their systems to track these fields. The Bureau understands that such system updates would be likely to cost less than $1,000 for each debt collector.[449]

At least one industry commenter asserted that one-time compliance costs would be significantly higher than $1,000, at least for collectors of medical debt. This commenter estimated costs of between $22,000 and $31,000 for implementation. The commenter noted that, for collectors of medical debt, an itemization of charges requires information about payments by the consumer's health insurance, increasing the complexity and cost of tracking the necessary information. The Bureau acknowledges that costs may be higher for some debt collectors. However, the Bureau's estimate is based on responses to the CFPB Debt Collection Operations Study, more than half of which came from debt collectors of medical debt. As such, the Bureau believes that, on average, its estimate of less than $1,000 in one-time costs is reasonable.

If debt collectors adjust their systems to produce notices including the new validation information, the Bureau does not expect there would be an increase in the ongoing costs of printing and sending validation notices. However, there could be ongoing costs related to the validation information requirements if the required data are not always available to debt collectors.[450] The Bureau understands that some creditors do not currently track post-default charges and credits in a way that can be readily transferred to debt collectors. However, the Bureau's understanding is that most creditors, including medical providers, do track this information, and many debt collectors already provide this information on validation notices. Further, debt collectors are already

[442] *Id.*

[443] The assumption of 140 million validation notices per year is based on an estimated 49 million consumers contacted by debt collectors each year and an assumption that each consumer receives an average of approximately 2.8 notices during the year.

[444] This assumes an hourly wage of $15 and taxes, benefits, and incentives of $7 per hour. *See* CFPB Debt Collection Operations Study, *supra* note 37, at 17 (reporting estimated debt collector wages between $10 and $20 per hour plus incentives).

[445] *See id.* at 33.

[446] In the Operations Study, over 85 percent of debt collectors surveyed by the Bureau reported using letter vendors. *Id.* at 32.

[447] *Id.* at 33.

[448] In the Bureau's Operations Study, 52 of 58 respondents reported receiving itemization of post-charge-off fees on at least some of their accounts. *Id.* at 23.

[449] *Id.* at 26.

[450] One industry trade group estimated that an itemization requirement would cost $600 million in professional fees to conduct legal analyses of HIPAA compliance for medical debt, $30 million for one-time system reprogramming for debt collectors, and $3 billion for one-time system reprogramming for creditors. The proposal allegedly would also result in billions of dollars in ongoing support costs and uncompensated medical care because, according to the commenter, the proposed requirement, if adopted, would increase the risks that hospitals might be unable to use debt collectors. As discussed in part V, the itemization requirement should not raise issues of HIPAA compliance that would require creditors to engage legal counsel in order to provide the required information, as HIPAA privacy regulations explicitly permit disclosure where required by law. While some one-time costs will be required so that collection and billing systems can incorporate the data needed to comply with the requirement, as discussed in this section, the Bureau understands that the required changes would not be far outside the scope of normal adjustments to billing and collection systems and does not have reason to believe the changes would be so expensive as to prevent hospitals from using debt collectors. The final rule permits debt collectors to use the date of the last statement or invoice provided to the consumer by a creditor as the itemization date. If providing a debt collector with itemization information were prohibitively expensive for a medical provider, such providers could avoid these costs by simply issuing a statement to the consumer.

required to disclose an itemization for some types of debt in at least one jurisdiction, New York State.[451]

In addition, as discussed in the section-by-section analysis of § 1006.34(b)(3), the final rule's itemization date definition permits debt collectors to select an itemization date that is feasible for the type of debt in collection and the information debt collectors receive. And § 1006.34(c)(2)(viii) requires itemization of fees, interest, and credits only subsequent to the selected itemization date. Thus, for example, if a debt collector selects the last statement date as the itemization date under § 1006.34(b)(3), and if the creditor has recently issued a statement to the consumer, the debt collector need only obtain and provide to the consumer an itemization with fees, interest, and credits subsequent to that last statement date. And, as discussed in the section-by-section analysis of § 1006.34(d)(2), a debt collector may provide the itemization on a separate page and retain the safe harbor for the rest of the validation notice.

Industry commenters asserted that there would be additional printing and mailing costs of the provision due to the tear-off portion of the model notice, which is formatted for use with a return envelope. The commenters argued that many debt collectors do not currently include return envelopes with their validation notices and that including a return envelope would increase mailing costs. The Bureau disagrees that this would be a cost of the rule, as the rule does not require including a return envelope with a mailed validation notice, the format of the tear-off portion notwithstanding. Given that it is not required, the Bureau expects that debt collectors will only begin including return envelopes if they find, in their own analysis, that the benefit exceeds the additional costs.

Several commenters discussed the potential for ongoing costs of providing the new validation information. One industry commenter expressed concern about the availability of the information required on the model validation notice for medical debt, as the commenter believed that the only available itemization date permitted by the proposal for these debts would be date of service (*i.e.,* the transaction date), and the commenter stated that date of service was currently only available from 17.2 percent of its clients. Another industry commenter noted that there would be costs associated with providing updated itemization dates for a debt that transfers between debt collectors.

Industry trade association commenters noted that there would be costs to creditors of providing the fields to debt collectors and that not all of the required fields are necessarily tracked by all creditors currently, particularly credit unions. The Bureau acknowledges that the FDCPA and this final rule may create indirect costs for creditors that use debt collectors, because the costs to debt collectors of complying with FDCPA requirements may be passed on to creditors and because debt collectors must receive certain information about debts in order to comply with FDCPA requirements. The information available to the Bureau does not suggest that any indirect costs to creditors of this provision will be large.

Further, one industry commenter asserted that the itemization requirement could competitively harm collectors of medical debt. This commenter asserted that medical care providers are currently unable to provide the required itemization information, and rather than incurring costs to provide this information, would switch to using debt collectors who do not comply with the law. This would put compliant debt collectors at a competitive disadvantage. As noted above, the Bureau acknowledges that the provision may affect the costs to creditors, including medical care providers, of using FDCPA debt collectors, because creditors must provide debt collectors with the necessary information for the validation notice. It is also possible that in some cases a less sophisticated creditor may employ a debt collector who does not attempt to comply with the rule. However, the Bureau finds it unlikely that this provision of the rule would lead to widespread non-compliance, at the expense of debt collectors who comply with the requirements of the rule. The Bureau, the FTC, and other Federal and State law enforcement agencies have and will continue to maintain vigorous enforcement of the FDCPA.[452] Any debt collector who obtained enough business through non-compliance with the rule to do material harm to debt collectors who comply with the rule would be likely to attract enforcement action from regulators. Moreover, the risk of reputational harm is likely to deter some medical providers from intentionally employing debt collectors who knowingly do not comply with the rule.

Other potential costs to debt collectors could arise if changes to the validation information affect how consumers respond, particularly whether they dispute the debt. As discussed above, because the validation information would include more detail, consumers might be more likely to recognize the debt and less likely to mistakenly dispute debts that they owe. On the other hand, the new consumer-response information would make it easier to dispute debts or request the name and address of the original creditor. Together with the additional information about consumers' ability to dispute that will be provided, this could increase the number of consumers who dispute or request original-creditor information. Similarly, some industry commenters argued that the tear-off portion of the model notice would make disputes easier, resulting in more disputes. The overall impact on dispute rates is unclear.

Any increases in dispute rates would not be likely to substantially reduce collection revenue, but increased dispute rates would increase debt collector costs. With respect to collections revenue, the Bureau expects that, with some fairly limited exceptions, consumers who choose to pay a debt are generally those who recognize that they owe the debt and want to pay it, and that in most cases the validation information would be unlikely to cause such consumers to dispute rather than pay.[453] With respect to costs, the disclosures could lead consumers who do not recognize the debt or who believe there is a problem with the amount demanded to dispute

[451] *See* 23 NYCRR 1.2(b) (requiring debt collectors to provide an itemized accounting of the debt within five days after the initial communication with a consumer in connection with the collection of certain types of charged-off debt, such as credit card debt). The fact that debt collectors subject to New York's requirements continue to operate and send validation notices in New York suggests that, although the itemization requirement may impose one-time adjustment costs on some creditors and debt collectors, ongoing costs are not prohibitive, at least for the types of debts for which New York has required itemization.

[452] *See, e.g.,* Bureau of Consumer Fin. Prot., *CFPB, FTC, State, and Federal Law Enforcement Partners Announce Nationwide Crackdown on Phantom and Abusive Debt Collection* (Sept. 29, 2020), *https://www.consumerfinance.gov/about-us/newsroom/cfpb-ftc-state-and-federal-law-enforcement-partners-announce-nationwide-crackdown-phantom-and-abusive-debt-collection.*

[453] While there is some evidence that consumers sometimes pay alleged debts even though they do not believe they owe them, such consumers may be motivated by factors, such as credit reporting concerns, that are not addressed by the validation notice itself. *See* Jeff Sovern *et al., Validation and Verification Vignettes: More Results from an Empirical Study of Consumer Understanding of Debt Collection Validation Notices,* at 46–47 (St. John's U., Working Paper No. 18–0016, 2018), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3219171.*

the debt rather than ignoring it. Responding to disputes is a costly activity for debt collectors, so an increase in dispute rates would increase these costs. As discussed above, covered persons surveyed by the Bureau indicated that most disputes took between five minutes and one hour of staff time to resolve, with 15 to 30 minutes being the most common amount of time.[454]

Alternative proposals to require Spanish-language disclosures. The Bureau considered proposals that would require debt collectors to provide a Spanish-language translation of the validation information under certain circumstances, such as on the reverse side of any English-language validation notice or if requested by a consumer. Consumers with limited English proficiency may benefit from translations of the validation information, and Spanish speakers represent the second-largest language group in the United States after English speakers.[455]

Requiring Spanish-language disclosures would impose costs on some debt collectors. A requirement to send a Spanish-language disclosure on the back of each validation notice could increase mailing costs for all validation notices that are sent by mail, because it would require information that would otherwise be printed on the back of validation notices, such as State-mandated disclosures, to be provided on a separate page. A requirement to provide Spanish-language validation notices upon request could lead to a smaller increase in mailing costs but could require debt collectors to develop and maintain systems for tracking a consumer's language preference and responding to that preference.

The Bureau understands that some debt collectors currently send validation notices in Spanish to some consumers. These debt collectors presumably believe that the increase in revenues from sending them to these consumers exceeds the costs of doing so. To the extent sending such notices is already prevalent, it would limit the consumer benefits of a provision that requires Spanish-language translations as well as the costs to debt collectors of such a provision, although there would still be costs associated with ensuring that such disclosures were made as required by regulation.

Consumer advocate and academic commenters argued that the Bureau should have required that the validation notice be in the language of the original transaction, including languages other than English or Spanish. The commenters noted that procedural hurdles, such as a mismatch between the consumers' primary language and the language of a disclosure, can have large effects on behavior. The Bureau notes that this alternative would impose significantly greater costs on debt collectors than the final rule, as they would need to maintain versions of the model notice for each such language. At the same time, the marginal benefit to consumers of the alternative suggested by commenters would be smaller, as fewer consumers communicate in languages other than English and Spanish.

3. Required Actions Prior to Furnishing Information

Section 1006.30(a)(1) prohibits a debt collector from furnishing information to a consumer reporting agency (CRA) about a debt before taking specific actions to contact the consumer about that debt. A debt collector can satisfy this requirement by: (i) Speaking to the consumer about the debt in person or by telephone; or (ii) placing a letter in the mail or sending an electronic message to the consumer about the debt and waiting a reasonable period of time to receive a notice of undeliverability, provided certain other conditions are satisfied. A validation notice is one type of letter or electronic communication debt collectors can use to satisfy § 1006.30(a)(1)(ii).

Potential benefits and costs to consumers. The final rule will help consumers to learn about an alleged debt before a debt collector furnishes adverse information to a CRA. If consumers believe that the information is incorrect, they will have an opportunity to dispute the debt.

When debt collectors furnish information about unpaid debts to CRAs, that information can appear on consumer credit reports, potentially limiting consumers' ability to obtain credit, employment, or housing. If consumers are unaware that information about a possible unpaid debt is being furnished to a CRA, then they may not realize that their ability to obtain credit, employment or housing may be affected by the debt's presence on their credit reports. They may pay more for credit or lose out on employment or housing because they are unaware that their credit scores have been negatively affected or they may discover the adverse information only when they apply for credit, employment, or housing.

To quantify the potential consumer benefits from the final rule, the Bureau would need to know: (1) How frequently consumers are unaware that debt collectors furnished information about their debts to CRAs but would become aware of it if debt collectors informed consumers prior to furnishing information; and (2) the benefit to these consumers of becoming aware they had a debt in collections.

In many cases, consumers will not be affected by the provision because many debt collectors already take one of the actions required by the final rule before furnishing information to CRAs. Many other consumers will not be affected by the provision because not all debt collectors furnish information to CRAs about the debts on which they are seeking to recover.

The Bureau understands that most debt collectors mail validation notices to consumers shortly after they receive accounts for collection.[456] A minority of debt collectors sometimes or always mail validation notices only after speaking with consumers (whether contact was initiated by the debt collector or the consumer).[457] The Bureau does not have representative data to estimate how often consumers would be affected by the provision, but the evidence suggests that a relatively small share of debt collectors furnish information to CRAs before providing a validation notice or taking one of the other actions required by the final rule. If, for example, debt collectors sent

[454] CFPB Debt Collection Operations Study, *supra* note 37, at 31. The discussion in ''Benefits to covered persons'' above provides an illustration of the potential impact on debt collectors of a change in dispute rates. Using the assumptions in that illustration, if the net impact of the proposal were to increase industrywide disputes by 1 million disputes per year, it could imply increased industry costs totaling around $8.25 million per year.

[455] In 2013, 38.4 million residents in the United States aged five and older spoke Spanish at home. *See* U.S. Census Bureau, *Facts for Features: Hispanic Heritage Month 2015* (Sept. 14, 2015), *https://www.census.gov/newsroom/facts-for-features/2015/cb15-ff18.html.*

[456] *See* CFPB Debt Collection Operations Study, *supra* note 37, at 28. One large industry commenter, which does furnish to the CRAs, also confirmed that it almost always mails a validation notice before furnishing. To comply with the final rule, these debt collectors would also need to wait a reasonable period of time to allow for notifications of non-delivery, and only furnish if they don't receive such notifications. The Bureau does not have information as to how many of these debt collectors currently take these additional steps. However, the Bureau expects that taking these additional steps would impose minimal costs on debt collectors that do not already take them.

[457] In the Bureau's Operations Study, 53 of 58 respondents said that they send a validation notice shortly after debt placement, and of those that do not, three respondents that said that they furnish data to CRAs. *Id.* During the meeting of the SBREFA Panel, only one small entity representative described additional burdens it would face as a result of a requirement to communicate with consumers before furnishing information to credit bureaus.

validation notices for an additional five percent of debts in collection, the provision could result in up to approximately seven million additional validation notices sent each year (assuming that no debt collectors would cease furnishing in response to the provision).[458]

Learning that a debt is in collections shortly after the collections process begins can help consumers prevent or mitigate harm from adverse information on their credit reports. This can be particularly important if the information about the debt is inaccurate because in those cases consumers who learn of the alleged debt can dispute the debt under the FDCPA or dispute the item of information under the FCRA. By informing consumers about the collection item before it is furnished to a CRA, the final rule will make it less likely that consumers learn about a collection item when they are in the process of applying for credit or other benefits, at which point they may feel pressure to resolve the item and may not have the opportunity to fully dispute the item.

An FTC report addressed the prevalence of collections-related errors in credit reports.[459] The FTC report analyzed data from a sample of 1,001 consumers and identified errors in the credit records of three nationwide CRAs. The report found collections-related errors in 4.9 percent of credit reports, and credit reports with documented errors contained, on average, 1.8 errors per report. The Bureau's Debt Collection Consumer Survey also suggests that debt collectors make collection errors, finding that 53 percent of consumers who said they had been contacted about one or more debts in collection said that these contacts included at least one debt the consumer thought was in error.[460]

Credit scores are based on a wide variety of information in consumer credit files. While many errors have only small effects on consumers' credit scores,[461] in some cases information in credit files about unpaid debts can have a reasonably large impact on credit scores. For example, analysis of telecommunications collection items in credit reports has shown that, while additional collection items have relatively small effects in some cases, they can have substantial effects for some consumers, with an average reduction in credit score of more than 41 points for super-prime consumers.[462] In some circumstances, these changes could lead to higher interest rates for consumers or denial of credit, particularly for borrowers with otherwise high credit scores.

Potential benefits and costs to covered persons. The final rule will affect the practices of debt collectors who sometimes furnish information about consumers' debts to CRAs before taking one of the required actions under the final rule. The Bureau understands that most debt collectors mail validation notices to consumers shortly after they receive the accounts for collections and before they furnish information on those accounts. These debt collectors either already would be in compliance with the final rule or could come into compliance with minimal additional cost.[463] Forty-five out of 58 debt collectors responding to the Bureau's Operations Study said that they furnish information to CRAs.[464] Of these respondents, all but three said that they send a validation notice upon account placement, such that the final rule's requirement would be satisfied as long as the debt collectors also wait a reasonable period of time to allow for notifications of non-delivery, and only furnish if they do not receive such notifications. These debt collectors will likely need to review their policies to ensure that validation notices are always sent (or validation information is provided in an initial communication) prior to reporting on the account, which the Bureau expects would involve a small one-time cost. Debt collectors that do not currently wait a reasonable period of time prior to furnishing to allow for notifications of non-delivery, accept non-delivery notifications, and only furnish if they do not receive such notifications would need to adopt these practices, but the Bureau expects this would impose minimal ongoing operational costs. Other debt collectors do not furnish information to CRAs at all and will not be affected by the requirement.

Debt collectors who furnish information to CRAs prior to communicating with consumers but provide validation notices to consumers only after they have been in contact with consumers will need to change their practices and would face increased costs as a result of the final rule. Because these debt collectors are already required to provide validation notices to consumers (unless validation information is provided in an initial communication or the debt has been paid), the Bureau expects that many already have systems in place for sending notices and will not face one-time compliance costs greater than those of other debt collectors.[465] However, these debt collectors will face ongoing costs from sending validation notices to more consumers than they otherwise would, at an estimated cost of $0.50 to $0.80 per debt if sent by mail.[466] To the extent debt collectors take advantage of opportunities to send validation notices electronically, the marginal cost of sending each notice is likely to be approximately zero. Alternatively, these debt collectors could cease furnishing information to CRAs until after they take the specific steps identified in the final rule, which could impact the effectiveness of their collection efforts.[467] Because debt collectors could choose the less burdensome of these options, the additional costs of delivering notices represent an upper bound on the burden of the provision for debt collectors.

[458] This estimate assumes 140 million validation notices are sent each year, based on an estimated 49 million consumers contacted by debt collectors each year and an assumption that each receives an average of approximately 2.8 notices during the year.

[459] Fed. Trade Comm'n, *Report to Congress under Section 319 of the Fair and Accurate Credit Transactions Act of 2003,* (Dec. 2012) *https://www.ftc.gov/sites/default/files/documents/reports/section-319-fair-and-accurate-credit-transactions-act-2003-fifth-interim-federal-trade-commission/130211factareport.pdf* (FTC Report to Congress).

[460] CFPB Debt Collection Consumer Survey, *supra* note 292, at 24.

[461] *See* FTC Report to Congress, *supra* note 459, at 43.

[462] *See* Brian Bucks *et al.,* Bureau of Consumer Fin. Prot., *Collection of Telecommunication Debt, https://files.consumerfinance.gov/f/documents/bcfp_consumer-credit-trends_collection-telecommunications-debt_082018.pdf* (Aug. 2018).

[463] In the Operations Study, 53 of 58 respondents said that they send a validation notice shortly after debt placement. CFPB Debt Collection Operations Study, *supra* note 37, at 28. To comply with the final rule, these debt collectors would also need to wait a reasonable period of time to allow for notifications of non-delivery, accept non-delivery notifications and only furnish if they don't receive such notifications. The Bureau does not have information as to how many of these debt collectors currently take these additional steps. However, the Bureau expects that taking these additional steps would impose minimal costs on debt collectors that do not already take them.

[464] *Id.* at 19.

[465] Debt collectors who do not currently have systems in place for sending notices will face one-time compliance costs to implement those systems.

[466] *See* CFPB Debt Collection Operations Study, *supra* note 37, at 32–33. One small entity representative on the Bureau's SBREFA Panel indicated that, for about one-half of its accounts, it currently sends validation notices only after speaking with a consumer, and that, if it were required to send validation notices to all consumers, it would incur additional mailing costs of $0.63 per mailing for an estimated 400,000 accounts per year. A small industry commenter asserted that mailing costs were significantly higher than $0.50–$0.80 per debt but did not provide an alternative figure.

[467] If debt collectors furnish information to CRAs less frequently this could make consumer reports less informative in general, which could have negative effects on the credit system by making it harder for creditors to assess credit risk.

Commenters noted several specific situations in which the proposed provision could, in the commenters' view, unduly burden debt collectors. One small industry commenter raised the concern that a bad address, which occurs in 15 percent of accounts at their agency, would stop collections. Another industry commenter noted that 3 percent of its notices are returned as undeliverable and argued that attempting to deliver a validation notice should count as a communication and thus allow furnishing. Another industry commenter noted that some States are ''closed'' in the sense that debt collectors based in other States are not allowed to deliver notices into those States. This commenter was concerned that the proposed provision would not allow furnishing of information about consumers in those States and argued that this will reduce credit report accuracy. A joint comment by an industry commenter and CRA argued that the proposed provision would be particularly problematic in the check verification space. The commenter noted that, in the case of bad checks, the debt collector generally does not have the consumer's address or telephone number and cannot communicate with the consumer directly. In these cases, the debt collector would report the bad check to a check verification CRA, but this could be prohibited under the proposed provision. The commenter argued that the proposed provision could undermine the reliability of the check payment system by making it impossible to track check fraud, among other things.

The Bureau agrees with some of the commenters with respect to these additional costs and has revised the final rule from the proposal to reduce or eliminate these costs. In particular, the Bureau has revised § 1006.30(a) to specify that, if a debt collector places a letter in the mail or sends an electronic message to the consumer about the debt, the debt collector must wait a reasonable period of time (with a safe harbor for waiting 14 consecutive days) before furnishing information about the debt to a CRA and, during that period, permit receipt of, and monitor for, notifications of undeliverability for mail and electronic messages. A debt collector who places a letter in the mail or sends an electronic message, does not receive a notice of undeliverability during that period, and furnishes information to a consumer reporting agency after the period ends has not violated the rule even if the debt collector subsequently receives a notice of undeliverability. Section 1006.30(a)(2) of the final rule also specifies that § 1006.30(a)(1) does not apply to the furnishing of information about a debt to a specialty check verification CRA. The Bureau believes these changes will reduce or eliminate many of the costs cited by the commenters.

H. Potential Reduction of Access by Consumers to Consumer Financial Products and Services

Economic theory indicates that it is possible for changes in debt collection rules, such as those contained in this final rule, to affect consumers' access to credit. Under economic theory, creditors should decide to extend credit based on the discounted expected value of the revenue stream from that extension of credit. This entails considering the possibility that the consumer will ultimately default and expected payments will decrease. If this final rule addressing disclosures were to increase collection costs or reduce revenue collected from delinquent debt, then this would reduce the return to lending, which in theory could lead lenders to increase the cost of lending, restrict availability of credit, or both.

As discussed in the November 2020 Final Rule, the Bureau has considered the available empirical data and research on the effect of State debt collection laws on the price and availability of credit.[468] That research shows that State debt collection laws affect the price and availability of credit in ways that theory would predict, but that effects are relatively small even for changes in State laws that are likely more significant than the provisions in this final rule.[469] In light of that research and the CCP analysis above, the Bureau concludes that the provisions in this final rule are unlikely to cause any significant reduction in access to consumer credit.

I. Potential Specific Impacts of the Rule

1. Depository Institutions and Credit Unions With $10 Billion or Less in Total Assets, as Described in Section 1026

Depository institutions and credit unions are generally not debt collectors under the FDCPA and therefore would not be covered under the final rule. Creditors could experience indirect effects from the final rule to the extent they hire FDCPA debt collectors or sell debt in default to such debt collectors. Such creditors could experience higher costs if debt collectors' costs increase and if debt collectors are able to pass those costs on to creditors. The Bureau understands that many depository institutions and credit unions with $10 billion or less in total assets rely on FDCPA debt collectors to collect uncollected amounts, but the Bureau does not have data indicating whether such institutions are more or less likely than other creditors to do so. The Bureau did not receive any comments on this issue with respect to the provisions in this final rule.

2. Impact of the Final Rule on Consumers in Rural Areas

Consumers in rural areas may experience benefits from the final rule that are different in certain respects from the benefits experienced by consumers in general. For example, consumers in rural areas may be more likely to borrow from small local banks and credit unions that may be less likely to outsource debt collection to FDCPA debt collectors.

The Bureau requested interested parties to provide data, research results, and other factual information on the impact of the proposed rule on consumers in rural areas, but the Bureau did not receive any comments on this subject.

VIII. Final Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct an Initial Regulatory Flexibility Analysis (IRFA) and a Final Regulatory Flexibility Analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements.[470] Section 604(a) of the RFA sets forth the required elements of the FRFA. Section 604(a)(1) requires a statement of the objectives of, and the legal basis for, the rule.[471] Section 604(a)(2) requires a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments. Section 604(a)(3) requires the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments. Section 604(a)(4) requires a description of and,

[468] *See* 84 FR 23274, 23389–91 (May 21, 2019).

[469] For example, one study found that additional State regulations on debt collectors' conduct caused the rate at which a credit inquiry led to a successful account opening to decline by less than 0.02 percentage points off a base rate of about 43 percent. *See id.* at 23389–90.

[470] 5 U.S.C. 603(a), 604(a).

[471] 5 U.S.C. 604(a)(1).

where feasible, an estimate of the number of small entities to which the rule will apply.[472] Section 604(a)(5) requires a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for the preparation of the report or record.[473] Section 604(a)(6) requires a description of any significant alternatives to the rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the rule on small entities.[474] Finally, section 604(a)(7) requires a description of the steps the agency has taken to minimize any additional cost of credit for small entities.[475]

A. Statement of the Objectives of, and Legal Basis for, the Final Rule

As discussed in part IV, the Bureau issues this rule pursuant to its authority under the FDCPA and the Dodd-Frank Act. The objectives of the final rule are to clarify and implement the FDCPA's provisions and to further the FDCPA's goals of eliminating abusive debt collection practices and ensuring that debt collectors who refrain from abusive debt collection practices are not competitively disadvantaged.[476] As the first Federal agency with authority under the FDCPA to prescribe substantive rules with respect to the collection of debts by debt collectors, the Bureau is requiring consumer disclosure requirements to provide greater clarity for both consumers and industry participants as to the information debt collectors must provide consumers to comply with the law. The Bureau intends that these clarifications will help to eliminate abusive debt collection practices and ensure that debt collectors who refrain from abusive debt collection practices are not competitively disadvantaged.[477]

As amended by the Dodd-Frank Act, FDCPA section 814(d) provides that the Bureau may ''prescribe rules with respect to the collection of debts by debt collectors,'' as that term is defined in the FDCPA.[478] Section 1022(a) of the Dodd-Frank Act provides that ''[t]he Bureau is authorized to exercise its authorities under Federal consumer financial law to administer, enforce, and otherwise implement the provisions of Federal consumer financial law.''[479] ''Federal consumer financial law'' includes title X of the Dodd-Frank Act and the FDCPA. The legal basis for the final rule is discussed in detail in the legal authority analysis in part IV and in the section-by-section analysis in part V.

B. Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis

The Bureau received comments on the IRFA from the Acting Chief Counsel for Advocacy of the Small Business Administration, which are discussed in the next section. The Bureau did not receive other comments that referenced the IRFA specifically; however, several commenters did raise issues about the burdens of the proposed rule's provisions, and the Bureau's response to these issues is discussed in parts V and VII above and in this part below.

C. Response to Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration

The Acting Chief Counsel for Advocacy of the Small Business Administration filed a public comment letter on the May 2019 proposed rule that discusses both the IRFA and certain of the proposed requirements (the ''first SBA letter''). The Acting Chief Counsel for Advocacy of the Small Business Administration also filed a public comment letter on the February 2020 supplemental proposed rule that discusses both the IRFA and the proposed requirements (the ''second SBA letter''). This section first responds to comments on the IRFA and then responds to the substantive comments on the proposed rule's provisions.

The first SBA letter notes that the proposed rule could impose costs to read and understand the rule and to train employees in new practices. The Bureau had discussed these costs in the context of some specific provisions but has added a more general discussion of these costs to section E of the FRFA, below.

The first SBA letter also notes that the Bureau claims some provisions will cause no significant impact because those provisions are already part of debt collectors' business practices, and argues that the Bureau should clarify what the benefit of such provisions is to consumers if they will not change debt collector practices. As discussed in part V above and the section 1022(b)(2) analysis of the proposed rule, the Bureau believes that, by clarifying the FDCPA's requirements, the rule will benefit both consumers and debt collectors, including small entities. Many market participants have identified a need for greater clarity in interpreting many of the FDCPA's provisions. For example, a trade group commenter emphasized that ambiguities in the FDCPA lead to unnecessary and costly litigation. The Bureau believes that there is a benefit to providing additional clarity about the FDCPA's requirements even where the vast majority of debt collectors follow practices that meet those requirements. The additional clarity helps those debt collectors to avoid unnecessary litigation and to have confidence in what practices do and do not violate the FDCPA. The additional clarity also makes it easier to establish when less scrupulous debt collectors have violated the statute and to hold them accountable, which benefits consumers as well as debt collectors who do comply with the law.

[472] 5 U.S.C. 604(a)(4).

[473] 5 U.S.C. 604(a)(5).

[474] 5 U.S.C. 604(a)(6).

[475] *Id.*

[476] *See* 15 U.S.C. 1692(e).

[477] *See id.*

[478] 15 U.S.C. 1692*l*(d).

[479] 12 U.S.C. 5512(a).

The first SBA letter points out that the proposed rule's Paperwork Reduction Act (PRA) section estimates 1,029,500 burden hours and argues that this could translate into millions of dollars in recordkeeping and reporting costs. Most of this burden is not attributable to the rule itself but rather to the requirements of the FDCPA. As discussed in the supporting statement accompanying the Bureau's information collection request, the PRA estimates include the burden not only of complying with the new requirements introduced by the final rule but also of complying with the FDCPA itself. These burdens had not previously been accounted for under the PRA. Thus, the large majority of the estimated burden hours represent the burden of complying with existing FDCPA provisions that exist independent of the rule, in particular the requirement to provide a validation notice under § 809(a) of the FDCPA and the requirement to respond to consumer disputes under § 809(b) of the FDCPA. There are, of course, burdens associated with other information collections that are being introduced or modified by the final rule, and those burdens are discussed in this FRFA as well as in the supporting statement.

The SBA letters also expressed several concerns about specific provisions of the proposed rule and recommended changes to those provisions. These concerns and recommendations, and the Bureau's response, are discussed in the section-by-section analysis of the relevant provisions in part V above.

D. Description and, Where Feasible, Provision of an Estimate of the Number of Small Entities to Which the Final Rule Will Apply

As discussed in the Small Business Review Panel Report, for the purposes of assessing the impacts of this final rule on small entities, ''small entities'' is defined in the RFA to include small businesses, small nonprofit organizations, and small government jurisdictions.[480] A ''small business'' is determined by application of SBA regulations in reference to the North American Industry Classification System (NAICS) classifications and size standards.[481] Under such standards, the Small Business Review Panel (Panel) identified four categories of small entities that may be subject to the final rule: Collection agencies (NAICS 561440) with annual receipts at or below the SBA size standard (currently $16.5 million), debt buyers (NAICS 522298) with annual receipts at or below the size standard (currently $41.5 million), collection law firms (NAICS 541110) with annual receipts at or below the size standard (currently $12 million), and servicers who acquire accounts in default. These servicers include depository institutions (NAICS 522110, 522120, and 522130) with assets at or below the size standard (currently $600 million) or non-depository institutions (NAICS 522390) with annual receipts at or below the size standard (currently $22 million). The Panel did not meet with small nonprofit organizations or small government jurisdictions.[482]

The following table provides the Bureau's estimate of the number and types of entities that may be affected by the final rule:

TABLE 1—ESTIMATED NUMBER OF AFFECTED ENTITIES AND SMALL ENTITIES BY CATEGORY

Category	NAICS	Small-entity threshold	Estimated total number of debt collectors within category	Estimated number of small-entity debt collectors within category
Collection agencies	561440	$16.5 million in annual receipts	9,000	8,800
Debt buyers	522298	$41.5 million in annual receipts	330	300
Collection law firms	541110	$12.0 million in annual receipts	1,000	950
Loan servicers	522110, 522120, and 522130 (depositories); 522390 (non-depositories).	$600 million in annual receipts for depository institutions; $22.0 million or less for non-depositories.	700	200

Descriptions of the four categories:

Collection agencies. The Census Bureau defines ''collection agencies'' (NAICS code 561440) as ''establishments primarily engaged in collecting payments for claims and remitting payments collected to their clients.''[483] According to the Census Bureau, in 2012 (the most recent year for which detailed data are available), there were approximately 4,000 collection agencies with paid employees in the United States. Of these, the Bureau estimates that 3,800 collection agencies have $16.5 million or less in annual receipts and are therefore small entities.[484] Census Bureau estimates indicate that in 2012 there were also more than 5,000 collection agencies without employees, all of which are presumably small entities.

Debt buyers. Debt buyers purchase delinquent accounts and attempt to collect amounts owed, either themselves or through agents. The Bureau estimates that there are approximately 330 debt buyers in the United States, and that a substantial majority of these are small entities.[485] Many debt buyers—particularly those that are small entities—also collect debt on behalf of other debt owners.[486]

Collection law firms. The Bureau estimates that there are 1,000 law firms in the United States that either have as their principal purpose the collection of

[480] 5 U.S.C. 601(6).

[481] The current SBA size standards are found on SBA's website, *http://www.sba.gov/content/table-small-business-size-standards.*

[482] Small Business Review Panel Report, *supra* note 40, at 29.

[483] As defined by the U.S. Census Bureau, collection agencies include entities that collect only commercial debt, and the proposed rule would apply only to debt collectors of consumer debt. However, the Bureau understands that relatively few collection agencies collect only commercial debt.

[484] The U.S. Census Bureau estimates average annual receipts of $95,000 per employee for collection agencies. Given this, the Bureau assumes that all firms with fewer than 100 employees and approximately one-half of the firms with 100 to 499 employees are small entities, which implies approximately 3,800 firms.

[485] The Receivables Management Association, the largest trade group for debt buyers, states that it has approximately 300 debt buyer members and believes that 90 percent of debt buyers are current members.

[486] The Bureau understands that debt buyers are generally nondepositories that specialize in debt buying and, in some cases, debt collection. The Bureau expects that debt buyers that are not collection agencies would be classified by the U.S. Census Bureau under ''all other nondepository credit intermediation'' (NAICS Code 522298).

consumer debt or regularly collect consumer debt owed to others, so that the proposed rule would apply to them. The Bureau estimates that 95 percent of such law firms are small entities.[487]

Loan servicers. Loan servicers would be covered by the final rule if they are covered by the FDCPA because, among other things, they acquire the right to service loans already in default.[488] The Bureau believes that this is most likely to occur with regard to companies that service mortgage loans or student loans. The Bureau estimates that approximately 200 such mortgage servicers may be small entities and that few, if any, student loan servicers that would be covered by the final rule are small.[489]

E. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of Classes of Small Entities That Will Be Subject to the Requirements and the Type of Professional Skills Necessary for the Preparation of the Report or Record

The final rule will not impose new reporting or recordkeeping requirements, but it will impose new compliance requirements on small entities subject to the rule.[490] The requirements and the costs associated with them are discussed below. In addition to the specific costs discussed below, all small entities will incur costs to read the rule and incorporate its provisions into their policies and procedures, and small entities with employees will need to train employees in new policies and procedures. The extent of training required will depend on debt collectors' existing practices and on the roles performed by individual employees. Debt collectors employ an estimated 123,000 workers.[491] If, on average, the rule required an additional hour of training for each of these employees, at an average cost of $22 per hour, the total training cost would be approximately $2,700,000.[492]

In evaluating the potential impacts of the rule on small entities, the Bureau takes as a baseline conduct in debt collection markets under the current legal framework governing debt collection. This includes debt collector practices as they currently exist, responding to the requirements of the FDCPA as currently interpreted by courts and law enforcement agencies, other Federal laws, and the rules and statutory requirements promulgated by the States. This baseline represents the status quo from which the impacts of this rule will be evaluated.

The Bureau requested that interested parties provide data and quantitative analysis of the benefits, costs, or impacts of the proposed rule on small entities but did not receive any comments on this subject.

The Bureau believes that, except where otherwise noted, the impacts discussed in part VII would apply to small entities to the same extent as to larger entities.

F. Description of Any Significant Alternatives to the Rule That Accomplish the Stated Objectives of the Applicable Statutes and Minimize Any Significant Economic Impact of the Rule on Small Entities

Section 604(a)(6) of the RFA requires the Bureau to describe in the FRFA any significant alternatives to the rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the rule on small entities.[493] In developing the rule, the Bureau has considered alternative provisions and believes that none of the alternatives considered would be as effective at accomplishing the stated objectives of the FDCPA and the applicable provisions of title X of the Dodd-Frank Act while minimizing the impact of the rule on small entities. Some of these alternatives are discussed in part V, above.

G. Discussion of Impact on Cost of Credit for Small Entities

Section 603(d) of the RFA requires the Bureau to consult with small entities regarding the potential impact of the proposed rule on the cost of credit for small entities and related matters.[494] To satisfy these statutory requirements, the Bureau provided notification to the Chief Counsel for Advocacy of the Small Business Administration (Chief Counsel) that the Bureau would collect the advice and recommendations of the same small entity representatives identified in consultation with the Chief Counsel through the SBREFA process concerning any projected impact of the proposed rule on the cost of credit for small entities. The Bureau sought to collect the advice and recommendations of the small entity representatives during the Small Business Review Panel meeting regarding the potential impact on the cost of business credit because, as small debt collectors with credit needs, the small entity representatives could provide valuable input on any such impact related to the proposed rule.

The Bureau's Small Business Review Panel Outline asked small entity representatives to comment on how the proposals under consideration would affect the cost of credit to small entities. During the SBREFA process, several small entity representatives said that the proposals under consideration at that time, which included time-barred debt disclosures among several other proposals, could have an impact on the cost of credit for them and for their small business clients. Some small entity representatives said that they use lines of credit in their business and that regulations that raise their costs or reduce their revenue could mean they are unable to meet covenants in their loan agreements, causing lenders to reduce access to capital or increase their borrowing costs.

The Bureau believes that the disclosures in the final rule will have little impact on the cost of credit to small entities. The Bureau does recognize that consumer credit could become more expensive and less available as a result of requirements that restrict the collection of debt; however, the Bureau does not anticipate that the requirements of this final rule will have any significant impact on the cost or availability of consumer credit. Many

[487] The primary trade association for collection attorneys, the National Creditors Bar Association (NCBA), states that it has approximately 600 law firm members, 95 percent of which are small entities. The Bureau estimates that approximately 60 percent of law firms that collect debt are NCBA members and that a similar fraction of non-member law firms are small entities.

[488] The Bureau expects that loan servicers are generally classified under NAICS code 522390, ''Other Activities Related to Credit Intermediation.'' Some depository institutions (NAICS codes 522110, 522120, and 522130) also service loans for others and may be covered by the final rule.

[489] Based on the December 2015 Call Report data as compiled by SNL Financial (with respect to insured depositories) and December 2015 data from the Nationwide Mortgage Licensing System and Registry (with respect to non-depositories), the Bureau estimates that there are approximately 9,000 small entities engaged in mortgage servicing, of which approximately 100 service more than 5,000 loans. *See* 81 FR 72160, 72363 (Oct. 19, 2016). The Bureau's estimate is based on the assumption that all those servicing more than 5,000 loans may acquire servicing of loans when loans are in default and that at most 100 of those servicing 5,000 loans or fewer acquire servicing of loans when loans are in default.

[490] While the final rule does not include new recordkeeping requirements, the Bureau notes that, by introducing a new compliance requirement, the rule may increase the cost of complying with recordkeeping requirements of the November 2020 Final Rule. This is because debt collectors would need to retain evidence of compliance with any additional compliance requirement.

[491] 2020 FDCPA Annual Report, *supra* note 12, at 7.

[492] The estimated hourly cost is based on an estimated wage of $15 per hour and taxes, benefits, and incentives of $7 per hour. *See* CFPB Debt Collection Operations Study, *supra* note 37, at 17 (describing estimated debt collector wages ranging from $10 to $20 per hour).

[493] 5 U.S.C. 604(a)(6).

[494] 5 U.S.C. 603(d).

small entities affected by the disclosures in the final rule use consumer credit as a source of credit and may, therefore, see costs rise if consumer credit availability decreases. The Bureau does not expect this to be a large effect and does not anticipate measurable impact.

IX. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA),[495] Federal agencies are generally required to seek approval from the Office of Management and Budget (OMB) for information collection requirements prior to implementation. Under the PRA, the Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to, an information collection unless the information collection displays a valid control number assigned by OMB.

As part of its continuing effort to reduce paperwork and respondent burden, the Bureau conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on the information collection requirements in accordance with the PRA. This helps ensure that the public understands the Bureau's requirements or instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Bureau can properly assess the impact of collection requirements on respondents.

The final rule amends 12 CFR part 1006 (Regulation F), which implements the FDCPA. The Bureau's OMB control number for Regulation F is 3170–0056; it expires April 30, 2022. This final rule along with the November 2020 Final Rule would revise the information collection requirements contained in Regulation F that OMB has approved under that OMB control number.

Under the final rule, the Bureau requires two information collection requirements in Regulation F beyond those required by the November 2020 Final Rule:

1. Validation notices (final rule § 1006.34).

2. Communication with consumers prior to furnishing information (final rule § 1006.30(a)).

These information collections are required to provide benefits for consumers and will be mandatory. Because the Bureau does not collect any information, no issue of confidentiality arises. The likely respondents are for-profit businesses that are FDCPA debt collectors.

The collections of information contained in this rule, and identified as such, as well as the information collections contained in the November 2020 final rule have been submitted to OMB for review under section 3507(d) of the PRA. A complete description of the information collection requirement, including the burden estimate methods, is provided in the information collection request (ICR) supporting statement that the Bureau has submitted to OMB under the requirements of the PRA. The Bureau will publish a separate notice in the **Federal Register** when these information collections have been approved by OMB.

Please send your comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Bureau of Consumer Financial Protection. Send these comments by email to *oira_submission@omb.eop.gov* or by fax to (202) 395–6974. If you wish to share your comments with the Bureau, please send a copy of these comments as described in the **ADDRESSES** section above. The ICR submitted to OMB requesting approval under the PRA for the information collection requirements contained herein is available at *www.regulations.gov* as well as on OMB's public-facing docket at *www.reginfo.gov.*

Title of Collection: Regulation F: Fair Debt Collection Practices Act.

OMB Control Number: 3170–0056.

Type of Review: Revision of a currently approved collection.

Affected Public: Private Sector.

Estimated Number of Respondents: 12,027.[496]

Estimated Total Annual Burden Hours: 881,000.

The Bureau has a continuing interest in the public's opinion of its collections of information. At any time, comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, may be sent to the Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552, or by email to *CFPB_PRA@cfpb.gov.*

Where applicable, the Bureau will display the control number assigned by OMB to any documents associated with any information collection requirements adopted in this rule.

X. Congressional Review Act

Pursuant to the Congressional Review Act,[497] the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States at least 60 days prior to the rule's published effective date. The Office of Information and Regulatory Affairs has designated this rule as a ''major rule'' as defined by 5 U.S.C. 804(2).

XI. Signing Authority

The Director of the Bureau, Kathleen L. Kraninger, having reviewed and approved this document, is delegating the authority to electronically sign this document to Grace Feola, a Bureau Federal Register Liaison, for purposes of publication in the **Federal Register**.

List of Subjects in 12 CFR Part 1006

Administrative practice and procedure, Consumer protection, Credit, Debt collection, Intergovernmental relations.

Authority and Issuance

For the reasons set forth above, the Bureau is further amending Regulation F, 12 CFR part 1006, as revised on November 30, 2020, at 85 FR 76734, effective November 30, 2021, as set forth below:

PART 1006—DEBT COLLECTION PRACTICES (REGULATION F)

■ 1. The authority citation for part 1006 continues to read as follows:

Authority: 12 U.S.C. 5512, 5514(b), 5532; 15 U.S.C. 1692*l*(d), 1692o, 7004.

Subpart A—General

■ 2. Section 1006.1 is amended by adding paragraph (c)(2) to read as follows:

§ 1006.1 Authority, purpose, and coverage.

* * * * *

(c) * * *

(2) Section 1006.34(c)(2)(iii) and (c)(3)(iv) applies to debt collectors only when they are collecting debt related to a consumer financial product or service as defined in § 1006.2(f).

■ 3. Section 1006.2 is amended by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 1006.2 Definitions.

* * * * *

[495] 44 U.S.C. 3501 *et seq.*

[496] The Bureau shares enforcement authority under the FDCPA with the Federal Trade Commission. To avoid double-counting, the Bureau allocates to itself half of the estimated paperwork burden under the final rule by dividing the burden hours even between the agencies. However, since the Bureau has joint authority over the respondents themselves, the Bureau retains the entity count of all affected respondents as shown above.

[497] 5 U.S.C. 801 *et seq.*

(e) *Consumer* means any natural person, whether living or deceased, obligated or allegedly obligated to pay any debt. For purposes of § 1006.6, the term *consumer* includes the persons described in § 1006.6(a).

(f) *Consumer financial product or service* has the same meaning given to it in section 1002(5) of the Dodd-Frank Act (12 U.S.C. 5481(5)).

* * * * *

Subpart B—Rules for FDCPA Debt Collectors

■ 4. Section 1006.26 is added to read as follows:

§ 1006.26 Collection of time-barred debts.

(a) *Definitions.* For purposes of this section:

(1) *Statute of limitations* means the period prescribed by applicable law for bringing a legal action against the consumer to collect a debt.

(2) *Time-barred debt* means a debt for which the applicable statute of limitations has expired.

(b) *Legal actions and threats of legal actions prohibited.* A debt collector must not bring or threaten to bring a legal action against a consumer to collect a time-barred debt. This paragraph (b) does not apply to proofs of claim filed in connection with a bankruptcy proceeding.

■ 5. Section 1006.30 is amended by adding paragraph (a) to read as follows:

§ 1006.30 Other prohibited practices.

(a) *Required actions prior to furnishing information*—(1) *In general.* Except as provided in paragraph (a)(2) of this section, a debt collector must not furnish to a consumer reporting agency, as defined in section 603(f) of the Fair Credit Reporting Act (15 U.S.C. 1681a(f)), information about a debt before the debt collector:

(i) Speaks to the consumer about the debt in person or by telephone; or

(ii) Places a letter in the mail or sends an electronic message to the consumer about the debt and waits a reasonable period of time to receive a notice of undeliverability. During the reasonable period, the debt collector must permit receipt of, and monitor for, notifications of undeliverability from communications providers. If the debt collector receives such a notification during the reasonable period, the debt collector must not furnish information about the debt to a consumer reporting agency until the debt collector otherwise satisfies this paragraph (a)(1).

(2) *Special rule—information furnished to certain specialty consumer reporting agencies.* Paragraph (a)(1) of this section does not apply to a debt collector's furnishing of information about a debt to a nationwide specialty consumer reporting agency that compiles and maintains information on a consumer's check writing history, as described in section 603(x)(3) of the Fair Credit Reporting Act (15 U.S.C. 1681a(x)(3)).

* * * * *

■ 6. Section 1006.34 is added to read as follows:

§ 1006.34 Notice for validation of debts.

(a) *Validation information required*—(1) *In general.* Except as provided in paragraph (a)(2) of this section, a debt collector must provide a consumer with the validation information required by paragraph (c) of this section either:

(i) By sending the consumer a validation notice in the manner required by § 1006.42:

(A) In the initial communication, as defined in paragraph (b)(2) of this section; or

(B) Within five days of that initial communication; or

(ii) By providing the validation information orally in the initial communication.

(2) *Exception.* A debt collector who otherwise would be required to send a validation notice pursuant to paragraph (a)(1)(i)(B) of this section is not required to do so if the consumer has paid the debt prior to the time that paragraph (a)(1)(i)(B) of this section would require the validation notice to be sent.

(b) *Definitions.* For purposes of this section:

(1) *Clear and conspicuous* means readily understandable. In the case of written and electronic disclosures, the location and type size also must be readily noticeable and legible to consumers, although no minimum type size is mandated. In the case of oral disclosures, the disclosures also must be given at a volume and speed sufficient for the consumer to hear and comprehend them.

(2) *Initial communication* means the first time that, in connection with the collection of a debt, a debt collector conveys information, directly or indirectly, regarding the debt to the consumer, other than a communication in the form of a formal pleading in a civil action, or any form or notice that does not relate to the collection of the debt and is expressly required by:

(i) The Internal Revenue Code of 1986 (26 U.S.C. 1 *et seq.*);

(ii) Title V of the Gramm-Leach-Bliley Act (15 U.S.C. 6801 through 6827); or

(iii) Any provision of Federal or State law or regulation mandating notice of a data security breach or privacy risk.

(3) *Itemization date* means any one of the following five reference dates for which a debt collector can ascertain the amount of the debt:

(i) The last statement date, which is the date of the last periodic statement or written account statement or invoice provided to the consumer by a creditor;

(ii) The charge-off date, which is the date the debt was charged off;

(iii) The last payment date, which is the date the last payment was applied to the debt;

(iv) The transaction date, which is the date of the transaction that gave rise to the debt; or

(v) The judgment date, which is the date of a final court judgment that determines the amount of the debt owed by the consumer.

(4) *Validation notice* means a written or electronic notice that provides the validation information required by paragraph (c) of this section.

(5) *Validation period* means the period starting on the date that a debt collector provides the validation information required by paragraph (c) of this section and ending 30 days after the consumer receives or is assumed to receive the validation information. For purposes of determining the end of the validation period, the debt collector may assume that a consumer receives the validation information on any date that is at least five days (excluding legal public holidays identified in 5 U.S.C. 6103(a), Saturdays, and Sundays) after the debt collector provides it.

(c) *Validation information.* Pursuant to paragraph (a)(1) of this section, a debt collector must provide the following validation information.

(1) *Debt collector communication disclosure.* The statement required by § 1006.18(e).

(2) *Information about the debt.* Except as provided in paragraph (c)(5) of this section:

(i) The debt collector's name and the mailing address at which the debt collector accepts disputes and requests for original-creditor information.

(ii) The consumer's name and mailing address.

(iii) If the debt collector is collecting a debt related to a consumer financial product or service as defined in § 1006.2(f), the name of the creditor to whom the debt was owed on the itemization date.

(iv) The account number, if any, associated with the debt on the itemization date, or a truncated version of that number.

(v) The name of the creditor to whom the debt currently is owed.

(vi) The itemization date.

(vii) The amount of the debt on the itemization date.

(viii) An itemization of the current amount of the debt reflecting interest, fees, payments, and credits since the itemization date. A debt collector may disclose the itemization on a separate page provided in the same communication with a validation notice, if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page.

(ix) The current amount of the debt.

(3) *Information about consumer protections.* (i) The date that the debt collector will consider the end date of the validation period and a statement that, if the consumer notifies the debt collector in writing on or before that date that the debt, or any portion of the debt, is disputed, the debt collector must cease collection of the debt, or the disputed portion of the debt, until the debt collector sends the consumer either verification of the debt or a copy of a judgment.

(ii) The date that the debt collector will consider the end date of the validation period and a statement that, if the consumer requests in writing on or before that date the name and address of the original creditor, the debt collector must cease collection of the debt until the debt collector sends the consumer the name and address of the original creditor, if different from the current creditor.

(iii) The date that the debt collector will consider the end date of the validation period and a statement that, unless the consumer contacts the debt collector to dispute the validity of the debt, or any portion of the debt, on or before that date, the debt collector will assume that the debt is valid.

(iv) If the debt collector is collecting debt related to a consumer financial product or service as defined in § 1006.2(f), a statement that informs the consumer that additional information regarding consumer protections in debt collection is available on the Bureau's website at *www.cfpb.gov/debt-collection.*

(v) If the debt collector sends the validation notice electronically, a statement explaining how a consumer can, as described in paragraphs (c)(4)(i) and (ii) of this section, dispute the debt or request original-creditor information electronically.

(4) *Consumer-response information.* The following information, segregated from the validation information required by paragraphs (c)(1) through (3) of this section and from any optional information included pursuant to paragraphs (d)(3)(i) and (ii), (d)(3)(iii)(A), (d)(3)(iv) and (v), (d)(3)(vi)(A), and (d)(3)(vii) and (viii) of this section, and, if provided on a validation notice, located at the bottom of the notice under the headings, ''How do you want to respond?'' and ''Check all that apply:'':

(i) *Dispute prompts.* The following statements, listed in the following order, and using the following phrasing or substantially similar phrasing, each next to a prompt:

(A) ''I want to dispute the debt because I think:'';

(B) ''This is not my debt.'';

(C) ''The amount is wrong.''; and

(D) ''Other (please describe on reverse or attach additional information).''

(ii) *Original-creditor information prompt.* The statement, ''I want you to send me the name and address of the original creditor.'', using that phrase or a substantially similar phrase, next to a prompt.

(iii) *Mailing addresses.* Mailing addresses for the consumer and the debt collector, which are the debt collector's and the consumer's names and mailing addresses as disclosed pursuant to § 1006.34(c)(2)(i) and (ii).

(5) *Special rule for certain residential mortgage debt.* For residential mortgage debt, if a periodic statement is required under Regulation Z, 12 CFR 1026.41, at the time a debt collector provides the validation notice, a debt collector need not provide the validation information required by paragraphs (c)(2)(vi) through (viii) of this section if the debt collector:

(i) Provides the consumer, in the same communication with the validation notice, a copy of the most recent periodic statement provided to the consumer under Regulation Z, 12 CFR 1026.41(b); and

(ii) Includes on the validation notice, where the validation information required by paragraphs (c)(2)(vi) through (viii) of this section would have appeared, a statement referring to that periodic statement.

(d) *Form of validation information*—(1) *In general.* The validation information required by paragraph (c) of this section must be clear and conspicuous.

(2) *Safe harbor*—(i) *In general.* Model Form B–1 in appendix B to this part contains the validation information required by paragraph (c) of this section and certain optional disclosures permitted by paragraph (d)(3) of this section. A debt collector who uses Model Form B–1 complies with the information and form requirements of paragraphs (c) and (d)(1) of this section, including if the debt collector:

(A) Omits any or all of the optional disclosures shown on Model Form B–1; or

(B) Adds any or all of the optional disclosures described in paragraph (d)(3) of this section that are not shown on Model Form B–1, provided that any such optional disclosures are no more prominent than any of the validation information required by paragraph (c) of this section.

(ii) *Certain disclosures on a separate page.* A debt collector who uses Model Form B–1 as described in paragraph (d)(2)(i) of this section and who, pursuant to paragraph (c)(2)(viii) or (c)(5) of this section, includes certain disclosures on a separate page in the same communication with the validation notice and, on the notice, the required statement referring to those disclosures, receives a safe harbor for compliance with the information and form requirements of paragraphs (c) and (d)(1) of this section except with respect to the disclosures on the separate page.

(iii) *Substantially similar form.* A debt collector who uses Model Form B–1 as described in paragraph (d)(2)(i) or (ii) of this section may make changes to the form and retain a safe harbor for compliance with the information and form requirements of paragraphs (c) and (d)(1) of this section provided that the form remains substantially similar to Model Form B–1.

(3) *Optional disclosures.* A debt collector may include any of the following information when providing the validation information required by paragraph (c) of this section. A debt collector who includes any of the following information receives the safe harbor described in paragraph (d)(2) of this section, provided that the debt collector otherwise uses Model Form B–1 in appendix B to this part, or a variation of Model Form B–1, as described in paragraph (d)(2) of this section.

(i) *Telephone contact information.* The debt collector's telephone contact information.

(ii) *Reference code.* A number or code that the debt collector uses to identify the debt or the consumer.

(iii) *Payment disclosures.* Either or both of the following phrases:

(A) The statement, ''Contact us about your payment options.'', using that phrase or a substantially similar phrase; and

(B) Below the consumer-response information required by paragraphs (c)(4)(i) and (ii) of this section, the statement, ''I enclosed this amount:'', using that phrase or a substantially similar phrase, payment instructions after that statement, and a prompt.

(iv) *Disclosures under applicable law*—(A) *Disclosures on the reverse of the validation notice.* On the reverse of

the validation notice, any disclosures that are specifically required by, or that provide safe harbors under, applicable law and, if any such disclosures are included, a statement on the front of the validation notice referring to those disclosures. Any such disclosures must not appear directly on the reverse of the consumer-response information required by paragraph (c)(4) of this section.

(B) *Disclosures on the front of the validation notice.* If a debt collector is collecting time-barred debt, on the front of the validation notice below the disclosure required by paragraph (c)(2)(ix) of this section, any time-barred debt disclosure that is specifically required by, or that provides a safe harbor under, applicable law, provided that applicable law specifies the content of the disclosure.

(v) *Information about electronic communications.* The following information:

(A) The debt collector's website and email address.

(B) If the validation information is not provided electronically, a statement explaining how a consumer can, as described in paragraphs (c)(4)(i) and (ii) of this section, dispute the debt or request original-creditor information electronically.

(vi) *Spanish-language translation disclosures.* Either or both of the following disclosures regarding a consumer's ability to request a Spanish-language translation of a validation notice:

(A) The statement, ''Póngase en contacto con nosotros para solicitar una copia de este formulario en español'' (which means ''Contact us to request a copy of this form in Spanish''), using that phrase or a substantially similar phrase in Spanish. If providing this optional disclosure, a debt collector may include supplemental information in Spanish that specifies how a consumer may request a Spanish-language validation notice.

(B) With the consumer-response information required by paragraph (c)(4) of this section, the statement ''Quiero este formulario en español'' (which means ''I want this form in Spanish''), using that phrase or a substantially similar phrase in Spanish, next to a prompt.

(vii) The merchant brand, affinity brand, or facility name, if any, associated with the debt.

(viii) If a debt collector is collecting debt other than debt related to a consumer financial product or service as defined in § 1006.2(f), the information specified in paragraph (c)(2)(iii) or (c)(3)(iv) of this section.

(4) *Validation notices delivered electronically.* If a debt collector delivers a validation notice electronically, a debt collector may, at its option, format the validation notice as follows:

(i) *Prompts.* Any prompt required by paragraph (c)(4)(i) or (ii) or paragraph (d)(3)(iii)(B) or (d)(3)(vi)(B) of this section may be displayed electronically as a fillable field.

(ii) *Hyperlinks.* Hyperlinks may be embedded that, when clicked:

(A) Connect a consumer to the debt collector's website;

(B) Connect a consumer to the Bureau's debt collection website as disclosed pursuant to paragraph (c)(3)(iv) of this section; or

(C) Permit a consumer to respond to the dispute and original-creditor information prompts required by paragraphs (c)(4)(i) and (ii) of this section.

(e) *Translation into other languages*—(1) *In general.* A debt collector may send a consumer a validation notice completely and accurately translated into any language if the debt collector:

(i) Sends the consumer an English-language validation notice in the same communication as the translated validation notice; or

(ii) Previously provided the consumer an English-language validation notice, in which case the debt collector need not send the consumer an English-language validation notice in the same communication as the translated validation notice.

(2) *Spanish-language validation notice—requirement to provide after optional disclosure.* A debt collector who includes in the validation information either or both of the optional disclosures described in paragraph (d)(3)(vi) of this section, and who thereafter receives a request from the consumer for a Spanish-language validation notice, must provide the consumer a validation notice completely and accurately translated into Spanish.

■ 7. Section 1006.38 is amended by revising paragraphs (a)(2), (b), and (c) to read as follows:

§ 1006.38 Disputes and requests for original-creditor information.

(a) * * *

(2) *Validation period* has the same meaning given to it in § 1006.34(b)(5).

(b) *Overshadowing of rights to dispute or request original-creditor information*—(1) *Prohibition.* During the validation period, a debt collector must not engage in any collection activities or communications that overshadow or are inconsistent with the disclosure of the consumer's rights to dispute the debt and to request the name and address of the original creditor.

(2) *Safe harbor.* A debt collector who uses Model Form B–1 in appendix B to this part in a manner described in § 1006.34(d)(2) has not thereby violated paragraph (b)(1) of this section.

(c) *Requests for original-creditor information.* Upon receipt of a request for the name and address of the original creditor submitted by the consumer in writing within the validation period, a debt collector must cease collection of the debt until the debt collector:

(1) *In general.* Sends the name and address of the original creditor to the consumer in writing or electronically in the manner required by § 1006.42; or

(2) *Special rule if the current creditor and the original creditor are the same.* In lieu of taking the actions described in paragraph (c)(1) of this section, reasonably determines that the original creditor is the same as the current creditor, notifies the consumer of that fact in writing or electronically in the manner required by § 1006.42, and refers the consumer to the validation information previously provided pursuant to § 1006.34(a)(1).

* * * * *

■ 8. Section 1006.42 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 1006.42 Sending required disclosures.

(a) * * *

(2) *Exceptions.* A debt collector need not comply with paragraph (a)(1) of this section when sending the disclosure required by § 1006.6(e) or § 1006.18(e) in writing or electronically, unless the disclosure is included on a notice required by § 1006.34(a)(1)(i) or § 1006.38(c) or (d)(2).

(b) *Requirements for certain disclosures sent electronically.* To comply with paragraph (a) of this section, a debt collector who sends the notice required by § 1006.34(a)(1)(i)(B), or the disclosures described in § 1006.38(c) or (d)(2)(i), electronically must do so in accordance with section 101(c) of the Electronic Signatures in Global and National Commerce Act (E–SIGN Act) (15 U.S.C. 7001(c)).

■ 9. Appendix B to part 1006 is added to read as follows:

Appendix B to Part 1006—Model Forms

B–1 Model Form for Validation Notice

BILLING CODE 4810–AM–P

North South Group
P.O. Box 123456
Pasadena, CA 91111-2222
(800) 123-4567 from 8am to 8pm EST, Monday to Saturday
www.example.com

To: Person A
2323 Park Street
Apartment 342
Bethesda, MD 20815

Reference: 584-345

North South Group is a debt collector. We are trying to collect a debt that you owe to Bank of Rockville. We will use any information you give us to help collect the debt.

Our information shows:

You had a Main Street Department Store credit card from Bank of Rockville with account number 123-456-789.

As of January 2, 2017, you owed:		$ 2,234.56
Between January 2, 2017 and today:		
You were charged this amount in interest:	+	$ 75.00
You were charged this amount in fees:	+	$ 25.00
You paid or were credited this amount toward the debt:	–	$ 50.00
Total amount of the debt now:		**$ 2,284.56**

How can you dispute the debt?

- **Call or write to us by August 28, 2020, to dispute all or part of the debt.** If you do not, we will assume that our information is correct.
- **If you write to us by August 28, 2020**, we must stop collection on any amount you dispute until we send you information that shows you owe the debt. You may use the form below or write to us without the form. You may also include supporting documents. We accept disputes electronically at www.example.com/dispute.

What else can you do?

- **Write to ask for the name and address of the original creditor, if different from the current creditor.** If you write by August 28, 2020, we must stop collection until we send you that information. You may use the form below or write to us without the form. We accept such requests electronically at www.example.com/request.
- **Go to www.cfpb.gov/debt-collection to learn more about your rights under federal law.** For instance, you have the right to stop or limit how we contact you.
- Contact us about your payment options.
- Póngase en contacto con nosotros para solicitar una copia de este formulario en español.

Notice: See reverse side for important information.

Mail this form to:
North South Group
P.O. Box 123456
Pasadena, CA 91111-2222

Person A
2323 Park Street
Apartment 342
Bethesda, MD 20815

How do you want to respond?

Check all that apply:

☐ **I want to dispute the debt because I think:**
- ☐ This is not my debt.
- ☐ The amount is wrong.
- ☐ Other (please describe on reverse or attach additional information).

☐ **I want you to send me the name and address of the original creditor.**

☐ **I enclosed this amount:** $

Make your check payable to *North South Group*. Include the reference number 584-345.

☐ **Quiero este formulario en español.**

BILLING CODE 4810–AM–C

■ 10. In supplement I to part 1006:

■ a. Under *Section 1006.30—Other Prohibited Practices,* the headings *30(a) Required actions prior to furnishing information,* and *30(a)(1) In general,* and paragraphs 1 and 2 are added.

■ b. *Section 1006.34—Notice for Validation of Debts* is added.

■ c. Under *Section 1006.38—Disputes and Requests for Original-Creditor Information,* the introductory text before *38(a) Definitions* is revised.

■ d. Under *Section 1006.100—Record Retention, 100(a) In general,* including the heading, is revised.

■ e. *Section 1006.104—Relation to State Laws* is added.

The additions and revisions read as follows:

Supplement I to Part 1006—Official Interpretations

* * * * *

Subpart B—Rules for FDCPA Debt Collectors

* * * * *

Section 1006.30—Other Prohibited Practices

30(a) Required actions prior to furnishing information.

30(a)(1) In general.

1. *About the debt.* Section 1006.30(a)(1) provides, in relevant part, that a debt collector must not furnish to

a consumer reporting agency, as defined in section 603(f) of the Fair Credit Reporting Act (15 U.S.C. 1681a(f)), information about a debt before taking one of the actions described in § 1006.30(a)(1)(i) or (ii). Each of the actions includes conveying information ''about the debt'' to the consumer. The validation information required by § 1006.34(c), including such information if provided in a validation notice, is information ''about the debt.''

2. *Reasonable period of time.* Section 1006.30(a)(1)(ii) provides, in relevant part, that a debt collector who places a letter about a debt in the mail, or who sends an electronic message about a debt to the consumer, must wait a reasonable period of time to receive a notice of undeliverability before furnishing information about the debt to a consumer reporting agency. The reasonable period of time begins on the date that the debt collector places the letter in the mail or sends the electronic message. A period of 14 consecutive days after the date that the debt collector places a letter in the mail or sends an electronic message is a reasonable period of time.

3. *Notices of undeliverability.* Section 1006.30(a)(1)(ii) provides, in relevant part, that, if a debt collector who places a letter about a debt in the mail, or who sends an electronic message about a debt to the consumer, receives a notice of undeliverability during the reasonable period of time, the debt collector must not furnish information about the debt to a consumer reporting agency until the debt collector otherwise satisfies paragraph (a)(1) of this section. A debt collector who does not receive a notice of undeliverability during the reasonable period and who thereafter furnishes information about the debt to a consumer reporting agency does not violate paragraph (a)(1) of this section even if the debt collector subsequently receives a notice of undeliverability. The following examples illustrate the rule:

i. Assume that, on May 1, a debt collector mails the consumer a validation notice as described in § 1006.34(a)(1)(i)(A). On May 10, the debt collector receives a notice of undeliverability and, without taking any additional action described in § 1006.30(a)(1), subsequently furnishes information regarding the debt to a consumer reporting agency. The debt collector has violated § 1006.30(a)(1).

ii. Assume that, on May 1, a debt collector mails the consumer a validation notice as described in § 1006.34(a)(1)(i)(A). On May 10, the debt collector receives a notice of undeliverability. On May 11, the debt collector mails the consumer another validation notice as described in § 1006.34(a)(1)(i)(A). From May 11 to May 24, the debt collector permits receipt of, monitors for, and does not receive, a notice of undeliverability and thereafter furnishes information regarding the debt to a consumer reporting agency. The debt collector has not violated § 1006.30(a)(1).

iii. Assume that, on May 1, a debt collector mails the consumer a validation notice as described in § 1006.34(a)(1)(i)(A). From May 1 to May 14, the debt collector permits receipt of, monitors for, and does not receive, a notice of undeliverability and thereafter furnishes information regarding the debt to a consumer reporting agency. After furnishing the information, the debt collector receives a notice of undeliverability. The debt collector has not violated § 1006.30(a)(1) and, without taking any further action, may furnish additional information about the debt to a consumer reporting agency.

* * * * *

Section 1006.34—Notice for Validation of Debts

34(a) Validation information required.

34(a)(1) In general.

1. *Deceased consumers.* Section 1006.34(a)(1) generally requires a debt collector to provide the validation information required by § 1006.34(c) either by sending the consumer a validation notice in the manner required by § 1006.42, or by providing the information orally in the debt collector's initial communication. If the debt collector knows or should know that the consumer is deceased, and if the debt collector has not previously provided the validation information to the deceased consumer, a person who is authorized to act on behalf of the deceased consumer's estate operates as the consumer for purposes of § 1006.34(a)(1). In such circumstances, to comply with § 1006.34(a)(1), a debt collector must provide the validation information to an individual that the debt collector identifies by name who is authorized to act on behalf of the deceased consumer's estate.

34(b) Definitions.

34(b)(2) Initial communication.

1. *Bankruptcy proofs of claim.* Section 1006.34(b)(2) defines initial communication and states that the term does not include a communication in the form of a formal pleading in a civil action. A proof of claim that a debt collector files in a bankruptcy proceeding in accordance with the requirements of the United States Bankruptcy Code (Title 11 of the U.S. Code) is a communication in the form of a formal pleading in a civil action and therefore is not an initial communication for purposes of § 1006.34.

34(b)(3) Itemization date.

1. *In general.* Section 1006.34(b)(3) defines itemization date for purposes of § 1006.34. Section 1006.34(b)(3) states that the itemization date is any one of five reference dates for which a debt collector can ascertain the amount of the debt. The reference dates are the last statement date, the charge-off date, the last payment date, the transaction date, and the judgment date. A debt collector may select any of these dates as the itemization date to comply with § 1006.34. Once a debt collector uses a reference date for a debt in a communication with a consumer, the debt collector must use that reference date for that debt consistently when providing the information required by § 1006.34(c) to that consumer. For example, if a debt collector uses the last statement date to determine and disclose the account number associated with the debt pursuant to § 1006.34(c)(2)(iv), the debt collector may not use the charge-off date to determine and disclose the amount of the debt pursuant to § 1006.34(c)(2)(vii).

2. *Subsequent debt collectors.* When selecting an itemization date pursuant to § 1006.34(b)(3), a debt collector may use a different reference date than a prior debt collector who attempted to collect the debt.

Paragraph 34(b)(3)(i).

1. *Last statement date.* Under § 1006.34(b)(3)(i), the last statement date is the date of the last periodic statement or written account statement or invoice provided to the consumer by a creditor. For purposes of § 1006.34(b)(3)(i), the last statement may be provided by a creditor or a third party acting on the creditor's behalf, including a creditor's service provider. However, a statement or invoice provided by a debt collector is not a last statement for purposes of § 1006.34(b)(3)(i), unless the debt collector is also a creditor.

Paragraph 34(b)(3)(iii).

1. *Last payment date.* Under § 1006.34(b)(3)(iii), the last payment date is the date the last payment was applied to the debt. A third-party payment applied to the debt, such as a payment from an auto repossession agent or an insurance company, can be a last payment for purposes of § 1006.34(b)(3)(iii).

Paragraph 34(b)(3)(iv).

1. *Transaction date.* Section 1006.34(b)(3)(iv) provides that the itemization date may be the date of the transaction that gave rise to the debt.

The transaction date is the date that the good or service that gave rise to the debt was provided or made available to the consumer. For example, the transaction date for a debt arising from a medical procedure may be the date the medical procedure was performed, and the transaction date for a consumer's gym membership may be the date the membership contract was executed. In some cases, a debt may have more than one transaction date. This could occur, for example, if a contract for a service is executed on one date and the service is performed on another date. If a debt has more than one transaction date, a debt collector may use any such date as the transaction date for purposes of § 1006.34(b)(3)(iv), but the debt collector must use whichever transaction date is selected consistently, as described in comment 34(b)(3)–1.

34(b)(5) Validation period.

1. *Assumed receipt of validation information.* Section 1006.34(b)(5) defines the validation period as the period starting on the date that a debt collector provides the validation information required by § 1006.34(c) and ending 30 days after the consumer receives or is assumed to receive it. Section 1006.34(c)(3)(i) through (iii) requires statements that specify the end date of the validation period. If a debt collector provides the validation information in writing or electronically, then, at the time that the debt collector calculates the validation period end date, the debt collector will know only the date on which the consumer is assumed to receive the validation information. In such cases, the debt collector may use that date to calculate the validation period end date even if the debt collector later learns that the consumer received the validation information on a different date.

2. *Updated validation period.* If a debt collector sends a subsequent validation notice to a consumer because the consumer did not receive the original validation notice and the consumer has not otherwise received the validation information required by § 1006.34(c), the debt collector must calculate the end date of the validation period specified in the § 1006.34(c)(3) disclosures based on the date the consumer receives or is assumed to receive the subsequent validation notice. For example, assume a debt collector sends a consumer a validation notice on January 1, and that notice is returned as undeliverable. After obtaining accurate location information, the debt collector sends the consumer a subsequent validation notice on January 15. Pursuant to § 1006.34(b)(5), the end date of the validation period specified in the § 1006.34(c)(3) disclosures is based on the date the consumer receives or is assumed to receive the validation notice sent on January 15.

34(c) Validation information.

34(c)(1) Debt collector communication disclosure.

1. *Statement required by § 1006.18(e).* Section 1006.34(c)(1) provides that validation information includes the statement required by § 1006.18(e). Section 1006.18(e)(1) requires a debt collector to disclose in its initial communication that the debt collector is attempting to collect a debt and that any information obtained will be used for that purpose. Section 1006.18(e)(2) requires a debt collector to disclose in each subsequent communication that the communication is from a debt collector. A debt collector who provides a validation notice as described in § 1006.34(a)(1)(i)(A) complies with § 1006.34(c)(1) by providing on the validation notice the disclosure required by § 1006.18(e)(1). A debt collector who provides a validation notice as described in § 1006.34(a)(1)(i)(B) complies with § 1006.34(c)(1) by providing either the disclosure required by § 1006.18(e)(1) or the disclosure required by § 1006.18(e)(2). The following example illustrates the rule:

i. ABC debt collector has an initial communication with the consumer by telephone. Within five days of that initial communication, ABC debt collector sends the consumer a validation notice using Model Form B–1 in appendix B to this part. ABC debt collector has complied with § 1006.34(c)(1) even though Model Form B–1 includes the disclosure described in § 1006.18(e)(1) rather than the disclosure described in § 1006.18(e)(2).

34(c)(2) Information about the debt.

Paragraph 34(c)(2)(i).

1. *Debt collector's name.* Section 1006.34(c)(2)(i) provides, in part, that validation information includes the debt collector's name. A debt collector may disclose its trade or doing-business-as name, instead of its legal name.

2. *Debt collector's mailing address.* Section 1006.34(c)(2)(i) provides, in part, that validation information includes the mailing address at which the debt collector accepts disputes and requests for original-creditor information. A debt collector may disclose a vendor's mailing address, if that is an address at which the debt collector accepts disputes and requests for original-creditor information.

Paragraph 34(c)(2)(ii).

1. *Consumer's name.* Section 1006.34(c)(2)(ii) provides, in part, that validation information includes the consumer's name. To satisfy the requirement to provide this validation information, a debt collector must disclose the version of the consumer's name that the debt collector reasonably determines is the most complete and accurate version of the name about which the debt collector has knowledge. A debt collector does not disclose the most complete and accurate version of the consumer's name if the debt collector omits known name information in a manner that creates a false, misleading, or confusing impression about the consumer's identity. For example, assume the creditor provides the consumer's first name, middle name, last name, and name suffix to the debt collector. In this scenario, the debt collector would reasonably determine that the most complete and accurate version of the consumer's name about which the debt collector has knowledge includes the first name, middle name, last name, and name suffix. If the debt collector omits any of this information, the debt collector has not satisfied the requirement to provide the consumer's name pursuant to § 1006.34(c)(2)(ii).

Paragraph 34(c)(2)(iii).

1. *Creditor's name.* Section 1006.34(c)(2)(iii) provides that, if a debt collector is collecting debt related to a consumer financial product or service as defined in § 1006.2(f), validation information includes the name of the creditor to whom the debt was owed on the itemization date. Pursuant to § 1006.34(c)(2)(iii), a debt collector may disclose this creditor's trade or doing-business-as name, instead of its legal name.

Paragraph 34(c)(2)(iv).

1. *Account number truncation.* Section 1006.34(c)(2)(iv) provides that validation information includes the account number, if any, associated with the debt on the itemization date, or a truncated version of that number. If a debt collector uses a truncated account number, the account number must remain recognizable. For example, a debt collector may truncate a credit card account number so that only the last four digits are provided.

Paragraph 34(c)(2)(v).

1. *Creditor's name.* Section 1006.34(c)(2)(v) provides that validation information includes the name of the creditor to whom the debt currently is owed. A debt collector may disclose this creditor's trade or doing-business-as name, instead of its legal name.

Paragraph 34(c)(2)(vii).

1. *Amount of the debt on the itemization date.* Section 1006.34(c)(2)(vii) provides that validation information includes the amount of the debt on the itemization

date. The amount of the debt on the itemization date includes any fees, interest, or other charges owed as of that date.

Paragraph 34(c)(2)(viii).

1. *Itemization of the debt.* Section 1006.34(c)(2)(viii) provides that validation information includes an itemization of the current amount of the debt reflecting interest, fees, payments, and credits since the itemization date. If providing a validation notice, a debt collector must include fields in the notice for all of these items even if none of the items have been assessed or applied to the debt since the itemization date. A debt collector may indicate that the value of a required field is ''0,'' ''none,'' or may state that no interest, fees, payments, or credits have been assessed or applied to the debt; a debt collector may not leave a required field blank.

2. *Itemization required by other applicable law.* If a debt collector is required by other applicable law to provide an itemization of the current amount of the debt with the validation information, the debt collector may comply with § 1006.34(c)(2)(viii) by disclosing the itemization required by other applicable law in lieu of the itemization described in § 1006.34(c)(2)(viii), if the itemization required by other applicable law is substantially similar to the itemization that appears on Model Form B–1 in appendix B to this part.

3. *Itemization on a separate page.* Section 1006.34(c)(2)(viii) provides that a debt collector may disclose the itemization of the current amount of the debt on a separate page provided in the same communication with a validation notice if the debt collector includes on the validation notice, where the itemization would have appeared, a statement referring to that separate page. A debt collector may comply with the requirement to refer to the separate page by, for example, including on the validation notice the statement, ''See the enclosed separate page for an itemization of the debt,'' situated next to the information about the current amount of the debt required by § 1006.34(c)(2)(ix).

4. *Debt collectors collecting multiple debts.* A debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(viii) by disclosing either a single, cumulative itemization on the validation notice or a separate itemization of each debt on a separate page or pages provided in the same communication as the validation notice.

Paragraph 34(c)(2)(ix).

1. *Current amount of the debt.* Section 1006.34(c)(2)(ix) provides that validation information includes the current amount of the debt (*i.e.,* the amount as of when the validation information is provided). For residential mortgage debt subject to Regulation Z, 12 CFR 1026.41, a debt collector may comply with the requirement to provide the current amount of the debt by providing the consumer the total balance of the outstanding mortgage, including principal, interest, fees, and other charges.

2. *Debt collectors collecting multiple debts.* A debt collector who combines multiple debts on a single validation notice complies with § 1006.34(c)(2)(ix) by disclosing on the validation notice a single cumulative figure that is the sum of the current amount of all the debts.

34(c)(3) Information about consumer protections.

Paragraph 34(c)(3)(v).

1. *Electronic communication media.* Section 1006.34(c)(3)(v) provides that, if the debt collector provides the validation notice electronically, validation information includes a statement explaining how a consumer can, as described in paragraphs (c)(4)(i) and (ii) of this section, dispute the debt or request original-creditor information electronically. A debt collector may provide the information required by § 1006.34(c)(3)(v) by including the statements, ''We accept disputes electronically at,'' using that phrase or a substantially similar phrase, followed by an email address or website portal that a consumer can use to take the action described in § 1006.34(c)(4)(i), and ''We accept original creditor information requests electronically,'' using that phrase or a substantially similar phrase, followed by an email address or website portal that a consumer can use to take the action described in § 1006.34(c)(4)(ii). If a debt collector accepts electronic communications from consumers through more than one medium, such as by email and through a website portal, the debt collector is required to provide information regarding only one of these media but may provide information on any additional media.

34(c)(4) Consumer-response information.

1. *Prompts.* If the validation information is provided in writing or electronically, a prompt required by § 1006.34(c)(4) may be formatted as a checkbox as in Model Form B–1 in appendix B to this part.

34(c)(5) Special rule for certain residential mortgage debt.

1. *In general.* Section 1006.34(c)(5) provides that, for residential mortgage debt, if a periodic statement is required under Regulation Z, 12 CFR 1026.41, at the time a debt collector provides the validation notice, a debt collector need not provide the validation information required by § 1006.34(c)(2)(vi) through (viii) if the debt collector provides the consumer, in the same communication with the validation notice, a copy of the most recent periodic statement provided to the consumer under 12 CFR 1026.41(b), and the debt collector includes on the validation notice, where the validation information required by paragraphs (c)(2)(vi) through (viii) of this section would have appeared, a statement referring to that periodic statement. A debt collector may comply with the requirement to refer to the periodic statement in the validation notice by, for example, including on the validation notice the statement, ''See the enclosed periodic statement for an itemization of the debt.''

34(d) Form of validation information.

34(d)(2) Safe harbor.

1. *In general.* A debt collector who provides a validation notice that is neither a notice described in § 1006.34(d)(2)(i) or (ii), nor a substantially similar notice as described in § 1006.34(d)(2)(iii), does not receive a safe harbor for compliance with the information and form requirements of § 1006.34(c) and (d)(1).

34(d)(2)(i) In general.

1. *Disclosure required by § 1006.18(e).* Section 1006.18(e)(1) requires a debt collector to disclose in its initial communication that the debt collector is attempting to collect a debt and that any information obtained will be used for that purpose. Section 1006.18(e)(2) requires a debt collector to disclose in each subsequent communication that the communication is from a debt collector. Model Form B–1 in appendix B to this part includes the disclosure required by § 1006.18(e)(1). A debt collector who uses Model Form B–1 to provide a validation notice as described in § 1006.34(a)(1)(i)(B) may replace the disclosure required by § 1006.18(e)(1) with the disclosure required by § 1006.18(e)(2) without losing the safe harbor described in § 1006.34(d)(2). See comment 34(c)(1)–1 for further guidance related to providing the disclosure required by § 1006.18(e) on a validation notice.

34(d)(2)(iii) Substantially similar form.

1. *Substantially similar form.* Pursuant to § 1006.34(d)(2)(iii), a debt collector who uses Model Form B–1 as described in § 1006.34(d)(2)(i) may make changes to the form and retain the safe harbor for compliance with the information and form requirements of

§ 1006.34(c) and (d)(1) provided that the form remains substantially similar in substance, clarity, and meaningful sequence to Model Form B–1. Permissible changes include, for example:

i. Modifications to remove language that could suggest liability for the debt if such language is not applicable. For example, if a debt collector sends a validation notice to a person who is authorized to act on behalf of the deceased consumer's estate (see comment 34(a)(1)–1), and that person is not liable for the debt, the debt collector may use the name of the deceased consumer instead of ''you'';

ii. Relocating the consumer-response information required by § 1006.34(c)(4) to facilitate mailing;

iii. Adding barcodes or QR codes, as long as the inclusion of such items does not violate § 1006.38(b);

iv. Adding the date the form is generated; and

v. Embedding hyperlinks, if delivering the form electronically.

34(d)(3) Optional disclosures.

34(d)(3)(i) Telephone contact information.

1. *In general.* Section 1006.34(d)(3)(i) permits a debt collector to include telephone contact information. Telephone contact information may include, for example, a telephone number as well as the times that the debt collector accepts consumer telephone calls.

34(d)(3)(iv) Disclosures under applicable law.

34(d)(3)(iv)(A) Disclosures on the reverse of the validation notice.

1. *In general.* Section 1006.34(d)(3)(iv)(A) permits, in relevant part, a debt collector to include on the reverse of the validation notice any disclosures that are specifically required by, or that provide safe harbors under, applicable law. If a debt collector provides a validation notice in the body of an email, the debt collector may, in lieu of including the disclosures permitted by § 1006.34(d)(3)(iv)(A) on the reverse of the validation notice, include them in the same communication below the content of the validation notice. Disclosures permitted by § 1006.34(d)(3)(iv)(A) include, for example, specific disclosures required by Federal, State, or municipal statutes or regulations, and specific disclosures required by judicial or administrative decisions or orders, including administrative consent orders. Such disclosures could include, for example, time-barred debt disclosures and disclosures that the current amount of the debt may increase or vary due to interest, fees, or other charges, provided that such disclosures are specifically required by applicable law.

2. *Statement referring to disclosures.* If a debt collector includes disclosures pursuant to § 1006.34(d)(3)(iv)(A), the debt collector must include a statement on the front of the validation notice referring to those disclosures. A debt collector may comply with the requirement to refer to the disclosures by including on the front of the validation notice the statement, ''Notice: See reverse side for important information,'' or a substantially similar statement. If, as permitted by comment 34(d)(3)(iv)(A)–1, a debt collector places the disclosures below the content of the validation notice, the debt collector may comply with the requirement to refer to the disclosures by stating, ''Notice: See below for important information,'' or a substantially similar statement.

34(d)(3)(iv)(B) Disclosures on the front of the validation notice.

1. *In general.* Section 1006.34(d)(3)(iv)(B) provides, in relevant part that, if a debt collector is collecting time-barred debt, the debt collector may include on the front of the validation notice any time-barred debt disclosure that is specifically required by, or that provides a safe harbor under, applicable law, provided that applicable law specifies the content of the disclosure. For example, if applicable State law requires a debt collector who is collecting time-barred debt to disclose to the consumer that the law limits how long a consumer can be sued on a debt and that the debt collector cannot or will not sue the consumer to collect it, the debt collector may include that disclosure on the front of the validation notice. See § 1006.26(a)(2) for the definition of time-barred debt. For purposes of § 1006.34(d)(3)(iv)(B), time-barred debt disclosures may include disclosures about revival of debt collectors' right to bring a legal action to enforce the debt.

34(d)(3)(vi) Spanish-language translation disclosures.

Paragraph 34(d)(3)(vi)(A).

1. *Supplemental information in Spanish.* Section 1006.34(d)(3)(vi)(A) permits a debt collector to include supplemental information in Spanish that specifies how a consumer may request a Spanish-language validation notice. For example, a debt collector may include a statement in Spanish that a consumer can request a Spanish-language validation notice by telephone or email, if the debt collector accepts consumer requests through those communication media.

Paragraph 34(d)(3)(vii).

1. *Merchant brand.* Section 1006.34(d)(3)(vii) permits a debt collector to include the merchant brand, if any, associated with debt. For example, assume that a debt collector is attempting to collect a consumer's credit card debt. The credit card was issued by ABC Bank and was co-branded XYZ Store. ''XYZ Store'' is the merchant brand.

2. *Affinity brand.* Section 1006.34(d)(3)(vii) permits a debt collector to include the affinity brand, if any, associated with the debt. For example, assume that a debt collector is attempting to collect a consumer's credit card debt. The credit card was issued by ABC Bank, and the logo for the College of Columbia appears on the credit card. ''College of Columbia'' is the affinity brand.

3. *Facility name.* Section 1006.34(d)(3)(vii) permits a debt collector to include the facility name, if any, associated with the debt. For example, assume that a debt collector is attempting to collect a consumer's medical debt. The medical debt relates to a treatment that the consumer received at ABC Hospital. ''ABC Hospital'' is the facility name.

34(e) Translation into other languages.

1. *Safe harbor for complete and accurate translation.* Section 1006.34(e) provides, among other things, that, if a debt collector sends a consumer a validation notice translated into a language other than English, the translation must be complete and accurate. The language of a validation notice that a debt collector obtains from the Bureau's website is considered a complete and accurate translation. Debt collectors are permitted to use other validation notice translations if they are complete and accurate.

Section 1006.38—Disputes and Requests for Original-Creditor Information

1. *In writing.* Section 1006.38 contains requirements related to a dispute or request for the name and address of the original creditor timely submitted in writing by the consumer. A consumer has disputed the debt or requested the name and address of the original creditor in writing for purposes of § 1006.38(c) or (d)(2) if the consumer, for example:

i. Mails the written dispute or request to the debt collector;

ii. Returns to the debt collector the consumer-response form that § 1006.34(c)(4) requires to appear on the validation notice and indicates on the form the dispute or request;

iii. Provides the dispute or request to the debt collector using a medium of electronic communication through which the debt collector accepts

electronic communications from consumers, such as an email address or a website portal; or

iv. Delivers the written dispute or request in person or by courier to the debt collector.

* * * * *

3. *Deceased consumers.* If the debt collector knows or should know that the consumer is deceased, and if the consumer has not previously disputed the debt or requested the name and address of the original creditor, a person who is authorized to act on behalf of the deceased consumer's estate operates as the consumer for purposes of § 1006.38. In such circumstances, to comply with § 1006.38(c) or (d)(2), respectively, a debt collector must respond to a request for the name and address of the original creditor or to a dispute timely submitted in writing by a person who is authorized to act on behalf of the deceased consumer's estate.

* * * * *

Subpart D—Miscellaneous

Section 1006.100—Record Retention

* * * * *

100(a) In general.

1. *Records that evidence compliance.* Section 1006.100(a) provides, in part, that a debt collector must retain records that are evidence of compliance or noncompliance with the FDCPA and this part. Thus, under § 1006.100(a), a debt collector must retain records that evidence that the debt collector performed the actions and made the disclosures required by the FDCPA and this part, as well as records that evidence that the debt collector refrained from conduct prohibited by the FDCPA and this part. If a record is of a type that could evidence compliance or noncompliance depending on the conduct of the debt collector that is revealed within the record, then the record is one that is evidence of compliance or noncompliance, and the debt collector must retain it. Such records include, but are not limited to, records that evidence that the debt collector's communications and attempts to communicate in connection with the collection of a debt complied (or did not comply) with the FDCPA and this part. For example, a debt collector must retain:

i. Telephone call logs as evidence of compliance or noncompliance with the prohibition against harassing telephone calls in § 1006.14(b)(1); and

ii. Copies of documents provided to consumers as evidence that the debt collector provided the information required by §§ 1006.34 and 1006.38 and met the delivery requirements of § 1006.42.

* * * * *

Section 1006.104—Relation to State Laws

1. *State law disclosure requirements.* The Act and the corresponding provisions of Regulation F do not annul, alter, or affect, or exempt any person subject to these requirements from complying with a disclosure requirement under applicable State law that describes additional protections under State law that are not inconsistent with the Act and Regulation F. A disclosure required by State law is not inconsistent with the FDCPA or Regulation F if the disclosure describes a protection that such law affords any consumer that is greater than the protection provided by the FDCPA or Regulation F.

Dated: December 18, 2020.

Grace Feola,

Federal Register Liaison, Bureau of Consumer Financial Protection.

[FR Doc. 2020–28422 Filed 1–15–21; 8:45 am]

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Part IX

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, et al.

Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, 455, and 460

[CMS–4190–F2]

RIN 0938–AT97

Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare Cost Plan program, and Programs of All-Inclusive Care for the Elderly (PACE) to implement certain sections of the Bipartisan Budget Act of 2018 and the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment—(SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act), enhance the Part C and D programs and the PACE program, codify several existing CMS policies, make required statutory changes, implement other technical changes, and make routine updates. As stated in the final rule that appeared in the **Federal Register** on June 2, 2020, CMS is fulfilling its intention to address the remaining proposals from the February 2020 proposed rule here. Although the provisions adopted in this second final rule will be in effect during 2021, most provisions will apply to coverage beginning January 1, 2022.

Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that were already in effect prior to this rule's appearance in the **Federal Register**, CMS reminds organizations, plan sponsors, and other readers that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the SUPPORT Act, CMS intends to implement these statutory provisions consistent with their effective provisions.

DATES:

Effective Date: These regulations are effective March 22, 2021.

Applicability Dates: Most of the provisions in this rule will be applicable to coverage beginning January 1, 2022, except as noted below.

The *Part D Income Related Monthly Adjustment Amount (IRMAA) calculation update* in § 423.286(d)(4)(ii) is applicable March 22, 2021. The provision defining targeted beneficiaries for MTM at § 423.153(d)(2) is applicable March 22, 2021. The provisions on automatic escalation to the independent outside entity under a Medicare Part D drug management program (DMP) at §§ 423.590(i) and 423.600(b) and the related provisions on information on appeal rights in the beneficiary notices at §§ 423.153(f)(5)(ii)(C)(*3*), 423.153(f)(6)(ii)(C)(*4*), and 423.153(f)(8)(i) are applicable March 22, 2021. The provisions defining the term ''parent organization'' for MA and Part D plans at §§ 422.2 and 423.4 are applicable March 22, 2021. The General Requirements for Applicable Integrated Plans and Continuation of Benefits provisions at §§ 422.629 and 422.632 are applicable March 22, 2021.

In order to help ensure that Part D sponsors have sufficient implementation time, the beneficiary real time benefit tool (RTBT) (§ 423.128(d)(4)) requirement will not be applicable until January 1, 2023.

Due to operational considerations, revisions to the Special Needs Plan Model of Care requirements in § 422.101(f) are intended for implementation (that is, applicability) for models of care for contract year 2023. Plans that are required to submit models of care for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for full implementation and enforcement of the final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

SUPPLEMENTARY INFORMATION: The Code of Federal Regulations (CFR) will be updated consistent with the respective effective date of each provision. The applicability and effective dates are discussed in the summary and preamble for each of these items. Because CMS is finalizing the call center, marketing, and communications requirements under §§ 422.111(h)(1), 422.2260 through 422.2274, §§ 423.128(d)(1), and 423.2260 through 423.2274 as applicable for the contract year and coverage beginning January 1, 2022, these requirements will apply to call center operations, marketing, and mandatory disclosures occurring in 2021 for enrollments made for contract year 2022.

FOR FURTHER INFORMATION CONTACT:

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs:

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018), and
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act).

The rule also includes a number of changes to: Strengthen and improve the Part C and D programs and the PACE program, codify in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other guidance documents, make required statutory changes, implement other technical changes, and make routine updates.

In the June 2020 final rule (85 FR 33796), CMS addressed a selection of proposals from the February 2020 proposed rule (85 FR 9002). In this final rule, CMS is addressing the remaining proposals from the February 2020 proposed rule with two exceptions: (1)

Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101) and (2) Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113). Therefore, we may address the two remaining proposals from the February 18, 2020, proposed rule (85 FR 9002) not included in this final rule in subsequent rulemaking.

In so doing, the final rule addresses the following needs for federal regulatory action as set forth below:

- The regulations implementing the provisions of BBA of 2018 relating to Medicare Advantage Special Needs Plans address, as directed by law, care management requirements through the development and implementation of models of care. Given the context of these provisions is a federal program, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions implementing the provisions of BBA of 2018 relating to the Coverage Gap Discount Program and the Part D Income Related Monthly Adjustment Amount (IRMAA) improve the operation of government programs by ensuring the regulations conform to the statute and the distribution of resources determined by Congress in statute. Given the context of these provisions is a federal program, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions implementing the SUPPORT Act address the misuse and abuse of opioids in the manners directed by Congress. This includes the provisions related to Mandatory Drug Management Programs, Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs, Automatic Escalation to External Review under a Medicare Part D Drug Management Program for At-Risk Beneficiaries, Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures, Section 2008 of the SUPPORT Act, Section 6063 of the SUPPORT Act, Beneficiaries' Education on Opioid Alternatives, and Beneficiaries with Sickle Cell Disease. Given the context of these provisions is a federal program or impacts on several federal programs, Congress has mandated a federal regulatory approach with respect to these provisions.
- The provisions which strengthen and improve the PACE program with respect to Service Delivery Request Processes under PACE improve the operation of government programs by ensuring documentation is available for oversight required by statute. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions relating to Beneficiary Real Time Benefit Tools address inadequate and incomplete information available to Part D beneficiaries with regards to the choices they have for prescription drugs. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions relating to permitting a second, ''preferred,'' specialty tier in Part D address externalities caused by the current specialty tier regulation—specifically the absence of negotiation leverage and incentives within the Part D specialty tier. Given the context of these provisions as a federal program, a federal regulatory approach is appropriate with respect to these provisions.
- The provisions relating to the Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System improve the operation of government programs by making updates to reflect changes in measures (thereby ensuring the government program does not use outdated methodologies) and clarifying existing regulations (thereby answering questions regulated parties may have). These and other provisions also codify sub-regulatory guidance, which is an improvement in that regulated parties and CMS have greater clarity regarding the application of these policies as a rule. Given the context of these provisions is a federal program, a federal regulatory approach is appropriate with respect to these provisions.

2. Summary of the Major Provisions

a. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (hereinafter referred to as CARA) included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). Under the DMPs in place today, Part D sponsors engage in case management of potential at-risk beneficiaries (PARBs) through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a beneficiary is determined to be at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit.

While the majority of Part D sponsors have already voluntarily implemented DMPs, CMS proposed regulations to implement section 2004 of the SUPPORT Act which require Part D sponsors to establish DMPs for plan years beginning on or after January 1, 2022.

CMS is finalizing the requirement for mandatory DMPs with an additional modification so that plans without a Pharmacy and Therapeutics (P&T) committee can comply with the DMP regulation.

b. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[1] In light of this fact, in section 2006 of the SUPPORT Act, Congress required CMS to include Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) as PARBs under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, in lieu of modifying the definition of ''potential at-risk beneficiary'' at § 423.100 as proposed, CMS is finalizing the clinical guideline criteria at new paragraph § 423.153(f)(16)(ii)(2) to include a Part D eligible individual who is identified as having a history of opioid-related overdose, beginning January 1, 2022. Inclusion of beneficiaries with a history of opioid-related overdose as PARBs in DMPs will allow Part D plan sponsors and providers to work together to closely assess these beneficiaries' opioid use and determine whether any additional action is warranted. The clinical guideline criteria CMS is finalizing at § 423.153(f)(16)(ii)(2) specify that both a principal diagnosis of opioid-related overdose and a recent Part D opioid prescription are required components to meet the definition of a PARB based on the history of opioid-related overdose. Additionally, CMS is making some revisions to the terminology used in the clinical

[1] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the U.S. Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

guideline criteria at § 423.153(f)(16)(ii)(2) from what was initially proposed in the definition at § 423.100 to better characterize the data sources and opioid prescription criteria to be used to identify beneficiaries meeting the definition of a PARB based on a history of opioid-related overdose. The clinical guideline criteria mirror the definition of ''potential at-risk beneficiary'' that was initially proposed but relocated to § 423.153(f)(16)(ii)(2) to improve clarity of the regulation text.

c. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA–PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D–4(a)(1)(a) of the Act. Section 6102 of the SUPPORT Act amended section 1860D–4(a)(1)(B) of the Act to require that Part D sponsors also must disclose to each enrollee information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA–PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. Section 6102 also amended section 1860D–4(a)(1)(C) to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees rather than disclosing the information to each plan enrollee. We are finalizing our proposal with only one modification to make the requirement applicable beginning January 1, 2022, rather than January 1, 2021 as proposed.

d. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CMS proposed that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution by the expiration of the adjudication timeframe applicable to the plan level appeal. We also proposed conforming revisions to the notices that are sent to beneficiaries. In the February 2020 proposed rule, we solicited feedback on these proposals. As a result, we received several comments related to the timeframe in which a plan sponsor has to forward the case file to the IRE. Specifically, commenters requested that plan sponsors have additional time beyond the applicable adjudication timeframe in which to assemble and forward the administrative case file to the IRE. As a result of this feedback, we are finalizing the automatic escalation provision with a modification to reflect that plan sponsors must forward the case file to the independent outside entity no later than 24 hours following the expiration of the adjudication timeframe applicable to the plan level appeal. This approach is consistent with regulations applicable to cases that must be forwarded to the IRE if the plan sponsor is untimely in its decision making and, we believe, remains consistent with the enrollee protections set forth in the SUPPORT Act. We are also finalizing the provisions related to beneficiary notices. The following provisions of this final rule are applicable 60 days after the publication date of this final rule: §§ 423.590(i) and 423.600(b) related to auto-forwarding redeterminations made under a DMP to the IRE and the provisions related to information on appeal rights in the beneficiary notices at §§ 423.153(f)(5)(ii)(C)(*3*), 423.153(f)(6)(ii)(C)(*4*), and 423.153(f)(8)(i).

e. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

In the proposed rule, CMS proposed to undertake rulemaking to implement the provisions outlined in sections 2008 and 6063 of the SUPPORT Act, which are summarized in the following sections (1) and (2). Implementing these provisions will allow CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans) to share data and information regarding unscrupulous actors, take swift action based on such data and information, and achieve enhanced outcomes in our efforts to fight the opioid crisis. In addition, this regulation will provide the means for more effective referrals to law enforcement based on plan sponsor reporting, ultimately resulting in reduced beneficiary harm and greater savings for the Medicare program.

(1) Section 2008 of the SUPPORT Act

Title XVIII of the Social Security Act (the Act) provides authority for CMS to suspend payments to Medicare fee-for-service (FFS) providers and suppliers pending an investigation of a credible allegation of fraud, unless a good cause exception applies. While Part D plan sponsors currently have the discretion to suspend payments to pharmacies in the plans' networks, section 2008 requires that plan sponsors' payment suspensions based on credible allegations of fraud be implemented in the same manner as CMS implements such payment suspensions in FFS Medicare. Under this provision, plan sponsors are required to notify the Secretary of the imposition of a payment suspension that is based on a credible allegation of fraud and may do so using a secure website portal. The reporting requirement applicable to plan sponsors will only apply to suspended payments based on credible allegations of fraud as required by section 2008 and will not extend to other payment suspensions for which plan sponsors already have authority. Section 2008 also clarifies that a fraud hotline tip, without further evidence, is not considered a credible fraud allegation for payment suspension purposes. The statutory effective date for section 2008 is for plan years beginning on or after January 1, 2020.

(2) Section 6063 of the SUPPORT Act

Section 6063 requires, effective not later than 2 years after the date of enactment, the Secretary to establish a secure internet website portal to enable the sharing of data among MA plans, prescription drug plans, and the Secretary, and referrals of ''substantiated or suspicious activities'' of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by eligible entities with a contract under section 1893 of the Act, such as a Medicare program integrity contractor. The Secretary is also required to use the portal to disseminate information to all MA plans and prescription drug plans on providers and suppliers that were referred to CMS for fraud, waste, and abuse in the last 12 months; were excluded or the subject of a payment suspension; are currently revoked from Medicare; or, for such plans that refer substantiated or suspicious activities to CMS, whether the related providers or suppliers were subject to administrative action for similar activities. The Secretary is required to define what constitutes substantiated or suspicious activities. Section 6063 specifies that a

fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

Section 6063 also requires the Secretary to disseminate quarterly reports to MA plans and prescription drug plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the portal. The Secretary's reports are to maintain the anonymity of information submitted by plans and to include administrative actions, opioid overprescribing information, and other data the Secretary, in consultation with stakeholders, determines important.

Beginning with plan year 2021, section 6063 also requires Part D plan sponsors to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

The applicability date of the section 2008 and section 6063 provisions will be for plan years beginning on or after January 1, 2022 because of several factors. The first factor is the need to ensure that the web-based portal is complete and operational for plan sponsor's use. While the development of the web-based portal began when the legislation was enacted, CMS was unable to complete the development of the portal in time for its full implementation in plan year 2021. In addition, the portal has required several key updates to reflect the requirements in this regulation. Additional factors include the time needed for plan sponsors to determine internal procedures to meet the requirements outlined in this rule; the need for CMS to obtain feedback from plan sponsors to address any challenges encountered with the web-based portal; and the need to provide plan sponsors with the opportunity to address any other operational challenges with implementing these provisions, including potential changes that may be needed due to the COVID–19 public health emergency. Furthermore, the applicability date is later than the effective dates in the SUPPORT Act because the publication of this final rule is occurring after the bid deadline for plan year 2021. However, where the statute is self-implementing, the delay in applicability of these regulations is not a barrier to enforcement of the statutory provisions.

f. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We have stated we will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time we are codifying additional existing rules for calculating the ratings used for MA Quality Bonus Payments, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns, and making additional technical clarifications. Unless otherwise stated, data will be collected and performance measured using these rules and regulations for the 2022 measurement period and the 2024 Star Ratings.

g. Permitting a Second, ''Preferred,'' Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We are finalizing regulations to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts drugs on these tiers from tiering exceptions to non-specialty tiers. Under this final rule, Part D sponsors will have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we will codify a maximum allowable cost sharing that would apply to the higher cost-sharing specialty tier. Further, we will require that if there are two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the proposed maximum allowable cost sharing.

We note that we did not propose to revise and are not revising § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. Because the exemption from tiering exceptions for specialty tier drugs under § 423.578(a)(6)(iii) as proposed would apply only to tiering exceptions to non-specialty tiers, the existing requirement at § 423.578(c)(3)(ii) will require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing, specialty tier.

To improve transparency, we will codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we will codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section IV.E.4. of this final rule. We determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty tier placement—based on a 30-day equivalent supply. Additionally, we base the determination of the specialty-tier cost threshold on the ingredient cost reported on the prescription drug event (PDE). We will also maintain a specialty-tier cost threshold for both specialty tiers that is set at a level that, in general, reflects drugs with monthly ingredient costs that are in the top 1 percent, as described further in section IV.E.6. of this final rule. Finally, we will adjust the specialty-tier cost threshold, in an increment of not less than 10 percent, when an annual analysis of PDE data shows that an adjustment is necessary to recalibrate the specialty-tier cost threshold so that it only reflects Part D drugs with the top one percent of monthly ingredient costs. We will determine annually whether the adjustment would be triggered and announce the specialty-tier cost threshold annually via an HPMS memorandum or a comparable guidance document.

We are finalizing these provisions as proposed, except that we are not finalizing our proposal to specify a specialty-tier cost threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-

approved Part D drugs. These provisions will apply for coverage year 2022.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will be in effect before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products,'' and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

h. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

This rule finalizes regulations to require that Part D plan sponsors implement a beneficiary real-time benefit tool (RTBT) by January 1, 2023. The RTBT must allow enrollees to view the information included in the prescriber RTBT system, which will include accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). This rule permits plans to use existing secure patient portals to fulfill this requirement, to develop a new portal, or use a computer application. Plans are required to make this information available to enrollees who call the plan's customer service call center.

In order to encourage enrollees to use the beneficiary RTBT, plans are permitted to offer rewards and incentives (RI) to their enrollees who log onto the beneficiary RTBT or seek to access this information via the plan's customer service call center, provided the value of the RI offered is a reasonable amount.

i. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

Currently, PACE participants or their designated representatives may request to initiate, eliminate or continue a service, and in response, the PACE organization must process this request under the requirements at § 460.104(d)(2). These requests are commonly referred to by CMS and the industry as ''service delivery requests.'' In response to feedback from PACE organizations and advocacy groups, and based on our experience monitoring PACE organizations' compliance with our current requirements, we proposed moving the requirements for processing service delivery requests from § 460.104(d)(2) and adding them to a new § 460.121 in order to increase transparency for participants and reduce confusion for PACE organizations. We also proposed modifying these provisions in order to reduce unnecessary burden on PACE organizations and eliminate unnecessary barriers for participants who have requested services that a PACE organization would be able to immediately approve. Specifically, we proposed to more clearly define what constitutes a service delivery request, and provide transparent requirements for how those requests would be processed by the PACE organization, including who can make a request, how a request can be made, and the timeframe for processing a service delivery request. We also proposed allowing the interdisciplinary team (IDT) to bypass the full processing of a service delivery request under the new proposed requirements in § 460.121 when the request can be approved in full by an IDT member at the time it is made. For all other service delivery requests that are brought to the IDT, we proposed maintaining the requirement that an in-person reassessment must be conducted prior to a service delivery request being denied, but we proposed eliminating the requirement that a reassessment (either in-person or through remote technology) be conducted when a service delivery request can be approved. Lastly, we proposed adding participant protections; specifically, we proposed increasing notification requirements in order to ensure participants understand why their request was denied, and we proposed adding reassessment criteria in order to ensure reassessments are meaningful to the service delivery request, and that the IDT takes them into consideration when rendering a decision.

We are finalizing these provisions as proposed, with some minor modifications. For example, all references to ''service delivery requests'' in §§ 460.104, 460.121 and 460.122 have been replaced with the term ''service determination request.'' In addition, we have modified § 460.121(d)(2) to limit service determination requests to requests that are received by PACE organization employees and contractors who provide direct care in the participant's residence, the PACE center, or while transporting participants.

j. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Beneficiaries with active cancer-related pain, residing in a long-term care facility, or receiving hospice, palliative, or end-of-life care currently meet the definition of ''exempt beneficiary'' with respect to DMPs in § 423.100. Section 1860D–4(c)(5)(C)(ii)(III) of the Act provides the Secretary with the authority to elect to treat other beneficiaries as exempted from DMPs. Due to concerns of misapplication of opioid restrictions in the sickle cell disease (SCD) patient population, CMS proposed that beneficiaries with SCD be classified as exempt beneficiaries. CMS is finalizing the definition of an exempted beneficiary to include beneficiaries with SCD as proposed with one modification to clarify that this definition is applicable starting in plan year 2022.

3. Summary of Costs and Benefits

Provision	Description	Primary impact to plans and sponsors, enrollees, and medicare trust fund as applicable
a. Mandatory Drug Management Programs (DMPs) (§ 423.153).	This provision will codify the SUPPORT Act requirement making it mandatory that Part D sponsors implement DMPs, starting in plan year 2022.	There is a 10 year cost of $4.0 million. Part D sponsors will incur s a special first year cost of 3.2 million with ongoing costs of $0.1 million in later years.

Provision	Description	Primary impact to plans and sponsors, enrollees, and medicare trust fund as applicable
b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153).	As finalized, this provision will require that, starting in plan year 2022, CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse or misuse under sponsors' DMPs.	Part D beneficiaries with a history of opioid-related overdose have higher than average drug costs. CMS estimates that as a result of reduced utilization of drugs for beneficiaries participating in DMPs, there will be a savings of 5 percent of the current annual drug costs for enrollees with a history of opioid overuse. After the first year, the reduction in drug utilization may result in an annual savings of $7.7 million to the Medicare Trust Fund resulting from reduced drug spending by beneficiaries. The costs for case management and related paperwork is estimated at $10.1 million annually.
c. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128).	CMS is finalizing requirements that Part D sponsors and MA–PDs must provide information on the risks of opioids and alternative therapies to all Part D beneficiaries with modification starting in plan year 2022.	The requirements set forth under 1860D–4(a)(1)(B) will cost approximately $0.5 million in the first year to account for one-time programming costs and $0.4 million in the following years.
d. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600).	Under this final rule, if a Part D sponsor denies a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. A plan sponsor must forward the case to the independent outside entity no later than 24 hours following the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, this final rule establishes conforming revisions to the notices that are sent to beneficiaries.	We estimate there will be about 28,600 appeals per year, of which 0.08 percent will be denied and automatically escalated to the independent review entity (IRE). Therefore, there are approximately 23 cases (0.08 percent * 28,600) annually affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46, and typically an IRE will take at most 1 hour to review, the total burden is about $4,656.58 (23 cases * $202.46 * 1 hour).
e. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2).	CMS is finalizing policies to implement two sections of the SUPPORT Act, which will—(1) require Part D plan sponsors to notify the Secretary of the imposition of a payment suspension on pharmacies that is based on a credible allegation of fraud, impose such payment suspensions consistent with the manner in which CMS implements payment suspensions in fee-for service Medicare, and report such information using a secure website portal; (2) define inappropriate prescribing with respect to opioids; (3) require plan sponsors to submit to the Secretary information on investigations and other actions related to inappropriate opioid prescribing; (4) define ''substantiated or suspicious activities'' related to fraud, waste, or abuse; and (5) establish a secure portal which would enable the sharing of data and referrals of ''substantiated or suspicious activities'' related to fraud, waste, or abuse among plan sponsors, CMS, and CMS's program integrity contractors.	While we believe there may be savings generated through actions taken by plans that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS and plans sponsors, as well as additional law enforcement actions, we cannot estimate the impact at this time. The Part C and Part D sponsors will incur an initial aggregate cost of $15.2 million with level subsequent year aggregate costs of $9.6 million.
f. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186).	We are codifying additional existing rules for calculating MA Quality Bonus Payments ratings, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns, and making additional technical clarifications.	There will be no, or negligible, impact on the Medicare Trust Fund from these provisions.
g. Permitting a Second, ''Preferred,'' Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578).	CMS is finalizing regulations to (1) allow Part D sponsors to establish a second, ''preferred,'' specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty-tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either specialty tier.	Permitting Part D sponsors to establish a second, ''preferred,'' specialty tier is unlikely to have a material impact on Part D costs to either the government or Part D enrollees.

Provision	Description	Primary impact to plans and sponsors, enrollees, and medicare trust fund as applicable
h. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128).	CMS is finalizing regulations to require that each Part D plan implement a beneficiary real time benefit tool by January 1, 2023. he RTBTI must enable enrollees to have the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements).	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on our estimates, we believe this will cost Part D plans about $4.0 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of $0.7 million in the first year, in order to implement the program, and $0.4 million in subsequent years in order to maintain the program. These are maximum impacts assuming all Part D sponsors choose to implement the rewards and incentives, and it remains to be seen whether or not this will be the case.
i. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121).	CMS is finalizing the process by which PACE organizations address service determination requests. Currently the IDT must determine the appropriate member(s) of the IDT to conduct a reassessment, perform a reassessment, and render a decision on each service determination request. However, our experience shows that approximately 40 percent of all requests could be immediately approved in full by an IDT member. We are therefore removing the obligation for a request to be brought to the IDT or for a reassessment to be conducted when a member of the IDT receives and can approve a service determination request in full at the time it is made. We are also removing the requirement to conduct a reassessment in response to a service determination request except when a request would be partially or fully denied.	The proposed revisions create efficiencies which are estimated to create cost savings of $16.8 million in the first year and gradually increase to $ 21.3 million in 2031. The net savings over 10 years is $193.8 million. The savings are true savings to PACE organizations as a result of reduced administrative burden.
j. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100).	CMS is finalizing that beneficiaries with SCD are classified as exempted from DMPs starting in plan year 2022.	We estimate that the impact of this provision is negligible because it will result in under 70 beneficiaries (*i.e.,* beneficiaries with SCD who meet DMP inclusion criteria by meeting the definition of a PARB) being exempted from DMPs.

B. Background

We received approximately 667 timely pieces of correspondence containing multiple comments for the provisions implemented within this final rule from the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (February 2020 proposed rule). Comments were submitted by MA health plans, Part D sponsors, MA enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, and other vendor and professional associations. As mentioned previously, we are finalizing the policies from the February 2020 proposed rule in more than one final rule. The first part titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), and contained a subset of regulatory changes that impacted MA organizations and Part D sponsors more immediately, including information needed to submit their bids by the statutory deadline (the first Monday in June). The majority of the remaining provisions are addressed here in this final rule.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based on the comments received. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings.

We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. CMS did not make any proposals in the February 2020 proposed rule on these topics, and as such, these out-of-scope public comments are not addressed in this final rule. The following paragraphs summarize the out-of-scope public comments.

We received comments about how CMS will assess compliance with PACE regulatory requirements, recommendations for changes to PACE grievance requirements, and a recommendation to require plan sponsors to automatically escalate all adverse Part D benefit appeals to the independent review entity. Related to Star Ratings, we received comments that CMS should only apply the Categorical Adjustment Index if it positively impacts a contract's Star Rating, and that we adopt completely new Star Ratings measures or change HEDIS measures during the COVID–19 pandemic. Related to establishing pharmacy performance measure reporting requirements, we received comments in favor of abolishing Direct and Indirect Remunerations, applying 100 percent of direct pharmacy price concessions at the point-of sale, prohibiting use of a scoring method that

solely uses contractual pay-for-performance metrics, and the inclusion of clinical data as part of any standardized performance measures.

With regard to our proposals to permit Part D sponsors to maintain up to two specialty tiers, several commenters expressed that, in general, tiered-formulary structures have misaligned incentives, and that specialty tiers (particularly a second specialty tier), exacerbate the impact of such misaligned incentives. These commenters expressed concerns over the transparency of Part D rebate mechanisms and suggested that Part D sponsors have incentives to grant more expensive products with preferred status even when preferred products are not always the least expensive products, which the commenters posited increases costs for both Part D enrollees and the government. Some commenters suggested that CMS should eliminate the specialty tier, reasoning that elimination of the specialty tier would only produce modest increases in premiums and cost sharing in other tiers. Some commenters also suggested that the tiers should be relabeled and reordered in the hierarchy relative to Part D enrollee cost sharing to be more consistent with current industry practices. Some commenters suggested that CMS should mandate that denials at the pharmacy counter trigger the appeals process. Other commenters suggested that Part D enrollees stabilized on a specialty drug be exempt from unfavorable coverage changes (for example, increased cost sharing) resulting from a secondary specialty tier. Some commenters suggested that CMS should adjust the Part D rebate sharing formulas to remove plan incentives for high-cost, high-rebate brand drugs. Some commenters encouraged CMS to investigate alternative catastrophic reinsurance models to incent the most savings for health plans implementing a preferred specialty tier. Some commenters suggested that, like private insurance plans with more than one specialty tier, CMS should establish an out-of-pocket max in Part D. Some commenters suggested a comprehensive reform of the Part D program. Some commenters suggested that transitioning to a biosimilar biological product on a lower specialty tier may have negative clinical implications for a patient stabilized on a reference product. (We refer readers to the Food and Drug Administration (FDA) regarding the safety and efficacy of biosimilar biological products, and their use in patients who have previously been treated with the reference product, as well as in patients who have not previously received the reference product.) Some commenters took the opportunity to suggest that CMS should expand the scope of our mid-year formulary change policy to include biosimilar biological products, reasoning that they are ''equivalent'' to the reference biological products. Some commenters suggested that CMS should improve the exceptions and appeal process. Some commenters suggested that CMS should ensure independent pharmacies cannot be excluded from providing non-preferred specialty tier drugs. Finally, some commenters suggested that CMS should institute conflict of interest provisions for pharmacy chains owned by PBMs. (We note that this rule, as we are finalizing it, would not provide Part D sponsors with any additional basis to exclude independent pharmacies from their networks.)

In response to proposed changes to the Coverage Gap Discount Program (CGDP), two commenters offered suggestions about how the Part D program could be more cost effective. One of these commenters urged CMS to prohibit Part D plans from using utilization management tools to steer utilization away from lower cost biosimilar products. The other commenter suggested that Congress change the CGDP in a way that would result in greater use of lower cost drugs throughout the program and suggested that the program's existence shifts the lower net cost determinations of generic and biosimilar products.

With regard to Medication Therapy Management (MTM), one commenter expressed concern about how pharmacists are paid for providing services, while another questioned the overall cost benefit of the MTM program.

A commenter recommended that CMS align exemption criteria for the Pharmacy Quality Alliance's Initial Opioid Prescribing Measures with DMP exemption criteria; however, these measures are not developed by CMS and are outside the scope of the proposed rule. We also received a number of comments that did not refer specifically to our Part D opioid proposals but more generally (1) referenced the opioid epidemic, (2) cited concerns that existing restrictions on opioid access may drive chronic pain patients to illicit markets and/or reduce their quality of life and functional status, (3) raised questions about Drug Enforcement Agency (DEA) actions against opioid prescribers and whether they address the root cause of the opioid epidemic, and (4) opined that interventions should be focused on illegal drugs.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

Congress authorized special needs plans (SNPs) as a type of Medicare Advantage (MA) plan designed to enroll individuals with special needs. The three types of SNPs are those designed for: (1) Institutionalized individuals (defined in § 422.2 as an individual continuously residing, or expecting to continuously reside, for 90 days or longer in specified facility) or institutionalized-equivalent (defined in § 422.2 as living in the community but requiring an institutional level of care, which is determined using a specified assessment instrument and conducted consistent with specified standards); (2) individuals entitled to medical assistance under a State Plan under title XIX of the Act; or (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP. As noted in the proposed rule (85 FR 9013 through 9014), there have been a number of changes to the requirements for MA SNPs since their initial authorization. We proposed changes to § 422.101(f) to implement and extend the latest of those statutory changes, made by the Bipartisan Budget Act of 2018 (BBA).

As of July 2019, there were 321 SNP contracts with 734 SNP plans that had at least 11 members. These figures included 208 Dual Eligible SNP contracts (D–SNPs) with 480 D–SNP plans with at least 11 members, 57 Institutional SNP contracts (I–SNPs) with 125 I–SNP plans with at least 11 members, and 56 Chronic or Disabling Condition SNP contracts (C–SNPs) with 129 C–SNP plans with at least 11 members. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).[2] The proposed rule summarized current processes and requirements for the models of care that all SNPs must use and follow under current law. (85 FR 9014)

The Bipartisan Budget Act of 2018 (BBA), enacted into law on February 9, 2018, amended section 1859(f) of the Act to include new care management requirements for C–SNPs. We proposed, and are finalizing here, regulations to

[2] For more information pertaining to chapter 16b of the Medicare Managed Care Manual, please see: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.*

implement the provisions of the BBA of 2018 and establishes new care management requirements at § 422.101(f) for all SNPs, including minimum benchmarks for SNP models of care. Due to operational considerations, the requirements we are finalizing at § 422.101(f) are intended for implementation for coverage beginning contract year 2023. Plans that are required to submit MOCs for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for the full implementation and enforcement of this final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

Specifically, we proposed the following:

- First, we proposed to implement the requirement in section 1859(f)(5)(B)(i) of the Act regarding the interdisciplinary team, or sometimes called the interdisciplinary care team (ICT), in an amendment to § 422.101(f)(1)(iii) that would require the team to include providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan, and in addition to implementing the statutory requirement for C–SNPs, extend the requirement to all SNPs.
- Second, we proposed to implement the requirement in section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee in a new paragraph (f)(1)(iv) of § 422.101 that would extend the requirement to all SNPs. Under our proposal, face-to-face encounters would have to be between each enrollee and a member of the enrollee's ICT or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent; we also proposed that a face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter.
- Third, we proposed to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C–SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. As with the other provisions in section 1859(f)(5)(B) of the Act, we proposed to extend this requirement to the model of care for all SNPs, in revisions to § 422.101(f)(1)(i).
- Fourth, we proposed to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C–SNPs. We proposed a new provision at § 422.101(f)(3)(ii) to require that, as part of the evaluation and approval of the SNP model of care, National Committee for Quality Assurance (NCQA) must evaluate whether goals were fulfilled from the previous model of care. We also proposed, in new paragraphs (f)(3)(ii)(A) through (C) that: (A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals; (B) plans submitting a new model of care must provide relevant information pertaining to the MOC's goals for review and approval; and (C) if the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. We also proposed to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs must submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3)(i), using the same language.
- Lastly, we proposed to implement new regulation text at § 422.101(f)(3)(iii) to impose the requirement for benchmarks to be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C–SNP model of care, and that the MOC can only be approved if each element meets a minimum benchmark. The proposed regulation in § 422.101(f)(3)(iii) would extend these benchmarks for all SNP models of care.

We proposed to extend the new requirements enacted by the BBA of 2018 to all SNP plan types for several reasons. We explained that these additional requirements are consistent with current regulations and sub-regulatory guidance CMS provides to all SNPs regarding care management and MOC compliance. Second, we believe that these proposed regulations are important safeguards to preserve the quality of care for all special needs individuals, including those enrolled in D–SNPs and I–SNPs and not just those enrolled in C–SNPs. Given the prevalence of medically complex chronic conditions among I–SNP and D–SNP enrollees, we believe the proper application of these new care improvement requirements would improve care for enrollees with complex chronic conditions. Finally, we stated that the application of multiple, different MOC standards would be operationally complex and burdensome for MA organizations that sponsor multiple SNP plan types, for instance, a D–SNP and a C–SNP. Our proposal would streamline operational and administrative obligations by making the different SNPs have similar requirements as well as establish minimum standards to benefit all special needs individuals in these plans.

In the proposed rule, we solicited comment on the extension of the new care management and MOC requirements for C–SNPs to the care management and MOC requirements for all SNP types and then discussed each of the specific proposed policies in turn. We address comments about the extension of the requirements to all SNP types first, followed by a review of each proposed policy and the relevant comments and the response to such comments. 1. Extension of the C–SNP requirements to all SNP types

Comment: CMS received a number of comments in support of or in opposition to the extension of C–SNP requirements, added to section 1859(f)(5) of the Act by the BBA of 2018, to apply to all SNP types, instead of limiting the applicability of these requirement to just C–SNPs. A handful of commenters were concerned about the applicability of several of the proposed regulations to I–SNP and D–SNP care management protocols with some arguing that the proposed rule would result in requirements that are duplicative of the current MOC approval process requirements. Several commenters specifically noted that SNPs of all types have existing processes and practices that cover the areas discussed in the proposed rule. They contend that the NCQA Model of Care, review, and scoring guidelines comprehensively cover the coordination of care, provider, and quality requirements outlined in the proposed rule. In addition, commenters noted that CMS audits include review of

performance by SNPs on these processes.

Response: Regarding the extension of section 1859(f)(5) of the Act to include all SNP types, we agree this rule is consistent with current CMS policy, including several current regulations implementing section 1859; the statute and several regulations establish similar requirements for all SNPs regardless of type. Specifically, section 1859(f)(5)(A) of the Act requires that MA organizations offering a SNP implement an evidence-based model of care. The MOC and other SNP-specific requirements have been incorporated into the MA application for MAOs that wish to offer a SNP so that these MAOs can demonstrate that they meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs. In the Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions (74 FR 1493), known hereafter as the January 2009 final rule, CMS outlined the overarching purpose of section 422.101(f) and noted that SNPs, regardless of type, are required to meet the same requirements including that each plan must have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to people with disabilities, frail older adults, and those near the end of life based on appropriate protocols. (74 FR 1498 through 1450) CMS's belief that these measures are critical to providing care to the types of special needs populations served by SNPs has not changed in the intervening years since finalizing § 422.101(f) in 2009. As noted in this section of this rule, for each specific provision we proposed and are finalizing at § 422.101(f), CMS is codifying certain requirements that are part of the current SNP MOC approval process. Rather than forcing a duplication of processes, we believe that SNPs have already implemented many of these new requirements into their MOC. Understanding this, we proposed and are finalizing these provisions in line with current MOC review and scoring guidelines, covering all facets of the MOC including care coordination, provider, and quality requirements.

As discussed in the proposed rule, extending the statutory requirements for C–SNPs to all SNPs will provide improvements to the care coordination model in all SNPs. For example, section 1859(f)(5)(B)(ii), as added by the BBA of 2018, requires C–SNPs to provide face-to-face encounters with each enrollee on an annual basis, consistent with standards adopted by CMS. We proposed and are finalizing, at § 422.101(f)(1)(iv), that all SNPs provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. Face-to-face encounters are appropriate to require for all SNP enrollees because these SNP enrollees have similar healthcare needs, including the need for treatment of multiple chronic conditions and for services such as care coordination.

Comment: Another comment supported the proposal, but added that CMS should explore the application of a more rigorous set of requirements focused on person-centered care to strengthen the MOC and meet the needs of SNP enrollees.

Response: We thank the commenter for their comment and suggestions. As proposed and finalized, the new provisions in § 422.101(f) provide both a structure for creating a care management process specifically designed to provide targeted care to individuals with special needs and allow flexibilities enabling plans to create innovative approaches to person-centered care. As noted in the Interim Final Rule with comment, titled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs'' (CMS–4138–IFC), issued in September 2008 (''September 2008 IFC'') (73 FR 54225, 54228), we expect the MA organizations that have the commitment and resources to serve vulnerable special needs beneficiaries through SNPs will perpetually evaluate their own model of care by collecting and analyzing performance data to continually improve their model of care. We also noted in the September 2008 IFC that CMS would continue to evaluate models of care through the analysis of SNP performance data and monitoring visits, the review of scientific research on the efficacy of other care models, and feedback from beneficiaries, advocacy groups, and healthcare professionals (73 FR 54228). The revisions to § 422.101(f) adopted in this final rule represent a continuation of this process to evaluate and refine SNP care management.

This final rule establishes and clarifies delivery of care standards for SNPs and codifies standards which we have included in other CMS guidance and instructions. As such, we are finalizing the revisions to paragraph (f) to § 422.101 generally as proposed to extend certain statutory requirements to all SNPs.

1. The Interdisciplinary Team (ICT) in the Management of Care

As amended by the BBA of 2018, section 1859(f)(5)(B)(i) of the Act requires the interdisciplinary team (ICT) of each C–SNP to include providers with specified expertise and training. We proposed to implement this through an amendment to § 422.101(f)(1)(iii) that would apply the requirement to all SNPs. We proposed to require that each MA organization offering a SNP plan must provide each enrollee with an ICT that includes providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

We explained in the proposed rule that MIPPA required SNPs to conduct initial and annual comprehensive health risk assessments, develop and implement an individualized plan of care, and implement an ICT for each beneficiary. Specifically, Section 1859(f)(5)(A)(ii)(III) of the Act requires all SNPs to use ICTs as part of offering a specialized MA plan for special needs individuals. As stated in the proposed rule, we believe that the combination of MIPPA's statutory elements and our regulatory prescription for the SNP model of care establishes a standardized architecture for effective care management while giving plans the flexibility to design the unique services and benefits that enable them to meet the needs and preferences of their target population. We believe our proposal, which amends paragraph (f)(1)(iii) and applies the additional requirements pertaining to demonstrated expertise and training of interdisciplinary team providers to all SNPs, is consistent with the MIPPA requirements and the rulemakings that first adopted requirements for the use of interdisciplinary teams (73 FR 54228, 74 FR 1498).

All SNPs must have an ICT to coordinate the delivery of services and benefits, but the current regulation provides flexibility as necessary for each SNP: One SNP may choose to contract with an ICT to deliver care in community health clinics; and another SNP may hire its team to deliver care in the home setting. Under the current rule, and our proposal, all SNPs must coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries. However, as we explained in the proposed rule, one SNP may coordinate care through a

telephonic connection among all stakeholders and another SNP may coordinate care through an electronic system using Web-based records and electronic mail accessed exclusively by the plan, network providers, and beneficiaries. All SNPs must coordinate the delivery of specialized benefits and services that meet the needs of their most vulnerable beneficiaries. However, D–SNPs may need to coordinate Medicaid services while an institutional SNP may need to facilitate hospice care for its beneficiaries near the end of life. We provided these examples in the proposed rule to demonstrate the variety of ways SNPs currently implement their systems of care and how we believe all SNP enrollees should have access to a team of providers with expertise and training that are appropriate for each individual enrollee.

We received the following comments and our responses follow:

Comment: A commenter recommended that CMS clarify that ''providers,'' as used in this section, follows the definition of ''provider'' in 42 CFR 422.2, and also recommended that CMS provide additional details about what constitutes ''demonstrated expertise and training.'' Specifically, the commenter requested that CMS clarify whether there are minimal expertise or training requirements that the provider must meet or whether each special needs plan would have discretion to make this determination.

Response: As proposed and finalized, § 422.101(f)(1)(iii) requires SNPs to use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan. Our current guidance for the MOC approval process provides that a SNP's MOC describe the composition of the ICT, including how the SNP determines ICT membership and the roles and responsibilities of each member. Additional information can be found in Chapter 5 of the MMCM, section 20.2.2, specifically guidance on MOC 2, Element D.[3] A compliant and well-developed MOC includes a description that specifies how the expertise and capabilities of the ICT members align with the identified clinical and social needs of the SNP beneficiaries. As proposed and as finalized, the requirement in § 422.101(f)(1)(iii) to have training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan means that individual providers and providers in one type of SNP (compared to other SNPs) may have training and expertise that differ based on the SNP-type or each individual enrollee's needs. For example, a C–SNP that targets diabetes mellitus may seek to establish an ICT for each enrollee that has a specialist with training and expertise in endocrinology while a D–SNP may want to establish ICTs for individual enrollees that focus on a particular set of chronic conditions or focus on specific service delivery needs for an enrollee, such as long-term services and supports. This is consistent with our current guidance and we believe that any additional burden here for SNPs will be minimal.

As defined in § 422.2, a provider is: (1) An individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; or (2) an entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. Therefore, the providers in the ICT must be licensed or certified to furnish the health care services they deliver. Under this new regulation, providers in an ICT must also be trained in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan, when applicable. We expect that plans are already meeting this requirement that members of the ICT have training and expertise specific to the SNP's target population based on MOC scoring guidelines provided to all SNPs by NCQA; for example, MOC submissions specify how the expertise and capabilities of the ICT members align with the identified clinical and social needs of the SNP enrollees and describe how specific care plans for enrollees are used to determine the composition of the ICT.[4] In conclusion, under the amendment to paragraph (f)(1)(iii) that we are finalizing here, all members of the ICT must be licensed or certified to deliver the applicable health care furnished to enrollees of the SNP in compliance with § 422.2 and all of the members of the ICT must have demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan. The revisions at § 422.101(f)(1)(iii) are being finalized as applicable beginning with 2023 so MOCs for that period will be reviewed and approved based on demonstrated compliance with this final rule. The specifics of the expertise and necessary training will vary with the SNP and the covered population, and we are not adopting specific, uniform minimum requirements for all providers in all SNPs ICTs.

The revisions at § 422.101(f)(1)(iii) are being finalized as applicable beginning 2023 so MOCs for that period and subsequent years will be reviewed and approved based on demonstrated compliance with the amendments to the regulation that we are finalizing here.

Comment: CMS received several comments regarding the extension of the new statutory interdisciplinary team requirements to D–SNPs and I–SNPs. Some commenters believed that plan implementation of additional ICT requirements would be unnecessarily burdensome because some D–SNPs have difficulty contracting with and requiring specialists to take part in the ICT process. Other commenters noted that the new rule would be redundant, given existing regulations and policies are already in place, including regulations applying to the institutional settings in which I–SNP beneficiaries reside. Some of these commenters noted that adding ICT requirements will increase the burden on long-term care facilities and may require some patients to be managed to different standards than others. Others noted that this provision could interfere with plans' current practices that promote the identification of providers from disciplines that are most relevant to the beneficiary's needs. Another commenter noted that for D–SNPs, there are credentialing and network adequacy standards already in place to ensure appropriate access for D–SNP enrollees to high-quality providers. Lastly, CMS received a comment stating that the ICT should include the enrollee's managed care long term services and supports (MLTSS) care manager in cases where the enrollee receives those services.

Response: We believe the revisions we proposed and are finalizing at § 422.101(f)(1)(iii) are consistent with the current review and approval process for each MOC submission under MOC 2, Element D. While there might be overlap and redundancies for § 422.101(f)(1)(iii) and existing standards either for SNPs and SNP MOCs or for institutional providers that furnish services to SNP enrollees, that only reinforces that finalizing

[3] Please see Chapter 5 of the MMCM, which can be found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c05.pdf.*

[4] The scoring guidelines can be found at: *https://snpmoc.ncqa.org/wp-content/uploads/MOC-Scoring-Guidelines_CY-2021-1.pdf.* See section MOC 2, Element D.

§ 422.101(f)(1)(iii) as proposed is appropriate. As SNPs are designed to furnish services and coordinate care based on the needs of its target population, ensuring that the providers and ICT that deliver that care have expertise that is specific to the target population is consistent with the overall goals of SNPs.

As noted in Chapter 5 of the MMCM, section 20.2.2, the role and conditions of MOC approval for the ICT are described in MOC 2 Element D. All SNPs are required in § 422.101(f) to implement an evidence based model of care (MOC) that has been evaluated and approved by the NCQA. As part of the approval process, SNPs are also required to meet ICT requirements under Element D. Each SNP must describe how its organization determines the composition of ICT membership. Under factor 1 of MOC 2, Element D, all SNPs must explain how the SNP facilitates the participation of beneficiaries and their caregiver(s) as members of the ICT. In addition, each SNP must describe how the beneficiary's Health Risk Assessment Tool (HRAT) and ICP are used to determine the composition of the ICT for each enrollee, including where additional team members are needed to meet the unique needs of a beneficiary. Lastly, SNPs must explain how the ICT uses health care outcomes to evaluate processes established to manage changes or adjustments to the beneficiary's health care needs on a continuous basis. The new regulation text concerning the ICT and the need to include providers with certain expertise and training are similar to these existing requirements and standards for the MOC, so any additional burden should be minimal. To the extent that a SNP is already using the needs and assessments of each enrollee to identify ICT members that are qualified and trained to meet that individual enrollee's unique needs (and does this for each enrollee), this new standard may require some additional documentation from the SNP about the demonstrated expertise, licensure and training of the ICT. CMS believes plans will be able to implement the new ICT provisions without significant changes to current processes based on two critical factors: (1) All SNPs are already required under § 422.101(f)(1)(iii) to establish an ICT for each enrollee, and thus, plans have in place steps for reviewing ICT composition and qualification; and (2) more importantly, SNPs are currently employing a process similar to the new provision for establishing an ICT as part of the MOC application approval process. Again, the new ICT provision is a natural extension of and generally codifies elements of the current MOC approval process covering the ICT, which should facilitate a seamless transition for SNPs as they implement the necessary processes to comply with new ICT requirements. These changes to the MOC, and the others contained in the amendments to § 422.101(f) will apply to MOCs and SNP performance for 2023. This means that SNPs submitting MOCs for 2023 will need to develop and implement their MOCs for 2023 based on the amendments in this final rule. However, CMS will not require SNPs that currently employ MOCs that have been approved by NCQA and are not due for review and approval in 2023 to resubmit their MOCs to demonstrate compliance with § 422.101(f)(1)(iii) as amended in this rule; so long as the SNP and its MOC meets all other requirements, the SNP may continue to operate under its current MOC based on how similar the ICT provision of this final rule is to current law and policy. We strongly encourage D–SNPs and I–SNPs that do not have MOCs up for review and approval for 2023 to review their MOCs and implement changes as necessary to ensure the interdisciplinary team for each enrollee includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

While the commenter states that some SNPs may face obstacles when seeking ICT participation from some providers (including certain types of specialists), CMS has not seen evidence suggesting such difficulties. Due to the similarity of § 422.101(f)(1)(iii) as revised in this rule to CMS's current policy and the standards used in NCQA reviews, it is likely that any difficulty that would lead to an inability to comply with this provision would have been apparent in past reviews of MOCs.

As we noted in the preamble of the proposed rule, SNPs are in the best position to identify an ICT with the appropriate expertise and training necessary to meet the clinical needs for each enrollee, based on the medical and behavioral health conditions of their member population and the SNP's developed expertise. We expect that an MA organization that offers a SNP for a particular population based on a chronic condition, on residence in an institution or needing a similar level of care as those who reside in an institution, or on eligibility for both Medicare and Medicaid, will have considered the needs of such populations in designing the plan and the network of providers. MA organizations are not required to offer SNPs and those that choose to do so must be capable of meeting the unique needs of the targeted population, including gaining the participation of specialists and other health care providers that have the most or best expertise for serving these vulnerable populations, consistent with the regulatory requirements. With respect to the inclusion of the enrollee's MLTSS care manager, we again defer to SNPs to determine the appropriate composition of the beneficiary's ICT in compliance with the MOC standards, which includes consultation with the beneficiary. This final rule is based on and reflects a policy that while all SNPs must develop and use an ICT to coordinate the delivery of services and benefits for each enrollee, the construction of the ICT must recognize and be built to address the needs and wishes of each individual enrollee.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(1)(iii) regarding ICT expertise and training as proposed without modification.

2. Face-to-Face Annual Encounters

We proposed to implement section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee. We proposed that the face-to-face encounter be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent. We also proposed to codify that a face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter. We proposed to adopt this in a new paragraph (f)(1)(iv) in § 422.101 that would extend the requirement to all SNPs. Under our proposal, SNPs would be required to provide an annual face-to-face visit that is in-person or by remote technology and occurs starting within the first 12 months of enrollment within the plan. For instance, a plan enrolling a beneficiary on October 1 would need to facilitate a face-to-face encounter with that enrollee by September 30th of the following year. We indicated in the proposed rule that SNPs should implement this requirement in a manner that honors

any enrollee's decision not to participate in any qualifying encounter.

We received the following comments and our responses follow:

Comment: CMS received a number of comments both supporting and opposing the requirement for SNPs to provide a face-to-face encounter with each enrollee. Some plans noted that this is already part of their program. Some commenters, however, were concerned that implementation could be a burden for enrollees, while others were concerned that the requirements would be particularly difficult for SNP types with larger enrollments, such as D–SNPs. Still others believed that the new regulation would be hard for plans to track encounters between enrollees and providers. Others suggested that CMS allow SNPs to use encounters with non-ICT plan contracted providers to meet this requirement.

Response: We are finalizing the proposal to add § 422.101(f)(1)(iv) to require each SNP to provide an annual face-to-face encounter with each enrollee, with some modifications to address concerns raised by the commenters. As proposed and finalized, the required face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter. The final rule requires, as proposed, that the MA organization provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff. And finally, we are also finalizing that the face-to-face encounter occur on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. However, we are finalizing additional flexibility as well for SNPs in connection with § 422.101(f)(1)(iv) by including that the required face-to-face encounter may also be with a contracted health plan provider and clarification as to the type of encounter that is required.

As we noted in the proposed rule, we intend for this requirement to be met in a number of different ways. In the proposed rule, we provided examples of encounters that would meet the requirement, including a visit to or by a member of an individual's interdisciplinary team or the plan's case management and coordination staff that perform clinical functions, such as direct beneficiary care. We agree with commenters that have requested that encounters with health care providers contracted with the enrollee's SNP qualify under the implementation of the final rule. This would include the enrollee's regular primary care physician, a specialist related to the enrollee's chronic condition, a behavioral health provider, health educator, social worker, and MLTSS plan staff or related MLTSS health care providers provided that such providers are (i) a member of the enrollee's interdisciplinary team; (ii) part of the plan's case management and coordination staff; or (iii) contracted plan healthcare providers. Requiring at a minimum that a healthcare provider with a contractual relationship with the SNP be part of the annual face-to-face encounter in this way will ensure that the annual encounter is a meaningful one from the perspective of the enrollee's overall health and wellbeing. We also believe that a healthcare provider with a contractual relationship will facilitate the sharing of critical health information among the plan, the ICT, and other key healthcare providers, and thus ensure coordination of care for the enrollee under § 422.112(b), and result in increased care coordination and facilitate any necessary follow-up care or referrals. Therefore, we are finalizing the new regulation at § 422.101(f)(1)(iv) with additional text to list contracted plan healthcare providers as well as members of the ICT and the plan's care coordination team. We defer to each SNP to identify which providers are part of the plan's case management and coordination staff or contracted plan healthcare providers so long as the SNP's policies are reasonable and not a means to evade compliance with the rule.

We intend for this mandatory face-to-face encounter to serve a clinical or care coordination/care management purpose. Ensuring that a special needs individual has been contacted by the SNP at least once a year and that there has been a face-to-face encounter that pertains to the individual's health care is a way of ensuring that the goals of a SNP are met. Examples of the necessary services or engagement happening during the required encounter include: (i) Engaging with the enrollee to manage, treat and oversee (or coordinate) their health care (such as furnishing preventive care included in the individualized care plan (ICP)); (ii) annual wellness visits and/or physicals; (iii) completion of a health risk assessment (HRA), such as the one annually required for all SNPs under the current regulation at § 422.101(f)(1); (iv) care plan review or other similar care coordination activities; or (v) health related education whereby the enrollee receives information or instructions critical to the maintenance of their health or implementing processes for maintaining the enrollee's health, such as the administration of a medication. These examples are not the only activities that satisfy the new regulatory requirement. Encounters may also address any concerns related to the enrollee's physical, mental/behavioral health, or overall health status, including functional status. Plans may also use qualifying encounters—those that meet qualifications as stipulated in this final rule—that are the result of plan efforts to satisfy state-mandated Medicaid or MTLSS requirements. We believe many SNPs would already meet this standard in current practice and have sufficient encounters on at least an annual basis with each enrollee that this new regulation will not be burdensome. Encounters that are sufficient to meet the regulatory requirement we are finalizing could occur either through regular visits by the enrollee to a member of the beneficiary's interdisciplinary team or through the care coordination process established by the plan's staff or contracted plan healthcare providers. We anticipate that, consistent with good clinical practice, concerns are addressed and any appropriate referrals, follow-up, and care coordination activities provided or scheduled as necessary as a result of these face-to-face encounters.

We are cognizant that enrollees should have the final authority over their health care and our proposed regulation text reflected this by requiring that these face-to-face encounters be as feasible and with the enrollee's consent. A SNP must comply with this requirement in a manner that honors any enrollee's decision not to participate in a face-to-face (either in-person or virtual) encounter. If an enrollee does not consent to the encounter required by § 422.101(f)(1)(iv), the plan should document that in order to demonstrate compliance with the regulation. The rule addresses feasibility barriers to a SNP providing for the required annual encounter, such as where a SNP enrollee may be non-responsive to plan outreach or the state of the member's health (such as if the member is dealing with a hospitalization) prohibits a face-to-face encounter with the type of provider or staff that are described in the final regulation. In these circumstances, CMS recognizes that a SNP may not be able to comply with the rule's mandate of an annual face-to-face encounter and we intend the ''as feasible'' standard in the regulation to address such situations. Since the enrollee has refused or because the SNP could not reach the enrollee after reasonable attempts, the plan has

complied with the requirement despite the lack of a qualified encounter. However, plans should document the basis or reason that a face-to-face encounter is not feasible in order to demonstrate that where there are no face-to-face encounters in the year, that failure is not a violation of the regulation. Note that a feasibility barrier does not include a SNP having to provide a reasonable accommodation, such as interpreter services, in order for the enrollee to participate in the encounter.

Lastly, restricting the manner of face-to-face encounters to those that are in-person or as a visual, real-time, interactive telehealth encounter is consistent with section 1859(f)(5)(B)(ii) of the Act as amended by section 50311 of the Bipartisan Budget Act of 2018. The statute requires CMS to set requirements for face-to-face encounters that must happen on an annual basis for C–SNPs; and in extending that requirement to I–SNPs and D–SNPs, we do not believe there is reason to develop different standards. For this specific requirement, we believe that a real-time, interactive, visual telehealth encounter permits face-to-face interaction even though electronic or telecommunications technology is used to facilitate the encounter. The real-time, interactive, visual encounter serves the same function and permits sufficiently similar engagement between the enrollee and the required member of the ICT, the SNP's case management or care coordination staff, or other contracted provider of the SNP as an in-person encounter for purposes of this specific requirement; our regulation here does not address when or how telehealth encounters may be clinically appropriate or sufficient but only specifically addresses the need for SNPs to ensure there is one annual encounter of a certain type for each enrollee. While not all covered services are necessarily appropriate to furnish through electronic means, MA plans (including SNPs) have broader flexibility in this regard under § 422.135. Therefore, face-to-face encounters required for all SNPs under this new rule may include visual, real-time, interactive telehealth encounters. As we noted in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Final Rule (hereinafter referred to as the April 2019 final rule), we believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Comment: A few commenters suggested that in the implementation of the face-to-face encounter requirement that SNPs should be allowed to develop their own technical specifications for capturing compliance with this requirement. For example, An MAO recommended that SNPs be allowed to capture verbal confirmation from members or providers of completed face-to-face encounters from external parties and/or telehealth encounters as evidence of compliance.

Response: CMS believes plans are in the best position to develop the processes and technical specifications for documenting how they meet this requirement and that a face-to-face encounter for purpose of satisfying this regulation has taken place. While § 422.101(f)(1)(iv) imposes some parameters for these encounters, there is a broad range of flexibility for how SNPs may meet the requirement. However, we clarify that our guidance here is specific to § 422.101(f)(1)(iv) and does not address any other Medicare program requirements. Because an encounter must pertain to the delivery of health care to the enrollee, we encourage SNPs to take the information from these encounters into account and to document them consistent with how other health care visits are documented. Lastly, CMS will monitor compliance with the requirement and consider additional rulemaking if necessary.

Comment: Several commenters suggested the addition of the face-to-face requirement would create additional reporting burden for plans associated with capturing compliance to the rule.

Response: We are also cognizant that new regulations sometimes include additional reporting or record keeping requirements. The final rule does not create any additional, explicit reporting requirements. However, SNPs are required under § 422.503(b)(4)(vi) to adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. CMS will be monitoring compliance by SNPs with this requirement. In addition, SNPs should have information about all health care encounters and deliveries of covered services for many purposes, including: Payment to providers for furnishing services; complying with the existing data submission requirements in § 422.310; and meeting the requirements of § 422.112(b)(4), which requires procedures for plans and their provider networks to have the information necessary for effective and continuous patient care and quality review.

Comment: Several commenters stated that some enrollees lack access to technology that would provide visual, real-time, interactive telehealth encounter, which may create a barrier to beneficiary participation in such encounters. Others requested that CMS allow telephonic encounters to count towards the annual face-to-face requirement under the new regulation.

Response: We are cognizant that enrollees should have the final authority over their health care and our proposed regulation text reflected this by requiring that these face-to-face encounters be as feasible and with the enrollee's consent. First, SNPs have the flexibility to meet the requirement for a face-to-face encounter, either in-person or virtually. We believe that many beneficiaries are already meeting the requirement through in-person face-to-face encounters with qualified healthcare providers, which we believe will create minimal additional burden for plans implementing this final rule. The final rule does not mandate that SNPs utilize a visual, real-time, interactive telehealth encounter, though it is a permissible option when appropriate. Second, the SNP must comply with this requirement in a manner that honors any enrollee's decision not to participate in a face-to-face (either in-person or virtual) encounter. If an enrollee does not consent to the encounter required by § 422.101(f)(1)(iv), the plan should document that in order to demonstrate compliance with the regulation. The rule addresses feasibility barriers to a SNP providing for the required annual encounter, such as where a SNP enrollee may be non-responsive to plan outreach or the state of the member's health (such as if the member is dealing with a hospitalization in an out-of-network facility) prohibits a face-to-face encounter. In these circumstances, CMS recognizes that a SNP may not be able to comply with the rule's mandate of an annual face-to-face encounter and we intend the ''as feasible'' standard in the regulation to address such situations. By clarifying that a face-to-face encounter for delivery of health care services by a contracted provider will satisfy this requirement, it seems likely that most SNPs will be able to meet this requirement for most enrollees, as most enrollees in SNPs receive health care

services at some point each year. If the enrollee has refused or because the SNP could not reach the enrollee after reasonable attempts, the plan would be considered to have complied with the requirement despite the lack of a qualified encounter.

This final rule allows many types of face-to-face encounters, including visual, real-time, interactive telehealth encounters, to suffice for meeting the requirement. We do not believe that telephonic encounters should count towards the fulfilling the requirements of § 422.101(f)(1)(iv) for several reasons. First, the statute at section 1859(f)(5)(B)(ii) of the Act is specific in requiring that the encounters provided annually must be face-to-face with individuals enrolled in the plan. An audio-only encounter does not meet the statutory requirement that the encounter be face-to-face. Even though the statutory requirement is for C–SNPs, we believe that requiring all SNPs to meet this standard is appropriate in light of the health care needs and characteristics of the other populations of special needs individuals. Second, an audio-only encounter does not permit the provider to see the patient to use visual clues (for example, bruising, physical symptoms, or lack of focus) that could indicate something is wrong with the patient. This is a requirement for only one visit of this type a year and does not prohibit the use of audio-only encounters when those are appropriate for addressing other health care needs or visits. Further, for enrollees who do not use telehealth or lack the technological resources for such encounters, in-person delivery of health care services from one of the types of providers described in the regulation satisfies this requirement; there is no requirement for telehealth-based encounters to be used instead of in-person encounters. However, we will continue to monitor the ability of beneficiaries to take part in virtual encounters, the applicability of non-telephonic face-to-face encounters, and to assess the adequacy of substituting telephonic encounters in addition to the set of qualifying face-to-face encounters for I–SNPs and D–SNPs through future rulemaking.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing § 422.101(f)(1)(iv) regarding face-to-face encounters substantially as proposed, but with modifications to clarify that the required face-to-face encounters pertain to the delivery of certain kinds of services (health care or care coordination services or care management) and must be with a contracted health care provider or certain SNP staff (a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff). In addition, our final regulation text at paragraph (f)(1)(iv) is somewhat reorganized from the proposed rule to improve the readability of the provision.

3. Health Risk Assessments and the SNP Enrollee's Individualized Care Plan

We proposed to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C–SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. We also proposed to extend this requirement to the model of care for all SNPs in revisions to § 422.101(f)(1)(i). Currently, MA organizations offering SNPs must conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as an annual HRA, using a comprehensive risk assessment tool that CMS may review during oversight activities. The proposed revision to paragraph (f)(1)(i) would also require the MA organization to ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii).

We received the following comments and our responses follow:

Comment: Several commenters sought clarification concerning what type of information must be included in the ICP from the HRA. In addition, a few commenters wanted to know what information plans could omit from the ICP while adhering to the regulation. Another commenter asked if D–SNPs would be permitted to align the HRA with other beneficiary assessments that some D–SNPs are required to submit for a state's requirement that enrollees be assessed as to Medicaid managed long-term services and supports (MLTSS) needs.

Response: Existing CMS guidance addresses the first part of these comments—pertaining to the information from the HRA that must be incorporated into the ICP—and that guidance is consistent with the regulatory provision being finalized at § 422.101(f)(1)(i). Chapter 5 of the Medicare Managed Care Manual, section 20.2.2, addresses how each SNP's MOC includes a clear and detailed description of the policies and procedures for completing the health risk assessment tool (HRAT).[5] Because this existing guidance adequately describes how information from the annual HRA is incorporated into the enrollee's ICP, the guidance remains applicable. Part of NCQA's review of SNP MOCs is an evaluation of MOC 2, Element B, which includes the following subfactors:

- How the organization uses the HRAT to develop and update the Individualized Care Plan (ICP) for each beneficiary (Element 2C).
- How the organization disseminates the HRAT information to the Interdisciplinary Care Team (ICT) and how the ICT uses that information (Element 2D).
- How the organization conducts the initial HRAT and annual reassessment for each beneficiary.
- The detailed plan and rationale for reviewing, analyzing and stratifying (if applicable), the HRA results.

Under Element B, the content of and methods used to conduct the HRAT have a direct effect on the development of the ICP and ongoing coordination of ICT activities. The HRAT must assess the medical, functional, cognitive, psychosocial and mental health needs of each SNP beneficiary, as noted in Chapter 5 of the MMCM, section 20.2.2.

To meet the requirements of the first 2 factors of MOC 2, Element B, the SNP's MOC must include a description of how the HRAT is used to develop and update, in a timely manner, the ICP for each beneficiary and how the HRAT information is disseminated to and used by the ICT. Under factor 3, the description must include the methodology used to coordinate the initial and annual HRAT for each beneficiary (for example, mailed questionnaire, in-person assessment, phone interview) and the timing of the assessments. There must be a provision in the MOC for reassessing beneficiaries if and when warranted by a health status change or care transition (for example, hospitalization or a change in medication). The SNP must describe in the MOC the SNP's process for attempting to contact beneficiaries and have them complete the HRAT, including provisions for beneficiaries that cannot or do not want to be contacted or complete the HRAT. This approach in our current guidance provides plans the flexibility to develop an ICP that is appropriate for each beneficiary based on and using HRA information; the requirement added to

[5] Please see Chapter 5 of the MMCM, which can be found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c05.pdf.*

§ 422.101(f)(1)(i) that each SNP ensure that results from the initial assessment and annual reassessment conducted for each enrollee are addressed in the individual's individualized care plan would be met by a SNP that does these things in its development of the MOC and the ICP. CMS intends to implement and enforce the revisions to § 422.101(f)(1)(i) consistent with existing CMS guidance regarding the information from the HRA and HRAT that must be incorporated into the ICP.

We understand that some D–SNPs may be required to complete and use other assessments related to the Medicaid program. Integrated D–SNPs may choose to combine Medicaid and Medicare assessments as long as the assessment includes a review of the medical, functional, cognitive, psychosocial and mental health needs of each SNP beneficiary and is described in the MOC. Other assessments may (or may not) require the same elements or scope as the HRA required of MA SNPs so alignment and overlap of the assessments and how they are used depends on the specifics of each situation. As we implement § 422.101(f)(1)(i), we will continue to monitor the alignment of multiple assessments on SNP enrollees to determine whether further rulemaking is necessary. However, plans have created an HRA process as part of their approved MOC in the past, so we do not anticipate that SNPs will have difficulty complying with the changes we are finalizing to § 422.101(f)(1)(i). To the extent that there is overlap and the HRA required by § 422.101(f)(1)(ii) can be aligned with other assessments conducted by the SNP, the MOC should include a description of that alignment, consistent with the standards in MOC 2, Element B of Chapter 5, § 20.2.2.

We believe the current factors outlined in MOC 2, Element B allows SNPs the flexibility to align a MOC-approved HRAT with other assessment tools (as noted above), and is consistent with the intent of the changes being finalized here in § 422.101(f)(1)(i). Current guidance will be the basis for how CMS will implement and enforce § 422.101(f)(1)(i) to ensure that SNPs incorporate and address the results from the initial assessment and annual reassessment conducted for each individual enrolled in the individual's individualized care plan.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(1)(i) as proposed without modification.

4. SNP Fulfillment of the Previous Year's MOC Goals

We also proposed to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C–SNPs. We proposed new regulation text at § 422.101(f)(3)(ii) to provide that, as part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care and plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals. Under our proposal, if the SNP MOC did not fulfill the previous MOC's goals, the plan must indicate in its MOC submission how it will achieve or revise those goals for the plan's next MOC. We also proposed to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs to submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3); our proposed paragraph (f)(3)(i) contains the same language as current § 422.101(f)(2)(vi).

We also proposed at paragraph (f)(3)(ii)(A) through (C) specific provisions regarding how NCQA would evaluate the MOC in terms of achievement of goals from the prior MOC. We explained how we intended that NCQA would determine whether each SNP, as part of NCQA's process for evaluation and approval of MOCs, provided adequate information to perform the evaluation required by § 422.101(f)(3)(ii) as well as whether the SNP met goals from the previous MOC submission. After stating that it is implicit in the evaluation of the MOC and the requirement for the SNP to submit relevant information that the information submitted by the SNP must be adequate for NCQA to use to evaluate the MOC, we solicited comment whether more explicit requirements on this point should be part of the regulation text.

We received the following comments on the proposal regarding evaluation of outlining and fulfillment of the MOC's goals and our responses follow:

Comment: CMS received several suggestions related to providing information for evaluation whether the SNP achieved the goals from the prior MOC. One commenter proposed CMS look to the Healthcare Effectiveness Data and Information Set (HEDIS) reporting and measures for direction. Another commenter suggested that CMS evaluate plan performance monitoring and evaluation metrics included in the MOC, and not goals included in the Individual Care Plan.

Response: We appreciate these suggestions as to the type and scope of information that should be used to evaluate whether a SNP has fulfilled the goals of its prior MOC. We clarify that it is the goals of the MOC (and whether those goals have been met) and not the goals of the ICP that are to be evaluated by NCQA under § 422.101(f)(3)(ii) as proposed and finalized.

We explained in the proposed rule that proposed § 422.101(f)(3)(ii) would align with our current guidance on the MOC submission and review process regarding SNP fulfillment of goals and summarized the current review process. (85 FR 9016) This includes the type of information submitted by SNPs and used by NCQA in evaluating whether the goals of a prior MOC have been fulfilled. Currently, all SNPs are required to identify and clearly define measurable goals and health outcomes as part of their model of care under MOC 4, Element B: Measurable Goals and Health Outcomes for the MOC, as addressed in Chapter 5 of the MMCM. It is critical for all SNPs to use the results of the quality performance indicators and measures to support ongoing improvement of the MOC, and all SNPs should continuously assess and evaluate plan quality outcomes. This is reflected in current guidance in Chapter 5, § 20.2.2 of the Medicare Managed Care Manual. MOC 4, Element B currently contains the following subfactors:

- Identify and define the measurable goals and health outcomes used to improve the health care needs of SNP beneficiaries.
- Identify specific beneficiary health outcome measures used to measure overall SNP population health outcomes at the plan level.
- Describe how the SNP establishes methods to assess and track the MOC's impact on SNP beneficiaries' health outcomes.
- Describe the processes and procedures the SNP will use to determine if health outcome goals are met.
- Explain the steps the SNP will take if goals are not met in the expected timeframe.

The measures identified in the MOC as part of addressing these subfactors are the measures that should be used in evaluating whether the goals of the prior MOC have been fulfilled. Current CMS guidance permits the SNP to identify

and describe the measures and data used by the SNP and does not require specific quality measures, such as HEDIS, be used. SNPs may use data and quality performance that CMS measures for the Star Ratings program or through the HEDIS surveys (or other surveys and required quality performance data) but are not limited to those measures and data sources. Subfactors 3 and 4 of Element B provide for descriptions of how the SNP assesses and tracks the impact of the MOC and determines if health outcome goals are met. As proposed and finalized, paragraph (f)(3)(ii)(A) does not list specific types of data or information but requires submission of relevant information pertaining to the MOC's goals and whether those goals were fulfilled. For example, a SNP may submit plan-level health or clinical goals such as controlling diabetes or improving mental health screening access, and provide data showing progress towards these goals. This means that the type and scope of data required are tied to what the MOC's goals are and how the previous MOC addressed MOC 4, Element B. At a minimum, the data and measures described in the previous MOC should be submitted under § 422.101(f)(3)(ii)(A) for determining whether the MOC's goals have been fulfilled but other data may be relevant and pertinent. We expect SNPs to make reasonable determinations about what other data could be submitted as relevant and pertinent for the NCQA evaluation that is required under § 422.101(f)(3)(ii).

For SNPs submitting their initial MOC, NCQA will evaluate the information under MOC 4 Element B as whether the SNP has set clearly definable and measurable goals and health outcomes in the MOC for the upcoming MOC period of performance. For the following submission year, the SNP MOC will be evaluated on whether the measurable goals and health outcomes set in the initial MOC were achieved. We proposed specific regulation text at § 422.101(f)(3)(ii)(B) that plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval and are finalizing that provision. This new regulation is consistent with our existing regulation and we intend that similar standards will be used going forward as those that are used now regarding the amount of information required from SNPs.

Comment: CMS received several comments expressing concern regarding the incorporation of MOC performance information and data from the previous MOC into the next submission. Commenters noted that plans would need to have complete information on the achievement of goals from the previous year before submission of the next year's MOC in order to meet the new requirement 42 CFR 422.101(f)(3)(ii), and that this short timeframe may prevent plans from being able to provide a complete representation of their performance from the previous year. Others sought further clarification regarding how plans should operationalize the regulation or specific metrics to be evaluated by NCQA.

Response: While we understand the commenters' concern about sufficient information being available each year about the previous year's MOC and performance, we believe that SNPs and NCQA can meet the requirements of the regulation. For SNPs submitting a MOC renewal after one year (because an annual review and approval is necessary), preliminary data from the immediately prior year can provide evidence to the level of fulfillment of the previous MOC's goals. For many I–SNPs and D–SNPs, they will be able to share findings from multiple years of data as part of this requirement because their MOCs will not necessarily need to be reviewed and approved on an annual basis. C–SNPs, which must submit annually under section 1859(f)(5)(B)(iv) of the Act, will be able to select preliminary findings each year from measures that provide evidence of progress on the MOC's goals. Further, for goals that are tied to building on prior performance or making incremental progress in the same or similar area each year, information about performance in more than one prior year may be relevant and pertinent to show how the SNP is fulfilling the MOC's goals. Under MOC 4, Element B of the MOC, SNPs must currently provide a description of the processes and procedures the plan will use to determine if health outcome goals are met. By sharing the findings from these processes, SNPs can outline achievable steps toward long term goals so that small steps using limited data year to year can be evaluated. Therefore, we believe that SNPs can effectively demonstrate progress to meet the requirements of § 422.101(f)(3)(ii).

As proposed and finalized, § 422.101(f)(3)(ii) requires, as part of the evaluation and approval of the SNP model of care, that NCQA evaluate whether goals were fulfilled from the previous model of care. To serve this purpose, the regulation also requires that:

- Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.
- Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.
- If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

In each MOC submission and evaluation of the MOC, the SNP must be able to demonstrate that it is continuing to work towards achieving the MOC goals even if the SNP requires additional time or metrics to evaluate the progress. Each MOC should reflect modification of the SNP's strategies to meet the goals of the MOC as needed. Again, under MOC 4 Element B, SNPs are currently submitting health outcome measures used to measure overall SNP population health outcomes at the plan level. SNPs may submit final or preliminary findings from these measures in order to provide evidence of progress as part of each MOC submission.

Comment: Several commenters questioned the applicability of the proposed regulation to D–SNPs and stated that dual eligible enrollees experience changes in eligibility based on their Medicaid status, which the commenters stated impacts the plan's ability to implement and operationalize the MOC.

Response: First, we believe that the process for setting health outcome goals and choosing a set of measures to determine progress permits all SNPs, including D–SNPs, to select measures that make sense for the population that the plan serves in so far as those measures speak to benchmarks, specific time frames, and how achieving those goals will be determined. A SNP that believes it suffers from disproportionate rates of disenrollment can seek to align outcome measures in a way that recognizes these perceived challenges; however, any measures that the plan selects must be approved by NCQA as part of the MOC approval process. Second, we also believe that the extension of the provision in this rule requiring fulfillment of the previous MOC's goals is consistent with current MOC approval requirements as outlined in Chapter 5, section 20.2.2 (Model of Care Scoring Criteria), as applied currently to all MOC types. The goal of performance improvement and quality measurement is to improve the SNP's ability to deliver high-quality health care services and benefits to its SNP enrollees; our commitment to this is

reflected in how it is explicitly stated in section 20.2.2 under MOC 4: MOC Quality Measurement and Performance Improvement, Element B: Measurable Goals and Health Outcomes for the MOC. This goal may be achieved as a result of increased organizational effectiveness and efficiency through incorporation of quality measurement and performance improvement concepts that drive organizational change. The leadership, managers and governing body of a SNP must have a comprehensive quality improvement program in place to measure its current level of performance and determine if organizational systems and processes must be modified, based on performance results.

In addition, section 20.2.2 of Chapter 5 of the Medicare Managed Care Manual provides additional information for plans to identify and clearly define measurable goals and health outcomes for the MOC in listing the five subfactors for Element B of MOC 4. Under factor 1, the SNP's description of measurable goals must include benchmarks, specific time frames, and how achieving goals will be determined. For factor 2, the SNP must include the specific data sources it will use for measurement for the stated health outcome measures. SNPs have flexibility in setting health outcome goals, particularly flexibility to align those goals with the population being served by the plan, but such measures must be approved by NCQA in its review of the MOC. The rule we are finalizing at §§ 422.101(f)(3)(ii) maintains the current level of flexibility for different SNP types in setting goals and the measures and data used to determine if the goals are met. By allowing such flexibilities, the regulation permits SNPs to take into account unique challenges facing their plan (such as potential changes in enrollment due to changes in eligibility for enrollees) and to set goals that allow SNPs to measure progress against these challenges.

For factor 2, the SNP must identify in the MOC the specific data sources it will use for measurement for the stated health outcome measures. We believe that the process for setting health outcome goals and choosing a set of measures to determine progress permits D–SNPs, and all SNPs, to select measures that makes sense for the population of beneficiaries that the plan serves in so far as those measures speak to benchmarks, specific time frames, and how achieving goals will be determined. The regulation we are finalizing at § 422.101(f)(3)(ii) maintains the level of flexibility for different SNP types as it is currently constructed through NCQA's MOC approval process. By allowing such flexibilities, plans can take into account unique challenges facing their plan and to set goals that allow SNPs to measure progress against these challenges.

After consideration of the comments and for the reasons outlined in the response to comments and in the proposed rule, we are finalizing the amendment to § 422.101(f)(3)(ii) as proposed without modification.

5. Establishing a Minimum Benchmark for Each Element of the SNP Model of Care

Finally, we proposed a new regulation at § 422.101(f)(3)(iii) imposing the requirement that benchmarks for each MOC element set by CMS must be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C–SNP model of care and that the MOC can only be approved if each element meets a minimum benchmark. We proposed to implement this requirement and a minimum 50% benchmark for all SNP models of care because medically complex conditions are found in enrollees across all SNP types and implementation of the benchmark requirement only for C–SNPs would be operationally challenging for MA organizations that operate more than one SNP. In the proposed rule, we stated that each SNP model of care would be evaluated based on a minimum benchmark for each of the four elements and how that was consistent with our current policy. Currently, each subfactor of a MOC element is valued at 0–4 points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60, which is then converted to percentage scores based on the number of total points received. We proposed that each element of the MOC must meet a minimum benchmark of 50 percent of total points as allotted, and a plan's MOC would only be approved if each element of the model of care meets the applicable minimum benchmark.

We received the following comments and our responses follow:

Comment: CMS received several comments that, while receptive to the establishment of the minimum benchmark as proposed, were concerned about the timing of the implementation of the rule. Commenters sought implementation to begin in Contract Year 2022.

Response: We are finalizing the changes to § 422.101(f) as being applicable for contract year 2023 and subsequent years. While this final rule will have an earlier effective date, making these provisions applicable for the period beginning January 1, 2023 provides time for MA organizations to plan and time for NCQA to implement these new standards for use in evaluating MOCs developed and submitted for 2023. Plans that are required to submit MOCs for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022. Moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for the full implementation and enforcement of this final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

Comment: A number of commenters asked for additional clarity regarding how CMS will implement the scoring of each MOC sub-element.

Response: First, we clarify that NCQA evaluates and scores the MOCs, as part of the NCQA approval requirement that has been in place since 2012 and that will be codified at § 422.101(f)(3) under this final rule. Second, we intend that scoring using the 50 percent benchmarks will be consistent with how MOCs are evaluated and scored now with the addition that the MOC submitted by the SNP must score at least 50% on each element; the scope, content and number of elements and the points available for each element remain the same as outlined in Chapter 5 of the Medicare Managed Care Manual, section 20.2.2.

Currently, the MOC narrative in Chapter 5 addresses four overarching categories: (1) Description of the SNP Population, (2) Care Coordination, (3) SNP Provider Network, and (4) MOC Quality Measurement & Performance Improvement. Each of the four categories is then comprised of a set of required elements, such as Element B: Subpopulation—Most Vulnerable Beneficiaries under the MOC 1 category. These elements and their various factors are reviewed and scored by NCQA and contribute to the overall score for that element. All total, there are 15 elements among the 4 MOC categories. A full list of categories, elements, and factors, as

well as additional guidance pertaining to MOC submission requirements and structure, can be found in Chapter 5 of the MMCM. As we explained in the proposed rule, there are a total of 60 points available, across all categories and elements. Each element is scored by NCQA on a range of 0 to 4. To meet the new standard at § 422.101(f)(3)(iii), each MOC must earn at least 2 points for each element.

As proposed and finalized, § 422.101(f)(3)(iii) does not alter the current characteristics or the number of categories, elements, and factors and the mandatory benchmarks will be applied at the element level. For example, the category MOC 2: Care Coordination is made up of five elements:

- Element A: SNP Staff Structure;
- Element B: Health Risk Assessment Tool (HRAT);
- Element C: Individualized Care Plan (ICP);
- Element D: Interdisciplinary Care Team (ICT); and
- Element E: Care Transition Protocols.

A SNP will need to meet a minimum benchmark score of 50 percent for each of Elements A–E. Failing to meet the minimum score in any one element would result in disapproval of the MOC by NCQA during the first round of evaluation. The current process and procedures for the evaluation is not changing under this final rule, so the SNP would be able to resubmit a revised MOC during the cure period after having an opportunity to address the failures identified by NQCA and to revise how the MOC addresses the applicable element(s).

Starting with the MOC for contract year 2023, each SNP will need to meet a minimum benchmark score of 50 percent for each element, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark. CMS and NCQA will provide an overview of any category and/or element deficiencies in our correspondence to plans at the completion of NCQA's MOC evaluation. In addition, each SNP MOC will need to meet an overall score in order to meet NCQA approval, as is the case now.

Comment: CMS received one comment concerned that the introduction of this new scoring process at the element level would potentially derail an otherwise worthy MOC submission.

Response: We believe the final rule is largely consistent with existing regulations and guidance regarding review of SNP MOC standards as plans already receive scores at the element level, though under our current policy approval is based only on the aggregate score. However, use of minimum benchmarks for each element serves important policy goals by ensuring that each MOC is minimally compliant and that each MOC addresses all of the elements. We also have concerns that the current system potentially allows a MOC to pass while containing a significant deficiency in a specific element. We believe continued guidance and training by CMS and NCQA will mitigate disruption that may stem from the changes associated with the new scoring process under § 422.101(f)(3)(iii).

As we noted in the proposed rule, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at MOC score data for contract year 2020, our proposed element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. Meaning 20 of the 273 MOCs in 2020 would have been required to resubmit during the cure period of the approval process. For comparison, for contract year 2020, under our current aggregate scoring system, seven plans were required to submit revised MOCs based on the current scoring system and an additional seven plans decided to withdraw their MOCs before the revision process, for a total of 14 MOCs. CMS intends to work with NCQA to ensure that the transition for SNPs to using the new scoring benchmarks for each element is as seamless as possible. Further, the cure period will provide an opportunity to make revisions to address deficiencies identified by NCQA for SNPs that must submit their MOCs for review and approval by NCQA for 2023.

Comment: A commenter expressed concerns that the amended scoring process would be particularly problematic for D–SNPs that enroll beneficiaries with significant and complex medical and social needs.

Response: We believe the MOC review and approval processes are structured to provide a uniform apparatus that already takes into account differences among SNP types and the populations that they serve. As a quality improvement tool, the MOC acts as an important roadmap for ensuring that the unique needs of SNP enrollees are addressed and is a fundamental component of SNP quality improvement. NCQA uses a review process that scores a MOC based on how well a plan has addressed process details and narrative descriptions. Each MOC renewal is an opportunity for a SNP to plan for, lay out, and implement improvements to its processes for each specific element and factor. Even when the MOC guidelines focus on quality improvement and enrollee health outcomes, the MOC review is centered on the SNP's processes and procedures used to determine if those health outcome goals are met. Under the MOC rubric, CMS does not intend for SNPs to meet specific metric thresholds denoting quality. For example, under MOC, Element B, factor 4, the MOC must describe how it determines if the goals described in factor 1 are met rather than address performance on a specific metric set by CMS. Regardless of SNP type, NCQA applies the review standards uniformly across each MOC submission under this regulation.

Comment: A commenter noted concern that the MOC benchmark was duplicative of the reporting and tracking of plan performance under the Star Rating system.

Response: The MOC requirement is distinct from the goals and purpose of the Star Ratings system so even though there may be some overlap in MA organization and SNP processes in order to successfully implement the MOC and achieve high Star Ratings, we do not believe that these are duplicative or that one should be eliminated in favor of the other.

Section 1859(f)(5)(A)(i) of the Act requires that all SNPs be approved by NCQA based on standards developed by the Secretary; this requirement was added by section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110–275) and became effective with the 2012 contract year. As provided in §§ 422.4(a)(1)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC. Therefore, all SNPs must submit their MOCs to CMS for NCQA evaluation, and an MA organization must develop separate MOCs to meet the needs of the targeted population for each SNP type it offers. NCQA, based on guidance from CMS, has applied scoring standards applicable to all SNP types. The MOC is a forward-looking tool used by SNPs to design processes to perform and improve their performance over a set time period. The Star Ratings system, on the other hand, is used to measure and provide comparative information about the performance of MA organizations on defined measures. Under sections 1853(o) and 1854(b) of the Act, Star Ratings are used in determining payment and beneficiary rebates for MA plans; CMS has adopted provisions, at §§ 422.504(a)(17) and 423.505(a)(26), to use historical, sustained poor

performance on the Star Ratings to evaluate compliance with MA and Part D program requirements and, thus, whether an MA contract should be terminated. In this way, the Star Ratings are retrospective and provide information about past performance, not the MA organization's intentions or plans for improvement and to address enrollee needs in the coming year. Even if past performance can sometimes predict future performance, the Star Ratings program is not the duplicative of a quality improvement program like the MOC. There are other differences between the Star Ratings program and the MOC review and approval process, but these differences in purpose are fundamental and sufficient to conclude that it is appropriate to use a minimum benchmark for approval of all SNP MOCs. Therefore, we are finalizing § 422.101(f)(3)(iii) as proposed to require use of a 50 percent minimum benchmark for each MOC element.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing amendments to § 422.101(f)(1) introductory text, (f)(1)(i), (f)(1)(iii), and (f)(2) introductory text and adding § 422.101(f)(1)(iv) and (f)(3). These provisions are finalized substantially as proposed with a modification in paragraph (f)(1)(iv) to set standards for the required face-to-face encounter.

B. Coverage Gap Discount Program Updates (§§ 423.100 and 423.2305)

We proposed to amend our regulations at §§ 423.100 (definition of applicable drug) and 423.2305 (determination of coverage gap discount) to reflect changes to the relevant statutory provisions made by the BBA of 2018. Sections 53113 and 53116 of the BBA of 2018 amended section 1860D–14A of the Act to (a) increase the coverage gap discount for applicable drugs from 50 to 70 percent of the negotiated price beginning in plan year 2019, and (b) revise the definition of an applicable drug to include biosimilar biological products, also beginning in plan year 2019.

Specifically, section 53116 of the BBA of 2018 revised the definition of ''discounted price,'' meaning the price provided to the beneficiary, in section 1860D–14A(g)(4)(A) of the Act to mean, for a plan year after 2018, 30 percent of the negotiated price. This means that the coverage gap discount is 70 percent, rather than 50 percent. To make our regulations consistent with this change, we proposed to amend the definition of ''applicable discount'' in § 423.2305 to provide that, with respect to a plan year after plan year 2018, the applicable discount is 70 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Section 53113 of the BBA of 2018 amended section 1860D–14A(g)(2)(A) of the Act to specify that biological products licensed under subsection (k) of section 351 of the Public Health Service Act (that is, biosimilar and interchangeable biological products) are excluded from the coverage gap discount program only with respect to plan years prior to 2019. Accordingly, CMS has treated biosimilar biological products as applicable drugs under the Discount Program since 2019. Therefore, we proposed to revise the definition of applicable drug at § 423.100 to specify that such biological products are excluded only for plan years prior to 2019.[6]

We received four comments on our proposal. The two comments that were within the scope of the rule were supportive of the proposed changes. Therefore, we are finalizing the regulatory change as proposed to amend the definition of ''applicable discount'' in § 423.2305 to increase the applicable discount from 50 to 70 percent of the negotiated price beginning in 2019, and to revise the definition of applicable drug at § 423.100 such that biosimilar biological products are excluded only for plan years before 2019. As previously noted, these changes are being made to update the regulations to reflect statutory and operational changes that became effective in 2019.

C. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts (§ 423.286)

Section 3308 of the Affordable Care Act amended section 1860D–13(a) of the Act and established an income-related monthly adjustment amount for Medicare Part D (hereinafter referred to as Part D–IRMAA) for beneficiaries whose modified adjusted gross income (MAGI) exceeds the same income threshold amount tiers established under section 1839(i) of the Act with respect to the Medicare Part B income-related monthly adjustment amount (Part B–IRMAA). The Part D–IRMAA is an amount that a beneficiary pays in addition to the monthly plan premium for Medicare prescription drug coverage under the Part D plan in which the beneficiary is enrolled when the beneficiary's MAGI is above the specified threshold.

The Part D–IRMAA income tiers mirror those established for the Part B–IRMAA. As specified in section 1839(i) of the Act, when the Part B–IRMAA went into effect in 2007, individuals and joint tax filers enrolled in Medicare Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, were assessed the Part B–IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, each dollar amount within the income threshold tiers shall be adjusted annually based on the Consumer Price Index (CPI). As a result of the annual adjustment, for calendar year 2010, the income threshold amounts had increased to reflect four income threshold amount tiers for individuals and joint tax filers whose modified adjusted gross income exceeded $85,000 and $170,000, respectively. (We note that section 3402 of the Affordable Care Act froze the income thresholds for 2011 through 2019 at the level established for 2010.)

Consistent with section 3308 of the Affordable Care Act, the Part D–IRMAA is calculated using the Part D national base beneficiary premium (BBP) and the applicable premium percentage (P) as follows: BBP × [(P − 25.5 percent)/25.5 percent]. The premium percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the Affordable Care Act required CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D–IRMAA no later than September 15 of each year, starting in 2010. Also, effective in 2010, CMS must provide SSA no later than October 15 of each year, with: (1) The modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D–IRMAA in accordance with section 1839 of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out Part D–IRMAA.

To determine a beneficiary's IRMAA, SSA considers the beneficiary's MAGI, together with their tax filing status, to determine the percentage of the: (1) Unsubsidized Medicare Part B premium the beneficiary must pay; and (2) cost of basic Medicare prescription drug coverage that the beneficiary must pay.

[6] Unless our policy specifically distinguishes biosimilar biological products from interchangeable biological products, we use the term ''biosimilar biological product(s)'' in this preamble to reference biosimilar or interchangeable (when such products become available) biological products.

Since the implementation of the Part D–IRMAA in 2011, subsequent revisions to the statute have modified the associated income tiers used in IRMAA calculations:

• Section 402 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, revised the income thresholds for the Part B– and Part D–IRMAA income groups such that beneficiaries with incomes greater than $85,000 but not more than $107,000 were required to pay 35 percent of Part B and Part D program costs; beneficiaries with incomes greater than $107,000 but not more than $133,500 would pay 50 percent of Part B and Part D program costs; beneficiaries with incomes greater than $133,500 but not more than $160,000 would pay 65 percent of Part B and Part D program costs; while beneficiaries with incomes greater than $160,000 were required to pay 80 percent of Part B and Part D program costs.

• Section 53114 of the Bipartisan Budget Agreement (BBA) of 2018 revised the income thresholds again such that, beginning in 2019, beneficiaries with incomes greater than $500,000 ($750,000 for joint tax filers) are required to pay 85 percent of program costs (an increase from 80 percent).

We proposed to revise § 423.286(d)(4)(ii) for consistency with the changes made by section 53114 of the BBA of 2018 and to make other technical changes to ensure that the calculations used in the methodology for updating Part D–IRMAA are described correctly. We proposed to remove the language ''the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent and the base beneficiary premium as determined under paragraph (c) of this section'' and replace it with ''the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5)/25.5).''

We received no comments on this proposal and are finalizing the proposed revisions to § 423.286(d)(4)(ii) without modification. Although we are finalizing this provision as applicable 60 days after publication, it codifies current policies so we anticipate that there will be no change in operations or administration of the MA and Part D programs and encourage MA organizations and Part D sponsors to take this final rule into account immediately. We note that the revisions to this provision that we are finalizing in this final rule simply codify the Part D–IMRAA calculation that is currently used by SSA.

III. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

A. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 2004 of the SUPPORT Act requires that all Part D sponsors must have established DMPs no later than January 1, 2022. We proposed to amend regulatory language at § 423.153(f) to reflect this requirement. As discussed in the proposed rule preamble, the Overutilization Monitoring System (OMS) criteria used to identify ''potential at-risk beneficiaries'' (PARBs) (defined in § 423.100) are based on a history of filling opioids from multiple doctors and/or multiple pharmacies. While implementation of DMPs has been optional since codified for 2019, 85.9 percent of Part D contracts in calendar year 2019 and 87.2 percent in calendar year 2020 have established DMPs to address opioid overutilization among their enrollees. Thus, of about 49 million beneficiaries who were enrolled in the Medicare Part D program in 2019, about 48.5 million enrollees (99 percent) are covered under Part D contracts that offer a DMP already. We received the following comments on this proposal and our responses follow:

Comment: CMS received numerous comments that were generally supportive of our proposal to codify the statutory requirement that all Part D plans implement a DMP.

Response: We thank commenters for their support.

Comment: Several commenters expressed concerns that enrollees being treated for pain would be forced, through mandatory DMPs, to see a new doctor or use a new pharmacy and that the proposed regulation would undermine the doctor-patient relationship.

Response: The concerns expressed in some of these comments appeared to reflect a misunderstanding of the requirements in section 2004 of the SUPPORT Act. Although section 2004 mandates the establishment of DMPs for all Part D sponsors beginning January 1, 2022, section 2004 did not expand DMPs' scope. Thus, it is not the case that a ''mandatory'' DMP would now require all Part D beneficiaries taking opioids to be subject to coverage limitations or quantity limits. Rather, the statute and the regulations we are finalizing in this rule will now require the few Part D sponsors who have not already established a DMP to do so. DMPs identify a subset of opioid users in the Part D program who may be at the highest risk of an adverse health event, for example, due to uncoordinated care. As mentioned in the proposed rule, CMS' internal analysis estimated that only 158 additional PARBs will be identified per year by applying the current minimum OMS criteria across all Part D contracts that do not already have DMPs in place. CMS expects that only a few of these additional beneficiaries will be subject to a coverage limitation after case management with their opioid prescribers.

CMS does not agree that DMP activities undermine the doctor-patient relationship. In fact, the goal of case management under a DMP is for Part D sponsors to assist prescribers in coordinating care for PARBs to ensure their opioid use is appropriate and medically necessary. The case management process increases safety and accountability within the doctor-patient relationship, as prescribers may or may not be aware that there are other prescribers of opioids or benzodiazepines for their patients. Any potential coverage limitation under a DMP is put in place only after the plan conducts case management, solicits the views of the enrollee's prescriber(s), and provides advance written notice to the enrollee. If a Part D sponsor implements a prescriber and/or a pharmacy limitation, the affected beneficiary is provided opportunities to select their preferred pharmacy and prescriber when they receive an Initial Notice of their PARB status and a Second Notice of their at-risk beneficiary (ARB) status, as described in regulation at § 423.153(f)(5)(ii)(4) and § 423.153(f)(6)(ii)(5). The sponsor is required to consider the beneficiary's preferences consistent with § 423.153(f)(9). These aspects of DMPs safeguard beneficiary's access to coverage of opioids, prescriber and pharmacy choice, and the integrity of the doctor/patient relationship.

Comment: Several commenters requested that PACE organizations be exempt from the requirement to establish a DMP. These commenters noted that drug utilization management programs, quality assurance measures, and medication therapy management (MTM) program requirements

(§ 423.153(a) through (d)) are currently waived for PACE under § 423.458(d). Commenters also stated that the PACE model of care already addresses opioid overutilization through use of a closed provider network; care coordination through primary care providers and the interdisciplinary team; proactive drug utilization review; and in-person health assessments already required for PACE enrollees.

Some of these commenters noted that, while the majority of PACE participants do not reside in an LTC facility, PACE participants are required to meet their state's eligibility criteria for nursing home care and therefore share characteristics with beneficiaries who are exempt from DMPs because they are residents of LTC facilities. They also state that PACE organizations typically contract with a single pharmacy which inherently coordinates access and achieves the goals of a DMP. One commenter noted that many PACE organizations do not have formularies and therefore no Pharmacy and Therapeutic (P&T) committee to develop and carry out DMP policies and procedures.

Response: CMS thanks these commenters for their feedback, but disagrees that PACE organizations should be exempt from the statutory requirement to establish a DMP. While the DMP statute does outline certain exempted beneficiaries, such as individuals with cancer or who reside in a LTC facility, it does not specify or contemplate exemptions based on Part D plan type. CMS notes that MA–PDs that require enrollees to access routine care from contracted and/or employed prescribers through an HMO or integrated care model are similarly required under Part 422 to provide coordinated care, but are not exempt from the DMP requirement. As commenters noted, PACE participants are an especially vulnerable Medicare population, and for those who live in the community, additional monitoring will serve as a valuable safeguard to help prevent misuse of opioids. Depending on the frequency of engagement between the participant and PACE organization, as well as participant preferences, the in-person assessments required under §§ 460.104 and 460.121 may not always coincide with identification through the OMS, and may present missed opportunities to intervene.

Under the existing regulatory framework where DMPs are voluntary, approximately 40 percent of PACE contracts have reported to CMS that they already have a DMP in place. In 2019, PACE enrollees accounted for 0.03 percent of all Part D enrollees belonging to a plan with a DMP, and 0.07 percent of Part D enrollees identified in OMS as PARBs because they met the minimum OMS criteria. Based on CMS' analysis used in the proposed rule, PACE enrollees account for 0.14 percent of total Part D enrollees identified as PARBs because they meet the criteria for history of opioid overdose (see discussion in this section of this rule), which is proportional to the number of PACE enrollees in Part D (for January 2020, 0.1 percent of all Part D enrollment). In other words, the likelihood of a PACE participant being identified as a PARB, either based on OMS criteria or history of opioid overdose, is at least as high as the likelihood of any Part D enrollee to meet those criteria. Therefore, a PACE participant is as likely as any other Part D enrollee to benefit from case management and should not be deprived of this aspect of the Part D program. As discussed in the proposed rule preamble, Part D sponsors with DMPs infrequently implement coverage limitations after case management. This reflects the goals of case management as a means through which Part D sponsors engage prescribers, gather relevant patient-specific information not available to CMS, such as more recent medical or prescription claims data, and seek to coordinate care tailored to the unique needs of the beneficiary. CMS expects the volume of PARBs identified through minimum OMS criteria in the PACE organizations that have not yet implemented a DMP will continue to be minimal and present a low overall burden for these organizations. As with other Part D plans, such burden includes conducting case management, implementing any needed coverage limitations, and reporting of case management outcomes and coverage limitations back to CMS via OMS. Reporting outcomes of case management provides CMS with valuable information to help track the safe use of opioids and benzodiazepines in the Part D program and serves as a means to document that case management occurred.

CMS agrees with commenters that a PACE organization, or for that matter, any Part D plan sponsor, that does not have a P&T committee would not be in compliance with existing § 423.153(f)(1), which requires approval of DMP policies and procedures by the ''applicable P&T committee.'' As specified in § 423.120(b), only Part D sponsors that use formularies must have a P&T committee, and CMS did not propose to broaden that requirement to apply to Part D sponsors that do not use formularies. For this reason, after consideration of the comments, CMS is amending the language at § 423.153(f)(1) to account for Part D sponsors, including PACE organizations, that do not have their own or a contracted P&T committee (for example, through their PBM) because they do not use a formulary. Such sponsors can comply with this requirement by having written DMP policies and procedures that are approved by the Part D sponsor's medical director and applicable clinical and other staff or contractors, as determined appropriate by the medical director. We have also added cross references to the existing regulations requiring that Part D sponsors have a medical director at § 423.562(a)(5), and for PACE organizations, at § 460.60(b).

Comment: Several commenters stated general concerns or recommendations regarding DMPs. Commenters expressed concerns regarding the misapplication of the CDC Guideline for Prescribing Opioids for Chronic Pain [7] and recommended that CMS direct sponsors towards appropriate disease-specific pain management guidelines. Additional recommendations included facilitating or encouraging providers to refer patients to non-pharmacologic therapies for pain; ensuring provider education about overdose and naloxone prescribing, including evaluation for substance use disorder; ensuring shared decision-making between beneficiaries and prescribers such that access to medically necessary opioids is not impeded; ensuring beneficiaries with a coverage limitation are not forced to use a pharmacy in which the sponsor has a financial interest; and generally ensuring DMP activities are non-punitive or stigmatizing.

Response: CMS appreciates the concerns and recommendations commenters shared regarding case management activities. We note that the recommendations are not inconsistent with the current DMP requirements.

In finalizing the regulatory framework for DMPs (83 FR 16440), CMS made a conscious effort that DMP activities would not be punitive or stigmatizing and would not inappropriately limit access or result in abrupt opioid tapering. This is consistent with the CDC's commentary [8] published in 2019,

[7] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. MMWR Recomm Rep 2016;65(No. RR–1):1–49. DOI: *http://dx.doi.org/10.15585/mmwr.rr6501e1*.

[8] *https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.*

which advised against the misapplication of the Guideline for Prescribing Opioids for Chronic Pain, including the inflexible application of the Guideline's dosage recommendations and policies that encourage abrupt tapering, sudden discontinuation, or dismissal of the patient from their physician.

CMS agrees that many of the suggestions proposed could be of value in many cases, and encourages sponsors to incorporate them, as appropriate, into their DMP policies and procedures, as well as protect against the unintended consequences identified by the CDC. Finally, CMS notes that beneficiaries are provided opportunities to select their preferred pharmacies and prescribers, if their plan intends to apply a pharmacy or prescriber limitation under the DMP. See § 423.153(f)(5)(ii)(4) and § 423.153(f)(6)(ii)(5).

Comment: A few commenters stated that mandatory DMPs are redundant with existing prescription drug monitoring programs (PDMPs).

Response: CMS disagrees that DMPs are redundant with PDMPs. PDMPs are state-level electronic databases that are used to collect information on all controlled substance prescriptions in a state. While PDMPs, which allow providers to access their patients' prescription history, are one tool to combat the opioid epidemic, PDMPs do not exist in all states, and health plans may not have access to them. Also, while CMS encourages providers to use PDMPs prior to issuing prescriptions for controlled substances, it is not mandatory for providers to do so in all states.[9] Therefore, CMS believes that DMPs provide additional value for ensuring safe opioid prescribing in the Part D program through the initiation of case management and care coordination activities. Moreover, the CARA statute required CMS to establish a regulatory framework for DMPs.

Comment: Several commenters requested CMS clarify existing guidance with regard to identification of PARBs, criteria for identifying exempt beneficiaries, reporting requirements for ARBs, and notice requirements for exempt beneficiaries. Several commenters provided additional recommendations, including suggestions to expand the list of frequently abused drugs to drugs beyond opioids and benzodiazepines (for example, other central nervous system depressants such as gabapentin) and allowing beneficiaries with existing beneficiary-specific POS edits that were implemented prior to 2019 be integrated into the DMP.

Response: CMS' proposal was to implement the statutory requirement that Part D sponsors establish DMPs as of January 1, 2022. As discussed in section VII.L, CMS also proposed to designate beneficiaries with sickle cell disease as exempted individuals in the regulation for purposes of a Part D sponsor's DMP. CMS did not propose any changes to the other existing requirements, except to solicit comment about case management for PARBs with a history of opioid related-overdose, which is discussed later in this section. CMS will consider revisions to the guidance and OMS criteria as appropriate. CMS also regularly reviews data submitted into OMS and MARx and will update guidance and/or communicate with sponsors if needed.

After consideration of the comments received, CMS is finalizing the proposal to make DMPs mandatory at § 423.153(f) with a modification at § 423.153(f)(1) to accommodate Part D plans, such as PACE organizations, that do not have a P&T committee, as described earlier.

B. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) and notify the sponsor of such identification, as those individuals must be included as PARBs for prescription drug abuse under their Part D plan's DMP. In line with this requirement, CMS proposed to modify the definition of ''potential at-risk beneficiary'' at § 423.100 to include a Part D eligible individual who is identified by CMS as having a history of opioid-related overdose, which is also defined in this regulation.

Based on the analyses and rationale described in detail in the proposed rule, CMS proposed to operationalize this definition by: (1) Using diagnosis codes that include both prescription and illicit opioid overdoses; (2) using a 12-month lookback period from the end of each OMS reporting quarter for record of opioid-related overdose; and (3) using a 6-month lookback period from the end of each OMS reporting quarter for record of a recent Part D opioid PDE. The number of unique beneficiaries identified under this proposal is approximately 18,268 annually (based on opioid-related overdose claims from July 1, 2017 to June 30, 2018). Under existing rules, which CMS did not propose to change, Part D sponsors with DMPs must conduct case management for each PARB identified by CMS through OMS, which includes sending written information to the beneficiary's prescribers that the beneficiary has been identified as a PARB. In expanding the definition of PARB by adding beneficiaries with a history of opioid overdose, Part D sponsors must conduct the same case management process for this additional group of beneficiaries that they currently conduct for PARBs identified based on their use of multiple opioid prescribers and/or pharmacies. As discussed in the proposed rule, CMS expects that case management for these individuals will involve sponsors communicating with their provider(s), who may or may not already be aware of the beneficiary's overdose history.[10] CMS also solicited comments on whether the proposal needed any additional features to facilitate the case management process for PARBs with a history of opioid-related overdose.

CMS received numerous comments on this provision, which were largely supportive of the proposal, with several commenters expressing concerns or requesting clarification on various aspects as discussed in this section of this rule.

Comment: A few commenters pointed out that the regulatory text defining potential at-risk beneficiary at § 423.100 was unclear with regard to whether both an overdose diagnosis and an opioid PDE were necessary to meet the new definition of a PARB based on the proposed regulation.

Response: In response to these comments, CMS clarifies that both criteria are required to meet the definition of a PARB with a history of opioid-related overdose. In order to improve overall clarity in this final rule, in lieu of revising the PARB definition at § 423.100 as proposed, we are incorporating the elements of the proposed definition into the clinical guideline regulation as criteria in a new paragraph at § 423.153(f)(16)(ii)(2). That is, the criteria initially proposed in the definition of PARB at § 423.100 have been relocated to the DMP clinical guidelines section of the regulation at § 423.153(f)(16)(ii)(2). CMS has also made some technical changes to the criteria now located at § 423.153(f)(16)(ii)(2) to clarify that a plan can use its own data to identify PARBs. Specifically, instead of referring to ''PDE,'' the criteria will refer to

[9] Centers for Disease Control and Prevention. What States Need to Know about PDMPs. Accessed June 10, 2020 from *https://www.cdc.gov/drugoverdose/pdmp/states.html.*

[10] Additionally, the beneficiary with an overdose may or may not meet OMS criteria.

''claim'' and the words ''has been submitted'' are struck from the criteria.

Comment: A few commenters expressed concern with identification of overdose based on diagnosis code, citing anecdotal reports that the codes are unreliable due to being assigned inappropriately or over-diagnosed in beneficiaries taking opioids who present for emergency care for other health conditions.

Response: CMS disagrees and was unable to find evidence to substantiate this claim specific to opioid-related overdose in the published literature. In the event a situation such as this does occur, during the case management process the prescriber will likely review the diagnosis and determine whether to discuss it with their patient on a case by case basis. Such review and discussion will present an opportunity for the provider to evaluate whether the diagnosis appears to be inaccurate and to communicate this information back to the sponsor's DMP.

Comment: A commenter suggested CMS include both primary and secondary diagnosis codes for opioid-related overdose to avoid under-reporting.

Response: CMS believes the principal diagnosis code is the most reliable means to identify overdoses in order to meet the statutory requirement for the reasons that follow.

According to the ICD–10–CM Official Guidelines for Coding and Reporting,[11] the principal diagnosis code is the condition, after study, to be chiefly responsible for occasioning the admission of a patient to the hospital. The terms principal and primary are used interchangeably to define the diagnosis that is sequenced first on a claim. Other diagnoses, including secondary diagnoses, are conditions that may coexist at the time of admission, or develop subsequently. As such, secondary diagnoses may capture overdoses not directly related to the beneficiary's recent use of opioids that triggered the overdose event. CMS' proposed criteria for identification of a PARB based on history of opioid overdose specifies ''recent'' overdose so that DMP activities can be the most relevant and impactful. Since secondary diagnoses may be historical, CMS does not believe that they as reliably reflect ''recent'' opioid-related overdoses as do principal diagnoses.

Taking program size into account, focusing on the principal or primary diagnosis chiefly responsible for the admission or event is most appropriate to capture overdoses related to a beneficiary's recent use of opioids and increase the likelihood that the beneficiary would benefit from case management. Using the same time period, diagnosis codes, PDE, and lookback period criteria described in the proposed rule methodology, CMS evaluated the number of PARBs that would be identified by the proposed definition, both including and excluding secondary diagnoses. Including secondary diagnosis codes for identification of opioid-related overdoses was found to increase the number of PARBs identified by about 40 percent (for a total of 25,566) relative to the number of PARBs identified only on the basis of principal diagnosis (18,268, as described in burden estimates). However, due to the limitations of secondary diagnoses themselves, described earlier, CMS believes the additional PARBs identified solely on the basis of a secondary diagnosis would not necessarily be those with the most relevant history of opioid-related overdose. Therefore, CMS does not believe that the increased program size due to including secondary diagnosis codes for the purpose of identifying PARBs is a cost-effective use of DMP resources, when these resources would be better focused on beneficiaries at highest risk of misuse or abuse.

In evaluating this comment, CMS noticed that the proposed regulatory language in the definition of PARB at § 423.100 was not sufficiently broad to include data sources and methodology discussed in the proposed rule. As mentioned in response to a prior comment, the criteria initially proposed in the definition of PARB at § 423.100 have been relocated to § 423.153(f)(16)(ii)(2). Specifically, in the clinical guideline criteria for identifying PARBs on the basis of history of opioid-related overdose at § 423.153(f)(16)(ii)(2), the words ''Medicare fee-for-service'' and ''code'' were stuck from what was in the initially proposed definition at § 423.100. This revised language, which CMS is finalizing, better reflects CMS' intention to use claims, including encounter data, resulting from healthcare visits involving opioid-related overdoses. With this modification, the broader criteria will encompass both inpatient and outpatient locations of care.

Comment: A commenter requested addition of the ICD–10 code Z91.5 for method suicide attempt to capture intentional overdose in the methodology CMS will use to identify PARBs based on history of opioid-related overdose.

Response: CMS disagrees, as the ICD–10 code Z91.5 indicates a history of self-harm, and does not specify self-harm via opioid use. Although the literature CMS cited in the proposed rule preamble does reference history of opioid-related overdose being a risk factor for future overdoses or suicide-related events, the SUPPORT Act directs CMS to identify beneficiaries with a history of opioid-related overdose. Thus, including the ICD–10 code for history of self-harm would be overly inclusive. Other ICD–10 codes are more specific to identify injury due to opioid-related poisoning or overdose, and are used in the methodology applied by CMS and described in more detail in the February 2020 proposed rule. CMS believes the ICD–10 codes used in this methodology will capture both intentional and unintentional overdoses.

Comment: A commenter pointed out that using Medicare data will not capture overdose history from new Medicare enrollees.

Response: CMS acknowledges this is a limitation to the methodology; however, it is not feasible to gather all non-Medicare claims data for Medicare beneficiaries. We believe using Medicare claims data strikes the right balance to permit inclusion of beneficiaries with a history of opioid-related overdose in DMPs without undue burden.

Comment: A commenter expressed the opinion that for beneficiaries with overdoses due to illicit opioids, coverage limitations on prescription opioids would not likely impact future overdose risk.

Response: CMS disagrees with the commenter's assertion given the criteria CMS has proposed for identifying a PARB based on history of opioid-related overdose. The statute requires that beneficiaries with a history of opioid-related overdose be included as PARBs without specifying that the overdose involve a prescription opioid; therefore, we believe it is appropriate to include beneficiaries with a history of illicit opioid overdose. In the methodology presented in the proposed rule, CMS discussed the fact that in some cases, it is not possible to identify whether an opioid that contributed to overdose was obtained legally or illicitly. CMS also notes that any beneficiaries identified in OMS due to a history of opioid overdose, regardless of whether such overdose was illicit, will have also received an opioid prescription, consistent with the proposed criteria. Thus, there is still a potential role for case management, including conveying the overdose diagnosis to the beneficiary's prescriber(s), who may

[11] *https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-Coding-Guidelines.pdf.*

consider this information for ongoing opioid prescribing or referral for other health services, with or without the implementation of a coverage limitation for Part D prescription opioids. For example, a prescriber may refer the beneficiary for medication-assisted treatment, if appropriate, based on evaluation of their patient.

Comment: A commenter suggested that CMS' proposal may discourage overdose patients who self-treated with naloxone from seeking follow-up medical care to avoid an overdose diagnosis and potential DMP enrollment.

Response: CMS appreciates the commenter's concerns for these beneficiaries, and recognize the stigma they may face because of such diagnosis. However, the statute requires including these beneficiaries as PARBs, and the commenter's concerns do not obviate the need for CMS, Part D plan sponsors, or health care providers from engaging in rigorous patient safety programs, especially for this vulnerable population. CMS encourages plan sponsors, prescribers, and advocacy organizations to assist in efforts to educate beneficiaries about the risks and benefits of opioid use, as well as their options for opioid use disorder treatment. See section III.D of this final rule for additional information about CMS' efforts, as well as the ''Information for Patients'' resource provided on the Drug Management Program page of the CMS website.[12]

Comment: A commenter requested clarification if a beneficiary would no longer be considered a PARB once they no longer meet the overdose criteria.

Response: It depends. Once a beneficiary is identified as a PARB based on a history of opioid-related overdose and reported to Part D sponsors, sponsors must review the case and submit responses through the OMS. CMS will update the guidance, including the OMS user guide, to account for scenarios appropriate to PARBs identified based on a history of opioid-related overdose, including where these beneficiaries simultaneously or at a different time meet the definition of a PARB based on the existing OMS criteria, or where the situation changes while the plan is engaged in review/case management.

Comment: Many commenters, while supportive of the proposed regulation, asked CMS to clarify expectations for case management, outline expectations for case management outcomes, and provide guidance for management of PARBs identified by a history of opioid-related overdose.

Response: CMS acknowledges these comments about Part D plans conducting case management with prescribers who are treating PARBs with a history of opioid-related overdose. Case management is an integral part of the DMP process. It serves the purpose of engaging in clinical contact with the prescribers of FADs, verifying whether the beneficiary is at risk for abuse or misuse of FADs, and obtaining agreement to a coverage limitation on FADs, if a limitation is deemed necessary. The goal of case management under a DMP is to improve patient safety and care coordination, while protecting beneficiary access to coverage of needed medications.

CMS expects that the overall elements of case management should be similar for all PARBs, regardless of whether identified by existing OMS criteria based on use of multiple opioid prescribers and/or pharmacies or on a history of opioid-related overdose. CMS continues to recognize that every case is unique and that the approach to case management will vary depending on many factors, such as the complexity of the case and the promptness with which prescribers respond to sponsors' outreach. CMS continues to encourage sponsors to use flexibility and clinical discretion depending on prescriber input and patient-related variables. Case management activities should align with desired goals of the DMP, for example, reducing multiple opioid prescribers and/or reducing risk of a subsequent overdose. In estimating the burden for this provision in the proposed rule, CMS estimated that beneficiaries with a history of opioid-related overdose would potentially have a higher rate of coverage limitations imposed by sponsors than beneficiaries meeting minimum or supplemental OMS criteria because a history of overdose is the most predictive risk factor for another overdose or suicide-related event.[13] However, this is only a pre-implementation estimate and CMS continues to emphasize that the implementation of coverage limitations should be based on individual risk factors and goals identified through case management.

Plan sponsors should continue to refer to CMS guidance on elements that may be incorporated into case management, including prescriber education on opioid overutilization, encouraging prescribers to perform or refer their patients for substance use disorder screening and/or assessment, referral for follow-up treatment with pain specialists or addiction treatment providers, if indicated, and encouraging prescribers to utilize PDMPs to which they have access.

DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. The U.S. Department of Health and Human Services also issues guidance for safe opioid prescribing, including naloxone co-prescribing.[14]

Comment: Many commenters inquired about sponsor flexibility with regard to identification of PARBs based on a sponsor's own claims data, applying the criteria to identify PARBs with a history of opioid-related overdose more frequently than the OMS quarterly reports, or using criteria beyond those proposed by CMS to identify beneficiaries at risk of overdose at the time of their first opioid fill.

Response: CMS appreciates these comments. Just as currently permitted with the minimum OMS criteria, sponsors are permitted to identify PARBs with a history of opioid-related overdose more frequently than the CMS-generated reports through OMS. CMS expects that Part D sponsors identify PARBs consistent with the revised clinical guidelines CMS is finalizing at § 423.153(f)(16)(ii)(2). The clinical guidelines specify a recent (that is, within the past 12 months) claim containing a principal diagnosis indicating opioid overdose and a recent claim (that is, within the past 6 months) for an opioid medication. Sponsors are required by regulation to submit responses through OMS within 30 days of the most recent OMS report for all CMS-identified or sponsor-identified beneficiaries. Sponsors do not need to wait to receive an OMS report from CMS to initiate case management for sponsor-identified cases and send beneficiary notices, if applicable. Also, as we previously noted, the clinical guidelines for identifying PARBs that we are finalizing in this rule no longer require that history of opioid-related overdose be determined by CMS. This better reflects sponsors' ability to identify PARBs meeting the clinical guidelines using their own data.

Comment: A commenter requested CMS report Part D beneficiaries to sponsors through OMS with overdose diagnoses, but without a subsequent

[12] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.*

[13] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the U.S. Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193–1201. doi: 10.1111/add.13774.

[14] *https://www.hhs.gov/opioids/prevention/safe-opioid-prescribing/index.html.*

opioid claim, to proactively target these additional beneficiaries who may be at risk. Another commenter stated that beneficiaries with a history of overdose are already being managed outside of DMPs and therefore DMP activities may be duplicative.

Response: CMS does not agree with the request to report beneficiaries with an overdose diagnosis but no subsequent opioid claim. As discussed in detail in the proposed rule preamble (85 FR 9026), it is essential that all Part D plan sponsors, including standalone PDPs, can identify a prescriber with whom to conduct case management.

Without the presence of an opioid claim, Part D DMPs are not implicated. This does not preclude plans from conducting outreach towards beneficiaries with a history of opioid-related overdose who have not received a Part D prescription opioid, if they are able to identify them. A plan may offer services or interventions tailored to these beneficiaries, as the purpose of the DMP is not to supplant other health care activities that may be of benefit to the beneficiary, but rather to promote safe opioid prescribing practices and utilization in the Part D program. However, these beneficiaries should not be included in DMPs unless they meet the clinical guidelines specified in § 423.153(f)(16).

Comment: Some commenters suggested a 6-month, as opposed to a 12-month, lookback to identify opioid-related overdoses. Commenters suggested this would enable more timely engagement with beneficiaries and align with the Pharmacy Quality Alliance's (PQA) Initial Opioid Prescribing (IOP) measure.

Response: CMS agrees that identifying beneficiaries as soon as possible after their opioid-related overdose is likely to make DMP activities most impactful; however, we disagree with changing the lookback to 6 months for two reasons. First, CMS describes the rationale for the 12-month lookback. Second, CMS describes why it is not relevant to align the lookback with PQA's IOP measure.

Using a 12-month lookback, CMS anticipates that the first report will contain the largest proportion of overdoses occurring greater than 6 months prior to the report being generated. Going forward, however, CMS anticipates that subsequent quarterly reports will reflect a greater proportion of more recent, and thus, more timely, claims and a smaller proportion of earlier claims that were delayed due to processing errors or late submissions.[15] CMS expects that with regular reporting, the majority of PARBs with a history of opioid-related overdose will be identified on a timely basis. As discussed in the proposed rule, 12 months allows CMS to identify the majority of overdoses and appears to reflect the window of time necessary to capture the majority of processed claims or encounters. CMS will evaluate the implementation of the new clinical guidelines to identify PARBs based on history of opioid-related overdose and revise the operational specifications in the future if needed.

The PQA's IOP measure set includes three separate measures. CMS has included one of these measures, IOP–LD (Initial Opioid Prescribing—Long Duration), in Part D sponsors' patient safety reports. The IOP–LD measure does not consider opioid overdoses; rather, it evaluates when there has been no other opioid prescription in the 90-day lookback period prior to the start of an opioid with a long duration of therapy. Because the IOP–LD measure is largely unrelated to the overdose lookback window, CMS is not persuaded to change the overdose lookback to align with the IOP–LD measure.

Comment: A commenter recommended that CMS exclude beneficiaries with only one opioid prescription during the lookback period from the definition of PARB with a history of opioid overdose. Specifically, the commenter raised concerns about the efficacy of using plan resources to engage emergency department prescribers in case management based on a one-time, short-term opioid prescription.

Response: While CMS understands the commenter's concerns about engaging emergency department prescribers in case management, CMS disagrees with the recommendation to exclude beneficiaries with only one opioid prescription during the lookback period. Given the level of risk to beneficiaries with a history of opioid-related overdose, CMS strongly believes the best policy approach is for plans to attempt to engage their opioid prescribers through case management, even if the prescriber only ordered a single prescription for the beneficiary. CMS does not believe it is appropriate to presume that all such opioid prescribers would decline to engage in case management, given the statutory requirement to include this population in DMPs. Additionally, the DMP regulation at § 423.153(f)(4)(ii) specifies the circumstances under which sponsors may implement a coverage limitation for FADs in the event prescribers are not responsive. Thus, reporting these beneficiaries in OMS as PARBs despite there only being one PDE provides the opportunity for prescriber engagement, but still maintains plan flexibility through the DMP in the event outreach is unsuccessful.

Comment: A commenter cited their concerns with including PARBs with a history of opioid-related overdose in DMPs in light of the Substance Abuse and Mental Health Services Administration's (SAMSHA) 42 CFR part 2 (''part 2'') regulations regarding disclosure of substance use disorder (SUD) information. The commenter expressed concern that because Part D sponsors would have to conduct case management with prescribers of all PARBs, which will include beneficiaries with a history of opioid-related overdose, CMS is in effect requiring Part D sponsors to disclose SUD information about beneficiaries to providers and that such disclosure would be in violation of the part 2 regulations. The commenter requested that CMS provide guidance and/or a safe harbor for sponsors making such disclosures to protect them from any compliance issues.

Response: CMS thanks the commenter for the comment. SAMSHA's part 2 regulations protect the confidentiality of SUD treatment records by restricting the circumstances under which part 2 programs or other lawful holders can disclose such records without the patient's consent. CMS considered these regulations in the development of our February 2020 proposed rule. The requirement to include beneficiaries with a history of opioid-related overdose as PARBs does not require Part D sponsors to disclose SUD information to providers under a DMP; rather, they are communicating to the prescriber as part of case management that the beneficiary has a history of opioid-related overdose. A diagnosis of overdose is not synonymous with SUD or SUD treatment, and CMS will not be reporting SUD treatment records, nor the specific overdose diagnosis code, to Part D plans via the OMS report. We anticipate reporting overdose history in the form of a binary indicator (*e.g.* ''yes/no,'' ''0/1,'' or other code) on the OMS report if the PARB was identified based on having a history of opioid-related overdose. Additional information, such as the date of overdose, may be provided as well. CMS will provide the updated OMS report file layout and

[15] CMS data indicates that, historically, 90% of FFS claims across all claim types are submitted within 3 months and 90% of MA encounters across all claim types are submitted within 12 months. See: *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

OMS technical guidance in advance of the 2022 contract year. The information CMS will provide in the OMS report will be limited such that 42 CFR part 2 does not apply to the disclosures required under this rule. The restrictions on disclosure and use of SUD information only apply to such information that ''would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.'' (42 CFR 2.12(a)(1)(i)). Furthermore, under part 2, overdose information that does not reveal the identity of an individual as a SUD patient is not covered by the part 2 rule. The rule does not apply to ''[a] diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved does not have a substance use disorder (*e.g.,* involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).'' (42 CFR 2.12(e)(4)(2)). As detailed in the proposed rule preamble, the diagnosis codes that CMS will use to identify PARBs with a history of opioid-related overdose do not capture the nature of the intent or circumstances of the overdose. CMS is making no assumptions as to the factors that contributed to the overdose, but rather, is deferring to the providers who will be engaged in case management to appropriately evaluate and triage their patients as necessary.

CMS has suggested in the previously cited November 20, 2018 DMP guidance memo that an element of case management could be encouraging prescribers to consider performing or referring their patients for SUD screening and/or assessment. The sponsor should not presume a beneficiary has SUD on the basis of the opioid overdose diagnosis.

Comment: A commenter recommended that beneficiaries with a history of opioid-related overdose be excluded from the criteria for identifying a PARB if there was a subsequent medical claim for opioid treatment program (OTP) services or a PDE for medication-assisted treatment (MAT). The commenter stated that case management through the DMP would not likely offer benefit since presence of either scenario would suggest that an intervention had already been made and risk factors are being addressed.

Response: CMS disagrees that beneficiaries with a claim for OTP services or MAT should be automatically excluded from the criteria for identifying a PARB. Referral to an OTP or initiation of MAT are not the only goals of case management through a DMP. While a claim for OTP services or MAT indicate that an intervention has begun, it does not necessarily mean that the intervention has been successful. CMS believes beneficiaries may still benefit from other elements of the DMP. For example, a coverage limitation on future opioid prescriptions may be beneficial for an individual while in treatment.

In reviewing this comment, CMS realized that the proposed rule had not specified how prescriptions for MAT were treated in the context of requiring an opioid prescription claim in addition to the opioid-related overdose diagnosis to meet the new PARB criteria. The methodology that CMS used to identify PARBs based on the proposed criteria excluded PDEs for MAT. Only PDEs for non-MAT opioids were included in the analysis and corresponding burden estimates. This is how CMS plans to operationalize the clinical guideline criteria for the purposes of reporting PARBs with a history of opioid-related overdose via OMS. CMS has revised the clinical guidelines at § 423.153(f)(16)(ii)(2) to clarify that prescriptions for MAT will not satisfy the opioid prescription claim criteria for identification of PARBs on the basis of history of opioid-related overdose. Therefore, a beneficiary who has at least one claim with a principal diagnosis indicating opioid overdose, but only has prescription claims for MAT and no other opioids, will not be included as a PARB in the OMS report.

Comment: A few commenters requested that CMS conduct outreach and education to prescribers regarding DMPs and the new criteria for identifying PARBs based on history of opioid-related overdose.

Response: CMS will update educational materials and guidance as appropriate.

Comment: Several commenters requested CMS provide updated model documents to reflect the new criteria for identifying PARBs based on opioid-related overdose history.

Response: Revisions have been made in accordance with the Paperwork Reduction Act (PRA) model notice revision process. Revised notices will be published in the **Federal Register** for public comment before being finalized and posted on the CMS website.[16]

Comment: Many commenters requested that CMS provide technical specifications, such as OMS report file layout and response codes, well in advance (that is, 6 months) of the expected implementation date so that sponsors would have sufficient time to update internal systems.

Response: CMS appreciates that plans will need time to make operational changes to incorporate this new beneficiary population into their DMPs, and intends to issue guidance and technical specifications to ensure such changes are in place prior to the compliance deadline.

Comment: A commenter recommended that naloxone prescribing should be mandatory.

Response: In the proposed rule, CMS stated that the provider should consider prescribing the beneficiary an opioid-reversal agent if they are newly aware of the beneficiary's history of opioid-related overdose and DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. CMS does not have statutory authority to mandate naloxone prescribing in Part D.

Comment: A commenter suggested that naloxone education be added to model beneficiary notice letters.

Response: CMS will consider this recommendation during the PRA model notice revision process. Revised notices will be published in the **Federal Register** for public comment before being finalized and posted on the CMS website.[17]

Comment: Some commenters requested clarification that the DMP exemptions still apply to PARBs identified based on history of opioid-related overdose.

Response: Section 1860D–4(c)(5)(C)(v)(I) of the Act specifies that beneficiaries who are not exempted individuals and who have a history of opioid-related overdose must be included as PARBs. Therefore, even if a beneficiary has a history of opioid-related overdose, if the beneficiary also meets the regulatory definition of an exempted beneficiary, as codified at § 423.100, that beneficiary is not to be included in a DMP. Beneficiaries with a known exemption will not be reported via OMS; however, it is possible that it will not be known whether a beneficiary is exempt until case management takes place. Thus, beneficiaries may initially be reported as PARBs but will later be found to be exempt. In this scenario, the beneficiary would no longer be considered a PARB. In response to this comment, CMS is making a technical change to the definition of potential at-risk beneficiary at § 423.100 to clarify that it excludes exempted beneficiaries.

[16] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.*

[17] *Ibid.*

This technical change is described in more detail in section VI.M.

After consideration of the comments received, CMS is not finalizing the remaining changes we had proposed to the definition of ''potential at-risk beneficiary'' at § 423.100. Rather, we are incorporating those proposed changes into the DMP clinical guidelines at § 423.153(f)(16)(ii)(2). Thus, the clinical guidelines used to identify PARBs, beginning January 1, 2022, will include a Part D eligible individual who is identified as having a history of opioid-related overdose and at least one recent opioid claim, in addition to the existing clinical guidelines based on obtaining frequently abused drugs from multiple prescribers and/or pharmacies. The finalized clinical guidelines for identifying PARBs with history of opioid-related overdose also include modifications to encompass potential data sources and clarify the exclusion of MAT from the opioid prescription component of the guidelines, as discussed earlier in this section.

C. Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amends section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs that are controlled substances when furnishing an in-home health risk assessment. Section 1852(n)(2) requires us to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances.

In order to implement the requirements of Section 1852(n)(1) for MA plans, CMS in its proposed rule (CMS 4190–P) proposed to revise the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2022, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with Section 1852(n)(1), we proposed that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we proposed that MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We proposed that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we did not propose to require MA plans to provide more specific instructions with respect to drug disposal, we did propose that the communication to enrollees would provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also proposed that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html.* We noted in our proposed rule that the safe disposal of drugs guidance at this website can be used for all medications not just medications that are controlled substances. We stated in our proposed rule that we believed that plan communications consistent with the standard on this website would furnish enrollees with sufficient information for proper disposal of controlled substances in their community. We thank commenters. We received 35 comments on this proposal; we summarize these comments and our responses to the comments follow.

Comment: A commenter expressed concern about the significant operational burden required in performing a health risk assessment in person. This commenter also recommends that CMS allow risk assessments through telehealth such as video conference or a phone call particularly in rural areas where access is an issue.

Response: In-home HRAs are performed in-person where the beneficiary resides and not via telehealth. However, we clarify that this rule is not requiring MA plans to conduct in-home HRAs. In-home HRAs are optional and MA plans may choose to conduct HRAs in this manner. Specifically, the information on the safe disposal of controlled substances is only required to be furnished when an MA plan chooses to conduct an in-home HRA. In this final rule, in consideration of the comments received, we have sought to minimize unnecessary plan burden while also ensuring consistency with the statutory requirement that enrollees who receive an in-home HRA are furnished useful and accessible information on the safe disposal of controlled substances. With the exception of MA SNP plans, all other MA plans are required under § 422.112(b)(4)(i) to make a best effort to conduct an HRA annually and generally do so as part of an enrollee's covered annual wellness visit (see 42 CFR 410.15), but there is no requirement that the HRA be conducted in-home. We note that MA special needs plans (SNPs), as part of their model of care, are required to conduct annual HRAs for their enrollees (42 CFR 422.101(f)(1)(i), but are also not required to conduct in-home HRAs.

Comment: A commenter asked us to clarify whether the requirement to furnish information about safe drug disposal during an in-home risk assessment applies to risk assessments conducted at other locations where seniors reside, such as senior-living centers, nursing homes or assisted living facilities.

Response: If the enrollee's primary residence is in an institutional setting (such as a nursing home) the enrollee typically will not be responsible for the disposal of unused medications. Therefore, for purposes of this requirement, we would not consider a health risk assessment furnished to an individual who is residing in an institutional setting such as a nursing facility to be an ''in-home'' health risk assessment, and the MA plan is not required to furnish the enrollee with the guidance on the safe disposal of controlled substances during the HRA as required at § 422.111(j). We have added language to § 422.111(j) clarifying this exception.

Comment: Several commenters questioned how CMS will confirm compliance with these disclosure requirements. The commenter asked CMS to clarify any member material requirements regarding confirming receipt of this information. For example, the commenter questioned whether enrollee attestations would be required. A commenter asked that CMS provide additional clarity about what must be included in the health risk assessment to be compliant with this requirement.

Response: MA plans conducting an in-home HRA must document the visit and their provision of the required disclosure to the enrollee as described at § 422.111(j). However, we are not imposing any additional requirements beyond written documentation that would otherwise be available to CMS upon review or audit that the safe disposal instructions have been met.

Comment: A commenter recommend that CMS explore additional methods to improve take-back programs, such as allowing direct-to-consumer incentives for returning unused opioids. The commenter proposed that rewards and incentives (R&I) could take the form of coupons, gift cards, and electronic deposits to a digital wallet, or other options chosen by the consumer. Another commenter also proposed that CMS explore mechanisms that reverse distributors use to return prescription drugs from healthcare providers and pharmacies back to manufacturers could be leveraged to enable manufacturer-funded incentives that could be shared with consumers. These commenters stated they believed R&I would help spur individuals to return substantially more unused prescription opioids.

Response: This comment is outside of the scope of this regulation. MA plans may offer R&I programs as specified in our regulations at § 422.134 in section V.D of this final rule.

Comment: A commenter stated that they will be furnishing free kits in a retail pharmacy chain that can be used to dispose of medications in the home. The commenter asked that CMS require plans to inform MA enrollees about this option. Another commenter indicated that they would be selling in-home drug deactivation kits and that CMS should inform MA enrollees of this option. This commenter recommended that CMS require that patient education include information about commercially available in-home disposal products that may be used in disposing of unused medications. Another commenter cited a report indicating that the use of in-home drug deactivation kits is a particularly effective way to facilitate the safe in-home disposal of controlled medications. This commenter also noted that drug deactivation kits would be particularly useful in rural areas where an authorized collector may not be nearby, and that the use of such kits would complement Take Back Day events and give consumers more options.

Response: We recognize that other technologies, such as drug deactivation kits, have been developed and can provide additional options for the safe disposal of unused medications in the home. Accordingly, we are revising the regulation text at § 422.111(j) (5) to add that the written and verbal information on the safe disposal of controlled medications may also include information about the availability of drug deactivation kits for in-home disposal of unused medications. Because these products may not be available to all enrollees and may have varying associated costs for the enrollee, CMS defers to MA organizations to determine whether and how to include such information. As we discuss in more detail in this section of this rule, MA plans have the flexibility to amend the information they furnish on the safe disposal of controlled substances to reflect innovations such as home drug disposal kits that may become available.

Comment: Several commenters asked that CMS develop a model document that all MA plans could present to enrollees regarding the safe disposal of controlled substances and identification of community Rx take back sites. Several commenters also recommend that this model information be developed and provided in a format, reading level, and use appropriate visuals to ensure understanding by Medicare beneficiaries. A commenter also asked that CMS consider including in the model general information on drug take-back sites. Another commenter states that with thousands of health plans offering Medicare Advantage products and thousands of health professionals providing HRAs, the need for a common educational document is clear.

Response: We do not believe that developing a model document will allow MA plans the flexibility to tailor their information to the local needs or changes in this rapidly evolving area. For example, the use and expanding availability of drug deactivation kits for in-home use is a relatively new development, and may vary in cost and availability across plans and depending on location. Other new developments or changes in how medications can be safely disposed may become available and we want to preserve the flexibility of MA plans to respond to possible future innovations in drug disposal methods by updating their information without depending on a CMS model document to make those changes. We believe that within the parameters we have established in this regulation, MA plans will have the flexibility to tailor their information to the specific conditions present in the rural, urban or metropolitan community where the enrollee receiving an in-home HRA resides. We expect that as with all written information furnished to MA enrollees that MA plans will use a format, reading level, and use appropriate visuals to aid understanding by Medicare beneficiaries consistent with § 422.2267, which we are adopting elsewhere in this rule.

Comment: Several commenters expressed concern about the burden of the proposed enrollee disclosure requirement. These commenters specifically mentioned that a verbal explanation of the safe disposal options and also the proposed requirement of identifying local take back sites are particularly burdensome. This commenter stated it would be impractical to tailor local takeback information for every individual nationwide who receives an in-home HRA. Rather, this commenter urges CMS to adopt a rule that the health professional's reference to the safe disposal website, where local takeback locations can be found, satisfies the requirement to provide such information.

Response: The regulations we are finalizing in this final rule will require the verbal instructions to supplement the written guidance on the safe disposal of medications when possible. However, verbal instruction is not required if the enrollee is impaired to a degree where they are unable to receive verbal information. To assist plans in furnishing a verbal communication to enrollees and reduce the burden we are revising the final rule to specify that MA plans will inform enrollees in writing and verbally of two or more drug take back sites that are consistent with the community pattern of access to drug take back sites where the enrollee resides. The verbal instructions should also note that the written instructions contain the DEA website where the enrollee can identify other community drug take back sites through a search engine where the enrollee can also find current information on the safe disposal of drugs. If the enrollee's spouse or caregiver is the responsible party it would be appropriate to furnish this information (written and verbal) to them when conducting an in-home HRA of an impaired enrollee. We have amended

§ 422.111(j) to clarify the information that should be shared with the enrollee when a verbal summary of the instructions is possible. We believe providing this information in both written and verbal format is important for the effective transmission of this information to help enrollees appreciate the importance of disposing of unused medications that are controlled substances and that the written document can be used for more details on how to dispose of these unused medications. With respect to identifying local take back sites we recognize that simply referencing a website would be less burdensome. However, as previously noted, in response to these comments, we are modifying our proposal and will require a written and verbal disclosure of at least two drug take back locations that are consistent with the enrollee's community pattern of access to drug take back sites. Specifically, the identified drug take back sites must be among the drug take back sites that are generally utilized by people residing in the same community as the enrollee receiving the in-home HRA. That is, drug take back sites that are physically located within the shortest travel times. While the identification of two drug take back sites available to the enrollee identifies two choices we encourage plans to identify additional community take back sites.

Comment: A commenter asked that rather than furnishing written guidance on the safe disposal of controlled substances the information could be furnished to all MA enrollees in ANOC/EOC documents. Another commenter states that adding this information to the MA plan website would also be less burdensome for members and health plans. One commenter recommends that CMS promote inclusion of safe disposal information within a member's enrollment welcome packet.

Response: We are implementing the statutory requirement at section 1852(n)(1), which requires that specific information on the safe disposal of controlled medications must be provided to MA enrollees who are furnished an in-home HRA. While we acknowledge that this information could be beneficial to other enrollees, given the specific statutory language referencing this subset of enrollees, we are not requiring the inclusion of this information in other MA plan communications, nor are we adding it to the EOC template. While not required, we recognize that information on safe disposal may be useful for all Medicare beneficiaries, and therefore we encourage MA plans to make it available to other plan enrollees, for example by posting it on their website.

Comment: Another commenter asks that CMS maintain flexibility for plans to provide beneficiary education and outreach in a way that best suits the needs of individual members while minimizing burden. A commenter asks that CMS allow plans the flexibility to determine what information to provide, including relying on existing, externally validated sources. For example, the U.S. Drug Enforcement Agency (DEA) website at *www.deatakeback.com* already hosts an up-to-date, searchable database of locations for safe disposal (located specifically at *https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1*), and local law enforcement stations routinely collect controlled substances or can direct beneficiaries elsewhere as needed.

Response: The proposed regulation at § 422.111(j)(1)(vi) (which we are renumbering as § 422.111(j)(6)) requires that MA plans include in their written guidance a link to the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html.*

However, we agree that the previously identified DEA website is a useful tool for locating drug take back sites available in specific communities. We will require that MA plans include a link to the DEA website in their written instructions and will require MA plans to provide a verbal summary of the written instruction noting the availability of the DEA website as a source for locating drug take back sites. Therefore, we are amending § 422.111(j)(2) to include the DEA link.

Comment: Several commenters stated that pharmacists are trusted and qualified and should be the source of information to inform enrollees about methods for the safe disposal of medications. The commenters stated that delivering this information to the beneficiary at the point of sale where the beneficiary gets or refills their prescription could be more effective . The commenter believed that at these times, information on safe disposal is more likely to be understood, and the drugs are more likely to be disposed of safely as part of the beneficiary's care routine (for example, expired medications can be disposed of at or near the same location where a new prescription is filled).

Response: As we have previously noted in this preamble, we are implementing the statutory requirement at Section 1855(n), which requires MA plan to furnish information on the safe disposal of controlled substances when conducting an in-home HRA. Elsewhere in this rule we discuss the statutory requirement for this information to be furnished as part of a Part D MTM program.

Comment: A commenter expressed concern that the various requirements for providing beneficiaries with safe disposal information may result in a beneficiary receiving multiple and varied messages with the adverse effect of beneficiary confusion and/or beneficiary resistance to the safe disposal message. This commenter recommends that CMS and plans make certain such efforts are coordinated with pharmacies to ensure consistent messaging, particularly around treatment alternatives.

Response: As we have previously discussed we are laying out parameters rather than mandating model language with respect to the information that MA plans must furnish to enrollees during an in-home HRA. We believe the parameters we are finalizing at § 422.111(j) give MA plans the flexibility to ensure that their written information remains reasonably consistent with the current drug disposal options available in the communities where their enrollees reside.

We thank the commenters for sharing their concerns and recommendations regarding our proposed implementation of Section 1855(n)(1) in the MA regulations at § 422.111(j). After careful examination of all comments received and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing § 422.111(j) with the following modifications from the proposal. We are renumbering § 422.111(j). We recognized the that DEA website is a useful tool for locating drug take back sites available in specific communities. We will require that MA plans include a link to the DEA website in their written guidance and note the availability of the DEA website as part of the verbal instructions to enrollee's when conducting in-home HRAs. Therefore, we are amending § 422.111(j)(2) (as renumbered) to include the DEA link at: *www.deatakeback.com which includes a page with a searchable database where drug take back sites nearest to a person's home can be identified at the following web link: https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1.*

We are also amending § 422.111(j)(4) to require that the written and verbal

instructions identify two or more drug take back sites available in the community where the enrollee resides. We are adding a new provision at § 422.111(j)(5) specifying that as part of its educational information on the safe disposal of controlled medications, the plan may inform enrollees in writing and verbally about the availability of drug disposal kits for the in-home disposal of unused medications. Finally, we are revising § 422.111(j) to clarify that for purposes of this requirement, a health risk assessment is not considered ''in home'' if the enrollee's primary place of residence, such as a nursing facility, manages the disposal of unused medications.

D. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA–PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D–4(a)(1)(a) of the Act. Section 6102 of the SUPPORT Act amended section 1860D–4(a)(1)(B) of the Act to require that Part D sponsors also must disclose to each enrollee, with respect to the treatment of pain, information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA–PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B. Section 6102 also amended section 1860D–4(a)(1)(C) to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period, rather than disclosing the information to each plan enrollee.

To implement section 6102, we proposed to amend our regulations at § 423.128 to require Part D sponsors to send information on opioid risks and alternative treatment information to all Part D enrollees, with the option to provide such information to a subset of such enrollees, in accordance with section 1860D–4(a)(1)(C), in lieu of providing it to all enrollees.

Paragraph (a) of section 423.128 requires Part D sponsors to disseminate specific plan information to enrollees, under which a sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS. Paragraph (b) lays out information requirements the plan must include for qualified prescription drug coverage offered under the Part D plan. We proposed to revise these requirements by adding paragraph subsection (b)(11) to mandate that Part D sponsors send information about the risks associated with prolonged opioid use, coverage of non-pharmacological therapies, devices, and non-opioid medications, for MA–PDs, coverage under the plan, and for PDPs, coverage under Parts A and B. Additionally, we proposed to add subsection (b)(11)(ii), which gives Part D sponsors the option of sending these resources to a subset of enrollees, in lieu of providing it to every enrollee. In the proposed rule, as shown in Table C1, we suggested 6 different enrollee subsets to whom sponsors could send the required opioid risk and alternate pain treatment coverage information, generally grouped by retrospective review of prescription opioid fills using several different timeframes, with the exception of the subgroup that contains all Part D enrollees. The lookback periods ranged from use of any opioids in last 2 years to greater than 90 days continuous use with a 7-day gap or less in the past year. Table C1 also shows the estimated number of enrollees in each suggested subgroup, as well as the estimated percent of total opioid users in Part D that each subgroup constitutes.

TABLE C1—SUGGESTED SUBSET OPTIONS TO RECEIVE EDUCATION ON OPIOID RISKS AND ALTERNATE TREATMENTS *

Subset	Suggested subset	Number of enrollees in this subset	Percent of total Part D opioid users
1	All Part D Enrollees	46,759,911	N/A
2	Any opioid use in last 2 years	16,134,063	100
3	Any opioid use in past year	11,027,271	100
4	7 days continuous opioid use	7,163,615	65
5	Greater than 30 days continuous opioid use, 7 day or less gap	3,816,731	35
6	Greater than 90 days continuous opioid use, 7 day or less gap	2,698,064	24

* All figures based on 2018 PDE data as of 7/6/2019, except subset 2 which is based on 2017 and 2018 PDE data. Beneficiaries were excluded from the opioid use subsets if they were in hospice, in a resident facility, or had a palliative care diagnosis (07/01/2018–12/31/2018). Beneficiaries were also excluded if they had a cancer diagnosis (01/01/2018–12/31/2018). No exclusions were applied to the all Part D enrollees figure (subset 1).

We specifically solicited comments from stakeholders on the various suggested subsets of enrollees to whom the required information could be sent, in order to determine if there was any consensus that might inform sponsors' decisions, whether based on our suggested subsets or otherwise.

Comment: Many commenters were supportive of our proposal as an additional means to support efforts to address the national opioid crisis.

Response: We thank these commenters for their support of the proposed provision.

Comment: A few commenters expressed concern about overreach in sending the required information to all Part D enrollees. They highlighted the potentially negative reactions enrollees may have if they receive this information without having record of a previous opioid prescription. Conversely, other commenters believed that it was important for all enrollees to receive the information whether or not they had a record of a prior opioid prescription, noting that successful public health campaigns are not always tailored to specific populations. Other commenters supporting that the information be disclosed to all Part D enrollees noted that some beneficiaries may have paid cash for opioids or used illicit ones, and thus would be missed in any subset based on prescription opioid use. A few commenters believed that plans could focus their efforts on beneficiaries who have received an opioid in the last 7 days, so as to not

be over-inclusive with the information disseminated to them. No other commenters suggested a different subset of enrollees to whom the information should be provided.

Response: We appreciate the commenters' feedback. Although some commenters offered their opinion on the enrollee population that might be the best group to receive the information, there was no consensus to inform sponsors' ultimate decisions on to whom to send the information. As we have noted, the statute leaves this decision to the sponsor's discretion.

Comment: Several commenters encouraged CMS to develop a model document for sponsors to use for consistent messaging about the risk of opioid use and coverage of alternative pain treatments.

Response: We do not believe a model document is appropriate or necessary. Both MA–PDs and standalone PDPs should be able to describe the risks of prolonged opioid use without a model document, as they possess the expertise in both the coverage and clinical use of drugs and their associated risks. In addition, Part D sponsors have available to them federal government websites as resources for consistent messaging. For example, the U.S. Department of Health and Human Services website (*https://www.hhs.gov/opioids/*) contains information about opioid risks and pain management options, and CMS' Pain Management website (*https://www.medicare.gov/coverage/pain-management*) also contains information about the risks of opioids and pain management.

Moreover, we anticipate that sponsors will require some flexibility when it comes to developing the content for these beneficiary notices, given that they have the discretion to choose a subset of enrollees to whom they will send the notices. Also, coverage of alternative pain treatments will likely vary among plans. Additionally, a plan's beneficiary population can be unique and opioid issues may vary regionally and over time. Thus, the degree of flexibility any model document would require to allow each plan to tailor its message and information to its specific plan population in terms of coverage of the risks of prolonged opioid use and alternate pain treatments would decrease the utility of a model document.

Comment: A commenter suggested that this information could be conveyed to Part D enrollees through the EOC.

Response: We respectfully disagree. While the EOC does contain information about plan coverage of alternate pain treatments, such as coverage of physical therapy services in an MA–PD, it is a very large document containing hundreds of pages of material, which is not the best method to provide the specific, cohesive, and concise information on opioid alternatives that is required under this provision.

Moreover, given that Section 6102 of the SUPPORT Act provides for specific opioid education to Part D beneficiaries, we do not believe that adding opioid risk and alternative pain treatment coverage to a lengthy technical document would draw sufficient attention to the required information. For this reason, we believe that a separate beneficiary communication is a more effective means of conveying this information. We may consider revising the EOC template in future years so that a plan may include this information; however, our current focus is on implementing the statutory requirement and believe it is best implemented as we proposed.

Comment: Some commenters requested clarification on whether Part D plans are permitted to send the required information electronically without prior consent of the beneficiary, based on requirements they referenced from § 423.128(b), which allowed for electronic delivery of EOCs without prior beneficiary authorization. Specifically, the regulation allowed plans to meet the disclosure and delivery requirements for certain documents by relying on notice of electronic posting and provision of the documents in hard copy when requested, when previously the documents, such as the EOC, had to be provided in hard copy.

Response: As stated under § 423.2267(d)(2)(ii), which we are finalizing as discussed elsewhere in this rule, we will not allow for electronic delivery without prior approval from the beneficiary for this type of material. Part D sponsors may only mail new and current enrollees a notice for electronic access to the EOC, Provider and Pharmacy Directories, and Formulary without beneficiary authorization. Conversely, the separate beneficiary notice on opioid risk and coverage of alternate pain treatment is a new document that will convey important safety information related to a national epidemic, and we want to make sure that beneficiaries will see the information. For this reason, we are not making any exceptions to § 423.2267(d) for this information, and Part D plans must obtain the beneficiary's consent before they may provide this information electronically.

Comment: As we noted earlier in section A, we received many general comments expressing concern that the opioid provisions of the proposed rule would limit access to pain medicine, including opioids.

Response: We are not persuaded that educating beneficiaries about the risks of opioid use and coverage of alternative pain treatments will prevent people who need opioids for treatment of their pain from receiving them. It is commonly accepted that beneficiaries should discuss their health care treatment choices and the potential risks associated with each choice with their health care providers, and that the more education beneficiaries have about their options and the associated risks when they have these conversations, the better able they will be to make the best choice for themselves in consultation with their providers.

After consideration of the comments received, we are finalizing the new requirement at § 423.128(b)(11) to disclose information to enrollees about opioid risks and alternatives without modification except thatthis provision will be applicable beginning on January 1, 2022 rather than January 1, 2021 as initially proposed. However, given the ongoing national opioid epidemic and public health emergency, we strongly encourage Part D sponsors to disclose this information to their enrollees in 2021, if possible. We also encourage sponsors to include information in these notices, as they deem appropriate, to help increase awareness among Part D enrollees about access to medication-assisted treatment (MAT) and naloxone. In this regard, we note that the CMS web page (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/Index*) includes information about the dispensing and administration of MAT medications (if applicable) now covered under the new Opioid Treatment Program (OTP) benefit under Medicare Part B. We also note that in the CY 2020 Call Letter, CMS previously encouraged Part D sponsors to engage in targeted education of enrollees on co-prescribing of naloxone,[18] and that this beneficiary notice may be an ideal avenue to include such information.

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We proposed to amend Part D Medication Therapy Management

[18] Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, page 204 (April 1, 2019). *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

(MTM) program requirements in § 423.153 to conform with the relevant SUPPORT Act provisions. The SUPPORT Act modifies MTM program requirements for Medicare Part D plans by expanding the population of beneficiaries who are targeted for MTM program enrollment (''targeted beneficiaries'') to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries. Section 6064 of the SUPPORT Act amended section 1860D–4(c)(2)(A)(ii) of the Act by adding a new provision requiring that ARBs be targeted for enrollment in the Part D plan's MTM program. We proposed to codify this requirement at § 423.153(d)(2). Section 6103 of the SUPPORT Act amended the MTM program requirements in section 1860D–4(c)(2)(B) of the Act by requiring Part D plans to provide MTM enrollees with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. We proposed to codify this requirement by adding new paragraphs at § 423.153(d)(1)(vii)(E) and (F).

1. ARBs and MTM

Under our proposed revisions to § 423.153(d), ARBs would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: (1) Enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and (2) enrollees who are determined to be ARBs under § 423.100.

Under our proposal, Part D sponsors would be required to automatically enroll all ARBs in their MTM programs on an opt-out only basis as required in § 423.153(d)(1)(v). We did not propose to change any existing MTM program requirements for targeted beneficiaries enrolled in a Part D sponsor's MTM program, including service requirements such as annual comprehensive medication reviews (CMRs) and targeted medication reviews (TMRs). Accordingly, the MTM program requirements would be the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they are targeted for enrollment based upon the existing criteria or because they are ARBs.

As discussed in detail in the February 2020 proposed rule (85 FR 9031), CMS encourages sponsors to design MTM interventions for this new population of targeted beneficiaries to reflect their simultaneous inclusion in the sponsors' DMPs. CMS also encourages sponsors to consult existing clinical guidelines, such as those issued by the Centers for Disease Control and Prevention for Prescribing Opioids for Chronic Pain,[19] when developing MTM strategies and materials. CMS solicited input into how sponsors can best coordinate DMPs and MTM programs and effectively perform outreach to offer MTM services. We also solicited feedback on how to leverage MTM services to improve medication use and reduce the risk of adverse events in this population, how to measure the quality of MTM services delivered, and how to increase meaningful engagement of the new target population in MTM. Lastly, we solicited comments on the type of information that we should use to monitor the impact of MTM services on ARBs, who will now be targeted for MTM services.

CMS also sought comment in the proposed rule on how the CMS Standardized Format (CMS–10396; OMB control number 0938–1154) might be modified in order to accommodate the new population of ARBs that will be enrolled in Part D sponsors' MTM programs. Additionally, CMS posted the CMR Standardized Format with rule-related changes in conjunction with the proposed rule. A version reflecting non-rule related revisions was posted in the **Federal Register** on February 24, 2020 (85 FR 10444) through the Paperwork Reduction Act (PRA) process with a 60-day public comment period. We also solicited feedback on whether using Health Level Seven (HL7®)-enabled CMRs could positively impact the sharing of CMR data with the prescriber for an MTM enrollee, and the value of encouraging Part D MTM providers to use FHIR-enabled platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

Comment: CMS received multiple comments expressing concerns about the timing of the proposed requirements to include ARBs in MTM programs and to provide information on safe disposal of controlled substances to beneficiaries enrolled in MTM. Commenters requested that CMS postpone implementation of the requirement to add ARBs to MTM programs until 2022, citing the time involved to develop an effective MTM program that would serve the new population, including the need to coordinate between MTM providers, behavioral health teams, DMPs, and others. They stated that plans will need time to create the systems required for information exchange to facilitate care coordination. One commenter pointed out that resources are currently being consumed by COVID–19 needs.

Response: Recognizing the impact of the COVID–19 public health emergency on plans and other stakeholders, we are modifying the regulation text at § 423.153(d)(1)(vii)(E) and § 423.153(d)(2)(ii) to specify that these changes to MTM programs must be implemented by Part D plan sponsors beginning January 1, 2022, rather than January 1, 2021 as initially proposed. The applicability date for § 423.153(d)(2) is 60 days after the date of publication of this final rule.

Comment: Many commenters opined on the usefulness of targeting ARBs for enrollment in the Part D MTM program. Some commenters believe that these beneficiaries would benefit from MTM interventions that would create additional opportunities to provide counseling and education to a generally underserved population. Other commenters expressed concern that targeting these beneficiaries for MTM would make this vulnerable population believe they are being singled out or stigmatized, or would increase the size of MTM programs. A commenter questioned CMS' authority to propose this requirement, calling our proposal ''bureaucratic over-reach.'' Other commenters stated that providing ARBs with both DMP and MTM services would be duplicative and potentially confusing; a commenter pointed out that plans often use one vendor to perform DMP-related services and another for MTM which could lead to a lack of coordination between service providers. A few commenters suggested alternative mechanisms to provide services to the ARBs such as enhancing DMPs or making a beneficiary's at risk status another condition to be considered when developing MTM targeted population.

Response: Section 6064 of the SUPPORT Act, as codified at section 1860D–4(c)(2)(A)(ii) of the Act, requires that Part D plan sponsors include ARBs in their MTM programs. As discussed in the proposed rule, the MTM program requirements are the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they are targeted for enrollment based upon the existing criteria or because they are ARBs. In order to

[19] Accessible at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

provide services for ARBs, plans will need to coordinate services across both their DMP and MTM program without regard for which vendors furnish such services. Part D plan sponsors are ultimately responsible for ensuring that all delegated functions are compliant with CMS requirements. See 42 CFR 423.505(i)(1). This includes making sure that downstream entities used to provide a plan's DMP and/or MTM program coordinate, as necessary, to ensure that communications with and services furnished to plan enrollees comply with applicable Part D requirements. To the extent that MTM can be provided within a plan's DMP while meeting all MTM service requirements, this approach would be permissible provided it complies with all other applicable Part D requirements. Further, if a plan wishes to target all PARBs for enrollment in its MTM program instead of only targeting ARBs, it is permitted to do so, provided that the plan meets all CMS requirements for both DMPs and MTM services. The criteria specified in the regulation reflect what is required under the Act, and do not preclude plans from electing to offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under § 423.153(d).[20]

Comment: Several commenters asked CMS for more direction in developing MTM programs that will meet the needs of the new cohort of beneficiaries.

Response: CMS typically gives plans the latitude to develop MTM programs that meet their beneficiaries' needs within the framework of the applicable statutory and regulatory requirements. Most Part D plans have gained experience with their ARB population through DMPs and earlier Part D opioid overutilization policy, and we expect plans to draw on this experience when working with their clinical teams, including any downstream entities, in developing clinically appropriate MTM interventions for these individuals. Consistent with section 1860D–4 (c)(2)(E) of the Act, MTM programs must be developed in cooperation with licensed and practicing pharmacists and physicians.

Comment: Multiple commenters expressed concerns that the addition of ARBs to the MTM population could impact the Part D MTM Program Completion Rate for CMR Star Rating measure, and expressed concerns that including the new population of MTM-eligible beneficiaries in the CMR completion rate might adversely affect a plan's overall Star rating. A commenter cited internal data indicating an expected CMR acceptance rate of 23 percent for current MTM-eligible beneficiaries who also meet the DMP criteria for ARBs. Commenters requested that CMS proactively implement safeguards in the scoring of this measure—some commenters suggesting the measure be excluded from Star Ratings and others asking that ARBs be excluded from the measure—in order to ensure plans with a high population of ARBs are not adversely and unintentionally affected.

Response: CMS appreciates these comments but believes it is premature to assume that ARBs will be less receptive to offers of MTM services than other beneficiaries prior to gaining program experience. Congress enacted a statutory requirement that Part D plans engage with this population through their MTM programs, and CMS expects plans to develop effective engagement strategies based on their beneficiary population and business model.

The MTM CMR completion rate is a Pharmacy Quality Alliance (PQA) endorsed measure. The denominator currently used to derive the measure includes all individuals who met the MTM eligibility criteria; therefore, while the methodology for the measure is outside the scope of our proposal, as currently defined, the measure would include ARBs beginning with the 2022 measurement period. The extent to which any potential change in a plan's rating on this measure may affect its overall Star Rating would also depend on that plan's performance on all other Star Ratings measures. Lastly, CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule (83 FR 16519 through 16589), published in April 2018, for performance periods beginning with 2019; that final rule lays out the methodology for the 2021 Star Ratings and beyond. If the measure steward changes the specifications for the MTM CMR completion rate measure, the process for CMS to update the Star Ratings measures is codified at § 423.184(d).

Comment: A few commenters expressed concerns about the types of reporting requirements that may be included when ARBs are enrolled into MTM programs, and requested that CMS clarify what those requirements will be. A few commenters urged CMS to consider reducing reporting elements in view of the additional beneficiaries that will be added to MTM programs.

Response: We are requiring plans to comply with the requirement to extend MTM to ARBs beginning on January 1, 2022, and therefore this requirement will not impact plan reporting until the 2022 plan year data, which is collected in early 2023. Part D reporting requirements for the 2021 plan year (CMS–10185; OMB control number: 0938–0992 expires December 31, 2023) have been approved by OMB and are available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.*

Comment: A commenter voiced support for conducting CMR sessions via telemedicine.

Response: We appreciate the reminder that the CMR can be provided via telemedicine, which may be preferable in many situations. The regulation at § 423.153(d)(1)(vii)(B)(*1*)(*i*) specifies that the annual CMR must be provided by an interactive, person-to-person, or telehealth consultation.

Comment: A few commenters requested additional information on when a beneficiary may be considered to be ''unable to accept the offer to participate'' in a CMR. These commenters contend that it may be necessary to conduct outreach to a provider in cases where barriers due to social determinants of health (SDOH) may prevent the beneficiary from accepting the offer of a CMR, while conducting the CMR with the prescriber would allow the member to receive the benefits that go with MTM programs.

Response: As we explained in the proposed rule, the only situation in which CMS would consider a beneficiary to be unable to accept an offer to participate in a CMR is when the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs. The CMS Standardized Format provides instructions for those circumstances. The flexibility to perform the CMR with a prescriber, caregiver or other authorized individual does not apply to situations where the sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address), if there is no evidence of cognitive impairment, or where the beneficiary declines the CMR offer. Further, perceived barriers due to a beneficiary's SDOH does not mean that the beneficiary is unable to participate in a CMR. MTM providers are expected to make sure that they engage the target population in a manner that these beneficiaries can

[20] See HPMS memorandum dated April 5, 2019, ''CY 2020 Medication Therapy Management Program Guidance and Submission Instructions'' at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf.*

understand and use, regardless of any language or other barriers that exist. We also want to caution that the failure to provide services to beneficiaries disadvantaged by poverty, language, or other SDOH suggests discriminatory practices, which may be in violation of the Social Security Act or other federal requirements regarding access to services.

Comment: A commenter asked CMS to clarify the definition of an ARB.

Response: An ARB, as defined at § 423.100, means a Part D eligible individual (1) who is: (i) Identified using clinical guidelines (also defined in § 423.100); (ii) not an exempted beneficiary; and (iii) determined to be at-risk for misuse or abuse of such frequently abused drugs (FADs) under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) with respect to whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an ARB (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

Comment: A commenter asked whether CMS expects to ''grandfather'' existing ARBs who have an active coverage limitation placed prior to January 1, 2021 that extends into the 2021 plan year, or whether the new MTM requirement would apply only to ARBs who are newly identified after January 1, 2021.

Response: As discussed earlier, under the regulation we are adopting in this final rule, Part D plan sponsors must comply with the requirement to include ARBs in MTM programs by January 1, 2022. Accordingly, all existing ARBs—that is, enrollees with an active limitation under a DMP as of January 1, 2022, although such limitation may have commenced prior to January 1, 2022—as well as ARBs identified on or after January 1, 2022, must be targeted for enrollment in MTM.

Comment: CMS received a number of comments on how to improve the Standardized Format including suggestions on the content and format. Most commenters indicated that electronic sharing of completed CMRs to the prescriber's EHR would promote continuity of care. These commenters urged CMS to produce a template that encouraged HL7®-enabled submissions. A commenter asked when a new MTM Standardized Format will be available for use and when MTM providers will be required to start using any newly developed format.

Response: We thank all commenters for their suggestions. Comments received in response to this regulation will be considered when finalizing the Standardized Format along with those received in response to the PRA package for the CMS Standardized Format (CMS–10396; OMB control number 0938–1154) that was published separately from the rule. An additional 30-day notice for CMS–10396 will be published for public comment following publication of this final rule, and a package will be delivered for OMB review. The 30-day notice will address the comments received in response to the rule- and non-rule solicitations, provide additional proposed revisions if applicable to address the comments, and propose a date for when the changes would become effective. The finalized Standardized Format will be released after approval by the OMB.

Comment: A commenter was concerned that the pecuniary interest of the sponsor will be the primary driver for MTM reviews and that it would create an incentive to ''say no'' to appropriate and safe opioid therapies for hundreds of thousands of pain patients.

Response: It appears that the commenter may be unfamiliar with the use and purpose of Part D MTM programs. The goal of MTM is to improve medication use and therapeutic outcomes driven by the individual beneficiary clinical needs and does not result in any denials of medications or services.

2. Information on Safe Disposal of Prescription Drugs That Are Controlled Substances for MTM Enrollees

Section 6103 of the SUPPORT Act added a new requirement that Part D plans provide beneficiaries enrolled in their MTM programs with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. To implement this new requirement, we proposed that Part D sponsors would be required to provide this information to all beneficiaries enrolled in their MTM programs at least annually, as part of the CMR or through the quarterly TMRs or follow up. Furthermore, while not required, we encouraged sponsors to provide information on safe disposal of all medications, not just controlled substances, to MTM enrollees.

Section 6103 of the SUPPORT Act states that the information provided to beneficiaries regarding safe disposal of prescription drugs that are controlled substances must meet the criteria established in section 1852(n)(2) of the Act, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal. Section 1852(n)(2) states that the Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate to ensure that the information provided to an individual sufficiently educates the individual on the safe disposal of prescription drugs that are controlled substances. We described our proposed criteria and requirements for MA plans to furnish information on safe disposal of controlled substances when providing an in-home health risk assessment and our proposal to codify these requirements in a new provision of the regulations at § 422.111(j) in section III.C. of the proposed rule. In section III.E.2 of the proposed rule, we proposed that Part D plans would be required to furnish materials in their MTM programs regarding safe disposal of prescription drugs that are controlled substances that meet the criteria specified in § 422.111(j). Under this proposal, Part D plans, like MA plans, would retain the flexibility to refine their educational materials based on updated information and/or on beneficiary feedback, so long as the materials meet the proposed criteria. Section 1860D–4(c)(2)(B)(ii) of the Act expressly directs that the information on safe disposal furnished as part of an MTM program meet the criteria established under section 1852(n)(2) of the Act for MA plans. Accordingly, to ensure consistency and to avoid burdening MA–PD plans with creating separate documents addressing safe disposal for purposes of conducting in-home health risk assessments and their MTM programs, we explained our belief that it is appropriate to apply the same criteria that would apply under the proposed provision at § 422.111(j) to MTM programs by including a reference to the requirements of § 422.111(j) in the regulation at § 423.153(d) governing MTM programs.

Specifically, we proposed to revise § 423.153(d)(1)(vii) to include a requirement that all MTM enrollees receive at least annually, as part of the CMR, a TMR, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal that meets the criteria in § 422.111(j).

Comment: A few commenters suggested that plans be allowed to include information on safe disposal in documents other than the TMR or CMR, or on a plan website. Another commenter suggested that the MTM program welcome letter (or written initial offer of the CMR) be used to convey safe disposal information as well, and asked if doing so would meet the intent of this requirement. This commenter stated that plans may have difficulty reaching beneficiaries after enrollment in the MTM program if they have disenrolled from the plan for any reason, and it would be useful for plans to have more ways to provide this important information.

Response: As an initial matter, we note that plans have no obligation to provide MTM services to beneficiaries once they have disenrolled from the plan. Given the importance of information on the safe disposal of medicines, we support posting the information on plan or network pharmacy websites, but we do not believe that website postings alone will fulfill the statutory requirement that the information be provided to individual MTM recipients. However, we do agree with the comment recommending that safe disposal information could be provided in an MTM program welcome letter. While the statutory language at section 1860D–4(c)(2)(B)(ii) of the Act does not identify a specific format for providing this information, CMS believes that using the MTM welcome letter meets the statutory intent. Beneficiaries would then have an opportunity to ask any clarifying questions during a follow-up MTM service, including during the CMR. While not specifically addressed in the comments received, we would also support sending the safe disposal information electronically, for example through a member portal, provided the plan can document that the individual received the information. Accordingly, in this final rule we are modifying the proposed regulation text at § 423.153(d)(1)(vii)(E) by including a reference to ''other MTM correspondence or service'' to give plans the flexibility to provide this information in the manner they determine is most effective for reaching the beneficiaries enrolled in their MTM program.

Comment: All those who commented on the proposed requirement to include materials on safe disposal were supportive of the concept. A few commenters expressed appreciation that the proposed requirements in § 423.153(d) echoed those proposed in § 422.111(j). Some also commented that newly-developed disposal technologies that make the medications unusable, such as in-home deactivation kits, provide a viable option for safe disposal of controlled substances, and supported requiring information about these options in the educational materials.

Response: We appreciate commenters' support for the concept of furnishing information on safe disposal to MTM enrollees. We agree that the types of products referenced by the commenters may present additional means for safe disposal of prescription drugs that would complement the approaches described in the proposed rule. Therefore, as discussed in section III.C of this preamble, in this final rule we are modifying the proposed regulation text at § 422.111(j)(5) to permit plans to include information about the availability of in-home deactivation kits in the enrollee's community, where applicable. MA–PD plans will be able to use the same communication materials on safe disposal to educate MTM enrollees as they use for enrollees receiving this information as part of an in-home health risk assessment under MA.

After consideration of the comments received, we are finalizing the proposed changes to the Part D MTM program requirements with the modifications discussed. We are finalizing our proposal to expand the definition of beneficiaries targeted for enrollment in MTM programs at § 423.153(d)(2) to include ARBs, as defined in § 423.100. We are finalizing the provision at § 423.153(d)(1)(vii)(E) with modifications to allow plans to meet the safe-disposal educational requirement through use of a CMR, TMR, or other MTM correspondence or service, such as an MTM welcome letter. We are finalizing as proposed the requirement at § 423.153(d)(1)(vii)(F) specifying that the information provided must comply with all requirements of § 422.111(j). Lastly, we are modifying the regulation text at § 423.153(d)(1)(vii)(E) and § 423.153(d)(2)(ii) to specify that these requirements are applicable beginning on January 1, 2022. As noted in the Executive Summary of this final rule, the revisions to § 423.153(d)(2) as a whole are applicable 60 days from the date of publication in the **Federal Register**.

E. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CARA amended the Act to include new authority for Medicare Part D drug management programs effective on or after January 1, 2019. If an enrollee is identified as at-risk under a drug management program (DMP), the individual has the right to appeal an at-risk determination under the rules in part 423, subparts M and U. In addition to the right to appeal an at-risk determination, an enrollee has the right to appeal the implementation of point-of-sale claim edits for frequently abused drugs that are specific to an ARB or a limitation of access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers or dispensed to the beneficiary by one or more network pharmacies (lock-in). Section 2007 of the SUPPORT Act amended section 1860D–4(c)(5) of the Act to require that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the independent outside entity contracted with the Secretary for review and resolution.

To implement the changes required by the SUPPORT Act, we proposed to revise the requirements related to adjudication timeframes and responsibilities for making redeterminations at § 423.590 by adding paragraph (i) to state that if on redetermination the plan sponsor affirms, in whole or in part, its decision related to an at-risk determination under a DMP in accordance with § 423.153(f), the plan sponsor must forward the case to the IRE by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of § 423.590. We also proposed revisions to the requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*). Specifically, we proposed that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution.

Finally, we proposed to revise § 423.600(b) to clarify that the requirement that the IRE solicit the views of the prescribing physician or other prescriber applies to decisions that are auto-forwarded to the IRE.

We summarize the comments we received on these proposals related to automatic escalation and respond to them as follows.

Comment: Several commenters expressed support for our proposal that if on redetermination a plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a DMP in accordance with § 423.153(f),

the plan sponsor must forward the case to the IRE for review and resolution. One commenter noted that it has been their experience in general that most patients do not formally contest their at-risk determination status, but the commenter supports a beneficiary's right to appeal. Some of the commenters that supported the proposal related to auto-escalation of these cases to the IRE also expressed specific concerns. A few commenters noted that requiring denied cases to be forwarded to the IRE by the expiration of the applicable adjudication timeframe will significantly decrease the amount of time that plans have to review at-risk redeterminations. These commenters stated that these types of cases generally take longer to complete due to more outreach and coordination between providers than other types of redetermination cases and that reducing the timeframe to complete these cases in order to prepare a case for the IRE will decrease the quality of the plan's review. One commenter stated the belief that CMS's proposed timeframe for auto-escalation is not realistic or achievable, noting that DMP cases are complicated, and multiple delegated entities must coordinate to prepare a complete case file for forwarding. Commenters stated that plans need time to prepare case files and to ensure their completeness by acquiring the complete case management information from the DMP team, and that plans should have the full adjudication time for review of these cases.

Commenters noted that, in situations where a plan affirms its denial of an at-risk determination, it would pose operational burden and challenges to complete a thorough investigation, reach a determination, and automatically forward the case to the IRE within the 72-hour adjudication timeframe for expedited determinations and the 7-day timeframe for standard at-risk determinations. A couple of commenters noted that plans are afforded 24 hours after the expiration of the adjudication timeframe to prepare and forward the case file to the IRE in those Part D benefit appeal cases in which the plan misses its adjudication timeframe. Some of the commenters suggested that plans be afforded 24 hours to prepare and send the case file to the IRE and other commenters suggested 48 or 72 hours from the end of the adjudication timeframe. A commenter believes that the process of automatic escalation to external review should be consistent with Part D requirements for standard or expedited requests, so as to mitigate any additional administrative burden and requests that CMS ensure that this process mirror Part D requirements so that the systems and policies in place are seamless.

Response: We thank the commenters for their overall support and agree with those commenters who expressed concern that requiring the administrative case file to be assembled and forwarded to the IRE within the applicable adjudication timeframe could unnecessarily curtail the amount of time a plan has to conduct a thorough review of the case. The regulations at § 423.590(c) and (e) that govern Part D benefit redeterminations require a case to be auto-forwarded to the IRE when the plan misses the adjudication timeframe. Specifically, a plan has 24 hours from the end of the applicable adjudication timeframe to send the case file to the Part D IRE. For consistency with how cases currently subject to auto-forwarding to the IRE are handled, we believe it is reasonable and permissible under the statute to allow plans up to an additional 24 hours after the expiration of the applicable redetermination adjudication timeframe to assemble and forward the administrative case file to the IRE. In this final rule, the proposed regulation text at § 423.590(i) has been modified to state that if on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

Comment: A few commenters disagreed with the proposals related to the DMP notices. Commenters stated that providing the appeal notification on the first notice does not add value to the beneficiary, since the first notice has a 30-day window to gain additional information, if necessary, before a final decision is made to implement a lock-in or POS edits. These commenters recommend that appeal language only be included on the second notice. To reduce member confusion, a few commenters urged CMS to consider addressing escalation to the IRE only in the second notice as it relates to redeterminations specifically, and to ensure that it is clear the IRE escalation process will only apply when a redetermination in whole or in part is denied. Commenters also noted that if CMS is going to update member notices for the DMP, it is critically important for plans to receive updates to the notices in a timely manner to allow plans sufficient time to revise, implement, and test new notices. A few commenters also requested that CMS update the model redetermination denial notice to account for auto-forwarding of an adverse DMP case to the Part D IRE.

Response: We thank the commenters for their perspective on the notices intended to inform at-risk beneficiaries of their rights under a plan sponsor's DMP. We proposed that the initial and second notice explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. SUPPORT Act section 2007 specifically requires that notice of the automatic escalation of adverse decisions be included on the initial and second notice. Therefore, we do not believe we have the discretion to omit information on this right from the initial notice, as suggested by some of the commenters. With respect to the model redetermination notice, we plan to update that model consistent with this final rule. However, we note that this notice is a model that plan sponsors have the discretion to modify.

Comment: A few commenters requested that CMS train the IRE appropriately to ensure consistent reviews of drug management cases. One commenter noted that these are unique case reviews and cannot simply be overturned by the IRE based on a provider attestation of medical necessity. The commenter also stated that the IRE should have specific criteria in place to conduct these reviews and, further, that plans should also have recourse to address instances when the IRE overturns a plan decision.

Response: We thank the commenter for these comments and note that the IRE is already conducting reviews of DMP cases based on published regulations and guidance that govern plan sponsor activities with respect to drug management programs. The IRE review function is a beneficiary protection set forth in statute and there may be instances where the independent review performed by the IRE will result in a plan's decision being overturned based on a finding of medical necessity given the facts and circumstances of the enrollee's case, including clinical information furnished by the enrollee's prescriber. If a plan believes the IRE has made an error in its decision making, the IRE's reconsideration decision may be reopened consistent with the rules at § 423.1980.

Comment: A couple of commenters expressed support for the proposal to require automatic escalation of DMP to

external review, but also urged the Secretary to either exercise his authority or support legislation to extend such auto-escalation to external review for all adverse appeal decisions regarding Part D drugs, similar to the rules applicable to Medicare Advantage appeals.

Response: We appreciate the commenters' support for the proposed rules related to automatic escalation of DMP appeals, but note that the comment related to extending automatic escalation to all Part D benefit appeals is outside the scope of this rule.

Comment: While recognizing that the automatic escalation provision is required under the SUPPORT Act, some commenters expressed specific concerns with this proposal. One commenter encouraged CMS to find a path that allows the beneficiary to exercise their appeal rights following the standard appeals process outlined in Part C and D guidance, as must all other Medicare beneficiaries who receive an adverse redetermination. The commenter stated that the SUPPORT Act creates a discrepancy in the uniformity of the Medicare benefit by devising a unique process for ARBs to have their denied redeterminations automatically auto-forwarded to the IRE. The commenter stated that CMS should clarify how the IRE might reach a decision other than the decision the plan reached in consultation with the at-risk beneficiary's prescriber and requested that CMS share with plans the additional data sources the IRE may have that plans will not. The commenter also requested that CMS provide plans any training materials that may be provided to the IRE to help process these reconsiderations. Another commenter expressed concern that the process of automatic escalation to an external reviewer sets up the patient's care for review involving third parties who may be unreasonably biased with an anti-opioid mindset and incentivized by institutional conflicts of interest, such as the reduction of costs to insurance companies. This commenter also noted that it has been his experience that outside reviews fail to reflect adequate perspective on the patient, their problems, and their care and that the process inevitably involves the patient or their doctor negotiating a complex and time consuming phone triage system and may require an hour or more of a physician's time.

Response: We appreciate the comments, but note that the automatic escalation of a beneficiary's case to the IRE is a statutory provision that creates a protection for beneficiaries who are in a DMP. Part of the competitive process of contracting with an outside independent entity involves consideration of any potential institutional conflicts of interest. The very nature of an outside independent review means that there may be cases where the IRE reaches a different decision from that reached by a plan, based on clinical information supplied by the enrollee's prescriber. The IRE is required to follow the same regulations and guidance related to DMPs as is followed by plan sponsors. There may be instances where the IRE's review of supporting documentation received from an enrollee's prescriber reasonably supports a different decision from that reached by the plan sponsor. With respect to the time an enrollee or prescriber may have to expend, automatic escalation to IRE review should reduce the time a beneficiary has to spend disputing a limitation on access under a DMP because, under this final rule, the beneficiary will no longer have to request IRE review. In addition, the IRE is required to solicit the views of the prescribing physician or other prescriber when it receives a case from a plan sponsor, which may reduce the time a physician or other prescriber will have to expend providing necessary clinical information to the IRE.

Comment: A commenter asked CMS to clarify how an ARB will exercise his or her appeal rights and whether the auto-forwarded denied appeal be considered the first level of appeal.

Response: As with Part D benefit appeals, an ARB exercises his or her right to appeal by requesting a redetermination from the plan, which is the first level of appeal. The IRE review is the second level of appeal, including those DMP cases that will be subject to auto-forwarding under this final rule.

Comment: A commenter questioned what the impact will be if the plan does not auto-forward the denied appeal within the required timeframe.

Response: The SUPPORT Act requires plans to auto-forward to the IRE for review and resolution those redeterminations where a plan affirms its denial, in whole or in part. As with other regulatory requirements, CMS can exercise enforcement authority to ensure plan compliance. Pursuant to contract provisions at § 423.505(b)(7), plan sponsors must comply with all requirements of 42 CFR part 423, subpart M governing coverage determinations, grievances, and appeals, and formulary exceptions and CMS may impose sanctions on any plan sponsor with a contract for violations listed in § 423.752(a).

Comment: A commenter questioned how these auto-forwarded redeterminations will be differentiated by CMS from other reviews forwarded to the IRE and requested that CMS clarify whether the auto-forwarded denial or the IRE's decision on the auto-forwarded redetermination will be included in reporting or audit universes.

Response: Adverse redetermination decisions related to coverage limitations imposed under a plan sponsor's DMP that will be auto-forwarded to the IRE consistent with this final rule will be reported by plan sponsors as adverse redetermination decisions. For purposes of any necessary data gathering, the Part D IRE will be able to distinguish cases that are auto-forwarded for untimeliness from the DMP appeals auto-forwarded to the Part D IRE. With respect to the audit universes, if a plan sponsor's decision was made during the relevant universe period, those redeterminations will be reported in the redeterminations universe. If the determination was fully or partially overturned by the IRE, ALJ, or MAC during the relevant universe period, the overturn decision will be reported in the Part D effectuations of overturned decisions universe.

Comment: Some commenters suggested that CMS define what a plan sponsor is to include in a case packet for auto-forwarded denials.

Response: We appreciate the commenters' suggestion and note that the Part D IRE's reconsideration procedures manual and case file transmittal form lists the documents that should be included by plan sponsors as part of the administrative case file. These documents will be updated, as necessary. For example, the case file transmittal form will be modified so that a plan sponsor can clearly indicate that a case is being automatically forwarded to the Part D IRE as a result of an adverse DMP redetermination.

Comment: A commenter asked whether the plan is required to notify the ARB, their prescriber(s) or others and, if so, questioned if there is a required timeframe to complete the notification.

Response: Redetermination decisions related to a denied redetermination involving a DMP are subject to existing notice requirements at §§ 423.590(a)(d) and (g).

Comment: A commenter who expressed support for the proposal requested clarification on whether the Part D sponsor or the Part C plan would be responsible for making this determination when the member is enrolled in a standalone PDP. The commenter requested clarification on whether it is the Part D sponsor's responsibility to forward a redetermination to IREs for all drugs for

any member enrolled in a DMP. We believe the commenter is asking about a situation where an individual is enrolled in an MA plan and a separate, standalone Part D drug plan and whether it is the responsibility of the standalone Part D drug plan to forward an adverse DMP plan appeal to the IRE.

Response: Consistent with section 1860D–4(c)(5)(E) of the Act, it is the responsibility of an enrollee's Part D plan sponsor to auto-forward to the IRE an adverse redetermination decision related to an individual's identification as an ARB, a coverage determination made under a DMP, the selection of prescriber or pharmacy under the DMP and information to be shared for subsequent plan enrollment.

Comment: A commenter that expressed support for automatically escalating redeterminations associated with DMP appeals to the Part D independent review entity (IRE) noted that automatically escalating an appeal for an at-risk determination to an IRE without having to wait for the enrollee or prescriber on their behalf to request a review will serve to reduce the lag time in final determinations being issued and enable patients to access needed care sooner. This commenter also noted support for proposed changes to the required initial and second notice in addition to adjudication timeframes and redetermination responsibilities. This commenter encouraged us to reiterate the need for the prescribing physician to provide all requested information associated with the adverse decision to the IRE within a timely manner. Further, the commenter urged us to consider requiring the IRE to make a good faith effort to obtain relevant information from the prescribing physician in instances in which there is not an automatic escalation as well to ensure consistency in the resolution of all cases involving Part D appeals.

Response: We appreciate the support for these proposals and agree that it is important for the prescriber to submit the clinical information necessary for a thorough adjudication of the case. In this final rule, we are finalizing our proposal to modify the existing regulations at § 423.600(b) such that the requirement that the IRE solicit the views of the prescribing physician or other prescriber and include a written account of the prescriber's views in the IRE's record will apply to adverse DMP redeterminations that will be auto-forwarded to the IRE.

Comment: A commenter expressed the belief that automatic escalation to the IRE weakens the authority of Part D plans as partners to CMS in the fight against the opioid epidemic. An ARB appealing a decision to lock them into a specific pharmacy for opioid prescriptions would essentially ''skip the line'' if a plan denies their appeal and then upholds the denial upon review. The commenter stated the belief that this is unfair to non-ARBs, who must then wait behind ARBs for an IRE decision. The commenter also believes that this diminishes the ability of the plan to impact the behavior of providers and that rather than making changes to prescribed therapies, providers will wait for the result of the redetermination. Further, commenter believes that automatic escalation removes the ability of the plan to reconsider its decision when more information is submitted to it. The commenter also believes that automatic escalation will increase denials because the turnaround time clock will expire prior to the IRE having full information, and the beneficiary's denial is likely to be upheld. The commenter recommends, to the extent that CMS cannot relax the requirements in this final rule, that CMS provide the IRE with opioid-specific training prior to receiving these automatically escalated cases, to minimize process-related denials. The commenter recommends that CMS broadly consider a creative approach to meeting the statutory intent behind this provision and delay its implementation, or at least enforcement, until it can implement a policy that does not punish Part D plans and does not punish beneficiaries (at-risk and otherwise) while appropriately administering the pharmacy lock-in program.

Response: As previously stated, the SUPPORT Act requires plan sponsors to auto-forward adverse DMP redeterminations to the IRE for review and resolution. We do not believe we have the discretion to interpret the statutory language in a manner that results in a plan sponsor not being required to auto-forward a denied DMP redetermination to the IRE for review and resolution. We continue to believe that, given the extensive case management involved in these types of cases, there will be very few cases that will be subject to auto-forwarding. We note that the IRE is already performing reviews of DMP cases based on existing regulations and guidance. We believe the intent of the SUPPORT Act provision requiring automatic escalation to the IRE is to enhance protections for at-risk beneficiaries and not intended to ''punish'' plans or beneficiaries. We disagree that this requirement weakens a plan sponsor's authority to partner with CMS in the fight against the opioid epidemic. As we've previously noted, the extensive case management involved with DMPs affords plans ample opportunity to work with an ARB to ensure appropriate limitations and will likely result in a very low volume of appeals.

Based on the comments we received, we are finalizing, with modification, our proposal to require a Part D plan sponsor to auto-forward to the IRE those redeterminations where a plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a DMP in accordance with § 423.153(f). Consistent with existing processes for untimely cases that are auto-forwarded to the IRE, we are modifying our proposal to state in this final rule that plans will be required to forward adverse DMP redetermination decisions to the IRE within 24 hours after expiration of the applicable adjudication timeframe. In addition, we are finalizing the proposed revision at § 423.600(b) that will apply the requirements related to the IRE soliciting the views of the prescribing physician or other prescriber if a case is forwarded to the IRE by a Part D plan sponsor. We are also finalizing the proposed requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*) to require that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. Finally, necessary modifications will be made to the Part D IRE's contract consistent with these final rules and related operational issues will be addressed in the IRE's reconsideration procedures manual. Pursuant to section 2007 of the SUPPORT Act, the automatic escalation provisions being finalized in this rule—at § 423.153(f)(5)(ii)(C)(*3*), § 423.153(f)(6)(ii)(C)(*4*)(*iii*), § 423.590(i), and § 423.600(b)—apply 60 days following publication of this final rule.

F. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

1. Medicare Parts C and D Anti-Fraud Efforts

CMS's role in overseeing the Medicare program includes ensuring that payments are made correctly and that fraud, waste, and abuse are prevented and detected. Failure to do so endangers the Trust Funds and may result in harm

to beneficiaries. CMS has established various regulations over the years to address potentially fraudulent and abusive behavior in Medicare Parts C and D. For instance, 42 CFR 424.535(a)(14)(i) addresses improper prescribing practices and permits CMS to revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part B or D drugs that is abusive or represents a threat to the health and safety of Medicare beneficiaries, or both.

2. SUPPORT Act—Sections 2008 and 6063

a. Background

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The Centers for Disease Control and Prevention (CDC) estimated 47,000 opioid overdose deaths in 2017, and 36 percent of those deaths involved prescription opioids.[21] On October 26, 2017, the Acting Health and Human Services Secretary, Eric D. Hargan, declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[22] This public health emergency has since been renewed several times by Secretary Alex M. Azar II.[23]

Section 2008 of the SUPPORT Act amends and adds several sections of the Act to address the concept of a ''credible allegation of fraud.'' Specifically:

• Sections 2008(a) and (b) of the SUPPORT Act amends sections 1860D–12(b) and 1857(f)(3) of the Act, respectively, by adding new requirements for Medicare Part D plan sponsors and MA organizations offering MA–PD plans. Specifically, the provisions—

++ Apply certain parts of section 1862(o) of the Act, regarding payment suspensions based on credible allegations of fraud, to Medicare Part D plan sponsors and MA organizations offering MA–PD plans, allowing them to impose payment suspensions on pharmacies in the same manner as these provisions apply to CMS.

++ Require these Part D plan sponsors and MA organizations offering MA–PD plans to notify the Secretary regarding the imposition of a payment suspension on a pharmacy pending an investigation of a credible allegation of fraud (but does not extend the requirement to report to the Secretary other payment suspensions for which plan sponsors already have authority).

++ Require this notification to be made such as via a secure internet website portal (or other successor technology) established under section 1859(i).

• Section 2008(d) of the SUPPORT Act, which amended section 1862(o) of the Act, states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

Although the effective date for these provisions of section 2008 of the SUPPORT Act is for plan years beginning on or after January 1, 2020, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary due to several factors. The first factor is the need to ensure that the web-based portal is complete and operational for plan sponsor's use. While the development of the web-based portal began when the legislation was enacted, CMS was unable to complete the development of the portal in time for its full implementation in plan year 2021. In addition, the portal has required several key updates to reflect the requirements in this regulation. Additional factors include the need to ensure the web-based portal is complete and operational for plan sponsor's use; the time needed for plan sponsors to determine internal procedures to meet the requirements outlined in this rule; the need for CMS to obtain feedback from plan sponsors to address any challenges encountered with the web-based portal; and the need to provide plan sponsors with the opportunity to address any other operational challenges with implementing these provisions, including potential changes that may be needed due to the COVID–19 public health emergency. Furthermore, the applicability date is later than the effective dates in the SUPPORT Act because the publication of this final rule is occurring after the bid deadline for plan year 2021. However, where the statute is self-implementing, the delay in applicability of these regulations is not a barrier to enforcement of the statutory provisions.

Section 6063(a) of the SUPPORT Act, which added a new paragraph (i)(1) to section 1859 of the Act, requires the following:

• The Secretary, after consultation with stakeholders, shall establish a secure web-based program integrity portal (or other successor technology) that would allow secure communication among the Secretary, MA plans, and prescription drug plans, as well as eligible entities with a contract under section 1893, such as Medicare program integrity contractors. The purpose is to enable, through the portal:

++ The referral by such plans of substantiated or suspicious activities (as defined by the Secretary) of a provider of services (including a prescriber) or supplier related to fraud, waste, or abuse for the purpose of initiating or assisting investigations conducted by the eligible entity; and

++ Data sharing among such MA plans, prescription drug plans, and the Secretary.

• The Secretary shall disseminate the following information to MA plans and prescription drug plans via the portal: (1) Providers and suppliers referred for substantiated or suspicious activities during the previous 12-month period; (2) providers and suppliers who are currently either excluded under section 1128 of the Act or subject to a payment suspension pursuant to section 1862(o) or otherwise; (3) providers and suppliers who are revoked from Medicare, and (4) in the case the plan makes a referral via the portal concerning substantiated or suspicious activities of fraud, waste, or abuse of a provider or supplier, the Secretary shall notify the plan if the related providers or suppliers were subject to administrative action under title XI or XVIII for similar activities.

• The Secretary shall, through rulemaking, specify what constitutes substantiated or suspicious activities of fraud, waste, or abuse, using guidance such as that provided in the CMS Pub. 100–08, Medicare Program Integrity Manual (PIM), chapter 4, section 4.8. In section 4.8 of the PIM, CMS provides guidance to its Medicare program integrity contractors on the disposition of cases referred to law enforcement. Similar to what is stated in section 2008(d) of the SUPPORT Act, a fraud hotline tip without further evidence does not constitute sufficient evidence for substantiated fraud, waste, or abuse.

• On at least a quarterly basis, the Secretary must make available to the plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. This information must be anonymized data submitted by plans without identifying the source of such information.

[21] *https://www.cdc.gov/drugoverdose/data/index.html.*

[22] *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[23] *https://www.phe.gov/emergency/news/healthehactions/phe/Pages/opioid-19apr2019.aspx.*

Although the effective date for these provisions of section 6063(a) of the SUPPORT Act is beginning not later than 2 years after the date of enactment, or by October 24, 2020, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary for the same reasons described previously in this section related to the provisions in section 2008 of the SUPPORT Act.

Furthermore, section 6063(b) of the SUPPORT Act, which amended section 1857(e) of the Act, requires MA organizations and Part D plan sponsors to submit to the Secretary, information on investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans, related to inappropriate prescribing of opioids. The Secretary shall, in consultation with stakeholders, establish a process under which MA organizations and Part D plan sponsors must submit this information. In addition, the Secretary shall establish a definition of inappropriate prescribing, which will reflect the reporting of investigations and other corrective actions taken by MA organizations and Part D plan sponsors to address inappropriate prescribing of opioids and the types of information that must be submitted.

Although the effective date for these provisions of section 6063(b) of the SUPPORT Act is for plan years beginning on or after January 1, 2021, we will be implementing these provisions with an applicability date that is for plan years beginning on or after January 1, 2022. This applicability date is necessary for the same reasons described previously in this section related to the provisions in section 2008 of the SUPPORT Act.

b. Need for Additional Measures

Existing regulations for MA and Part D plan sponsors in §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) specify that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs to CMS or its designee. (We note that § 422.503(b) generally outlines requirements that MA organizations must meet. Section 423.504(b) outlines conditions necessary to contract as a Part D plan sponsor.) Presently, MA organizations and Part D plan sponsors voluntarily report such data to CMS through either—(1) direct submissions to CMS, or (2) communication with the Investigations Medicare Drug Integrity Contractor (IMEDIC). Given the gravity of the nationwide opioid epidemic and the need for CMS and the plans to have as much information about potential and actual prescribing misbehavior as possible in order to halt such misbehavior, we are taking further regulatory action consistent with sections 2008 and 6063. Sections 2008 and 6063 of the SUPPORT Act provide the authority to establish regulations to implement a requirement for plans to report certain related data.

3. Proposed Provisions

Consistent with the foregoing discussion, we proposed the following regulatory provisions to implement sections 2008 and 6063 of the SUPPORT Act. As explained, some of our proposals modify or supplement existing regulations, while others establish new regulatory paragraphs altogether. Regulations related to Part C are addressed in 42 CFR part 422; those pertaining to Part D are addressed in 42 CFR part 423. Regulations pertaining to or contained in other areas of title 42 will be noted as such.

a. Definitions

The definitions outlined in this section of this rule will be effective following the required statutory deadlines for each reporting piece described in the SUPPORT Act. In the proposed rule, we proposed the definitions of substantiated or suspicious activities of fraud, waste or abuse and fraud hotline tip would be effective beginning October 24, 2020, and the definitions of inappropriate prescribing of opioids and credible allegations of fraud would be effective beginning January 1, 2021.

(1) Substantiated or Suspicious Activities of Fraud, Waste, or Abuse

We indicated earlier that section 6063(a) of the SUPPORT Act added a new section 1859(i)(1) to the Act requiring the establishment of a regulatory definition of ''substantiated or suspicious activities of fraud, waste, or abuse,'' using guidance such as that in CMS Pub. 100–08, PIM, chapter 4, section. 4.8. To this end, we proposed to add to §§ 422.500 and 423.4 a definition specifying that substantiated or suspicious activities of fraud, waste or abuse means and includes, but is not limited to allegations that a provider of services (including a prescriber) or supplier: Engaged in a pattern of improper billing; submitted improper claims with suspected knowledge of their falsity; submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or is the subject of a fraud hotline tip verified by further evidence. Consistent with the reference in section 6063(a) of the SUPPORT Act to chapter 4 of the PIM, our proposed definition largely mirrored that in section 4.8 of the PIM. We also believe that this definition is, importantly, broad enough to capture a wide variety of activities that could threaten Medicare beneficiaries and the Trust Funds. We solicited public comment on this definition.

We received several comments on the definition of ''substantiated or suspicious activities of fraud, waste or abuse'' and our responses to those comments follow.

Comment: A professional organization supported this definition and mentioned that it would ensure targeted streamlined fraud reporting.

Response: We appreciate the comment and support of the definition and we are finalizing the definition as proposed.

Comment: Several commenters raised concerns with the definition of substantiated and suspicious activity. Some commenters requested additional information regarding the scope of the definition. One commenter recommended that CMS provide additional guidance on the definition of ''pattern of improper billing.'' Other commenters wanted to know what specific criteria will be used for substantiated and suspicious reporting. Another commenter was concerned with CMS's use of language such as ''substantiated'' and ''suspicious.''

Response: In defining what constitutes substantiated or suspicious activities of fraud, waste, and abuse, we looked to guidance currently in the Medicare Program Integrity Manual 4.8. Section 6063 of the SUPPORT Act further clarifies that a fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse. We believe the definition that we are finalizing will address the commenters' concerns as it reflects the SUPPORT Act requirement to establish the definition using guidance such as that provided in the Medicare Program Integrity Manual 4.8. In an effort to be consistent across our programs, we believe the definition as proposed provides a similar context for what is to be reported as the PIM outlines for fee-for-service. Based on the comments received and our responses we are finalizing the proposed definition without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(2) Inappropriate Prescribing of Opioids

Section 6063(b) of the SUPPORT Act, as mentioned previously, states the Secretary is required to establish: (1) A definition of inappropriate prescribing; and (2) a method for determining if a provider of services meets that definition. MA organizations and Part D Plan Sponsors must report actions they take related to inappropriate prescribing of opioids. We accordingly proposed to add the following definition of inappropriate prescribing with respect to opioids to §§ 422.500 and 423.4. We proposed that inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D Plan Sponsors, there is an established pattern of potential fraud, waste and abuse related to prescribing of opioids, as reported by the Plan Sponsors.

In determining whether inappropriate prescribing of opioids has occurred we proposed that plan sponsors may consider any number of factors including, but not limited to the following: Documentation of a patient's medical condition; identified instances of patient harm or death; medical records, including claims (if available); concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm; levels of Morphine Milligram Equivalent (MME) dosages prescribed; absent clinical indication or documentation in the care management plan, or in a manner that may indicate diversion; State level prescription drug monitoring program (PDMP) data; geography, time and distance between a prescriber and the patient; refill frequency and factors associated with increased risk of opioid overdose.

We believe the many steps that CMS, the CDC, and HHS have taken in response to the nation's opioid crisis have had an overall positive impact on clinician prescribing patterns, resulting in safer and more conscientious opioid prescribing across clinician types and across the settings where beneficiaries receive treatment for pain, and have also resulted in heightened public awareness of the risks associated with opioid medications. For example, recent HHS guidance [24] highlights the importance of judicious opioid prescribing that minimizes risk and; urges collaborative, measured approaches to opioid dose escalation, dose reduction, and discontinuation; furthermore, a 2019 HHS Task Force report [25] outlines best practices for multimodal approaches to pain care. In this definition, we recognized that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing based on the clinician's professional judgement, including, the beneficiary's clinical indications and characteristics, whether the prescription is for an initial versus a subsequent dose, clinical setting in which the beneficiary is being treated, and various other factors. We sought public comments on specific populations or diagnoses that could be excluded for purposes of this definition, such as cancer, hospice, and/or sickle cell patients. Based upon widely accepted principles of statistical analysis and taking into account clinical considerations mentioned previously, we noted that CMS may consider certain statistical deviations to be instances of inappropriate prescribing of opioids. We requested evidence from clinical experts regarding evidence based guidelines for opioid prescribing across clinical specialties and care settings that could be considered to develop meaningful and appropriate outlier methodologies. Therefore, we proposed that inappropriate prescribing of opioids should be based on an established pattern as previously described in this section utilizing many parameters.

We solicited public comment on other reasonable measures of inappropriate prescribing of opioids.

We received numerous comments regarding the definition of inappropriate prescribing and on other reasonable measures of inappropriate prescribing of opioids and our responses follow.

Comment: Two professional associations supported the definition outlined in the rule.

Response: We appreciate the comments from prescribing professionals that also support our proposed definition. We will be finalizing the definition, as described in this final rule.

Comment: We received comments from one advocacy group which criticize the definition of ''inappropriate prescribing''. The comments made by the advocacy group were also referred to by several other individual commenters who endorsed their concerns. The advocacy group asserted that CMS's proposal contains an inappropriate view of the ''risks'' of opioid prescribing for people in pain, which could be used for denial of pain treatment.'' As an alternative, they recommend better training of physicians in the management of chronic pain. Furthermore, the commenters noted that HHS' actions have focused on ''what is likely to be a minor problem (physician overprescribing)'' instead of illegal drug use and abuse.

Response: Section 6063 of the SUPPORT ACT required us to adopt a definition of inappropriate prescribing of opioids. In response to the statement that overprescribing may be a minor problem, we disagree and cite a real example of how prescribing authority can be used inappropriately. In September 2019, federal law enforcement officials announced ''charges against 13 individuals across five Appalachian federal districts for alleged offenses relating to the over prescription of controlled substances through 'pill mill' clinics. Of those charged, 12 were charged for their role in unlawfully distributing opioids and other controlled substances and 11 were physicians. The alleged conduct resulted in the distribution of more than 17 million pills.'' [26] In relation to concerns raised about provider education and training, we would note that the subject is out of scope for this regulation.

Comment: One commenter stated that CMS should consider certain statistical outliers and/or individual beneficiary cases of overutilization while another commenter stated that the definition of inappropriate prescribing must be limited to suspected fraud, not only outlier prescribing patterns. Another commenter noted that CMS should amend the proposed definition of inappropriate prescribing to ''potential'' with ''material and repeated intentional acts of''. Another commenter recommended that CMS add reasonable measures of inappropriate prescribing of opioids- for example, CMS should consider including any off-guideline use, including prescriptions for large quantities to opioid-naïve members. Another commenter believed that a peer physician from the same specialty, after considering specific patient needs, is most qualified to determine whether opioids have been prescribing appropriately. Another commenter was concerned that without specifically defining ''inappropriate prescribing'' a subjective approach may be taken in initiating actions involving suspicious

[24] ''HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics'' found at *https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf.*

[25] *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

[26] *https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13.*

activities that may warrant investigation.

Response: We believe the proposed rule was clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. The list of factors is not meant to be exhaustive list of factors that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. The information provided in the definition is sufficient and will assist the agency in identifying providers with patterns of potential fraud, waste and abuse related to opioid prescribing. It is important to note that most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids.

Comment: A few commenters believe the insurance companies' authority is too broad in determining inappropriate prescribing.

Response: The Medicare prescription drug benefit is delivered through Medicare Part D plans and many of the plan sponsors are insurance companies. We have considered industry guidelines and policies in defining inappropriate prescribing. Most Part D plan sponsors already have Special Investigative Units which have detection and prevention procedures in place to address cases of inappropriate prescribing of opioids.

Comment: A commenter stated that although the definition of inappropriate prescribing calls for a more comprehensive review, there are concerns that the focus will be on dose and quantity without consideration of other factors that affect patients and physicians.

Response: As we have stated in our previous responses to comments, we believe the proposed rule was clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. The list of factors is not meant to be an exhaustive list that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. In addition to the list of factors, we have also considered industry guidelines and policies in defining inappropriate prescribing. We believe the information provided is sufficient in assisting plans to identify established patterns of potential fraud, waste and abuse related to prescribing of opioids. As we stated previously in this section, most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids. However, under section 6063 of the SUPPORT Act, plans will now be required to report any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

Comment: There were numerous commenters who suggested that CMS consider exceptions such as Long Term Care, cancer survivors, high risk surgical patients, chronic pain, end stage chronic lung disease and rare genetic disorders, when reviewing for inappropriate prescribing. There were also comments that recommended that CMS consider prescriber specialties when defining inappropriate prescribing. One commenter suggested that CMS specify that the factors listed does not include an exhaustive list of patterns that would contribute to inappropriate opioid prescribing. A commenter also expressed concern that CMS creating blanket exclusions from the analysis has the potential for fraud and recommended that CMS not exclude any drug type, specific populations or diagnosis.

Response: As mentioned in the preamble, we recognize that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing. Cancer, hospice, and sickle cell patients have been identified as exclusions in other sections of the regulation, such as the updated drug management program provisions at § 423.100. To ensure that vulnerable populations continue to have access to care, we are finalizing the proposed definition of inappropriate prescribing with a modification such that beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services will be exempt from consideration for the inappropriate prescribing of opioids. We clarify that LTC, in this context, means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act. These exemptions were added to be consistent with other areas of the proposed regulation as well as the current regulatory exemptions at § 423.100. However, just as plan sponsors may consider a number of factors such as MME levels, concurrent prescribing of opioids with an opioid potentiator, and time and distance between the prescriber and the patient when determining inappropriate prescribing of opioids, plan sponsors may also apply the same judgment when considering other diseases or clinical factors or scenarios that have not been listed in the definition. Plan sponsors should use all information available to them in determining inappropriate opioid prescribing. These exclusions also do not preclude plan sponsors from reporting on a voluntary basis under §§ 422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(G)(3).

Comment: Several comments were received in response to use of MME levels as a factor in determining opioid overprescribing. Commenters were concerned that CMS does not exempt opioid use disorder treatment from MME guidelines. Another commenter stated a consensus definition of MME dosages does not exist and expressed concern with a policy that allows Plan Sponsors to rely on MME dosages. Another commenter mentioned that the MME is not an appropriate factor in determining abuse. A commenter suggested excluding MME levels as a factor in any analysis of inappropriate prescribing.

Response: We believe the proposed rule is clear in that plan sponsors may consider a number of factors when determining what constitutes inappropriate prescribing of opioids. Most Part D plan sponsors already have detection and prevention measures in place to address cases of inappropriate prescribing of opioids. It is our understanding that MME are already utilized as part of many plan sponsors measures to address FWA. As such, we believe MME is an important factor that might be considered when identifying inappropriate prescribing of opioids. The list of factors is not meant to be an exhaustive list of factors that would contribute to the identification of fraud waste and abuse related to inappropriate prescribing of opioids. The information provided in the definition is sufficient in assisting plans to identify established patterns of potential fraud, waste and abuse related to prescribing of opioids.

Comment: There were comments seeking clarification regarding if a pharmacy would be considered a provider and could be identified as having ''Inappropriate Prescribing of Opioids,'' or if this proposed policy would only refer to actual medical professionals who can prescribe opioids.

Response: Based on the comments, there may be some misunderstanding of the reporting requirements cited in section 2008 of the SUPPORT Act versus section 6063 of the SUPPORT Act. Section 2008 of the SUPPORT Act requires plan sponsors to notify the Secretary of the imposition of a pharmacy payment suspension that is

based on a credible allegation of fraud. That reporting will be done using a secure website portal. Section 6063 of the SUPPORT Act requires reporting information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. For purposes of section 6063(b), plan sponsors may consider a pharmacy a supplier.

Comment: Commenters expressed concern with the use of geography, time and distance between the prescriber and the patient as a factor for opioid overprescribing. Specifically, one commenter stated that many people are forced to travel long distances not because of doctor shopping or pharmacy hopping, but because pain clinics have been shut down and primary doctors are refusing to see pain patients. Another commenter stated that for people with complex disabilities, geographically distant specialists may be the best (or only) care providers available. Another commenter stated that absent of fraud, high dosage and distance should not be considered indicators of inappropriate prescribing.

Response: We realize that there may be some circumstances in which a beneficiary may travel a considerable distance for access to a pharmacy or provider, for legitimate reasons. Plan sponsors may consider any number of factors when determining what constitutes inappropriate prescribing of opioids, in addition to geography time and distance. The list included in the proposed rule is not meant to be an exhaustive list of factors that may be used in the identification of fraud waste and abuse related to inappropriate prescribing of opioids.

Comment: We received several comments stating that illicit drugs, not prescription drugs, have contributed to the opioid crisis. Commenters also requested that CMS monitor to ensure that these actions do not encourage providers to be unnecessarily conservative when prescribing opioids which could limit access to older adults. Commenters also noted that CMS should encourage plan sponsors to align best practices, as published in the HHS Pain Management Best Practices Inter-Agency Task Force report.

Response: In response to the statement that illicit drugs, not prescription drugs, have contributed to the opioid, we disagree and cite a real example of how prescribing of prescription opioids can be used inappropriately. In September 2019, federal law enforcement officials announced ''charges against 13 individuals across five Appalachian federal districts for alleged offenses relating to the over prescription of controlled substances through 'pill mill' clinics. Of those charged, 12 were charged for their role in unlawfully distributing opioids and other controlled substances and 11 were physicians. The alleged conduct resulted in the distribution of more than 17 million pills.'' [27] Our proposed provisions are to ensure that fraud, waste, and abuse are prevented and detected and our Medicare population is protected from harm from opioid prescriptions. We have established several regulations over the years to promote patient safety and address potentially fraudulent and abusive behavior in Medicare Parts C and D. We are considering ways to effectively monitor the impact of these provisions. The provisions in the SUPPORT Act that we proposed to implement will add additional ways to ensure effective monitoring and oversight of prescribing practices related to opioids.

Based on the overwhelming feedback from health plans, professional societies, advocacy groups and individuals, we have determined there is a need to add exemptions when determining inappropriate prescribing of opioids. While there is no way to include every possible disease state that could be considered, we will add beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services as exclusions. These disease states were selected not only because they are clinically applicable but they align with existing exemptions in other CMS policies, such as the updated drug management program provisions at § 423.100. In addition, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(3) Credible Allegation of Fraud

Somewhat similar to section 6063(a) of the SUPPORT Act, section 2008(d) of the SUPPORT Act states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud. The term ''credible allegation of fraud'' is currently defined at §§ 405.370 and 455.2 (which, respectively, apply to Medicare and Medicaid) as an allegation from any source including, but not limited to the following: (1) Fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability, and, in the case of § 455.2, the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

To address the requirements of section 2008(d) of the SUPPORT Act, we proposed to revise the term ''credible allegation of fraud'' in §§ 405.370 and 455.2 as follows. We proposed that the existing version of paragraph (1) in both §§ 405.370 and 455.2 would be amended to state ''Fraud hotline tips verified by further evidence.'' The existing version of paragraph (2) and (3) would remain unchanged. Similarly, we proposed to add in § 423.4 a definition of credible allegation of fraud stating that a credible allegation of fraud is an allegation from any source including, but not limited to: Fraud hotline tips verified by further evidence; claims data mining; patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. In the case of § 423.4, we proposed that examples of claims data mining would include, but are not limited to, prescription drug events and encounter data mining. We solicited public comment on this definition.

We received several comments on the definition of Credible Allegation of Fraud and our responses follow.

Comment: A professional organization supported the proposed revised definition of credible allegation of fraud.

Response: We appreciate the comments from prescribing professionals that also support our proposed definition. We are finalizing the definition, as proposed in this final rule.

Comment: A commenter expressed concern that a credible allegation results in damage to the professional reputations of doctors and pharmacists.

Response: We note that credible allegation of fraud in this context is used when plan sponsors are implementing payment suspensions of pharmacies. Plan sponsors already have the authority to implement a payment suspension at their discretion according to their contracts with the pharmacies. When they implement a payment suspension that is based on a credible allegation of fraud and meets the regulatory definition, now they must report it to CMS. We have defined

[27] *https://www.justice.gov/opa/pr/second-appalachian-region-prescription-opioid-strikeforce-takedown-results-charges-against-13.*

credible allegations of fraud under § 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent is to only apply definitions for MA and Part D plans that are consistent with regulatory standards that are applied to both traditional Medicare and Medicaid. Accordingly, plan sponsors currently impose payment suspensions based on credible allegations of fraud and we recognize that MA and Part D plans currently use multiple sources in determining what may be considered ''credible allegation of fraud'' as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse.

Comment: Some commenters requested that CMS provide examples of credible evidence and provide clarification on the standards, thresholds and responsible party for reporting. One commenter believes that examples will assist plans in determining credible allegations of fraud and address fraudulent opioid prescribing. Another commenter recommended that CMS proactively communicate with plans on fraud schemes to assist in enhancing the plans oversight efforts.

Response: The regulations are being amended as specified in the SUPPORT Act section 2008(d) to extend a consistent regulatory definition for MA and Part D plans. We have defined credible allegations of fraud under 405.370 in previous rulemaking. As noted previously, the Plans will be required to report payment suspensions of pharmacies to CMS based on credible allegations of fraud. Accordingly, we recognize that MA and Part D plans currently may use a variety of sources in determining what may be considered ''credible allegation of fraud'' as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse. We also conduct regular training and education for Plan Sponsors on fraud detection and prevention and provides opportunities for the Plans to share information on fraud schemes. Therefore, we will continue to allow plans the flexibility in determining credible allegations of fraud and will finalize this provision without additional examples other than what is currently defined.

Comment: A commenter recommended amending the proposed definition of credible allegation to an allegation from a plan of a material and repeated pattern of intentional violations of law or regulations that has been confirmed beyond suspicion through independent evidence. Allegations by third parties, including False Claims Act cases, law enforcement investigations and provider audits shall not constitute credible allegations of fraud.

Response: We have defined credible allegations of fraud under 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent of this provision is to implement the SUPPORT ACT which extends a consistent definition for MA and Part D plans. Accordingly, we recognize that MA and Part D plans currently use a variety of sources in determining what may be considered ''credible allegation of fraud'' as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse. We will proceed as noted previously in this section with finalizing the proposed definition without modification.

Comment: An association supported the proposed revision of the regulatory definition of credible allegation of fraud described in the proposed rule, changing ''fraud hotline complaints'' to ''fraud hotline tips verified by further evidence.'' Another association also specifically supported our proposal that a fraud hotline top without further evidence shall be not be treated as credible allegation of fraud.

Response: We appreciate the support for the proposal to further define credible allegation of fraud by expanding the definition of fraud hotline complaint to fraud hotline tips verified by further evidence. We believe this will further assist plans in determining cases of fraud.

Comment: A commenter recommended that CMS provide training programs for health plan fraud units and guidance regarding the definition of credible allegation.

Response: We have defined credible allegations of fraud under 405.370 in previous rulemaking. The regulations are being amended as specified in the SUPPORT Act section 2008(d). The intent is to only establish similar and consistent definitions for MA and Part D plans. We conduct regular training and education for Plan Sponsors on fraud detection and prevention and provides opportunities for the Plans to share information on fraud schemes. We recognize that MA and Part D plans currently use a variety of sources in determining what may be considered ''credible allegation of fraud'' as part of ensuring measures have been implemented to prevent, detect and correct fraud, waste and abuse.

Comment: A commenter specifically did not support the definition of credible allegation of fraud given that further evidence is not defined.

Response: The definition uses plain language and is intended to allow flexibility since evidence to corroborate the fraud hotline complaint or tip would vary on a case by case basis. Additionally, Part D sponsors have systems in place and experience with the evaluation and verification of fraud hotline tips.

Based on the comments received and our responses we are finalizing the provision as proposed without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(4) Fraud Hotline Tip

Sections 2008(d) and 6063(a) of the SUPPORT Act require the Secretary to define a fraud hotline tip. To this end, we proposed to add to §§ 405.370, 422.500, 423.4, and 455.2 a plain language definition of this term. We proposed that a fraud hotline tip would be defined as a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the federal government's HHS Office of the Inspector General (OIG) Hotline or a health plan's fraud hotline. This definition is intended to be broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's fraud hotline. Many private plans, which have their own fraud reporting hotlines, participate as plan sponsors in Medicare Part D and this definition would seek to reflect their processes for reporting information on potential fraud, waste and abuse. We solicited public comment on this definition.

We received several comments on the definition of Fraud Hotline Tip. Our responses to those comments follow.

Comment: Several commenters supported the proposed definition of a fraud hotline tip including a professional association. Commenters that were supportive agreed that this definition will assist plans on ensuring investigative measures are taken and focus on those that indicate fraud.

Response: We appreciate the support and feedback on the proposal to further define a fraud hotline tip. As mentioned in the proposed rule we believe the definition is broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's hotline.

Comment: A commenter also recommended that CMS provide examples of other communications that may be submitted through a fraud reporting phone number or website.

Response: As mentioned in the proposed regulation, the definition is intended to be broad in an effort to allow flexibility. Part D sponsors are currently required to have systems established to receive and process fraud hotline tips. Therefore, we believe many Part D sponsors have the experience with using ''other communications'' which could include information such as supporting documentation submitted with the tip that may be used to support a complaint or document potential fraud.

Comment: Another commenter urged that CMS ensure tips are verified before they are used to suspend a provider or prescriber.

Response: The definition proposed does include language to state that a fraud hotline tip must be verified by further evidence. As mentioned in the proposed regulation the definition is intended to be broad in an effort to allow flexibility since many plan sponsors have a fraud hotline and systems established for receiving and verifying potential fraud.

Based on the comments received and our responses we are finalizing the provision as proposed without modification; however, the applicability date for this definition will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

b. Reporting

(1) Vehicle for Reporting

We stated that we planned to utilize a module within the HPMS as the program integrity portal for information collection and dissemination. We stated that the portal would serve as the core repository for the data addressed in sections 2008 and 6063 of the SUPPORT Act. We stated that the program integrity portal would not duplicate reporting requirements and is the only source that would be used to report and disseminate information as required in the final rule. Such data and the regular submission and dissemination of this important information would, in our view, strengthen CMS' ability to oversee plan sponsors' efforts to maintain an effective fraud, waste, and abuse program. We further believe that data sharing via use of a portal would, in conjunction with our proposals, help accomplish the following objectives in our efforts to alleviate the opioid epidemic:

- Enable CMS to perform data analysis to identify fraud schemes.
- Facilitate transparency among CMS and plan sponsors through the exchange of information.
- Provide better information and education to plan sponsors on potential fraud, waste, and abuse issues, thus enabling plan sponsors to investigate and take action based on such data.
- Improve fraud detection across the Medicare program, accordingly allowing for increased recovery of taxpayer funds and enrollee expenditures (for example, premiums, co-insurance, other plan cost sharing).
- Provide more effective support, including leads, to plan sponsors and law enforcement.
- Increase beneficiary safety through increased oversight measures.

We received a few comments on our planned reporting vehicle and our responses follow.

Comment: Several commenters noted reporting through a new HPMS module will create duplication of information and recommended that CMS institute one consistent reporting mechanism since plans can report directly to the MEDIC or into the HPMS, allow greater access to expedite reporting and provide further clarification where Part D sponsors should report.

Response: The program integrity portal will not duplicate reporting requirements and is the only source that will be used to report and disseminate information as required in the final rule.

Comment: A commenter inquired about the difference between the new portal and existing HPMS module and also questioned how plans will be assured that CMS will investigate the allegations submitted.

Response: The current Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) module in HPMS will continue to serve as a repository for data projects that plan sponsors currently use as leads and a resource in conducting oversight of their fraud detection and prevention efforts. The new program integrity portal in HPMS will be the primary source for plan sponsors to submit information related to the inappropriate prescribing of opioids, payment suspensions of Part D pharmacies, and referral of substantiated or suspicious activities of a provider of services or supplier related to fraud, waste, and abuse.

(2) Type of Data To Be Reported by Plans

Sections 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), as noted, state that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs, respectively, to CMS or its designee. To conform to the aforementioned requirements of sections 2008(a) and (b) and section 6063(b) of the SUPPORT Act, we proposed to add new regulatory language, effective beginning in 2021, in parts 422 and 423 as stated throughout this section.

First, we proposed new language at §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to include the new provisions. The new §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would state that the MA organization or Part D plan sponsor, respectively, must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

- Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and
- Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

Second, the new §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) would require the data referenced in proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to be submitted via the program integrity portal. We proposed that MA organizations and Part D plan sponsors would have to submit the data elements, specified later in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by plan sponsors; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

- Date of Referral
- Part C or Part D Issue
- Complainant Name.
- Complainant Phone.
- Complainant Fax.
- Complainant Email.
- Complainant Organization Name.
- Complainant Address.
- Complainant City.
- Complainant State.
- Complainant Zip.
- Plan Name/Contract Number.
- Plan Tracking Number.
- Parent Organization.
- Pharmacy Benefit Manager.
- Beneficiary Name.
- Beneficiary Phone.
- Beneficiary Health Insurance Claim Number (HICN)
- Beneficiary Medicare Beneficiary Identifier (MBI).
- Beneficiary Address.
- Beneficiary City.
- Beneficiary State.
- Beneficiary Zip.
- Beneficiary Date of Birth (DOB).
- Beneficiary Primary language.
- Beneficiary requires Special Accommodations. If Yes, Describe.
- Beneficiary Medicare Plan Name.
- Beneficiary Member ID Number.
- Whether the Beneficiary is a Subject.
- Did the complainant contact the beneficiary? If Yes, is there a Report of the Contact?
- Subject Name.
- Subject Tax Identification Number (TIN).
- Does the Subject have Multiple TIN's? If Yes, provide.
- Subject NPI.
- Subject DEA Number.
- Subject Medicare Provider Number.
- Subject Business.
- Subject Phone Number.
- Subject Address.
- Subject City.
- Subject State.
- Subject Zip.
- Subject Business or Specialty Description.
- Secondary Subject Name.
- Secondary Subject Tax Identification Number (TIN)
- Does the Secondary Subject have Multiple TIN's? If Yes, provide.
- Secondary Subject NPI.
- Secondary Subject DEA Number.
- Secondary Subject Medicare Provider Number.
- Secondary Subject Business.
- Secondary Subject Phone Number.
- Secondary Subject Address.
- Secondary Subject City.
- Secondary Subject State.
- Secondary Subject Zip.
- Secondary Subject Business or Specialty Description.
- Complaint Prior MEDIC Case Number.
- Period of Review.
- Complaint Potential Medicare Exposure.
- Whether Medical Records are Available.
- Whether Medical Records were Reviewed.
- Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
- What Law Enforcement Agency(ies) has it been Referred to.
- Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.
- Whether the submission has indicated Patient Harm or Potential Patient Harm.
- Whether the submission has been Referred. If so, provide Date Accepted.
- What Agency was it Referred to.
- Description of Allegations/Plan Sponsor Findings.

We noted that the requirement for reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies under new § 422.503(b)(4)(vi)(G)(*4*) would only apply to Medicare Part C in the context of Medicare Advantage Prescription Drug Plans (MA–PD plans). We stated our belief that this information is necessary to enable CMS to fully and completely understand the identity of the applicable party, the specific behavior involved, and the status of the action. We solicited public comment on these requirements.

We received several comments on the ability to impose payment suspensions on pharmacies and our responses to those comments follow.

Comment: A commenter supported CMS' implementation of the SUPPORT Act language that a fraud hotline tip, without further evidence, is not a credible fraud allegation for payment suspension purposes. However, the commenter was concerned that CMS did not include what guidelines should be taken into consideration for procedures and data collection.

Response: We appreciate the commenter's support. However, many plan sponsors currently implement payment suspensions based on credible allegations of fraud and other reasons that may be contractual in nature. We believe that plan sponsors have established procedures and data collection based on their existing internal policies and procedures and as part of their fraud, waste and abuse oversight and monitoring efforts. The data will be reported through a program integrity portal that is discussed further later in this regulation.

Comment: Commenters requested that CMS further clarify the definition of a payment suspension, such as what entities are subject to payment suspensions, whether payment suspensions are applicable to physicians, and the applicable standards and responsible parties for making determinations.

Response: We believe the proposed regulation is clear in defining that a Part D pharmacy payment suspension based on credible allegation of fraud is applicable to Part D pharmacies. Additionally, we believe the proposed regulation is clear in stating that Part D plan sponsors are responsible for determining if a payment suspension should be implemented. Part D plan sponsors currently impose payment suspensions for other reasons that may be contractual in nature. Part D plan sponsors are responsible for oversight of their contracted entities, such as pharmacy benefit managers (PBMs) and pharmacies, and have established policies and procedures in their contractual arrangements.

Comment: A commenter recommended that CMS consider a targeted approach to payment suspensions, which would include pharmacy claim adjudications suspensions that would allow non-problematic claims from suspected pharmacies to be processed and paid. Another commenter questioned if CMS will have a process to reverse or deny payments.

Response: Part D plan sponsors and MA–PD plans have the authority to impose payment suspensions based on a credible allegation of fraud. However, Part D plan sponsors and MA–PD plans also may consider a targeted approach to payment suspensions pursuant to contractual agreements. Part D plan sponsors and MA–PD plans are responsible for oversight of their contracted entities, such as PBMs and pharmacies, and have established policies and procedures in their contractual arrangements.

Comment: A commenter opposed CMS' proposal to suspend payments to fee-for-service (FFS) providers and suppliers pending a credible allegation of fraud, given that patients and providers can be at risk for an uncertain amount of time. The commenter also opposed the definition for credible allegation of fraud based on the need to establish clear guidance on how long a payment suspension will last and the concern that LTC's will be financially liable.

Response: We appreciate this feedback; however, although we proposed a modification to the reference to fraud hotline complains in 42 CFR 405.370, our proposal did not discuss payment suspensions for fee-for-service providers generally. Instead, the scope of this rule is limited to payment suspensions imposed on pharmacies by Part D plan sponsors. Part D plan sponsors currently conduct pharmacy payment suspensions based on credible allegations of fraud. This final rule is requiring Part D plan sponsors to report to CMS any pharmacy payment suspensions based on credible allegations of fraud through a website portal. The length of a payment suspension may vary based on the situation and the plan sponsors own business agreements.

Comment: We received a couple of comments regarding how the reporting of payment suspensions may interfere or preempt state-level requirements regarding payment to pharmacies.

Response: We have contractual agreements with the Part D plan sponsors and do not oversee contractual relationships between a plan sponsor, PBM and participating pharmacies. Part D Plan sponsors already have the authority to implement payment suspensions for pharmacies based on credible allegations of fraud. However, Section 2008 of the SUPPORT Act requires Part D plan sponsors to report those payment suspensions to the Secretary.

The requirement for Part D plan sponsors to report pharmacy payment suspensions based on credible allegations of fraud does not replace state law and this new federal requirement will not affect existing state statutes and regulations. We believe addressing specific state statutes and regulations are outside the scope of this regulation.

Comment: We received several comments expressing concerns with ensuring pharmacies have due process rights, an appeals process and advance notice prior to implementing a payment suspension. One commenter opposed this proposed regulation because it lacks fundamental due process protections for pharmacies. Another commenter noted that pharmacies should not be subject to payment suspension without greater certainty of fraud. Additionally, the commenter noted that pharmacies should receive advance notice of potential allegations of fraud and afforded an expeditious appeals process prior to any payment suspension. Commenters also noted that payment suspensions should not occur until there is legal evidence and also requested that CMS provide guidance on ensuring that plan actions against pharmacies are fully grounded with evidence and provides pharmacies the ability to quickly address complaints and prevent suspension of payment.

Response: Section 2008 authorizes Part D sponsors and MA–PD plans to suspend payments based on a credible allegation of fraud. Part D plan sponsors and MA–PD plans may currently impose payment suspensions for other reasons that may be contractual in nature. We have clarified the definition for credible allegation of fraud, fraud hotline tip, and substantiated and suspicious activities of fraud, waste and abuse. We decline to accept the recommendation because Part D plan sponsors and MA–PD plans are responsible for oversight of their contracted entities, such as PBMs and pharmacies and have established policies and procedures in their contractual arrangements.

We received a few comments on the data elements to be submitted by plans and our responses follow.

Comment: A commenter recommended that CMS allow flexibility in submitting data elements and allow Part D sponsors to enter ''blank'' fields if certain information is not available and not restrict the number of users. Commenter also recommended that information provided to Part D sponsors from the website portal be used for informational purposes only. However, if action is required on behalf of the Part D sponsors, then CMS should clearly specify.

Response: In response to the comment, we are clarifying that plan sponsors will be provided reporting flexibility within the portal when information is not available or not relevant to the referral being reported. The comment also allowed us the opportunity to re-evaluate the level of detail that we were requiring in the regulatory text for the data reported. We are modifying the regulatory text to reflect broad categories of information that will be collected rather than individual data elements. The data categories, as applicable, include referral information and actions taken by the plan sponsor on the referral.

Examples of the types of data to be collected in these categories include, but are not limited to, identifying information on the complainant, beneficiary, and subject of the referral, description of the referral (that is, services not rendered, prescriptions billed but the beneficiary never received, and identity theft), and any actions taken (that is, conducted an audit of the provider, referred the provider to the IMEDIC or Law Enforcement, or removed a provider from their network). The categories of data that we are making final in the regulatory text will provide flexibility.

The commenter also inquired if action is required on behalf of the Part D sponsors based on information provided from the website portal. The quarterly reports we are sharing will assist plan sponsors with their monitoring and oversight efforts. These reports themselves are not a sufficient basis for a Medicare Part D plan sponsor to take action without conducting its own supporting analysis of specific data. We urge plan sponsors to confirm potential fraud waste and abuse through a reliance upon their own established protocols. Any actions taken as a result of the reports and the Sponsors follow-up activities should be reported through the website portal. We also note, in response to the commenter, that plan sponsors will also have the ability to allow access to multiple users.

Comment: Commenters also requested that CMS clarify why the required data elements list both the HICN and the MBI. Commenters also requested clarification who should the reporting be submitted to and the method that should be utilized.

Response: In response to the comment, we are clarifying that only the MBI will be utilized, as part of the broad category of referral information, to ensure that the beneficiary's information is captured appropriately. Plan sponsors will be required to report information through the program integrity portal in HPMS.

Based on the comments received and our responses we are modifying the regulatory text regarding the data to be reported. The final regulation text reflects the broad categories of data that CMS will employ in the construction of the data that will be required for plans to submit to the program integrity portal. In addition, the applicability date for plan sponsor reporting will be for plan years beginning on or after January 1, 2022 for reasons previously discussed in this section.

(3) Timing of Plan Sponsor's reporting

We proposed in new §§ 422.503(b)(4)(vi)(G)(*6*)(*i*) and 423.504(b)(4)(vi)(G)(*6*)(*i*) MA organizations and Part D plan sponsors would be required to notify the Secretary, or its designee of a payment suspension described in §§ 422.503(b)(4)(vi)(G)(*4*)(*i*) and 423.504(b)(4)(vi)(G)(*4*)(*i*) 14 days prior to implementation of the payment suspension. This timeframe will allow

us to provide our law enforcement partners sufficient notice of a payment suspension to be implemented that may impact an ongoing investigation into the subject. We proposed that §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*) plans would be required to submit the information described in §§ 422.503(b)(4)(vi)(G)(*4*)(*ii*) and 423.504(b)(4)(vi)(G)(*4*)(*ii*) no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We proposed that plans would be required to submit information beginning in 2021. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31). We believe that quarterly updates would be frequent enough to ensure that the portal contains accurate and recent data while giving plans sufficient time to furnish questioned information. We solicited public comment on the timing of reporting by plans

We received several comments on the timing of reporting by plans and our responses to those comments follow.

Comment: We received numerous comments regarding the 14-day advance notice to CMS for payment suspensions. Most commenters are concerned that this gives the bad actors too much time to continue the fraudulent activity which could result in millions of dollars lost, prevent overutilization of services and more importantly, beneficiary harm. A commenter suggested a 72-hour wait period instead of 14 days. Another commenter recommended allowing plans 72 hours to notify CMS after the suspension rather than 14 days prior to the suspension. One commenter recommended immediate payment suspension of pharmacies and then provide referral within 14 days to CMS. Another commenter mentioned that allowing plans to submit payment suspension immediately and provide an update monthly will reduce burden for plans sponsors and PBMs. Another commenter recommended CMS provide a list of providers for plans to review prior to initiation of a payment suspension which would require plans to notify the agency within 14 days prior to implementing. Additionally, if providers are not included in the notification plans would notify the agency within 5–10 days of the payment suspension which would align with many Medicaid state guidelines. Commenters also expressed confusion regarding whether plans were being prohibited from suspending immediately. Another commenter recommended removal of a suspension if it is determined that there is no good cause.

Response: Based on comments received requesting a reduced timeframe for advance notice of imposing payment suspensions and balancing that with concerns raised by our federal law enforcement partners to ensure deconfliction, we will finalize the provision with a 7-day advance notice requirement with a limited exception. The advance notice provides collaboration and necessary deconfliction with law enforcement but also allows an exception for instances where more immediate payment suspension is warranted. For example, the exception would allow for immediate suspension when a plan has concerns regarding a credible allegation of fraud which may involve potential patient harm.

Comment: Commenters also recommended that CMS allow exceptions from the proposed quarterly reporting when disclosure may jeopardize an ongoing investigation. Commenters also requested that CMS extend reporting to 30 days of the close of the quarter versus the proposed 15 days to allow data gathering and quality assurance before the report submission.

Response: Based on the comments received we will modify the proposed provision to extend the reporting timeframe for plan sponsors to 30 days after the close of the quarter. We will not modify to allow exceptions to the reporting requirement. Based on the comments received and our responses in this section we are finalizing the following two policies with modification.

- We will require a 7-day advance notice with exemptions in certain cases, such as potential for beneficiary harm.
- We will adjust the timeline for submission to 30 days after the close of the quarter. The applicability date for plan sponsor reporting has been postponed until January 1, 2022.

(4) Requirements and Timing of CMS' Reports

As mentioned earlier in this final rule, section 6063(a) of the SUPPORT Act requires the Secretary make available to the plans, not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Moreover, the information must be anonymized data submitted by plans without identifying the source of such information.

Section 6063 of the SUPPORT Act requires the Secretary provide reports no less frequently than quarterly. Consistent with this requirement, we proposed in the new §§ 422.503(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) and 423.504(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) that we will provide MA organizations and Part D plan sponsors with data report(s) or links to data no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We proposed to provide this information beginning in 2021. For the first quarterly report (April 15, 2021), the report will reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021. Similar to the timing requirements related to new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*), we believe that quarterly updates would strike a suitable balance between the need for frequently updated information while giving us time to review and analyze this data in preparation for complying with new §§ 422.503(b)(4)(vi)(G)(*4*) through (*7*) and 423.504(b)(4)(vi)(G)(*4*) through (*7*). We solicited public comment on the timing of CMS dissemination of reports to plans.

We received no comments on this proposal and therefore are finalizing this provision without modification; however, the applicability date for the quarterly reports will be for plan years beginning on or after January 1, 2022 for reasons previously discussed.

IV. Enhancements to the Part C and D Programs

A. Out-of-Network Telehealth at Plan Option

On April 16, 2019, CMS finalized requirements for MA plans offering additional telehealth benefits (ATBs).[28] Section 50323 of the BBA of 2018 created a new subsection (m) of section 1852 of the Act, authorizing MA plans to offer ATBs to enrollees starting in plan year 2020 and treat ATBs as basic benefits. In the April 2019 final rule, we finalized a new regulation at § 422.135

[28] *https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

to implement that authority. As part of the parameters for the provision of ATBs, we finalized a requirement, at § 422.135(d), that MA plans furnishing ATBs only do so using contracted providers, and § 422.135 specifically provides that benefits furnished by a non-contracted provider through electronic exchange (defined in the regulation) may only be covered by an MA plan as a supplemental benefit.

In the February 2020 proposed rule, we solicited comment on whether § 422.135(d) should be revised to allow all MA plan types, including PPOs, to offer ATBs through non-contracted providers and treat them as basic benefits under MA.

We received many responses to this request for comment. We thank the commenters for the time and effort that went into developing these detailed responses and feedback for CMS. We will carefully review and consider all input received from stakeholders as we determine whether to revise § 422.135(d) to allow MA plans to offer ATBs through non-contracted providers. At this time, we are not revising any requirements at § 422.135, and any revisions regarding ATBs will be proposed through future notice and comment rulemaking.

B. Supplemental Benefits, Including Reductions in Cost Sharing (§ 422.102)

In the Medicare Program; Establishment of the Medicare Advantage Program Final Rule, published in the **Federal Register** on January 28, 2005 (hereinafter referred to as the January 2005 MA final rule) (70 FR 4588, 4617), CMS established that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act only as a mandatory supplemental benefit and codified that policy at § 422.102(a)(4). In order to clarify the scope of section 1854(e)(4)(A) of the Act, we proposed in the February 2020 proposed rule to amend § 422.102(a)(4) and add new rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to further clarify the different circumstances in which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit; we also proposed to specifically authorize certain flexibility in the mechanisms by which an MA plan may make reductions in cost sharing available.

Currently, reductions in cost sharing are an allowable supplemental benefit in the MA program and may include:

- Reductions in the cost-sharing for Parts A and B benefits compared to the actuarially equivalent package of Parts A and B benefits; and
- Reductions in cost-sharing for Part C supplemental benefits, for example provided for specific services for enrollees that meet specific medical criteria, such that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits.

We proposed to codify regulation text to clarify that reductions in cost sharing for both (1) Part A and B benefits and (2) covered items and services that are not basic benefits are allowable supplemental benefits but may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). We proposed to revise the current language at § 422.102(a)(4) by inserting the phrase ''for Part A and B benefits'' after the cite to section 1854(e)(4)(A) of the Act, and to add a new paragraph (a)(5) to specify that reduced cost sharing may be applied to items and services that are not basic benefits. Under our proposal, the reductions in cost sharing for both categories may only be provided as a mandatory supplemental benefit.

We explained in the proposed rule that MA plans may currently choose to structure mandatory supplemental benefits that are in the form of cost sharing reductions in a few ways. For example, the current rules permit MA plans to offer, as a supplemental benefit, a manual reimbursement process or use of a debit card to reduce cost sharing towards plan covered services or to provide coverage of 100 percent of the cost of covered items. MA plans may also decide to offer, as a supplemental benefit, a reduction in enrollee's costs through a maximum allowance. An MA plan may establish a dollar amount of coverage that may be used to reduce cost sharing towards plan covered services and subject to a plan-established annual limit; enrollees can ''spend'' the allowance on cost sharing for whichever covered benefits the enrollee chooses. In both scenarios, MA plans are expected to administer the benefit in a manner that ensures the debit card and/or allowance can only be used towards plan-covered services. We proposed to codify these flexibilities in how reductions in cost sharing are offered at § 422.102(a)(6)(i) and (ii). We clarified in the proposed rule that these flexibilities are only for Part C supplemental benefits, as defined in § 422.100(c) and discussed in section VI.F. of the proposed rule (and section V.E. of this final rule) and that cost sharing for Part D drugs is not included in these flexibilities.

As proposed, the flexibilities identified would be permitted only as a mandatory supplemental benefit, which is why we proposed to codify them in § 422.102(a). Further, we explained that the flexibility was only for items and services that are identified in the MA plan's bid and marketing and communication materials as covered benefits and proposed the regulation text using the terms ''covered benefits'' and ''coverage of items and services'' to make that clear. Under our proposal and consistent with current guidance in Chapter 4 of the Medicare Managed Care Manual, § 40.3 (allowing debit cards to be used for plan-covered over-the-counter (OTC) items under the conditions that the card is exclusively linked to the OTC covered items and has a dollar limit tied to the benefit maximum), MA plans would not be able to offer use of a debit card for purchase of items or services that are not covered. We stated that a debit card could be utilized as a reimbursement mechanism or as a means for the MA plan to make its payment for an item or service; in either case, the use of the card would have to be tied to coverage of the benefit. Like all other MA coverage, the flexibilities we proposed would be limited to the specific plan year and we clarified that this authority to use debit cards or a basket of benefits up to a set value from which an enrollee can choose cannot be rolled over into subsequent years. We proposed specific text in paragraph (a)(6) limiting these forms of supplemental benefits to the specific plan year to emphasize that rolling over benefits to the following plan year is not permitted.

We explained in the proposed rule that for both benefit options, MA plans would have the flexibility to establish a maximum plan benefit coverage amount for supplemental benefits or a combined amount that includes multiple supplemental benefits, such as a combined maximum plan benefit coverage amount that applies to dental and vision benefits. We reiterated that plans may not offer reimbursement, including through use of a debit card, to pay for items and services that are not covered by the plan and that reductions in cost sharing as a supplemental benefit are subject to an annual limit that the enrollee can ''spend'' on cost sharing for whichever *covered benefits* the enrollee chooses. Under our proposal, MA plans could use a receipt-based reimbursement system or provide the dollar amount on a debit card (linked to an appropriate merchant and item/service codes) so that the enrollee may pay the cost sharing at the point of service. Our proposal was to codify and clarify existing guidance and practices and we stated that it was not expected

to have additional impact above current operating expenses. We also stated that the proposal would not impose any new collection of information requirements.

We thank commenters for helping inform CMS' Reductions in Cost Sharing policy. We received 11 comments on this proposal; we summarize them and our responses follow:

Comment: Many comments were supportive of this proposal.

Response: We thank commenters for their feedback.

Comment: A commenter suggested CMS confirm that plans may implement allowances as a multi-year benefit.

Response: We cannot confirm this and it would not be permitted. As proposed and finalized, the changes adopted here are for benefits offered in each plan year and cannot be rolled over or spread across multiple plan years. This is necessary for a number of reasons. CMS only has one-year contracts with MAOs; as such, there is no guarantee that a particular plan will continue into the following year. Additionally, there is also no guarantee an enrollee will remain in a plan from year to year as an enrollee has the option to change plans each year. Further, and more importantly, bids must be submitted by MA organizations each year, showing the revenue requirements for furnishing benefits for the contract year; bids are compared to benchmarks that are set each year and used to determine the amount of beneficiary rebates under § 422.266. Under § 422.266, these rebates may be used to pay the premium for the supplemental benefits described in § 422.102(a)(6) or to buy down Part B or Part D premiums; use of the beneficiary rebate for payment of a premium for supplemental benefits in a different plan year is not permitted and would be inconsistent with the statutory requirement in section 1854(b)(1)(C) of the Act that MA plans provide the rebate to enrollees for the applicable year. It is not consistent with our regulations on bidding (§§ 422.250 through 422.266) for an MA plan to have a multi-year benefit.

Comment: A commenter suggested CMS allow plans to offer reductions in cost sharing for items and services that are not covered. This commenter also suggested CMS not subject reductions to cost sharing or allowances to an annual limit.

Response: In order to have a reduction in cost sharing, there has to be a covered benefit. We allow plans to have a debit card to cover cost sharing but they must identify the benefits as covered either in the plan benefit package (PBP) category or notes in the bid. Consistent with this, all the items and services for which payment may be made (in the form of a reduction in cost sharing that would otherwise apply for the item or service or in the form of the MA plan's payment of its share of the amount owed to the provider) must meet the requirements to be a supplemental benefit. These requirements are discussed in section V.C. of this final rule regarding our proposal to amend § 422.100(c)(2) to codify the requirements for supplemental benefits.

Comment: A commenter requested CMS provide additional guidance on how plans can make sure that supplemental benefits furnished in the form of an allowance meet the ''primarily health related'' requirement as enrollees typically have discretion in how they use these allowance-based dollars.

Response: The MA plan must ensure that its coverage, whether through reimbursement or direct payment, of items and services is consistent with the rules for supplemental benefits. The flexibility provided in this allowance benefit to permit the enrollee to choose among covered benefits does not change the rules for what may be covered. For an MA plan that uses a receipt-based reimbursement method of administering this allowance benefit, the MA plan must ensure that the receipts support a determination that reimbursement is being provided only for items and services that are covered supplemental benefits. We understand that debit and stored value cards can be programmed to permit their use only for purchase of specific items and services and at certain locations, such as cost sharing payments at a physician's office or payment for primarily health-related items such as bandages at a pharmacy. If an MA organization is unable to limit use of a debit or stored value card to the appropriate providers and covered benefits (such as through programming limits to certain merchant codes or inventory information approval system codes) to ensure compliance with §§ 422.100(c)(2) and 422.102(a), use of a debit or stored value card as a means of reimbursing or providing reductions in cost sharing may not be appropriate by that MA organization. We note that the Internal Revenue Service has provided guidance on how debit and stored value cards are permitted in connection with health savings accounts and flexible spending accounts when the cards are capable of being limited to qualified expenses; see, for example: Revenue Ruling 2003–43, 2003–21 I.R.B. 935, available at *IRS.gov/pub/irs-drop/rr-03-43.pdf.* We also clarify here that use of a stored value or debit card is not the covered supplemental benefit; such cards are only a means by which the MA plan makes direct payment to the provider for or reimbursement to the enrollee for the covered items and services.

The covered items and services that are paid or reimbursed this way must meet the requirements and standards to be supplemental benefits (or to be basic benefits in the case of reducing the cost sharing for a Part A or B covered benefit). Related to this, we reiterate that that payment of or reimbursement of cost sharing for Part D benefits by an MA plan is not a permissible supplemental benefit. To clarify this, we are finalizing § 422.102(a)(5) with additional text that Part D cost sharing may not be reduced or paid as a Part C supplemental benefit. MA plans may, under § 422.266, use rebates to pay the premiums for Part D benefits, including the premiums for supplemental drug coverage described at § 423.104(f)(1)(ii). For more information on the types of items and services that may be covered by an MA plan as a supplemental benefit, we direct readers to the April 27, 2018 memo titled ''Reinterpretation of ''Primarily Health Related'' for Supplemental Benefits'' and section V.C of this rule, which codifies those requirements for details.

Comment: A commenter expressed concern about potential limits on these benefits and the idea that financial need must be proven in order to allow access.

Response: Reduced cost sharing as a supplemental benefit must follow the requirements concerning supplemental benefits, which include uniformity requirements § 422.100(d) discussed in section V.C of this final rule. That is, if a plan chooses to offer reduced cost sharing as a supplemental benefit, it must be offered uniformly to plan enrollees. MA plans may not offer supplemental benefits based on financial need. Because of the unique nature of Special Supplemental Benefits for the Chronically Ill (SSBCI) and the statutory authority for those benefits to not be primarily health related, the recently adopted rule at § 422.102(f)(2)(iii) permits an MA plan to consider social determinants of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. (85 FR 33801, 33804) However, MA plans may not use social determinants, such as financial need, as the sole basis for determining eligibility for SSBCI.

Comment: A commenter mentioned that while stated in the preamble, CMS did not include specific regulation text stating that reduced cost sharing for basic benefits, specifically as it relates to

the value of Part A and B benefits, is permitted.

Response: In the proposed rule, we included amendatory instructions to clarify that reductions in cost sharing for Part A and B benefits may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). Specifically, CMS proposed to revise the current language at § 422.102(a)(4) by inserting the phrase ''for Part A and B benefits''. (85 FR 9213) Thus, specific regulation text clarifying that reduced cost sharing for basic benefits, specifically for Part A and B benefits, is permitted as a supplemental benefit was included in the proposed language. We are finalizing this language.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to § 422.102(a)(4) and (a)(6)(i) and (ii) as proposed and are adding language to § 422.102(a)(5) further clarifying that cost sharing for Part D drugs is not included in these flexibilities.

C. Referral/Finder's Fees (§§ 422.2274 and 423.2274)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, published in the **Federal Register** on May 23, 2014 (79 FR 29960) (the May 2014 final rule), CMS codified rules in §§ 422.2274(h) and 423.2274(h) for MA organizations and Part D sponsors to pay agents and brokers for referrals of beneficiaries for enrollment in MA and Part D plans, also known as finder's fees. Currently, under §§ 422.2274(h) and 423.2274(h), CMS sets a referral fee limit that reflects an amount CMS determined is reasonably expected to provide financial incentive for an agent or broker to refer a beneficiary for an enrollment into a plan that is not the most appropriate to meet his or her needs. This is consistent with sections 1851(j)(2) and 1860D–1(*l*) of the Act, which direct that the Secretary set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs. In an HPMS memo dated May 29, 2020, CMS limited referral fees to $100 for MA plans and $25 for PDP plans. Since referral fees are part of the definition of the term compensation in §§ 422.2274 and 423.2274, organizations may not pay independent agents more than the regulatory limits; CMS regulates referral fees as part of CMS's regulations on the compensation paid by the plan to an agent/broker for an enrollment, even if referral fees are paid separately from commissions or compensation for completed enrollments. CMS explained in the February 2020 proposed rule that because referral fees are already incorporated into compensation, limiting the amount of a referral fee does not impact the statutory requirement that CMS guidelines for compensation to an agent or broke incentivize the agent or broker enrolling a beneficiary in the plan that best meets their health care needs. CMS also explained in the proposed rule that for captive and employed agents and brokers, who only sell coverage for one organization, referral fees would not have any impact on how much the captive or employed agent is himself or herself paid.

Therefore, CMS proposed to remove §§ 422.2274(h) and 423.2274(h) and thereby eliminate the specific limitation on the amount a referral or finder fee paid by a plan to an agent or broker. CMS explained generally how the current regulation treats compensation as background for our proposal. As currently codified at §§ 422.2274(b) and 423.2274(b), compensation for initial enrollments may not exceed the fair market value and compensation for renewal enrollments may not exceed 50 percent of the fair market value. Compensation is defined in the same current regulation, at paragraph (a), as all monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes or awards, and referral or finder fees. By eliminating the individual referral fee limit, our proposal would restructure the regulation to only provide a limit on referral fees within the overall limit of Fair Market Value (FMV) that applies to all compensation. CMS proposed to clarify that MA organizations and Part D sponsors have the ability to compensate agents for referrals, provided that the total dollar amount does not exceed FMV. CMS explained that the primary value for this proposed additional flexibility would be in connection with independent agents, as CMS believes that for captive and employed agents, referral/finder fees do not play a factor in making sure the agent enrolls the beneficiary in the best plan, since captive and employed agents only sell for one organization. CMS therefore proposed to eliminate the current specific limit on finder or referral fees that is codified at paragraph (h). CMS also explained that because the definition of compensation already includes referral or finder fees (which CMS did not propose to change), the result of this specific proposal would be an overall limit on compensation for initial and renewal enrollments that would include finder or referral fees. In section VI.H. of the proposed rule, CMS proposed additional changes for §§ 422.2274(g) and 423.2274(g) regarding agent and broker compensation for Part C and Part D enrollments; and under those proposals, the definition of compensation would continue to include finder or referral fees. As a result, the limits on overall compensation continued to include finder or referral fees under the proposed rule. CMS solicited comment on whether removing the limit on referral/finder's fees would generate concerns such as those discussed in the 2010 Call Letter for MA organizations issued March 30, 2009; CMS's October 19, 2011, memo entitled ''Excessive Referral Fees for Enrollments;'' or the May 2014 final rule that codified the referral/finder's fees limits in regulation. As background, these concerns included marketing practices designed to circumvent compensation limitations.

The comments CMS received on this specific proposal regarding referral/finders' fees and our responses to them follow.

Comment: Several commenters stated that referrals and enrollments are different activities and therefore, CMS should consider payment for these activities separately. The commenters pointed out that referrals are used to generate sales leads, that not all leads result in an enrollment, and when a lead does result in enrollment, referral and finder's fees are typically not paid to the individual completing the sale. Some commenters pointed out that referral fees are not always provided to individuals as part of the compensation they are paid for an enrollment. The commenters suggested referral fees be removed from compensation and that a separate, reasonable limit be placed on referral fees. A commenter pointed out that the removal of the limit on referral fees would result in larger, well-financed health plans paying brokers more for referrals and that this would cause smaller health plans to lose out on broker referrals.

Response: CMS agrees with the commenters that referral fees and compensation are different types of payments and that plans distinguish between referral fees for sales leads and compensation to agents and brokers for enrollments. We understand that referral fees are a distinct part of market practices which we have determined, based on comments, should not be

modified. We also realize that our proposal to remove specific limits on referral fees may put plans that can pay higher referral fees at an advantage over other plans. Based on the issues identified through comments we are maintaining the status quo. As such, CMS is finalizing a separate limit on referral fees in §§ 422.2274(f) and 423.2274(f) and is codifying the dollar figures currently used as the limits for referral fees. The current sub-regulatory policy has in place a $25 referral fee limit for PDPs and a $100 referral fee limit for MA–PDs. The proposal was to remove the current limits since referral fees are part of compensation paid to an agent for an enrollment. However, commenters pointed out that referral fees are not always provided to individuals as part of the compensation they are paid for an enrollment. Therefore, we are finalizing a specific dollar limit on fees paid for a single referral, recommendation, provision (as in providing a lead), or other means of referring a beneficiary to an agent, broker or other entity for potential enrollment in a plan instead of finalizing our proposal.

Section 1851(j)(2)(D) of the Social Security Act requires CMS to establish limitations to ensure that the use of compensation creates incentives for the agent/broker to enroll a beneficiary in a plan that best meets their needs. CMS does not require referral fees to be contingent on a beneficiary being enrolled in a plan because referral fees are essentially payments for sales leads. Plans may determine the circumstances as to when they pay referral fees (for example, based on whether the lead chooses to enroll in the plan), provided such payment is in accordance with the requirements in this final rule. Therefore, referral fees are a different type of payment than the payments that we regulate as compensation to an agent or broker for enrollment of a beneficiary in a plan. Based on this, CMS is finalizing changes to the definition of the term ''compensation'' (codified in §§ 422.2274(a) and 423.2274(a)) to remove referral or finder fees from the list of what compensation includes. As discussed in more detail in section V.E of this final rule, compensation as defined in paragraph (a) is regulated as payment that is based on enrollment in a plan. CMS is finalizing a new §§ 422.2274(f) and 423.2274(f) to provide that payments may be made to individuals for the referral, recommendation, provision, or other means of referring beneficiaries to an agent/broker or other entity for potential enrollment into a plan and that such payments may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a standalone PDP.

Comment: A commenter requested more transparency into payment of both referral fees and renewal fees. The commenter also suggested that CMS eliminate the renewal compensation for agents, stating that 98 percent of beneficiaries remain in the same plan or make a plan change to a ''like'' plan (that is, a plan that is similar enough to the previous plan that it does not result in a change of the renewal payment status to the agent/broker). The commenter stated that the renewal compensation created an un-level playing field between community-based non-profit plans and national competitors.

Response: We believe that the commenter may be conflating referral fees and renewal compensation. Referral fees are paid by plans for sales leads while renewal compensation is paid by a plan to an agent or broker for enrollments. The dollar amount of the limit on referral fees under the current regulation was set by CMS in subregulatory guidance, applying the regulatory standard that referral fees not exceed an amount that could be reasonably expected to provide a financial incentive to enroll a beneficiary in a plan that is not appropriate to the beneficiary's needs. Here, we are finalizing a specific dollar amount as the limit on referral fees: $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan. Plans may pay an amount per referral that is less than this limit but must not pay more than this limit. By establishing a specific dollar limit for referral fees in regulation, CMS is creating a level playing field for all plans who pay referral fees according to this policy. CMS is not including any type of increase to the referral fees since referrals do not require the same type of effort or have the same requirements that are associated with compensation.

The limit on renewal compensation is 50 percent of the fair market value (FMV) set for initial enrollment year compensation, as provided in §§ 422.2274(b)(ii) and 423.2274(b)(ii) of the current regulations and in §§ 422.2274(d)(3) and 423.2274(d)(3) of this final rule. As defined in §§ 422.2274(a) and 423.2274(a) in this final rule, FMV is calculated each year by increasing the prior year's FMV dollar amount by the MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312. This provision permits a change each year in compensation to agents and brokers that aligns with the change in the growth of per capita costs. Agents provide valuable assistance to beneficiaries whether the beneficiary is enrolling into a plan for the first time or staying in their existing plan. Many beneficiaries depend on their agents to assist them in reviewing their choices each year and helping them make a determination on whether to remain in their existing plan or to move into a new plan. Renewal compensation provides an incentive to provide such assistance to enrollees and we believe such compensation is appropriate to limit under our statutory responsibility to regulate compensation for agents and brokers. In addition, permitting renewal compensation avoids providing an inadvertent and unintended incentive for agents and brokers to churn beneficiaries through new enrollments into different plans each year in order to generate stable income.

After consideration of the comments and for the reasons outlined in the proposed rule, we are finalizing the definition of ''compensation'' (§§ 422.2274(a) and 423.2274(a)) without including referral and finder's fees and are finalizing a new paragraph (f) in §§ 422.2274 and 423.2274 to impose specific limits on the payment amount for referral and finder's fees for MA and Part D enrollments.

D. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codified a policy to adjust Star Ratings for disasters, and finalized some measure updates. In the June 2020 final rule, CMS finalized an increase in the weight of patient experience/complaints and

access measures from 2 to 4 for the 2023 Star Ratings. To further increase the predictability and stability of the Star Ratings system, we also finalized our proposal to directly remove outliers through Tukey outlier deletion before applying the clustering methodology to calculate the cut points, but we delayed the application of Tukey outlier deletion until the 2022 measurement year which coincides with the 2024 Star Ratings. We also finalized the removal of the Rheumatoid Arthritis Management measure and updated the Part D Statin Use in Persons with Diabetes measure weighting category for the 2021 measurement year and the 2023 Star Ratings.

In the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule placed on display at the Office of the Federal Register website on March 31, 2020 (hereinafter referred to as the March 31st COVID–19 IFC), CMS adopted a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID–19 pandemic. The changes adopted in the March 31st COVID–19 IFC addressed the need of health and drug plans and their providers to adapt their current care practices in light of the public health emergency (PHE) for COVID–19 and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. In addition to needing to address data collections scheduled for 2020 during the initial part of the PHE, we believe that there will be changes in measure-level scores because of increased healthcare utilization due to COVID–19, reduced or delayed non-COVID–19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID–19 inpatient utilization. We realize that this will impact the data collected during the 2020 measurement year which will impact the 2022 Part C and D Star Ratings. Thus, as part of the March 31st COVID–19 IFC, we made some adjustments to account for the potential decreases in measure-level scores so health and drug plans can have some degree of certainty knowing how the Star Ratings will be adjusted and can continue their focus on patients who are most in need right now.

Specifically, the March 31st COVID–19 IFC:

- Eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data otherwise collected in 2020 and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the PHE for COVID–19);
- Establishes how we would calculate or assign Star Ratings for 2021 in the event that CMS's functions had become focused on only continued performance of essential Agency functions and the Agency and/or its contractors did not have the ability to calculate the 2021 Star Ratings;
- Modifies the current rules for the 2021 Star Ratings to replace any measure that had a systemic data quality issue for all plans due to the COVID–19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- Replaces the measures calculated based on HOS data collections with earlier values that are not affected by the public health threats posed by COVID–19 for the 2022 Star Ratings in the event that we were unable to complete Health Outcomes Survey (HOS) data collection in 2020 (for the 2022 Star Ratings) due to the PHE for COVID–19;
- Removes guardrails (*i.e.,* measure-specific caps on cut point changes from one year to the next) for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;
- Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and
- Revises the definition of ''new MA plan'' so that for purposes of 2022 QBPs based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings are based in part on data for the 2018 performance period.

Please see the March 31st COVID–19 IFC for further information on these changes for the 2021 and 2022 Star Ratings. In addition, the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule (CMS–3401–IFC) which appeared in the **Federal Register** on September 2, 2020 (hereinafter referred to as the September 2nd IFC), modifies application of the extreme and uncontrollable circumstances policy for the calculation of the 2022 Part C and D Star Ratings to address the PHE for COVID–19 to: (1) Remove the 60 percent exclusion rule for cut point calculations for non-CAHPS measures; and (2) remove the 60 percent exclusion rule for the determination of the performance summary and variance thresholds for the Reward Factor. These changes were made by amending the regulations at §§ 422.166(i)(11) and 423.186(i)(9).

In the February 2020 proposed rule, in addition to the policies addressed in the June 2020 final rule, we proposed to implement substantive updates to the specifications of the Health Outcomes Survey (HOS) outcome measures, add two new Part C measures to the Star Ratings program, clarify the rules around consolidations when data are missing due to data integrity concerns, and add several technical clarifications. We also proposed to codify additional existing rules for calculating MA Quality Bonus Payment (QBP) ratings. We proposed these changes to apply to the 2021 measurement period and the 2023 Star Ratings, but as discussed in this final rule, we are finalizing these policies from the proposed rule (that is, data would be collected and performance measured) for the 2022 measurement period and the 2024 Star Ratings.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the proposal and comments we received on each proposal and provide our responses.

2. Definitions (§ 422.252)

We proposed to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. Under our proposed changes, *New MA plan* would mean a plan that: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. In addition, we proposed to add text to the definition to explicitly explain that the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies.

Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard. For example,

if a parent organization is listed for an MA contract in April 2019, and that parent organization does not have any other MA contracts at any point during April 2017–April 2019, the plans under the MA contract would be considered new MA plans for 2020 QBP purposes.

We received no comments on the proposed amended definition in § 422.252 for a new MA plan and are finalizing the policy as proposed for the reasons outlined in the proposed rule and this final rule. However, we are not finalizing the last sentence included in the proposed regulation text because the proposed regulation text mistakenly included a sentence repeating how we would identify parent organizations in April of the calendar year before the payment year.[29] Although we are finalizing this provision as applicable beginning January 1, 2022, we reiterate that it codifies current policies that have been in place since 2012 (76 FR 21486). In addition, we note that the regulation text finalized here includes the language adopted in the March 31st COVID–19 IFC (CMS–1744–IFC) to govern how the definition is applied for 2021 Star Ratings (85 FR 19290).

3. Contract Consolidations (§§ 422.162(b)(3)(iv), 422.164(g)(1)(iii)(A), 423.182(b)(3)(ii), and 423.184(g)(1)(ii)(A))

The process for calculating the measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). We proposed to add a rule to account for instances when the measure score is missing from the consumed or surviving contract(s) due to a data integrity issue as described at §§ 422.164(g)(1)(i) and (ii) and 423.184(g)(1)(i) and (ii). CMS proposed to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. We proposed that these rules would apply for contract consolidations approved on or after January 1, 2021. First, we proposed minor technical changes to the regulation text in §§ 422.162(b)(3)(iv)(A) and (B) and 423.182(b)(3)(ii)(A) and (B) to improve the clarity of the regulation text. Second, we proposed to redesignate the current regulation text (with the technical changes) as new paragraphs (b)(3)(iv)(A)(*1*) and (b)(3)(iv)(B)(*1*) and (b)(3)(ii)(A)(*1*) and (b)(3)(ii)(B)(*1*) of these regulations and to codify this new rule for contract consolidations approved on or after January 1, 2021 as §§ 422.162(b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) and 423.182(b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*). We also proposed an additional rule at §§ 422.164(g)(1)(iii)(A) and 423.184(g)(1)(iii)(A) to address how the Timeliness Monitoring Project (TMP) or audit data are handled when two or more contracts consolidate. We proposed that the TMP or audit data will be combined for the consumed and surviving contracts before carrying out the methodology as provided in paragraphs B through N (for Part C) and paragraphs B through L (for Part D). We proposed that these rules would apply for contract consolidations approved on or after January 1, 2021 and the proposed regulation text included language to that effect. We proposed to redesignate the current regulation text as new paragraphs (g)(1)(iii)(A)(*1*) and (g)(1)(ii)(A)(*1*) of these regulations and to codify this new rule for contract consolidations on or after January 1, 2021 as paragraphs (g)(1)(iii)(A)(*2*) and (g)(1)(ii)(A)(*2*).

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Commenters supported the proposals related to how to calculate scores when either the surviving or the consumed contract has a measure-level data integrity issue. A commenter recommended in these instances that the preview reports should include the combined TMP data for contracts that consolidate.

Response: We appreciate these comments and will be combining the TMP data in preview reports for the surviving and consumed contracts.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the changes as proposed to §§ 422.162(b)(3)(iv), 422.164(g)(1)(iii)(A), 423.182(b)(3)(ii), and 423.184(g)(1)(ii)(A) with a revision to the applicable date. Given the timing of the finalization of this rule, we are finalizing the provisions as applying to contract consolidations that are approved on or after January 1, 2022.

4. Adding and Updating Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Star Ratings program. As discussed in the April 2018 final rule, due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance document with publication of the Star Ratings. In the February 2020 proposed rule, CMS proposed measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2021.

a. Proposed Measure Updates—Updates to the Improving or Maintaining Physical Health Measure and Improving or Maintaining Mental Health Measure From the HOS (Part C).

In accordance with § 422.164(d)(2), we proposed substantive updates to two measures from the Medicare Health Outcomes Survey (HOS): The Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure.

First, we proposed to change the case-mix adjustment (CMA) for these measures. Case-mix adjustment is critical to measuring and comparing longitudinal changes in the physical and mental health of beneficiaries across MA contracts. To ensure fair and comparable contract-level scores, it is important to account for differences in beneficiary characteristics across contracts for these two measures. CMS proposed to modify the current approach used for adjusting for differences in the case-mix of enrollees across contracts for these two measures. The proposed approach would improve the case-mix model performance and simplify the implementation and interpretation of case-mix results when particular case-mix variables, such as household income, are missing. The current method for handling missing case-mix variables results in a reduced number of case-mix variables used for a beneficiary because it does not use any of the case-mix variables in a group of adjusters if one is missing from the group (see 2021 Medicare Part C & D Star Ratings Technical Notes Attachment A for a full description of the current HOS case-mix methodology). CMS stated in the proposed rule that this ''all-or-nothing'' approach for each group of adjusters may not be as efficient as alternative approaches for handling missing case-mix adjusters. Under the proposed change, when an adjuster is missing for

[29] The following sentence is excluded from the regulatory text: Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard.

a beneficiary, it would be replaced with the mean value for that adjuster for other beneficiaries in the same contract who also supply data for the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures. This proposed approach has been used for the Medicare Advantage and Prescription Drug Plan CAHPS surveys for many years (see 2021 Medicare Part C & D Star Ratings Technical Notes Attachment A for a description of the CAHPS case-mix methodology). In simulation models, this approach either outperformed the current approach for predicting outcomes or matched the current approach. The proposed rule also explained how the proposed approach is easier to implement than the current approach as replacing the missing adjuster values with the contract mean scores for those adjusters rather than deleting the grouping of adjusters is less burdensome because it involves fewer steps and is easier to replicate and understand.

Second, we proposed to increase the minimum required denominator from 30 to 100 for the two measures. The proposed increase to the minimum denominator would bring these measures into alignment with the denominator requirements for the HEDIS measures that come from the HOS survey and increase the reliability for these measures compared to the current reporting threshold of 30.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: A majority of commenters expressed support for a simplified case-mix methodology, increased minimum denominator, and CMS's continued efforts to improve the quality and transparency of HOS measures. Some commenters stated that the new methodology for dealing with missing data will make the case-mix algorithm more accurate and help ensure fair and comparable contract level results by strengthening the measures' ability to adjust for beneficiary level differences. A commenter suggested removing HOS measures from the Star Ratings entirely, but most who expressed concerns about the proposed changes recommended CMS move the two HOS outcome measures to the display page for 2 years to allow stakeholders sufficient time to review. Some commenters noted that these changes are substantive.

Response: CMS appreciates the support for the proposed methodological changes. CMS agrees that the case-mix change is a substantive update as described at § 422.164(d)(2), so the provision there for placing an updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings applies. Thus, CMS will move these two HOS outcomes measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, as updated, to the display page for the 2024 and 2025 Star Ratings. Though CMS has the option of retaining the current specifications of these outcome measures in Star Ratings while stakeholders review and study the updated measures, our regulations do not require their retention during this interim period. Given the importance of patient-reported outcome measures in the Star Ratings program, CMS is opting to let stakeholders review the updated measures on the display page without simultaneously considering an alternate specification in the Star Ratings. We explained in the April 2018 final rule that we may continue use of a legacy measure if the updated measure expands the population covered in the measure or the measure otherwise is critical to the Star Ratings (83 FR 16537).

Comment: A commenter stated that these two HOS measures reflect experiences, not outcomes, and therefore should not be weighted as outcome measures. Another commenter stated that it is inappropriate to assign self-reported measures the weight of 3. A few commenters suggested CMS reduce the weight of the two HOS outcome measures to 1.5 or 2. Several commenters requested CMS clarify the weight of the two updated measures once they are reintroduced to the Star Ratings.

Response: The Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure both focus on key outcomes for a health plan: Improving or maintaining the physical health and mental health of its enrollees. These measures reflect the outcomes of the plan's entire membership based on the members' perceptions of their own health. Thus, these measures do not measure patient experiences or beliefs about the health plan but measure changes over 2 years in the physical and mental health status of the enrollees in an MA contract. The weights of measures are assigned by measure type as codified at § 422.166(e). These measures (Improving or Maintaining Physical Health and Improving or Maintaining Mental Health) are considered outcome measures; thus, as codified at § 422.166(e)(1)(i), they receive a weight of 3. Under CMS's process to add, update, and remove measures used to calculate the Star Ratings codified at § 422.164, substantive updates to an existing measure result in the updated measure being on the display page for at least 2 years prior to its reintroduction to the Star Ratings. For weighting purposes, a substantively updated measure is treated as a new measure, and as described at § 422.166(e)(2), will receive a weight of 1 for the first year in the Star Ratings. In subsequent years, an updated measure is assigned the weight associated with its category. Thus, the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures will receive a weight of 1 in the 2026 Star Ratings and a weight of 3 in the 2027 Star Ratings and beyond.

Comment: Several commenters expressed concern about the cultural relevance of the survey questions, the applicability of the two HOS outcome measures to the LIS/DE and disabled populations, and the robustness of the case-mix models to control for these differences. A commenter suggested the Improving or Maintaining Physical Health measure conflates functional status with health and pointed out that persons with functional limitations can still be in good health. Another commenter questioned the role of death in the statistical adjustment models that examine changes in expected physical health.

Response: There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best to control for their impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries within a contract or across contracts over time. CMS also continues to test and refine the HOS instrument with these issues in mind to ensure that survey questions are relevant to different populations. The current longitudinal measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, adjust for a wide variety of beneficiary demographic and socioeconomic characteristics to control for differences in these characteristics across contracts. MA organizations are held accountable for risk-adjusted changes in functioning, including mortality, because to ignore death as a physical health outcome would result in misleading results. We agree that people with functional limitations can be in

good health and this is accounted for in the Improving or Maintaining Physical Health measure since it examines person-level changes from a baseline period to a follow-up period 2 years later. The HOS methodology takes into account the case mix of enrollees within each plan and controls for pre-existing baseline differences, including age, sociodemographic characteristics, functional status, and chronic medical conditions as reported in the HOS survey, to statistically adjust each plan's expected outcomes, including survival rate, based on national averages when calculating the results for Improving or Maintaining Physical Health. Mortality is not considered in the calculation of Improving or Maintaining Mental Health.

Comment: Several commenters expressed concern about the HOS survey, including whether increasing the minimum denominator to 100 would improve the stability of the specific measures. A few commenters urged CMS to consider an even larger increase. Another commenter recommended that CMS not implement the change until there is clear evidence it will enhance measure stability in the Star Ratings. Several commenters suggested involving stakeholders in future changes to the survey methodology, because of their implications for measures. Many commenters noted that these are significant changes to specifications, while additional changes may also be needed to improve the measures, such as to further increase reliability and stability of the measures.

Response: We have considered stakeholder feedback in the development of measures of clinical outcomes in the Part C and Part D Star Ratings program. The HOS was developed over the course of 2 decades under the guidance of several Technical Expert Panels (TEPs) of industry experts and its survey questions are derived from well-established patient reported outcome measures (PROs) that reflect clinical standards. Patients are the ultimate source of information on patient outcomes and CMS is committed to developing meaningful measures for quality measurement and improvement that enhance outcomes for beneficiaries. CMS continues to solicit stakeholder feedback on PROs, most recently through the 2020 draft Call Letter dated January 30, 2019 and the Star Ratings TEP on April 30, 2019. Additionally, CMS routinely seeks broad stakeholder input regarding measure enhancements, while maintaining scientific objectivity and independence throughout the process.

Our analyses do not show volatility of HOS measures in the Star Ratings, and in particular of the two outcome measures, which because of their weight in the Star Ratings calculation are of most concern to plans and sponsors. As an example, most plans maintained or gained stars on HOS measures between 2019 and 2020, and while there is some movement in the Star Ratings, the change is generally not acute. Only one plan dropped from 5 stars to 1 star for Improving or Maintaining Physical Health, while 68 percent of plans had no change or an increase in stars for the measure, and 85 percent had no change or an increase in stars for Improving or Maintaining Mental Health. Analyses of movement in Star Ratings for these outcome measures do not raise concerns about stability, even over longer periods of time.

While CMS does not have concerns about the stability of the two outcome measures derived from HOS, we understand how much plans have at stake in their HOS-derived Star Ratings. Out of an abundance of caution and to be responsive to stakeholder concerns, we are taking a number of steps. One is to increase the denominator size to further increase reliability. In addition, and as CMS stated in the 2021 Rate Announcement, we are exploring alternative PROs as potential replacements for the existing HOS outcome measures in the future; we are particularly interested in less complex replacements that would facilitate MA plans directing their quality improvement efforts on a health focus relevant to their enrollee population.

Comment: A commenter suggested the HOS survey should not be fielded during the COVID–19 pandemic because of the burden the survey places on plan members and the impact of the pandemic on their health, and recommended that HOS baselines be considered unavailable through 2023.

Response: As stated in the March 31st COVID–19 IFC (CMS–1744–IFC), CMS delayed the HOS survey for 2020 until the late summer so as not to risk the health and safety of survey vendor staff during the initial stages of the pandemic. Since survey vendors have put in place procedures to safely administer the surveys, consistent with the HPMS memo released on July 20, 2020 titled ''2020 Medicare Health Outcomes Survey (HOS) and HOS-Modified (HOS–M),'' CMS fielded the HOS and HOS–M surveys in mid-August through mid-November of 2020. Longitudinal studies like the HOS are vital to understanding the immediate and long-term impacts of the COVID–19 pandemic on beneficiaries and health care. The survey is voluntary for plan members so they are empowered to decide whether to respond.

Comment: A commenter requested help identifying their members who complete the survey so that they can do a root-cause analysis of any issues reported or found. The commenter mentioned a long lag time of approximately 3 years between baseline survey administration and when plans receive results and requested real-time data on patient outcomes.

Response: It is by design that CMS does not provide the identity of respondents until both baseline and follow-up surveying are complete in order to preserve the integrity of the sample and reliability of the results. Patient outcomes cannot be calculated using only baseline data, since the outcomes measured through this survey are the changes in physical and mental health status over time. It is important to protect the confidentiality of the survey respondents to limit the possibility of plans focusing solely on baseline survey respondents for quality improvement (in order to achieve higher scores) rather than a broad segment of the plan enrollment (which would improve the quality of care provided to the plan's overall population). HOS is a cohort study, and each year, the survey is administered to a new cohort, or group, from each contract both at the beginning and end of a 2-year period. The analysis of longitudinal data is complex, but CMS is actively striving to decrease the timeframe between completion of follow-up survey data collection and distribution of performance measurement data while maintaining the usefulness, reliability, and accuracy of the measures. In addition, CMS is working toward improved presentation of HOS performance measurement results that will include updates to the annual baseline and performance measurement reports and enhancements to the HPMS HOS module, beginning in CY 2021.

Comment: A few commenters requested as much detail be made public about the statistics for HOS as CMS publishes for CAHPS.

Response: While the timing and presentation of HOS and CAHPS results differ, both surveys provide comprehensive information and reports to each contract describing contract-specific findings and also publish information about the methodology and case-mix adjustments. As HOS is a longitudinal survey and CAHPS is an annual, cross-sectional survey, there are differences in methodology and statistics. CMS provides stakeholders and the public with similar levels of

transparency and detail on both surveys. HOS case-mix variables are published in each contract's Performance Measurement Report and coefficients are published on the HOS website and in Attachment A of the Star Ratings Technical Notes each year. Contract-specific baseline reports are currently distributed to plans in the spring of the year following baseline data collection. Performance Measurement reports are distributed in the summer of the year following follow-up data collection. Star Ratings data and aggregate score analysis reports are available in the HOS module in HPMS to allow easier data validation and score comparisons at the contract, state, region, and national levels for the core HOS physical and mental health outcome measures. Additional information about HOS and its methodology can be found at *www.HOSonline.org.* While there are differences, we believe that the extent and scope of HOS data provided to organizations is more than sufficient and comparable to the CAHPS data furnished to plans.

Comment: A commenter expressed some concern about the overlap of existing measures with the measure proposed in the 2021 Advanced Notice.

Response: In the 2021 Advance Notice, we stated that we planned to post the longitudinal Physical Functioning Activities of Daily Living (PFADL) change measure on the 2021 and 2022 display pages and that we may consider that PFADL measure for the Star Ratings in the future, pending rulemaking. Prior to potentially proposing this measure through future rulemaking, CMS would submit this measure through the Measures Under Consideration process to be reviewed by the Measure Applications Partnership which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, as required by Section 3014 of the Affordable Care Act. The 2021 Advance Notice also stated that given the complexities of the existing HOS measures, CMS is committed to exploring alternative PROs to replace the existing HOS outcome measures. We are particularly interested in replacements that would be simpler and more direct for plans to use and to focus their quality improvement efforts. If we propose to add the PFADL measure to the Star Ratings in future rulemaking, we will consider using it to replace existing measures.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized in this final rule, we are finalizing the proposed specification changes for the Improving or Maintaining Physical Health measure and Improving or Maintaining Mental Health measure but for measurement year 2022 instead of 2021. These measures would be moved to display for the 2024 and 2025 Star Ratings as the case-mix specification change is substantive as described at § 422.164(d)(2) and returned to the Star Ratings program for the 2026 Star Ratings.

b. Proposed Measure Additions

As discussed in the April 2018 final rule (83 FR 16440), new measures may be added to the Star Ratings through rulemaking and §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4) provide for reporting new measures on the display page for a minimum of 2 years before they are added to the Star Ratings program. In advance of adopting new measures through rulemaking, CMS also solicits feedback using the Advance Notice and Rate Announcement process. CMS is working with the National Committee for Quality Assurance (NCQA) to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. In the 2019 Call Letter, CMS discussed these two potential new Part C measures and finalized them in the 2020 Call Letter for the 2020 display page, which used 2018 measurement year data. In the February 2020 NPRM, CMS proposed to add the HEDIS Transitions of Care and the HEDIS Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions measures to the 2023 Star Ratings covering the contract year 2021 performance period. We stated that we would have these new Part C measures on the display page for 3 years, starting with the 2020 display page, prior to adding them to the Star Ratings program. In addition, we also discussed in the proposed rule how we would follow the pre-rulemaking process that is used in other CMS programs under section 1890A of the Social Security Act. Both of these proposed measures were submitted and reviewed through that process.

(1) Transitions of Care (Part C)

The HEDIS Transitions of Care (TRC) measure is the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year: (1) Notification of inpatient admission and discharge; (2) receipt of discharge information; (3) patient engagement after inpatient discharge; and (4) medication reconciliation post-discharge. The TRC measure was first placed on the 2020 display page.

We explained in the proposed rule how NCQA, based on stakeholder input, was exploring a few non-substantive measure specification changes. The first change, for all measure indicators, is to broaden the forms of communications from one outpatient medical record to other forms of communication such as admission, discharge, and transfer record feeds, health information exchanges, and shared electronic medical records. The second is to change the notifications and receipts from 'on the day of admission or discharge or the following day' to 'on the day of admission or discharge or within the following two calendar days.' A third is to change one of the six criteria of the Receipt of Discharge Information indicator from 'instructions to the primary care providers or ongoing care provider for patient care' to 'instructions for patient care post-discharge.' We stated how these three changes are considered non-substantive since they include additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A), add alternative data sources as described at § 422.164(d)(1)(v), and do not change the population covered by the measure. Our proposal therefore was to adopt the TRC measure with or without the updates NCQA was considering at the time the proposed rule was issued. After publication of the NPRM, we also discussed this measure in the CY 2021 Advance Notice and Rate Announcement, reiterating how NCQA was considering these three non-substantive updates to the measure that we currently have on display. The comments CMS received to the CY 2021 Advance Notice and Rate Announcement were similar to those being addressed here. These include requests for clarifications and additional time to implement the measure, as well as concerns about the coordination of information especially with out-of-network providers.

The intent of this measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events. The TRC measure excludes members in hospice and is based on the number of discharges, not members. Currently the TRC measure is on the display page and we proposed to

add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period. On July 1, 2020, NCQA published the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans [30] which included the listed measure specification changes to be implemented for data collected in 2021 covering the 2020 measurement period. Therefore, all three non-substantive updates have been adopted by the measure steward.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Many commenters fully support the intent of this measure which is to improve continuity of care for MA members as they transition from inpatient to outpatient settings.

Response: CMS thanks commenters for the support of this measure. The TRC measure has been on the display page since 2020 covering the 2018 measurement period and we believe it provides important information about MA plan quality. Under this final rule, CMS will keep this measure, with the updates NCQA finalized following the publication of the proposed rule, which included these measure specification changes to be implemented for data collected in 2021 covering the 2020 measurement period. The TRC measure will remain on the 2023 display page (for the 2021 measurement year) in light of the timing of this final rule, and will move off the display page for the 2022 measurement period for use in calculating the 2024 Star Ratings.

Comment: Several commenters recommended that the measure indicators should include all providers who can appropriately support a beneficiary during a care transition, including providers other than PCPs. A commenter suggested that pharmaceutical outreach activities be included in the 'patient engagement after discharge' category.

Response: The measure does allow for a variety of provider types and care providers to take action to meet the intent of the TRC indicators. However, the information that is used to meet the numerator of each indicator must be documented in the outpatient record that is accessible by the PCP or ongoing care provider. An ongoing care provider is defined as ''the practitioner who assumes responsibility for the member's care.'' This definition is provided in the measure specifications and is intentionally broad because NCQA recognizes there are a variety of provider types who might be coordinating patient care. As proposed and adopted, the specifications for this measure do include a variety of providers that may be taking over the responsibility of managing the patient's care. The TRC measure is for the most part focused on getting information into any outpatient record that is accessible to the PCP or ongoing care provider. Pharmaceutical outreach activities would be included in the 'patient engagement after discharge' category if they are included in the patient's outpatient records. The Medication Reconciliation indicator is the only indicator where a provider type is specified for who can take action since it specifies that medications must be reconciled by a prescribing practitioner, clinical pharmacist, or registered nurse.

Comment: A commenter argued that not only a patient's PCP but their plan should be notified of an admission and a discharge. Another commenter suggested that notifications of inpatient admissions and discharges should prioritize alignment for dually eligible members (that is, both the patient's Medicare and Medicaid providers should be notified).

Response: CMS appreciates these comments and shared them with NCQA, the measure steward. Currently, the measure only focuses on notifications that go to the PCP or ongoing care provider. The measure is specified for Medicare plans, so plans will determine the provider that meets the intent of the measure (which may include Medicaid providers treating dually eligible enrollees). Although the measure only focuses on notifications that go to the PCP or ongoing care provider, there is nothing in this measure that would prevent notifications also going to the health plan, subject to otherwise applicable laws on privacy and disclosure of health information. Further, we still believe it is important to implement this measure since transitions from the inpatient setting often result in poor care coordination, including communication gaps between inpatient providers and the PCP or ongoing care provider; unplanned medication changes; incomplete diagnostic work-ups; and inadequate patient, caregiver, and provider understanding of diagnoses, medication, and follow-up needs. This measure will put more emphasis on these issues for both providers and health plans.

Comment: Some commenters suggested that the original timeframe for notifications is too short, especially for out-of-network facilities.

Response: In the proposed rule and in the 2021 Rate Announcement, we stated how NCQA is considering a revision to the timeframe for the Notification of Inpatient Admission and Receipt of Discharge Information indicators for this measure to ''the day of admission or discharge, or within the following two calendar days.'' This change clarifies expectations for documentation related to admissions or discharges that take place over the weekend. This change was approved by NCQA's Committee on Performance Measurement following the release of the proposed rule and is included in the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans released on July 1, 2020, to be implemented for data collected in 2021 covering the 2020 measurement period. Starting with the 2022 Display measure, the TRC measure will include the expanded timeframe for the receipt of discharge information.

Comment: Several commenters stated that the composite nature of the measure may not appropriately account for variation of performance on the different elements and may not allow for understanding of the individual components. A number of commenters suggested that the four components of the composite measure be reported as separate Star Ratings measures.

Response: To minimize the number of new Star Rating measures to lessen complexity in the Star Ratings program, CMS is planning to average the four components into one composite measure for reporting in the Star Ratings program. Currently, the four components and the composite measure that combines the four components are reported on the display page. The four components of this composite measure will continue to be reported as separate measures on the display page so as to be available to plans for use in their quality improvement projects and to other stakeholders who want an additional breakdown of the data even though only the composite measure will be used in the Star Ratings. The composite measure will be displayed on Medicare Plan Finder as one measure focused on TRC to simplify the information publicly available on the website for consumers and so as not to overwhelm them with too many measures. This approach allows CMS to publicly report all included data, while directing audiences to the most helpful level of complexity for the reported results.

Comment: Some commenters suggested the current Medication Reconciliation Post-Discharge measure should remain as a separate Star Ratings measure since they believe it drives

[30] *http://store.ncqa.org/index.php/performance-measurement.html#vol2).*

improved outcomes, while others recommended retiring the current Medication Reconciliation measure after implementation of the TRC measure. Ultimately, commenters requested to know what impact the introduction of the TRC measure will have on the current Medication Reconciliation measure. A commenter suggested that if the Medication Reconciliation measure is to be incorporated into the TRC measure, NCQA should continue to permit organizations to use the hybrid data collection method.

Response: As noted in the proposed rule and the 2021 Rate Announcement, NCQA was considering revisions to the TRC measure to the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from ''the outpatient medical record as well as other information accessible to the primary care provider or ongoing care provider''. This change, which is included in the HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2: Technical Specifications for Health Plans released on July 1, 2020, will be implemented for the 2020 measurement year and enables the specification to capture additional communication forms (for example, admissions, discharges, and transfers feeds, shared electronic medical records) that occur regularly in the field and meet the intent of the TRC measure. This change also ensures that scores for the Medication Reconciliation Post-Discharge component of the TRC measure and the scores for the standalone Medication Reconciliation Post-Discharge measure currently in the Star Ratings match exactly. As such, the additional stand-alone Medication Reconciliation Post-Discharge measure would no longer need to be separately reported by health plans. The hybrid option for reporting the Medication Reconciliation component of the TRC measure will remain for the foreseeable future.

Comment: Some commenters stated that the recent changes to the TRC measure described in the proposed rule are substantive and so the measure should remain on the display page.

Response: CMS believes that the updates to this measure are non-substantive since they add additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A), include alternative data sources as described at § 422.164(d)(1)(v), and do not change the population covered by the measure. As discussed in the April 2018 final rule, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change is not considered substantive because the sponsoring organization generally benefits from that change. In addition, the type of administrative change made here has no impact on the current clinical practices of the plan or its providers. However, CMS has decided to delay the implementation of this measure to the 2022 measurement year for the 2024 Star Ratings year given the timing of this final rule and in recognition of the challenges of implementing new measures during the COVID–19 pandemic. This will provide an additional year for plans prior to implementation in the Star Ratings program.

Comment: A few commenters recommended that the TRC measure not be included in the Star Ratings until it is further improved. Other commenters noted that processes are not always in place to provide notifications to PCPs in a consistent or timely manner, especially for out-of-network facilities. A commenter suggested that this measure is primarily a measure of data interoperability and exchange capabilities between providers, capabilities which are not under plans' control. Several commenters mentioned the substantial amount of medical review work entailed for this measure, especially for the notification of admissions and discharges. Plans often require physicians to submit records for abstraction which places a considerable burden on physician practices. In other words, although this measure is a plan measure, commenters pointed out that data collection is often the responsibility of physician groups and plans do not have sufficient control or involvement to achieve consistent high performance. Further, a commenter expressed concern that the measure moves away from NCQA's focus on moving towards more digital measures. Several commenters requested further clarity on measure specifications such as how plans should indicate the use of other acceptable communication forms for this measure.

Response: The intent of the TRC measure is to ensure a seamless transition from inpatient to outpatient settings for MA enrollees to improve the delivery and coordination of care following an inpatient stay. When a beneficiary moves from an inpatient to outpatient setting, there is often poor coordination of care, communication lapses between the inpatient and outpatient providers, inadvertent medication changes, and a lack of understanding among patients, caregivers, and providers about the follow-up and ongoing care needs following the hospitalization. Given the critical importance of a seamless transition from the inpatient to outpatient setting, CMS believes it is important to adopt the current measure and for plans to make sure their providers are ensuring that there is a seamless transition between the inpatient to outpatient setting.

This measure is intended to address the very gaps in communication and interoperability that are noted in the comments. Unfortunately, the current state of standards and coding do not support a fully administrative or digital specification at this time. NCQA is continuing to work with standards developers on addressing this issue and will assess the feasibility of converting this measure to a fully administrative specification when the standards for information sharing and coding are updated to support such an approach. The measure assesses if the notification of admission or receipt of discharge information was received and documented within the timeframe specified in the measure and is agnostic about the form of communication for the Notification of Admission and Receipt of Discharge Information indicators. CMS shared these comments with NCQA, the measure steward, for consideration as they make future updates to this measure.

Comment: Some commenters stated this measure focuses on documentation of events rather than the substance of the transition experience.

Response: CMS believes this measure does focus on the substance and purpose of the transition experience, which is to improve health outcomes. The measure is not simply about documentation but about whether notification was made, discharge information was received, patients were engaged, and medication was reconciled. Poor hospital transitions are not only associated with poor health outcomes but also increased health care utilization and cost, duplicative medical services, medication errors, and increased emergency department visits and readmissions. Incentivizing better transition experiences, where these activities take place and are documented for a treating provider who furnishes post-discharge care, is an important goal served by this measure.

Comment: A commenter suggested that I–SNP members should be excluded from the measure.

Response: I–SNP members should be receiving the same care coordination as enrollees of other plan types so CMS believes it is appropriate to use this measure for such plans as well. NCQA

has examined an exclusion for I–SNP members in the past and discussed this exclusion with its advisory panels. The panels agreed that I–SNP members should be included in the measure because this is a vulnerable population that requires care coordination. We agree with that conclusion and will use this measure for I–SNPs as well as other MA plans.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the addition of the Transitions of Care (Part C) measure in the Star Ratings program with a delay of 1 year in light of the timing of this final rule. That is, CMS will implement this measure using data from the 2022 measurement year for the 2024 Star Ratings year. This measure is currently on the display page with the current specifications. The Transitions of Care measure with the updates recently finalized by NCQA for the 2020 measurement year will be on the display page for 2022 and 2023 before being used in the 2024 Star Ratings. By delaying the addition of this measure to the Star Ratings program until 2024 Star Ratings, this also allows plans more time in recognition of the challenges of implementing new measures in the program during the COVID–19 pandemic.

(2) Follow-Up After Emergency Department Visit for People With Multiple High-Risk Chronic Conditions (Part C)

CMS proposed to add a new HEDIS measure assessing follow-up care provided after an emergency department (ED) visit for people with multiple high-risk chronic conditions. This measure is the percentage of ED visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. Eligible members whose ED visits are used in the measure must have two or more of the following chronic conditions: Chronic obstructive pulmonary disease (COPD) and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack. The following meet the criteria to qualify as a follow-up service for purposes of the measure: An outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management. Patients with multiple chronic conditions are more likely to have complex care needs, and follow-up after an acute event, like an ED visit, can help prevent the development of more severe complications. We proposed to add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Many commenters fully support the intent of this measure which is to provide continuity and coordination of care to persons with multiple chronic conditions.

Response: CMS thanks commenters for the support of this measure.

Comment: Several commenters did not support the measure. Some suggested that the 7-day time period for receipt of a follow-up service is too short. Commenters argued that it can take more than 7 days for an ED claim to be processed and submitted to a plan, actions which must occur before a PCP is aware of a patient's ED visit. They stated this situation is compounded by the fact that ED visits require no preauthorization, so a PCP has no forewarning of a potential ED visit. They stated that though there are many actions which define a follow-up service—such as outpatient or telehealth physical or behavioral health visits, phone visits, or care management services—the average time to schedule a follow-up meeting with a PCP is typically longer than 7 days.

Response: CMS continues to believe that the measure is appropriate for use in the Star Ratings. This measure is focused on a very vulnerable population that should have prompt follow-up after a visit to the ED. The 7-day timeframe was recommended by NCQA's advisory panels and chosen for its potential to improve quality of care, especially because patients with multiple chronic conditions who do not receive follow-up after visiting the ED show increased rates of hospital admissions and 30-day readmissions. In addition, the lack of real-time data exchange is a critical system issue that the NCQA advisory panels cited should be addressed by this measure.

The Medicare population includes a large number of individuals and older adults with high-risk multiple chronic conditions who often receive care from multiple providers and settings and, as a result, are more likely to experience fragmented care and adverse healthcare outcomes, including an increased likelihood of ED visits.[31] [32] Medicare beneficiaries with multiple chronic conditions require high levels of care coordination, particularly as they transition from the ED to the community. During these transitions, they often face communication lapses between ED and outpatient providers and inadequate patient, caregiver and provider understanding of diagnoses, medication and follow-up needs.[33] [34] [35] [36] This poor care coordination results in an increased risk for medication errors, repeat ED visits, hospitalizations, nursing home admissions, and death.[37] [38] Medicare beneficiaries with multiple chronic conditions not only experience poorer health outcomes, but also greater health care utilization (for example, physician use, hospitalizations, ED use, and medication use) and costs (for example, medication, out-of-pocket, and total health care).[39] Medicare beneficiaries with multiple chronic conditions are some of the heaviest users of high-cost, preventable services such as those

[31] AHRQ. 2010. Multiple Chronic Conditions Chartbook. ''2010 Medical Expenditure Panel Survey Data.'' *https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf* (Accessed January 11, 2017).

[32] Agency for Healthcare Quality and Research (AHRQ). 2012. ''Coordinating Care for Adults with Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions.'' *https://pcmh.ahrq.gov/sites/default/files/attachments/coordinating-care-for-adults-with-complex-care-needs-white-paper.pdf.*

[33] Altman, R., J.S. Shapiro, T. Moore and G.J. Kuperman. 2012. ''Notifications of hospital events to outpatient clinicians using health information exchange: A post-implementation survey.'' *Journal of Innovation in Health Informatics* 20(4).

[34] Coleman, E.A., R.A. Berenson. 2004. ''Lost in transition: Challenges and opportunities for improving the quality of transitional care.'' *Annals of Internal Medicine* 141(7).

[35] Dunnion, M.E., and B. Kelly. 2005. ''From the emergency department to home.'' *Journal of Clinical Nursing* 14(6), 776–85.

[36] Rowland, K., A.K. Maitra, D.A. Richardson, K. Hudson and K.W. Woodhouse. 1990. ''The discharge of elderly patients from an accident and emergency department: Functional changes and risk of readmission.'' *Age Ageing* 19(6), 415–18.

[37] Hastings, S.N., E.Z. Oddone, G. Fillenbaum, R.J. Sloane and K.E. Schmader. 2008. ''Frequency and predictors of adverse health outcomes in older Medicare beneficiaries discharged from the emergency department.'' *Medical Care* 46(8), 771–7.

[38] Niedzwiecki, M., K. Baicker, M. Wilson, D.M. Cutler and Z. Obermeyer. 2016. ''Short-term outcomes for Medicare beneficiaries after low-acuity visits to emergency departments and clinics.'' *Medical Care* 54(5), 498–503.

[39] Lehnert, T., D. Heider, H. Leicht, S. Heinrich, S. Corrieri, M. Luppa, S. Riedel-Heller and H.H. Konig. 2011. ''Review: health care utilization and costs of elderly persons with multiple chronic conditions.'' *Medical Care Research & Review* 68(4), 387–420.

offered by the ED.[40] [41] An estimated 75 percent of health care spending is on people with multiple chronic conditions.[42] [43] Improving the timeliness of communications about ED care, as required to perform well on these measures, should not only improve care, but reduce costs as well. Because of this context, we believe that collection and use of this measure in the Star Ratings is important in order to incent contracts to provide the best care possible for vulnerable enrollees.

Comment: Some commenters noted that the measure judges plans for actions that facilities must take. Plans stated they are not always informed by facility providers of ED visits, especially by out-of-network or out-of-area facilities. Plans claimed sending notifications of an ED visit is under the sole influence of the facility. On the other hand, facility providers argued the measure puts burden on them to provide information to the plans on a very quick basis. Both plans and facility providers stated that data sharing between plans and facilities is difficult. A commenter suggested this measure might be more suited as a facility quality measure.

Response: CMS recognizes the challenges inherent in quickly and successfully communicating patient information among different types of providers. CMS believes, however, that plans are in a critical position to help coordinate the care of their members and help improve the timeliness and quality of the communications that occur among EDs, inpatient facilities, and outpatient providers. This is important because the Medicare population includes a large number of individuals and older adults with high-risk multiple chronic conditions (MCC) who often receive care from multiple providers and settings and, as a result, are more likely to experience fragmented care and adverse healthcare outcomes, including an increased likelihood of ED visits. NCQA's first year analysis results for this measure indicated that most MA contracts (approximately 92 percent) were able to report a valid rate for the measure the first year that the measure was implemented.

Comment: Some commenters wanted CMS to delay the inclusion of the measure in the Star Ratings program and suggested that it will take time to establish data sharing protocols among providers and facilities, especially with out-of-network facilities. They stated data sharing protocols are challenging.

Response: The Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions measure was placed on the 2020 display page covering the 2018 measurement year. This measure was slated to remain on the display page through 2022. This measure, however, will remain an additional year on the display page since CMS is now delaying the implementation of this measure to the 2022 measurement or performance year and the 2024 Star Ratings year given the timing of this final rule. This gives plans more time to establish data sharing protocols that allow them to facilitate timely follow-up after ED visits.

Comment: Some commenters requested modifications of the measure specifications. For example, some commenters wanted the list of services categorized as follow-up services expanded to include community resources, medication reconciliation, and services from long-term care facilities. Also, commenters suggested excluding patients released from the ED to skilled nursing facilities; not including managed long-term services and supports plans since they already have follow-up services in place; excluding inappropriate ED visits; excluding observations stays as a follow-up service; and including metabolic acidosis, cancer, and diabetes as chronic conditions.

Response: The purpose of this measure is to focus on the care provided by MA plans. CMS is working to expand efforts to better evaluate health plans' successes at effective care coordination, and we believe the addition of this measure will both add to our understanding of plan efforts to effectively coordinate care as well as encourage all plans to further focus on improving care coordination for their vulnerable enrollees. We have shared these comments with NCQA, the measure developer, and they will consider additional exclusions and inclusions for future updates to the measure, but we believe the measure as currently specified gets at the direct efforts of MA plans coordinating the care of Medicare enrollees with multiple high-risk chronic conditions following an ED visit. Therefore, we are adopting the measure for use in the Star Ratings program.

Comment: A few commenters mentioned that since psychiatric diagnoses are always coded secondary to any physical diagnosis, there are HIPAA and confidentiality concerns about disclosing information on patients with secondary substance abuse or psychiatric diagnoses. Such disclosures require patient consent. In addition, some commenters stated that it can be difficult to accurately capture data to track appropriate follow-up psychiatric care given confidentiality concerns.

Response: MA plans and providers must comply with applicable privacy and information protection laws and CMS is not providing guidance in this final rule on the specific assertions about restrictions under applicable privacy and information protection laws, such as HIPAA or 45 CFR part 2. However, the measure does not require a plan or facility to violate applicable law. CMS and NCQA will continue to monitor any issues that might arise due to patient confidentiality or consent with regard to information sharing. NCQA, in its testing protocols, has not observed this issue to cause any major barriers to reporting this measure to date.

Comment: A couple of commenters recommended risk adjustment to account for plans with large low socio-economic status, dual eligible and homeless populations.

Response: We will include this measure as one of the candidate measures for the calculation of the Categorical Adjustment Index (CAI). As stated at §§ 422.166(f)(2)(iii) and 423.186(f)(2)(iii), CAI values are determined using all measures in the candidate measure set after applying the following exclusions: The measure is already adjusted for socio-economic status, the measure focuses on a plan or provider-level issue, the measure is scheduled for retirement in the Star Ratings year that the CAI is being applied, or the measure is a SNP-only measure. It is also important to note that this measure focuses on prompt follow-up for beneficiaries with multiple chronic conditions which is a very vulnerable population. If additional risk factors such as low socio-economic status further increase these patients' levels of vulnerability, it is even more critical for this population to have

[40] CMS. 2012. *Chronic Conditions among Medicare Beneficiaries, Chartbook,* 2012 Edition. Baltimore, MD. *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf* (Accessed July 19, 2016).

[41] Lochner, K.A., and C.S. Cox. 2013. *Prevalence of multiple chronic conditions among Medicare beneficiaries, United States, 2010. https://www.cdc.gov/pcd/issues/2013/12_0137.htm* (Accessed January 11, 2017).

[42] CDC. 2009. *The power of prevention: Chronic disease . . . the public health challenge of the 21st century. http://www.cdc.gov/chronicdisease/pdf/2009-power-of-prevention.pdf* (Accessed January 24, 2017).

[43] Care Innovations. 2013. ''Cost Control for Chronic Conditions: An Imperative for MA Plans.'' The Business Case for Remote Care Management (RCM). *https://www.rmhpcommunity.org/sites/default/files/resource/The%20Business%20Case%20for%20RCM.pdf* (Accessed January 24, 2017).

prompt follow-up after visiting the ED. Further, this measure takes into account a wide variety of follow-up services to count, including telephone calls and telehealth visits, making it easier for the plan to tailor the follow-up to the enrollee or to specific enrollee populations. For example, if a beneficiary does not have transportation to get to an appointment with a provider, the follow-up can happen through a phone call with the provider.

Comment: A couple of comments stated that no new measures should be introduced into the Star Ratings program this year given the COVID–19 pandemic.

Response: Under our proposal this measure was slated to remain on the display page through 2022 Star Ratings and be used for the 2023 Star Ratings. This measure, however, will remain on the display page through 2023 since CMS is now delaying the implementation of this measure to the 2022 measurement year and the 2024 Star Ratings as a result of the timing of this final rule. Additionally, this will give plans an additional year to adjust to this new measure given any challenges from the COVID–19 pandemic.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the addition of the Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (Part C) measure in the Star Ratings program beginning with the 2022 measurement year and the 2024 Star Ratings. This delay compared to our proposal addresses both the timing of this final rule and the recognition that it is more challenging to adapt to new measures during the COVID–19 pandemic.

The changes to the Star Ratings measures we are adopting in this final rule are summarized in Table D1.

TABLE D1—NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2022

[The measure descriptions listed in this table are high-level descriptions. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) Numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually, consistent with the applicable final rules adopting changes to the Star Ratings system. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2020 are produced in the fall of 2019. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2020, the measurement period is referencing the 1/1/2018–12/31/2018 period.]

Measure	Measure description	Domain	Measure category and weight	Data source	Measurement period	NQF endorsement	Statistical method for assigning star ratings	Reporting requirements by contract type
Part C Measure								
Transitions of Care (TRC).	Percentage of discharges for members 18 years of age and older who had each of the following: (1) Notification of admission and post-discharge: (2) receipt of discharge information, (3) patient engagement, and (4) medication reconciliation.	Managing Chronic (Long Term) Conditions.	Process Measure: Weight of 1.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	Not Available	Clustering	MA-PD and MA-only.
Follow-up after ED Visit for People with Multiple High-Risk Chronic Conditions (FMC).	Percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following chronic conditions: COPD and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.	Managing Chronic (Long Term) Conditions.	Process Measure: Weight of 1.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	Not Available	Clustering	MA-PD and MA-only.

*NCQA HEDIS Measurement Year 2020 & Measurement Year 2021, Volume 2.

5. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

We proposed to modify §§ 422.166(i)(8) and 423.186(i)(6) to clarify the rules for how the adjustment for extreme and uncontrollable circumstances would apply where there are missing data, including data missing because of a data integrity issue as defined at §§ 422.164(g)(1) and 423.184(g)(1). In addition, we solicited comment in the proposed rule on a previously adopted policy regarding application of the adjustment for extreme and uncontrollable circumstances where a contract's service area was affected by disaster(s) in successive years, including whether additional changes were necessary.

We explained in the February 2020 proposed rule how we adopted the current policy for treating contracts impacted by separate disasters that occur in successive years taking into account concerns about looking back too many years for contracts affected by disasters multiple years in a row; we are also concerned about including too many measurement periods in 1 year of Star Ratings. We explained that the adjustment for extreme and uncontrollable circumstances also must consider operational feasibility, because using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings. We reiterated that we must balance concerns about using older data with concerns about using data based on performance that has been impacted by

consecutive disasters. We explained as well how we believe that the current regulation achieves an appropriate balance.

We finalized in the April 2019 final rule a policy effective for the 2022 Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by different disasters for 2 consecutive years. Such multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverts to their 2021 Star Rating on a given measure for the 2022 Star Ratings, the 2021 Star Rating is not used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the contract's 2022 Star Rating would have been, absent any disaster adjustments.

The rule for treatment of multiple year-affected contracts was established to limit the age of data that will be carried forward into the Star Ratings. We use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We finalized this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. The provisions at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) include this rule for how ratings for these measures are adjusted in these circumstances. We solicited comment on this policy and whether further adjustments are necessary.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: A commenter appreciated CMS's proposed amendment to add to §§ 422.166(i)(8) and 423.186(i)(6) to clarify that missing data include situations where there is a data integrity issue as defined at §§ 422.164(g)(1) and 423.184(g)(1).

Response: We appreciate the support for the data integrity policy. Sections 422.166(i)(8) and 423.186(i)(6) currently provide that for an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described elsewhere in the regulation applies. We proposed a clarification and are finalizing changes to state that the term ''missing data'' under the rule includes data where there is a data integrity issue as defined in §§ 422.164(g)(1) and 423.184(g)(1). Under the rules as finalized, when there is a data integrity issue in the current or previous year, the final measure rating comes from the current year.

Comment: A few commenters supported CMS's policy to adjust Star Ratings for FEMA-designated Individual Assistance area disasters for contracts that have been affected by consecutive year disasters and had at least 25 percent of enrollees residing in those areas. A commenter suggested CMS consider lowering this percentage if the situation warrants, and another requested that CMS drop the threshold for relief below the current 25 percent to determine the contracts impacted and the current 60 percent to exclude contracts from the cut point calculations for doubly-affected contracts or provide relief based on the proportion of members likely impacted.

Response: We appreciate the support for the methodology for multiple year-affected contracts codified at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv). We continue to believe that the 25 percent threshold is appropriate in the vast majority of situations where the adjustment for extreme and uncontrollable circumstances would apply. The 25 percent threshold for measure star adjustments was codified in the April 2019 final rule to ensure that disaster adjustments are limited to contracts that we believe may have experienced a real impact from extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. We believe using the same 25 percent threshold for multiple year-affected disaster adjustments as for single year disaster adjustments is appropriate for the same reasons and to ensure administrative efficiency and transparency for applying this adjustment. We addressed similar concerns about the 25 percent threshold being too high in the April 2019 final rule (84 FR 15773 through 15774). The 60 percent threshold for excluding numeric values for affected contracts from cut points and Reward Factor calculations was also codified in the April 2019 final rule; that threshold is not relevant to the adjustment for multiple year-affected contracts and we do not believe that it is necessary or appropriate to change that threshold here. We explained that threshold in the April 2019 final rule (84 FR 15771 through 15774).

Comment: A few commenters requested that CMS reconsider the current policy for adjusting Star Ratings calculations in consecutive years of extreme and uncontrollable circumstances and instead consider a multi-year lookback period, which would include the most recent period not impacted by extreme and uncontrollable circumstances. A commenter suggested CMS could use the parent organization average or the industry average instead.

Response: As we stated in the April 2019 final rule, we are concerned about looking back too many years for contracts affected by disasters multiple years in a row, as well as about including too many measurement periods in 1 year of Star Ratings. This could result in looking back different years for different contracts since we would need to look back to the latest year with no disasters for each contract. Carrying forward very old data into the Star Ratings for many years, especially in situations where large numbers of contracts are impacted by disasters in a given year or in areas that are more prone to disasters, could erode incentives for plans to provide high quality care for their beneficiaries even in the face of a disaster.

Further, using a multi-year lookback for contracts affected by disasters would be operationally very complex since for each contract we could be comparing to a different year of data that is unaffected, in particular in areas that are prone to disasters, and could put CMS at risk of not producing Star Ratings in time for open enrollment. It would also make it difficult to provide transparency to plans and could be misleading to consumers. CMS has an obligation to ensure that Star Ratings data are useful for providing comparative plan information to beneficiaries because part of the purpose and authority for the Star Ratings is to provide comparative information to beneficiaries under sections 1851(d) and 1869D–1(c) of the Act. We strive to provide as up-to-date and accurate information on plan quality and performance as possible to beneficiaries. For areas that are prone to disasters in particular, beneficiaries deserve to have some indication if that means that the plan they are considering does not perform well when a disaster strikes or maintains high quality ratings despite those challenges. We finalized the existing policy for contracts that are affected by disasters in successive years in order to balance concerns about either using older data or using data based on performance impacted by consecutive disasters.

As to the suggestion to assign the parent organization average or industry average for contracts that have been impacted by disasters for multiple years, we do not believe this appropriately holds contracts accountable for their performance or allows them to distinguish themselves in disaster situations. We remind contracts that §§ 422.504(o) and 423.505(p) require MA organizations and Part D sponsors to develop, maintain, and implement a business continuity plan that ensures restoration of operations following disruptions such as disasters. Contracts are still responsible for providing care to their beneficiaries during disasters, so it would not be fair or appropriate to simply award them a rating that is based on the performance of other plans. Further, the Star Ratings are used for payment purposes and using the performance of other plans as the basis to award a quality bonus increase or increased rebate percentage to a contract is inconsistent with the purpose of those payment policies to reward MA organizations that excel.

Comment: A commenter suggested CMS could consider a hold harmless provision for plans with significant losses in Star Ratings across the multi-year lookback period.

Response: The disaster policies already address how extreme and uncontrollable circumstances may have a negative impact on the Star Ratings of an MA or Part D plan. We do not believe additional hold harmless provisions are needed for multiple year-affected contracts as it could weaken plan accountability and incentives to provide high quality care in disaster situations.

Comment: Several commenters suggested CMS expand the current rule for contracts impacted by two different disasters in consecutive years to include contracts impacted by a single disaster spanning multiple years.

Response: The introductory language of paragraph (i) of both §§ 422.166 and 423.186 states that we use the incident start date to determine which year of Star Ratings can be adjusted for a particular disaster, regardless of whether the incident period lasts until another calendar year. As we explained in the April 2019 final rule (84 FR 15774), in some cases the incident period end date changes, which would make it difficult operationally to determine which Star Ratings year is impacted. We believe limiting adjustments for a single disaster to 1 year is appropriate to avoid adversely impacting CMS's operational timelines for analyzing data and calculating Star Ratings. For example, if a disaster is extended into the next measurement year we would potentially need to recalculate and reissue ratings. We also want to limit the impact and effects on contracts that do meet the definition of ''affected contract.'' We are concerned, for example, about the integrity of the ratings and reliability of the comparisons if cut points do not take into account the performance of an increasing number of affected contracts or if cut points have to be recalculated after they are released. We also want to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years.

Comment: A couple commenters requested clarification about how CMS handles situations where a contract is affected by multiple disasters in the same year.

Response: We use the percent of enrollment impacted by qualifying disasters to determine eligibility for disaster adjustments. That is, contracts impacted by multiple qualifying disasters in the same year are eligible for the disaster relief as long as a total of 25 percent or more of their enrollees reside in Individual Assistance areas. CMS rolls up the enrollment for each contract at the state/county level; when more than one enrollment period applies (that is, because the contract was affected by more than one disaster), an average of the enrollments from each of corresponding enrollment periods where the contract was affected is used to calculate the total percent of a contract's enrollees in a FEMA-designated Individual Assistance area during extreme and uncontrollable circumstances. This is described in detail in the Medicare Part C & D Star Ratings Technical Notes Attachment Q: Identification of Contracts Affected by Disasters (*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData,* page 143 of 2020 Star Ratings Technical Notes).

Comment: We received a number of comments about the impact of COVID–19 on Star Ratings, for example asking whether and how CMS would adjust for the impact of COVID–19 for 2021 Star Ratings and beyond.

Response: The public health emergency incident start date for COVID–19 was in 2020, so adjustments under the extreme and uncontrollable events policy at §§ 422.166(i) and 423.186(i) will apply to the 2022 Star Ratings. The March 31st COVID–19 IFC addressed the immediate impact of the pandemic on the Part C and D Star Ratings program and made additional modifications for the 2022 Star Ratings, in recognition that the COVID–19 pandemic may impact performance on the Star Ratings measures during the 2020 measurement period. CMS will continue to monitor the impact of COVID–19 on the healthcare system and Part C and D plans. The September 2nd COVID–19 IFC modifies the calculation of the 2022 Part C and D Star Ratings to address the application of the extreme and uncontrollable circumstances policy. We direct readers to our summary of those two interim final rules with comment in section IV.D.1 of this final rule.

Comment: Several commenters requested that CMS expand the current extreme and uncontrollable circumstance policy for single year disasters, for example to include HHS-declared public health emergencies, Fire Management Assistance Grant (FMAG) declarations, governor declarations of a state of emergency, or state-level public health emergencies that extend beyond a national emergency period. A few stated if a contract gets the same Star Rating in both years, CMS should take the higher of the 2 years' measure scores in order to ensure that plans and beneficiaries are truly held harmless in the event of a disaster. Several commenters suggested modifications to how the improvement measures are handled when there are disasters. For example, we received suggestions to hold contracts harmless in improvement when there are disasters.

Response: The changes suggested by commenters for expanding the adjustments for single year disasters are significant in scope and of the type that would require analysis and consideration by CMS before proposing changes to the current regulations. As we noted in the April 2019 final rule (84 FR 15773), we use the Star Rating for the measure-level comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. We use the corresponding measure scores for improvement calculations in order to maintain consistency in the years being compared. We only revert to the previous year's measure Star Rating if it is higher (§§ 422.166(i)(2)(iv), 422.166(i)(3)(iv), 422.166(i)(4)(v), 422.166(i)(6)(i), 423.186(i)(2)(iv), and 423.186(i)(4)(i)).

Summary of Regulatory Changes

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the addition of §§ 422.166(i)(8) and 423.186(i)(6) as proposed. These changes are applicable to the 2022 measurement year and the 2024 Star Ratings. We do not believe additional

revisions to the rules for multiple year-affected contracts described at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) are necessary to address the impacts of the PHE for the COVID–19 pandemic in light of the September 2nd COVID–19 IFC.

6. Quality Bonus Payment Rules (§§ 422.162(b)(4) and 422.166(d)(2)(vi))

We proposed several amendments to §§ 422.162(b)(4) and 422.166(d)(2)(vi) to codify our current policies for using the Star Ratings to calculate quality bonus payment percentage increases (QBPs) and determine beneficiary rebates for MA organizations.

The Affordable Care Act amended sections 1853(n) and 1853(o) of the Act to require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star Quality Rating system. The Affordable Care Act also amended section 1854(b)(1)(C) of the Act to change the share of savings available to MA organizations and that they must provide to enrollees as the beneficiary rebate, mandating that the level of rebate is tied to the level of an MA organization's QBP rating. As a result, beginning in 2012, quality as measured by the 5-star Quality Rating System directly affected the monthly payment amount MA organizations receive from CMS. At the time the QBPs were implemented, CMS codified at § 422.260 an administrative review process available to MA organizations for payment determinations based on the quality bonuses. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal request under § 422.260(c) if they believe there is a calculation error or incorrect data are used.

In the April 2018 final rule, we codified at § 422.160(b)(2) that the ratings calculated and assigned under this subpart are used to provide quality ratings on a 5-star rating system used in determining QBPs and rebate retention allowances. Historically, the QBP rating rules have been announced through the Advance Notice and Rate Announcement since section 1853(b) of the Act authorizes an advance notice and rate announcement to solicit comment for proposed changes and announce changes to the MA payment methodology. The QBPs are used as part of setting the MA benchmarks and capitation rates for counties (and thus, MA service areas) each year. As we have codified in regulation the methodology for the Star Ratings over the last couple of years, we proposed in the February 2020 proposed rule to clarify the rules around assigning QBP ratings, codify the rules around assigning QBP ratings for new contracts under existing parent organizations, and amend the definition of new MA plan that is codified at § 422.252 by clarifying how we apply the definition. Our proposal was to codify current policy (for how we have historically assigned QBP ratings) as generally adopted and implemented through the section 1853(b) process, without substantive changes.

Historically, for contracts that receive a numeric Star Rating, the final QBP rating released in April for the following contract year would be the contract's highest rating as defined at § 422.162(a) (that is, overall or summary rating). Section 422.260(a) states that the QBP determinations are made based on the overall rating for MA–PDs and the Part C summary rating for MA-only contracts. We proposed to add language at § 422.162(b)(4) stating that for contracts that receive a numeric Star Rating, the final QBP rating is released in April of each year for the following contract year and that the QBP rating is the contract's highest rating, as that term is defined at § 422.162(a). We also proposed to clarify in the regulation text that the QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies. For example, the 2020 QBPs were released in April 2019 and based on the Star Ratings published in October 2018. For MA contracts that offer Part D, the QBP rating would be the numeric overall Star Rating. For MA contracts that do not offer Part D (MA-only, MSA, and some PFFS contracts), the QBP rating would be the numeric Part C summary rating. We also proposed adding language at § 422.162(b)(4)(ii) clarifying that the contract QBP rating is applied to each plan benefit package under the contract.

We explained in the February 2020 proposed rule that if a contract does not have sufficient data to calculate and assign Star Ratings for a given year because it is a new MA plan or low enrollment contract, § 422.166(d)(2)(v) provides the rules for assigning a QBP rating. That regulation references the definitions at § 422.252. We proposed to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. We address that proposal in section IV.D.2 of this rule.

We also proposed to add rules at § 422.166(d)(2)(vi) for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of either low enrollment contracts or new MA plans at § 422.252. Our proposal was to codify the policy that has been in place since the 2012 Rate Announcement: Any new contract under an existing parent organization that has had MA contract(s) with CMS in the previous 3 years receives an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. We also addressed that policy in a proposed rule for CY 2012 that appeared in the **Federal Register** on November 22, 2010 (''Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes'') (75 FR 71190, 71219) and the related final rule that appeared in the **Federal Register** on April 15, 2011 (76 FR 21432, 21486 through 21490). We explained in the February 2020 proposed rule that we intended for this policy to continue uninterrupted so that the calculation of QBPs remains stable and transparent to stakeholders. Codifying the policy explicitly, as well as how it is applied, would serve this purpose.

We proposed to add at § 422.166(d)(2)(vi)(A) that any new contract under an existing parent organization that has other MA contracts with numeric Star Ratings in November (when the preliminary QBP ratings are calculated for the contract year that begins 14 months later) would be assigned the enrollment-weighted average of the highest Star Rating of all other MA contracts under the parent organization that will be active as of April the following year. The Star Ratings used in this calculation would be the whole or half Star Ratings that are publicly displayed. For the 2021 QBPs, for any new contracts under an existing parent organization, we explained how the policy would be applied as follows:

(i) We identify the parent organization of the new contract in November 2019.

(ii) We identify the MA contracts held by that parent organization in November 2019, when the preliminary 2021 QBP ratings are posted for review. For preliminary QBP ratings, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2019 that we anticipated to still be in existence and held by that parent organization in April 2020.

(iii) Using the enrollment in those other MA contracts as of November 2019, we calculated the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iv) In April 2020, we update the enrollment-weighted average rating based on any changes to the parent

organization of existing contracts, using the November 2019 enrollment in the contracts. The enrollment-weighted average rating includes the ratings of any contract(s) that the parent organization has acquired since November 2019. This enrollment-weighted average is used as the 2021 QBP rating for the new MA contract under the parent organization for payment in 2021. We release these QBP ratings in April of the year before the payment year (for 2021 QBPs, in April of 2020).

Because our proposal was to codify existing and current policy without change, we followed these steps to identify the QBP ratings for new contracts of existing MA parent organizations for 2021 QBPs.

We proposed to add at § 422.166(d)(2)(vi)(B) that if a new contract is under a parent organization that does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years. The QBP rating would be the enrollment-weighted average of the MA contracts' highest-level Star Ratings from the most recent year that had been rated for that parent organization. We explained using an example: If in November 2019 there were no other MA contracts under the parent organization with numeric 2020 Star Ratings, we would go back first to the 2019 Star Ratings and then the 2018 Star Ratings. Under our existing policy, and thus under the proposal, if there were MA contract(s) in the parent organization with Star Ratings in any of the previous 3 years, the QBP rating was the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year rated. Under our existing policy, and thus under the proposal, the Star Ratings used in this calculation would be the rounded Star Ratings (whole or half star) that are publicly displayed on *www.medicare.gov.*

We explained in the February 2020 proposed rule how the policy works by using another illustration for the 2021 QBPs. For a new contract(s) under a parent organization that did not have any MA contracts in November 2019:

(i) We identify the MA contracts held by that parent organization in November 2018. If the parent organization had other MA contracts in November 2018, we use the numeric Star Ratings issued in October 2018 for those MA contracts that were held by the parent organization in November 2018.

(ii) Using the enrollment in those other MA contracts as of November 2018, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This enrollment-weighted average is used as the 2021 QBP rating for the new MA contract for that parent organization, for payment in 2021 and is released to the MA organization for the new contract in April of 2020.

Because our proposal was to codify existing and current policy without change, we followed these steps for the 2021 QBPs where applicable. And for any new contract(s) under a parent organization that did not have any MA contracts in November 2018 and 2019, we provided an illustration (again for the 2021 QBPs) as follows:

(i) We identified the MA contracts held by that parent organization in November 2017. If the parent organization had other MA contracts in November 2017, we used the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2017.

(ii) Using the enrollment in those other MA contracts as of November 2017, we calculated the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This is used as the 2021 QBP rating for the new MA contract for payment in 2021 and is released to the MA organization for the new contract in April 2020.

We explicitly explained how if there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 (for QBP purposes) and § 422.166(d)(2)(v) (for other purposes). Our proposal was to codify existing and current policy without change, and we followed these steps for the 2021 QBPs where applicable. Under this final rule, we will follow the same steps for the 2022 QBPs.

We proposed the rules for calculating the enrollment-weighted average and addressing changes in parent organizations in new paragraphs (d)(2)(iv)(C) through (E) at § 422.166. We proposed to add at § 422.166(d)(2)(vi)(C) that the enrollment used in the enrollment-weighted calculations is the November enrollment in the year the Star Ratings are released. The enrollment data are currently posted publicly at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.*

We also proposed at § 422.166(d)(2)(vi)(D) that the QBP ratings would be updated for any changes in a contract's parent organization prior to the release of the final QBP ratings in April of each year. We explained that under our proposal, the same rules described at § 422.166(d)(2)(vi)(A), (B), and (C) would be applied to the new contract using the new parent organization information. We provided an example, again using the 2021 QBPs: In April 2020 when the final QBP ratings were released, the enrollment-weighted average rating would include the ratings of any MA contract(s) that the parent organization had acquired since November 2019. Thus, if a parent organization buys an existing contract it would be included in the enrollment-weighted average. We also proposed at § 422.166(d)(2)(vi)(E) to codify our current practice that once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are possible for QBP purposes.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Several commenters expressed support for codifying the QBP rating policies in regulation and provided support for the existing policies.

Response: CMS appreciates the support.

Comment: A commenter expressed concern that the QBP rating is based on too many measures and should be based on a small set of measures related to patient experience and outcomes at the geographic level.

Response: The regulation at § 422.260(b), revised in the April 2018 final rule, provides that the QBP determination methodology is the quality ratings system specified in subpart 166 of part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. The methodology for the quality ratings system was codified for the 2019 measurement year and 2021 Star Ratings in the April 2018 final rule. Further, that amendment to § 422.260(b) was merely codification of a longstanding policy, discussed in the CY 2012 proposed rule (75 FR 71219, 71221) and the CY 2012 final rule (76 FR 21486 through 21490). We did not propose to change that rule and do not believe it is necessary or appropriate at this time.

In the April 2018 final rule, we stated that the Star Rating system provides information in a summary fashion that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care and is based on a delicate balance of measuring numerous aspects of quality and the need for a

small data set that minimizes reporting burden on the industry (83 FR 16520). Most commenters supported the principles underlying the Star Ratings program as described in the April 2018 final rule and made various suggestions for additional measure concepts to include. We do not believe that a change to the ratings used for QBP purposes is appropriate at this time and, even if we did, we believe that such a significant change from current practice as suggested in the comment should be subject to additional analysis and the opportunity for public comment via the rulemaking process. Our current Part C and D Star Ratings contractor, RAND Corporation, is currently soliciting input from their Technical Expert Panel on suggested potential changes to the mix and number of measures included in the Star Ratings program for consideration in the future. For more information about the Technical Expert Panels, please see *https://www.rand.org/health-care/projects/star-ratings-analyses.html.*

Comment: A couple of commenters suggested that all new contracts be treated as qualifying contracts and received the 3.5 percentage increase in the benchmark, regardless of whether the parent organization has other MA contracts. A commenter focused on this being fairer to new entrants, while another commenter focused on the statutory provision at 1857(c)(4) of the Social Security Act that guards against contracts leaving and then immediately re-entering the MA program.

Response: Historically, we have followed the rules to assign QBP ratings for a new contract under an existing parent organization that were first adopted in the 2012 Advance Notice and Rate Announcement and the April 2011 final rule that codified the definition of a new MA plan. New contracts under existing parent organizations have traditionally received the weighted average of the ratings of the contracts under the parent organization to minimize the incentive to create new contracts to qualify for a QBP. If the overall performance of an organization is poor, that organization otherwise would have incentives to game the system to be treated as a qualifying plan for QBP purposes for 3 years. This would ignore information that CMS has about the overall performance of the contracts under the parent organization given at least some of the administrative systems are shared across contracts within a parent organization. If there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 since CMS does not have recent experience with the organization.

New contracts under existing parent organizations do not necessarily qualify for a QBP; thus, this policy is not unfair to new entrants. Additionally, new entrants where the parent organization does not have recent experience as an MA contract are treated as qualifying plans for 3 years until they have enough data to assess their performance. For the 2021 QBP ratings, 47 percent of the new contracts under existing parent organizations received 3.5 stars or less; thus, these new contracts did not qualify for QBPs. We understand that 1857(c)(4) guards against contracts leaving and immediately entering the MA program, but we believe it is still important to guard against existing contracts opening up new contracts primarily to be treated as qualifying contracts for QBP purposes.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the methodology to calculate the QBP ratings as proposed at §§ 422.162(b)(4) and 422.166(d)(2)(vi) with a slight revision of the text to further clarify that the enrollment figures used in the enrollment-weighted QBP rating calculations are the November enrollment in the year the Star Ratings are released. Our proposal was to codify existing and current policy without change, and under this final rule, we will follow the same steps as prior years for calculating the 2022 QBPs.

E. Permitting a Second, ''Preferred,'' Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

1. Overview and Summary

Section 1860D–2(b)(2) of the Act, which establishes the parameters of the Part D program's Defined Standard benefit, allows for alternative benefit designs that are actuarially equivalent to the Defined Standard benefit, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan designs. Use of a specialty tier provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs. Our policy for the specialty tier has aimed to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority.

Section 1860D–4(g)(2) of the Act requires Part D sponsors to have an exceptions process under which a beneficiary who is enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the plan's tiered cost-sharing structure. The statute provides that under the exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if certain conditions are met. The statute grants CMS authority to establish guidelines under which Part D enrollees may request exceptions to tiered cost-sharing structures and under which a determination with respect to such a request is made. Under § 423.578(a), we require each Part D sponsor that manages its benefit through the use of a tiered formulary to establish and maintain reasonable and complete exceptions procedures subject to our approval. The Part D sponsor must grant an exception when it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement that the preferred drug: (i) Would not be as effective for the enrollee as the requested drug; (ii) would have adverse effects for the enrollee; or (iii) both.

However, if Part D sponsors were to permit tiering exceptions to allow Part D enrollees to obtain drugs on specialty tiers at a lower cost sharing applicable to non-specialty tiers, they would also likely increase Part D premiums as well as cost sharing for non-specialty tiers. In other words, the ability to get lower cost sharing on specialty-tier Part D drugs through tiering exceptions means that costs would likely go up elsewhere—such as by increasing the cost sharing on generic drug tiers—in order to keep the benefit design actuarially equivalent to the Defined Standard. Consequently, in permitting Part D sponsors to maintain a specialty tier, we also implemented a regulation (most recently § 423.578(a)(6)(iii)) that permits (but does not require) Part D sponsors to exempt Part D drugs placed on the specialty tier from their tiering exceptions processes.

Accordingly, to restrict the specialty tier to only the highest-cost Part D drugs, beginning in 2007,[44] [45] we

[44] For 2007, we established the specialty-tier cost threshold at a negotiated price of $500 per month. Please see Medicare Modernization Act 2007 Final Guidelines—Formularies. *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/cy07formularyguidance.pdf.*

[45] The specialty-tier cost threshold was increased to $600 per month in 2008, and remained at $600

Continued

developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier.[46] Additionally, to prevent discriminatory formulary structures, in particular to protect Part D enrollees with certain disease types that are treated only by specialty-tier eligible drugs, our guidance[47] has set the maximum allowable cost sharing for specialty-tier Part D drugs between 25 and 33 percent coinsurance (25/33 percent).

We have not previously permitted Part D sponsors to structure their plans with more than one specialty tier. Pointing to factors such as the introduction of biosimilar biological products to the market[48] and recent higher pricing of some generic drugs relative to brand drug costs, some stakeholders requested that we reconsider this policy. They posited, for instance, that creating an additional specialty tier could improve the ability of Part D sponsors to negotiate with pharmaceutical manufacturers to help lower the prices of high-cost Part D drugs. Moreover, in its June 2016 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*), the Medicare Payment Advisory Commission (MedPAC) suggested that allowing plans to maintain two specialty tiers with differential cost sharing could potentially encourage the use of lower-cost biosimilar[49] biological products and encourage competition among existing specialty Part D drugs. More recently, some commenters on our Draft 2020 Call Letter (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf*) took the opportunity to advocate for a second specialty tier.

Improving Part D enrollee access to needed drugs and lowering drug costs are central goals for CMS. Accordingly, in the hopes of providing flexibility that will promote these goals, we proposed to allow (but not require) Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. Under this policy, Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the specialty-tier cost threshold that would be established according to the methodology we proposed and the requirements of our formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we proposed to codify a maximum allowable cost sharing that would apply to a single specialty tier, or, if a Part D sponsor has a plan with two specialty tiers, to the higher cost-sharing, specialty tier. Further, we proposed to require that if a Part D sponsor has a plan with two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the higher cost-sharing, specialty tier.

We note that we did not propose any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a Part D drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. The exemption from tiering exceptions for specialty-tier Part D drugs, at § 423.578(a)(6)(iii), would apply only to tiering exceptions to non-specialty tiers (meaning, when the tiering exception request is for the specialty-tier Part D drug to be covered at a cost-sharing level that applies to a non-specialty tier). Under our proposal, we would require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing, specialty tier to the lower cost-sharing, specialty tier.

To improve transparency, we proposed to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we proposed to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, inclusive (that is, 25 percent ≤ maximum allowable cost sharing ≤ 33 percent), depending on whether the plan includes a deductible, as described further in section IV.E.4. of this final rule.

We also proposed to determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty-tier placement—based on a 30-day equivalent supply. Additionally, we proposed to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the PDE. This would be a change from our current policy, which uses the negotiated price reflected on the PDE. Under our proposal, the specialty-tier cost threshold would apply to both specialty tiers.

To respond to comments on our Draft 2020 Call Letter requesting that the specialty-tier cost threshold be increased regularly, we also proposed to maintain a specialty-tier cost threshold that is set at a level that, in general, reflects Part D drugs with monthly ingredient costs that are in the top 1 percent of all monthly ingredient costs, as described further in section IV.E.6. of this final rule. We proposed to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDEs shows that recalibration of the specialty-tier cost threshold is necessary to continue to reflect only Part D drugs with the top 1 percent of monthly ingredient costs. We proposed to annually: (1) Determine whether the adjustment would be triggered, and (2) announce the specialty-tier cost threshold.

2. A Second, ''Preferred,'' Specialty Tier

Placement on the specialty tier can play an important role in maintaining lower cost sharing on non-specialty tiers. The non-specialty, non-preferred brand/drug tiers frequently have cost sharing equal to as much as 50 percent coinsurance. This means that Part D enrollees would pay considerably more after application of coinsurance for a high-cost drug if it appeared on a non-specialty, non-preferred brand/drug tier with, for instance, 50 percent cost sharing as opposed to placement on the specialty tier, which has been subject to lower cost-sharing requirements. For this reason, we reject the recommendation of some commenters on our Draft 2020 Call Letter that we eliminate the specialty tier altogether.

To the opposite effect, as discussed in section IV.E.1 of this final rule, other

per month from contract years 2008 through 2016. See *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf* and *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.*

[46] See, for instance, Draft 2020 Call Letter, pages 178–179 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf*), and Final 2020 Call Letter, page 208 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*).

[47] See section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf* and page 21 of the 2020 Bid Submission User Manual, Chapter 7: Plan Benefit Package Rx Drugs Section. The Bid Submission User Manual for 2020 is available at the following pathway after logging into the Health Plan Management System (HPMS): Plan Bids > Bid Submission > Contract Year 2020 > View Documentation > Bid Submission User Manual.

[48] See the April 2018 final rule for more background on biosimilar biological products (83 FR 16610).

[49] Unless our policy specifically distinguishes biosimilar biological products from interchangeable biological products, we use the term ''biosimilar biological product(s)'' in this preamble to reference biosimilar or interchangeable (when such products become available) biological products.

stakeholders, including MedPAC, have recommended that we permit Part D sponsors to maintain a second specialty tier. Stakeholders favoring this approach have posited that this change would: (1) Improve the ability of Part D sponsors and pharmacy benefit managers (PBMs) to negotiate better rebates [50] with manufacturers by enabling them to establish a preferred specialty tier that distinguishes between high-cost drugs and effectively encourages the use of preferred specialty-tier Part D drugs; (2) reduce costs for Part D enrollees, not only through direct cost-sharing savings associated with a lower cost-sharing, ''preferred'' specialty tier, but also indirectly, through the lowered premiums for all Part D enrollees that could result from better rebates on specialty-tier Part D drugs; and (3) reduce our costs directly through lower drug costs because lower cost sharing would delay a Part D enrollee's entry into the catastrophic phase of the benefit in which the government is responsible for 80 percent of the costs.

Consistent with our ongoing efforts to implement new strategies that can help lower drug prices and increase competition, we proposed to permit Part D sponsors to have up to two specialty tiers by permitting a new preferred specialty tier. However, driven by ongoing concerns over actuarial equivalence and discriminatory benefit designs, in order to strike the appropriate balance between plan flexibility and Part D enrollee access, we also needed to carefully weigh the following factors: (1) Tiering exceptions between the two specialty tiers or to other, non-specialty tiers; (2) the maximum allowable cost sharing for each specialty tier; and (3) tier composition (that is, the selection of Part D drugs for each specialty tier). The regulatory text to allow up to two specialty tiers (which reflects our consideration of these factors) and other related proposals are discussed in the following sections of this preamble.

We received 82 public comments concerning our proposal to permit Part D sponsors to maintain up to two specialty tiers. Although there was some overlap in stakeholder categories, 81 comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. The remaining comment was from an individual beneficiary. A summary of the comments and our responses follow.

Comment: Many commenters supported CMS's proposal.

Response: We thank the commenters for their support.

Comment: Some commenters advocated that CMS should abolish specialty tiers altogether, finding them to be outdated and discriminatory to the Part D enrollees whose conditions require they take Part D drugs placed on the specialty tiers. Similarly, these commenters suggested that specialty tiers are unique to prescription drug benefits with no equivalent in the medical benefit and run counter to the purpose of insurance altogether by effectively serving as what the commenter termed ''reverse insurance,'' reasoning that the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit.

Response: We thank the commenters for this perspective. However, the use of specialty tiers in the commercial market predates the Part D program by several years, and there is widespread use of two specialty tiers in employer-based plans, with some plans using two or more specialty tiers since at least 2014.[51] [52] [53] [54] [55] [56] [57] Additionally, Part D enrollee cost sharing for the specialty tier(s) in Part D, with a maximum allowable cost sharing of 25/33 percent coinsurance is equal to, or, in the case of the preferred, specialty tier that has cost sharing less than the 25/33 percent maximum, better than cost sharing under the Defined Standard benefit. Because cost sharing under the Defined Standard benefit is provided for by statute, neither cost sharing under the Defined Standard benefit nor specialty-tier cost sharing, which is better than the Defined Standard benefit, is discriminatory. Moreover, a hallmark of Medicare Part D is that it relies on market forces to provide prescription drug benefits to Part D enrollees, and, as a public benefit that is administered by the private insurance market, it is incumbent upon us to keep abreast of industry standards for the provision of this benefit while also balancing Part D enrollee access to prescription drugs. While the use of a specialty tier may be counterintuitive, it is a tool widely used in the industry to address a highly volatile market for high-cost Part D drugs. Although there are distinctions between commercial plans and the Medicare Part D program, we believe this particular option is worth pursuing, not only because of the possibility that benefits could ensue, but most centrally because we do not anticipate that permitting a second, preferred specialty tier would lead to additional harms for Part D enrollees given our proposed Part D enrollee protections, such as retention of the 25/33 percent maximum allowable cost sharing.

We also disagree with the assertion that the specialty tier(s) serve as a perverse, ''reverse insurance'' whereby the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit. We believe this reasoning is flawed because the specialty tier is aligned with the Defined Standard benefit, and the Part D plan bid requirements also necessitate that the benefit structure below the specialty tier also be actuarially equivalent to the Defined Standard benefit. Therefore, the use of specialty-tier eligible drugs has no differential impact on lowering the premiums and cost sharing on non-specialty tiers for the rest of the benefit.

Lastly, we believe that providing Part D sponsors the ability to make business decisions regarding the distribution of insurance risk, as permitted by the statute and while retaining central Part D enrollee protections, reflects the goals of the Part D program, which aim to provide flexibilities, when possible, that could enable Part D sponsors to offer robust formularies with lower costs.

Comment: Some commenters expressed concern that, although CMS proposed to permit Part D sponsors to maintain up to two specialty tiers, CMS did not propose corresponding regulatory text to this effect. Some commenters urged CMS to clarify that a second specialty tier is voluntary, and other commenters urged CMS to clarify

[50] In this section of this final rule, by ''rebates,'' we are broadly referring to either retrospective or point-of-sale (POS) rebates or discounts.

[51] The following link provides access to the Kaiser Family Foundation's archives of the annual Employer Health Benefits Survey. *https://www.kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/.*

[52] Kaiser Family Foundation 2014 Employer Health Benefits Annual Survey, Pages 164 and 166, *http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report.*

[53] Kaiser Family Foundation 2015 Employer Health Benefits Annual Survey, Pages 160–162, *http://files.kff.org/attachment/report-2015-employer-health-benefits-survey.*

[54] Kaiser Family Foundation 2016 Employer Health Benefits Annual Survey, Pages 172–174, *http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey.*

[55] Kaiser Family Foundation 2017 Employer Health Benefits Annual Survey, Page 156, *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[56] Kaiser Family Foundation 2018 Employer Health Benefits Annual Survey, Page 161, *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[57] Kaiser Family Foundation 2019 Employer Health Benefits Annual Survey, Page 161, *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019.*

that a second specialty tier would be in addition to the total number of allowed drug tiers, rather than in place of an existing tier.

Response: We proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers; additionally, as discussed in section IV.E.3 of this final rule, we also proposed to amend § 423.578(a)(6)(iii) to reflect the possibility of a second specialty tier. Maintaining one or two specialty tier(s) is voluntary. Similarly, we also clarify that a second specialty tier would be in addition to, not in lieu of, the six existing tiers for actuarially equivalent benefit designs.

Comment: Some commenters suggested that this proposal would limit access to specialty-tier Part D drugs, complicate an already complicated benefit structure/process for Part D enrollees, and/or would involve additional, burdensome utilization management for prescribers. Some commenters urged CMS to do a demonstration or pilot before finalizing the proposals to permit a second specialty tier, while others urged CMS to monitor the uptake of the use of a second specialty tier.

Response: We do not anticipate adverse effects to Part D enrollees' access to specialty-tier Part D drugs by allowing Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier, as we have proposed, either in terms of formulary access or Part D enrollee cost sharing. This is due in large part to the other Part D enrollee protections we proposed in conjunction with our proposal to permit Part D sponsors to maintain a second specialty tier (notably, tiering exceptions between the two specialty tiers and maximum allowable cost sharing, as discussed in sections IV.E.3., and IV.E.4., respectively, of this final rule). As we do not anticipate that permitting a second, preferred specialty tier would lead to harm for any Part D enrollees, it seems reasonable to provide the requested flexibility, as proposed, to Part D sponsors. We are mindful of the need to minimize complexity and make our rules as transparent as possible. However, we believe that the risk of confusion will be outweighed by the potential for Part D sponsors to provide their enrollees with improved access to specialty-tier Part D drugs because improved competition for preferred specialty tier formulary placement results in better negotiations for Part D sponsors, which could result in lower cost sharing for Part D enrollees.

Many specialty-tier Part D drugs already require utilization management, including prior authorization and/or step therapy to access the drug, and then monitoring the enrollee once therapy has been initiated. Utilization management requirements are subject to the requirements of our annual formulary review and approval process under § 423.120(b)(2). (We detailed the components of our annual formulary review and approval process in our May 2019 final rule (84 FR 23835).) As part of this review and approval process, we perform multiple reviews related to the clinical appropriateness of both tier composition and utilization management strategies. For additional information, please also see section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.*) Additionally, the same specialty-tier cost threshold would apply to both specialty tiers. In other words, there is no difference in eligibility for specialty-tier placement between the two specialty tiers, and therefore, specialty-tier eligible Part D drugs would be divided between the two specialty tiers. Consequently, we do not anticipate that allowing a second specialty tier would introduce significant utilization management beyond what is already required or increase the number of drugs placed on a specialty tier.

In finalizing our proposals to permit Part D sponsors to maintain up to two specialty tiers, we intend to monitor the uptake of the use of a second specialty tier. We are unclear about, generally, what the commenters believe we would research in a demonstration or pilot, and do not believe one is necessary given the Part D enrollee protections we are finalizing as part of this final rule.

Comment: Some commenters suggested that CMS should not finalize the proposals regarding permitting Part D to maintain up to two specialty tiers for 2021 and that CMS should clarify that the bids for coverage year 2021 will be based on existing rules. Some commenters mentioned that CMS needs to issue new guidance regarding the Plan Bid Package (PBP) Beta Software, which currently does not provide the functionality to file a preferred specialty tier, and that to maintain compliance, CMS needs to provide the specific filing requirements for the second tier. Some commenters suggested that with these changes, CMS must continue to improve written and online materials to provide clear, unbiased, user-friendly language and graphics, and engage in public campaigns to inform and educate Part D enrollees and their caregivers about benefit designs and cost sharing obligations. Some commenters suggested that if CMS finalizes our proposals to permit Part D sponsors to maintain up to two specialty tiers, that CMS will need to ''recodify'' guidance in the ''Coverage Determination Manual.'' Some commenters suggested that CMS should institute a generic/biosimilar utilization Star ratings measure focused on specialty-tier drugs.

Response: The proposals regarding permitting Part D sponsors to maintain up to two specialty tiers that are being finalized in this rulemaking will be in effect for coverage year 2022. Additionally, we intend to issue program instructions regarding the filing of two specialty tiers in the Contract Year (CY) 2022 Part D Bidding Instructions. In the May 22, 2020 HPMS memo titled, ''Updated Contract Year (CY) 2021 Final Part D Bidding Instructions,'' we instructed that bids for coverage year 2021 will be based on existing rules for the specialty tier. We continue to regularly review our policies regarding marketing and other communication materials and expect Part D sponsors to follow the requirements that are being finalized elsewhere in this final rule. Although we assume the commenters referring to the ''Coverage Determination Manual'' meant our Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf,* we are not clear on what the commenters believe needs to be ''re''-codified, and welcome further input on this matter. In our Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (available at *https://www.cms.gov/files/document/2021-announcement.pdf*), we discussed the potential to develop measures to assess generic and biosimilar utilization in the Medicare Part D program, and we continue to review feedback for a potential future measure.

We are finalizing without modification our proposals to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers. The proposals regarding permitting Part D sponsors to maintain up to two specialty tiers that are being finalized in this rulemaking will apply for coverage year 2022.

To retain the policies in effect before coverage year 2022, we are amending § 423.578(a)(6)(iii) by adding paragraph

(A) to cross reference the definition of specialty tier which will be in effect before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products,'' and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

3. Two Specialty Tiers and Tiering Exceptions

As discussed in section IV.E.1. of this final rule, section 1860D–4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the Part D sponsor's tiered cost-sharing structure. Additionally, Part D sponsors are required under this section of the statute to create an exceptions process to handle such requests, consistent with guidelines we established (see section 40.5.1 of Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*). However, section 1860D–4(g)(2) of the Act does not require tiering exceptions in every case, and rather, indicates that tiering exceptions might not be covered in every instance, by recognizing that non-preferred Part D drugs ''could'' be covered at the cost sharing applicable to preferred Part D drugs.

As discussed in section IV.E.1. of this final rule, the requirement that Part D plans be actuarially equivalent to the Defined Standard benefit means that if Part D sponsors were required to permit Part D enrollees to obtain Part D drugs on specialty tiers at non-specialty-tier cost sharing, Part D sponsors might need to increase premiums, cost sharing for non-specialty tiers, or both. To avoid such increased costs, in the Medicare Program; Medicare Prescription Drug Benefit Final Rule (hereinafter referred to as the January 2005 Part D final rule, 70 FR 4193), we finalized § 423.578(a)(7), which provided that Part D sponsors with a tier for very high cost and unique items, such as genomic and biotech products (in other words, a specialty tier), could exempt such drugs from its tiering exception process (70 FR 4353). In our April 2018 final rule, we revised and redesignated § 423.578(a)(7) as § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains a specialty tier, the Part D sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for tiering exceptions. While the current policy does not require that Part D sponsors use a specialty tier, or exempt the drugs on such tier from tiering exceptions, nearly all do use a specialty tier and also exempt the drugs on such tier from tiering exceptions.

Section 1860D–4(g)(2) of the Act stipulates that under a tiering exception, a non-preferred Part D drug could be covered under the terms applicable for preferred Part D drugs if the prescriber determines that the preferred Part D drug for treatment of the same condition would not be as effective for the Part D enrollee, would have adverse effects for the Part D enrollee, or both. Thus, the statutory basis for approval of tiering exceptions requests is the presence of (a) clinically appropriate, therapeutically alternative Part D drug(s) on a lower cost-sharing tier of the plan's formulary, and a statement from the prescriber indicating that the alternative drug(s) would not be as effective for that enrollee or would cause adverse effects for the enrollee, or both. Therefore, even if a Part D sponsor permitted tiering exceptions for Part D drugs on the specialty tier to non-specialty tiers, tiering exceptions requests would not be approvable if the plan's formulary did not include any clinically appropriate, therapeutically alternative Part D drugs on a lower cost-sharing tier. For example, suppose that a biological product, ''Biologic A,'' and another biological product that is indicated for the same condition, ''Biologic B,'' are both on the specialty tier with no clinically appropriate, therapeutically alternative Part D drugs on a lower cost-sharing tier. If the Part D enrollee's prescriber were to write a prescription for Biologic A, and the prescriber were to request a tiering exception, because Biologic B, the clinically appropriate therapeutic alternative, is on the same tier as Biologic A, and not a lower cost-sharing tier, the tiering exception request would be denied. For further explanation of tiering exceptions requirements, please see § 423.578(a)(6).

Permitting Part D sponsors to exempt Part D drugs on a higher cost-sharing, specialty tier from any tiering exceptions, even to a lower cost-sharing, preferred specialty tier, could improve Part D sponsors' ability to negotiate better rebates. Nevertheless, unlike our justification for allowing Part D plans to exempt a specialty tier from tiering exceptions to lower-cost, non-specialty tiers, granting tiering exceptions from the higher cost-sharing, specialty tier to the preferred specialty tier is less likely to lead to increased premiums or cost sharing to meet actuarial requirements (than granting tiering exceptions from a specialty tier to a non-specialty tier) because we would apply the same specialty-tier cost threshold to both specialty tiers. Our current belief is that improved negotiation alone is not sufficient to justify permitting Part D sponsors to exempt drugs on the higher cost-sharing, specialty tier from requests for tiering exceptions to the preferred, specialty-tier cost sharing. We note that we did not propose to require Part D sponsors to permit tiering exceptions from either specialty tier to lower, non-specialty tiers, and our policy would not change current regulations at § 423.578(c)(3)(ii) that require Part D sponsors to cover drugs for which a tiering exception was approved at the cost-sharing level that applies to the preferred alternative(s). This means that Part D sponsors would be required to grant tiering exceptions for Part D drugs from the higher cost-sharing, specialty tier to the preferred specialty tier if tiering exceptions requirements are met (for instance, when a Part D enrollee cannot take an applicable therapeutic alternative on the preferred specialty tier). Specifically, we proposed to amend § 423.578(a)(6)(iii) (1) to reflect the possibility of two specialty tiers and (2) by adding at the end the phrase ''to non-specialty tiers'' to clarify that a Part D sponsor may design its tiering exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exceptions to non-specialty tiers. Consequently, the existing policy at § 423.578(c)(3)(ii) would require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. While we would not require Part D sponsors to permit tiering exceptions to non-specialty tiers for Part D drugs on a specialty tier, nothing precludes a Part D sponsor from doing so, insofar as their plan benefit design remains actuarially equivalent to the Defined Standard benefit.

Alternatively, we considered permitting Part D sponsors to exempt drugs on either specialty tier from all tiering exceptions, even between the two specialty tiers, as is provided under

the existing regulations at § 423.578(a)(6)(iii). We do not believe maintaining the current exemption would be discriminatory in light of our proposal, discussed in section IV.E.4 of this final rule, to set the same maximum allowable cost sharing (that is, 25/33 percent) currently applied for a single specialty to-the higher cost-sharing, specialty tier and to also require the preferred specialty tier to have cost sharing below that of the higher cost-sharing, specialty tier. With the proposed maximum allowable cost sharing, Part D enrollees would pay no more for a drug on either specialty tier than is the case under our current policy. And, as noted previously, maintaining the current exemption from all tiering exceptions for specialty-tier Part D drugs could allow Part D sponsors to negotiate better rebates. On the other hand, our proposal to require Part D sponsors with two specialty tiers to permit tiering exceptions from the higher cost-sharing, specialty tier to the lower-cost sharing, preferred specialty tier would provide an important Part D enrollee protection when there is a therapeutic alternative on the lower cost-sharing, preferred specialty tier that the Part D enrollee is unable to take. Accordingly, we invited comment on the benefits or drawbacks of maintaining the current policy under § 423.578(a)(6)(iii) that, if we were to finalize our proposal to permit Part D sponsors to have up to two specialty tiers, would apply to permit Part D sponsors to exempt drugs on a specialty tier from the tiering exceptions process altogether.

We note that, as part of our proposed change at § 423.578(a)(6)(iii), we also proposed a technical change to remove the phrase ''and biological products.'' While the specialty tier usually includes biological products, in the context of the Part D program, biological products already are included in the definition of a Part D drug at § 423.100. Therefore, the phrase ''Part D drugs and biological products'' is redundant and potentially misleading. Consequently, we proposed to remove the phrase ''and biological products.''

To summarize, we proposed to amend § 423.578(a)(6)(iii) to: (1) Reflect the possibility of a second specialty tier, (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception *to non-specialty tiers,* and (3) remove the phrase ''and biological products.'' Additionally, we proposed to maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, although contingent on finalizing our proposal to permit Part D sponsors to maintain up to two specialty tiers, we solicited comment on maintaining the existing policy at § 423.578(a)(6)(iii), thereby permitting Part D sponsors to exempt drugs on either specialty tier from the tiering exceptions process altogether.

We received 35 public comments concerning our proposal to require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage (for the approved Part D drug on the higher cost-sharing, specialty tier) at the cost-sharing level that applies to the preferred alternative Part D drug on the lower cost-sharing, preferred specialty tier, and 32 public comments concerning our proposal that Part D sponsors can extend to both specialty tiers their current ability to design their exceptions processes to exempt Part D drugs on the specialty tier from tiering exceptions to non-specialty tiers (while requiring tiering exceptions between the two specialty tiers). We received 9 public comments concerning the alternative on which we solicited comment to permit Part D sponsors to design their exceptions processes to exempt drugs on either specialty tier from the tiering exceptions process altogether.

We received no comments on our proposal to amend § 423.578(a)(6)(iii) by removing the phrase ''and biological products'' and therefore are finalizing this provision without modification.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Many commenters supported CMS's proposals. However, some commenters opposed CMS's proposal that Part D sponsors be permitted to design their exceptions processes to exempt Part D drugs on the specialty tiers(s) from tiering exceptions to non-specialty tiers (while requiring tiering exceptions between the two specialty tiers) and also opposed the alternative on which CMS solicited comment to permit Part D sponsors to design their exceptions processes to exempt drugs on either specialty tier from the tiering exceptions process altogether. Some of these commenters, in advocating that CMS require tiering exceptions from the specialty tiers to the non-specialty tiers, found any exemption of the specialty tiers from tiering exceptions to be both discriminatory and a violation of Part D enrollees' statutory rights. Some commenters believed that CMS's proposals and the alternative on which CMS solicited comment prohibited Part D sponsors from offering tiering exceptions.

Response: We thank the commenters who supported our proposals for their support. We disagree that permitting Part D sponsors to design their exceptions processes to exempt Part D drugs on the specialty tier(s) from tiering exceptions to the non-specialty tiers is discriminatory or a violation of Part D enrollees' statutory rights.

Since the beginning of the Part D program, as reflected in our January 2005 Part D final rule, it has been our policy to permit Part D plans to exempt drugs on the specialty tier from tiering exceptions. We did not propose to change this exemption, but rather to adapt it to the possibility of a plan's having two specialty tiers. Historically, the specialty tier has aligned with the Defined Standard benefit, which does not have tiers, and therefore no tiering exceptions. The alignment with the Defined Standard benefit meant that an enrollee's cost sharing for a specialty tier drug would not exceed what would otherwise apply under the Defined Standard benefit, and that tiering exceptions similarly would not be available. We disagree with commenters that exempting the specialty tier(s) from tiering exceptions to non-specialty tiers is discriminatory precisely because of its alignment with the Defined Standard benefit, which, as previously noted, has no tiers, and therefore no tiering exceptions. Moreover, by the same rationale, we do not believe that permitting Part D sponsors to design their exceptions processes to exempt Part D drugs on the specialty tier(s) from tiering exceptions to non-specialty tiers violates a Part D enrollee's rights. As noted earlier, we believe section 1860D–4(g)(2) of the Act does not require tiering exceptions in every case. The addition of a second, preferred specialty tier does not change this analysis, particularly in light of the parameters we are finalizing (described elsewhere in this rule) that cap specialty tier cost sharing at the level that remains aligned with the Defined Standard benefit.

In response to comments regarding whether Part D sponsors should be required to permit tiering exceptions

request from the higher-cost specialty tier to the lower-cost specialty tier, we are finalizing our proposal, and not adopting the alternative we considered. We continue to believe that a Part D drug's placement on a specialty tier can play an important role in maintaining lower cost sharing on non-specialty tiers, and we must balance the ability to get lower cost sharing on specialty-tier Part D drugs through tiering exceptions with the requirement that plans be actuarially equivalent to the Defined Standard benefit. Consequently, while we are not changing our policy that permits Part D sponsors to exempt drugs from tiering exceptions between the specialty and non-specialty tiers, as was originally envisioned by § 423.578(a)(6)(iii), we believe that requiring Part D sponsors to design their tiering exceptions processes to permit tiering exceptions between the two specialty tiers, as provided at § 423.578(c)(3)(ii), strikes the appropriate balance.

Finally, we wish to clarify that Part D sponsors are not required to have a specialty tier at all, and under the provisions we are finalizing, can choose one, two, or no specialty tier(s). Similarly, Part D sponsors are not required to permit tiering exceptions from a specialty tier to a non-specialty tier. However, Part D sponsors also are permitted to design their tiering exceptions processes in such a way as to permit these tiering exceptions from a specialty tier to a non-specialty tier if they wish, so long as the plan's benefit design remains actuarially equivalent to the Defined Standard benefit.

We are finalizing without modification our proposals to amend § 423.578(a)(6)(iii) to: (1) Reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers. Additionally, the existing policy at § 423.578(c)(3)(ii) applies as to the two specialty tiers, meaning that Part D sponsors must permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier at the cost sharing that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, we intend to monitor the uptake of the use of a second specialty tier, and may revisit our decision to require plans to allow tiering exceptions between the two specialty tiers in future rulemaking.

Comment: Some commenters suggested that specialty tiers and tiering exceptions have no clinical basis. They reasoned that, because of this, CMS should define several terms (such as ''specialty drug.'' and ''specialty pharmacy'') and provide additional clinical guidance for Part D sponsors when implementing a second specialty tier. Other commenters added that CMS should delay implementation of CMS's proposals to permit two specialty tiers in order to undertake further rulemaking to refine CMS's proposal with additional details regarding clinically based Part D enrollee protections.

Response: We acknowledge that we have based a Part D drug's eligibility for placement on the specialty tier on whether such Part D drug meets the dollar-per-month amount of the specialty-tier cost threshold. However, our application of the tiering exceptions policy has been, and remains, rooted in a clinical basis. To illustrate, while the specialty tier in Part D is limited to the highest-cost Part D drugs, these drugs are often relatively more structurally complicated, and apply to complex conditions, including, but not limited to, cancer, Hepatitis C, HIV/AIDS, Multiple Sclerosis, and Rheumatoid Arthritis. Section 1860D–4(g)(2) of the Act specifies that under a tiering exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescriber determines that the preferred drug (for treatment of the same condition) would not be as effective for the individual, would have adverse effects for the individual, or both. Therefore, tiering exceptions always have a clinical basis, and requiring tiering exceptions between the two specialty tiers reinforces the clinical deliberations Part D sponsors must undertake when considering formulary inclusion and tier composition with regard to specialty-tier Part D drugs. Because the pharmacy practice landscape is changing so rapidly, and because the considerations are so varied, we continue to believe that any attempt by us to define ''specialty drug'' or ''specialty pharmacy'' is not warranted at this time. Nonetheless, throughout this final rule, we have opted to use the term ''specialty-tier drug'' instead of ''specialty drug'' in order to clarify that our discussion is limited to drugs which meet specialty-tier cost threshold and are therefore eligible for inclusion on a specialty tier in Part D.

Comment: Some commenters stated that the tiering exceptions process is confusing for Part D enrollees, and suggested that CMS should eliminate tiering exceptions altogether. Other commenters provided that permitting tiering exceptions between the specialty tiers but not to non-specialty tiers would be confusing to Part D enrollees. Some of these commenters suggested that CMS should allow tiering exceptions from the specialty to the non-specialty tiers, while others suggested that CMS should require tiering exceptions from the specialty to the non-specialty tiers.

Response: We are mindful of the need to minimize complexity and make our rules as transparent as possible. We appreciate the commenters' perspectives and welcome further detail on both the difficulties that Part D enrollees encounter during the exceptions and appeals process as well as any changes to our marketing and communications materials that could better address these difficulties.

However, we believe that any additional complexity arising from permitting a second specialty tier will be outweighed by the potential to improve enrollee access to specialty-tier Part D drugs. We did not propose to change our policy that permits Part D sponsors to exempt a specialty tier from tier exceptions to a non-specialty tier. Section 1860D–4(g)(2) of the Act provides that Part D enrollees may request exceptions from tiered cost-sharing structures. For this reason, we decline to either eliminate tiering exceptions altogether or require Part D sponsors to permit tiering exceptions from the specialty tiers to the non-specialty tiers. Regarding the request that we should allow tiering exceptions from the specialty to the non-specialty tiers, we note that this is already permitted under § 423.578(a)(6)(iii), and Part D sponsors will continue to have this option under the finalized version of this regulation.

Comment: Some commenters suggested that Part D enrollees who have undergone step therapy, failed other therapies, won a coverage determination or appeal, or a combination of the above, should have non-specialty, preferred cost sharing.

Response: While we appreciate the commenters' perspectives, we did not propose, and decline to adopt, these changes. For further explanation of tiering exceptions requirements and the associated cost sharing, please see § 423.578(a)(6) and section 40.5.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (available at *https://www.cms.gov/Medicare/and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*).

Additionally, section 40.5.2 of the Parts C & D Enrollee Grievances,

Organization/Coverage Determinations, and Appeals Guidance discusses the parameters for cost sharing under formulary exceptions. Unlike under the tiering exceptions regulations, the regulations do not specify what level of cost sharing applies when an exception is approved under the formulary exceptions process. Rather, the regulations at § 423.578(b)(2)(iii) require that the plan's formulary exceptions process must address the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

Comment: Some commenters suggested CMS could use CMS's annual formulary review and approval process to prevent discriminatory plan benefit designs, although some commenters asserted CMS has not been transparent about how it conducts the discrimination review. Some commenters suggested that CMS should exempt the specialty tiers from the discrimination review altogether, and some suggested that CMS's formulary review and approval process should evaluate both tiers as a whole instead of each tier independently. Finally, some commenters asserted that additional discrimination reviews on higher specialty tier will lead to more exception requests and thus additional administrative burden for plan sponsors.

Response: As we discussed in our final rule, titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' published in the **Federal Register** on May 23, 2019 (hereinafter referred to as our May 2019 final rule, 84 FR 23835), our annual formulary review and approval process is designed to ensure that Part D formularies do not substantially discourage enrollment by certain beneficiaries and that the formularies include adequate representation of all necessary Part D drug categories or classes for the Medicare population. In other words, our annual formulary review and approval process is designed to prevent discriminatory plan benefit designs. As part of that review and approval process, we assess all tiers both individually and together for the formulary as a whole, and that approach will continue with respect to plans that choose to establish two specialty tiers. Please see our May 2019 rule for additional detail on the components of the annual formulary review and approval process (84 FR 23835). Finally, although we do not understand the commenters' assertion that additional discrimination reviews on the higher cost-sharing, specialty tier will lead to more exception requests and thus additional administrative burden, we welcome additional detail on this issue for consideration in future rulemaking.

Comment: Some commenters suggested that CMS should review all tiering exceptions requests after implementation. Some commenters requested that CMS enforce the existing exceptions and appeals processes.

Response: We monitor and enforce the requirements of our coverage determinations and appeals processes, including tiering exceptions, through the Complaints Tracking Module (CTM), regional CMS account managers, Part D reporting requirements, and program audits. (See *https://www.cms.gov/files/document/cy2020part-d-reporting-requirements.pdf* for more detail about reporting requirements.) Additionally, in recent years, we have undertaken efforts to improve our exceptions and appeals processes, including improving clarity of the exceptions timeframes for Part D drugs. (See our final rule, titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for years 2020 and 2021,'' published in the **Federal Register** on April 16, 2019, hereinafter referred to as our April 2019 rule, 84 FR 15777.) We appreciate the commenters' perspectives and welcome further detail on both the difficulties that Part D enrollees encounter during the exceptions and appeals processes as well as any changes to our marketing and communications materials that could better address these difficulties.

We are finalizing without modification our proposals to amend § 423.578(a)(6)(iii) to: (1) Reflect the possibility of a second specialty tier, (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers, and (3) remove the phrase ''and biological products.'' Additionally, we will maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier.

4. Two Specialty Tiers and Maximum Allowable Cost Sharing

At the start of the Part D program, although we provided Part D sponsors the option to exempt specialty tiers from the tiering exceptions process, we remained concerned that exempting the specialty tier from tiering exceptions could potentially be discriminatory for Part D enrollees with certain diseases only treated by specialty tier-eligible drugs, and thus in conflict with the statutory directive under section 1860D–11(e)(2)(D) of the Act that we disapprove any ''design of the plan and its benefits (including any formulary and tiered-formulary structure) that are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.'' Using this authority, we aligned the cost-sharing limit for Part D drugs on the specialty tier with the Defined Standard benefit at section 1860D–2(b)(2)(A) of the Act. Consequently, we established a ''25/33 percent'' maximum allowable cost sharing for the specialty tier, meaning that we would approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL (that is, 25 percent ≤ maximum allowable cost sharing ≤ 33 percent). In other words, under actuarially equivalent alternative prescription drug coverage designs, we allow the maximum allowable cost sharing for the specialty tier to be between 25 and 33 percent coinsurance, inclusive, if the Part D plan has a decreased deductible, such that the maximum allowable cost sharing equates to 25 percent coinsurance plus the standard deductible. We derived the maximum allowable cost sharing of 33 percent coinsurance for plans with no deductible under alternative prescription drug coverage by adding the allowable deductible to the 25 percent maximum allowable cost sharing between the deductible and initial coverage limit (ICL) and dividing the resultant value by the ICL. The following calculations illustrate how we derived the maximum allowable cost sharing for the specialty tier.

a. Derivation of 33 percent maximum allowable cost sharing for plans with no deductible.

In 2006, under the Defined Standard benefit, the maximum deductible was $250, and the ICL was $2,250. The maximum allowable cost sharing between the deductible and the ICL was, as it is today, 25 percent coinsurance. (This example uses contract year 2006 numbers for simplicity, but the concepts presented still apply to current guidance.)

$2,250 ICL − $250 deductible = $2,000 difference × 0.25 = $500 maximum allowable cost sharing after the deductible and before the ICL for specialty-tier Part D drugs in plans with the standard deductible.

$500 maximum (previous calculation) + $250 deductible = $750 maximum for plans with no deductible.

Therefore, the maximum allowable coinsurance before the ICL for specialty-tier Part D drugs in plans with no deductible is $750 divided by the $2,250 ICL ≈ 0.33, or 33 percent coinsurance.

b. Derivation of maximum allowable cost sharing for plans with deductible between $0 and the maximum deductible.

Plans with deductibles between $0 and $250 are permitted to have maximum allowable cost sharing for specialty-tier Part D drugs between the deductible and the ICL of between $500 and $750 (that is, coinsurance between 25 and 33 percent, inclusive) provided that such cost sharing added to the deductible is $750.

For example, using contract year 2006 numbers, if the deductible was $100, the maximum coinsurance that the plan could charge for specialty-tier Part D drugs between the deductible and the ICL would have been approximately 30 percent:

$750 − $100 deductible = $650 maximum allowable cost sharing (that is, $650 + $100 = $750).

$2,250 ICL − $100 deductible = $2,150 difference

$650 divided by $2,150 ≈ 0.30, or 30 percent

Therefore, the maximum allowable coinsurance between the $100 deductible and the $2,250 ICL ≈ 0.30, or 30 percent coinsurance. (This 30 percent represents mathematical rounding from the actual calculated value.)

Because section 1860D–2(b)(2) of the Act requires that plan benefit designs be actuarially equivalent to the Defined Standard benefit, the cost sharing for high-cost drugs would likely increase without the use of a specialty tier. This is because often the specialty tier has lower cost sharing than the non-specialty, non-preferred brand/drug tiers, which frequently have cost sharing as much as 50 percent coinsurance. Additionally, many specialty tier-eligible Part D drugs, particularly biological products, often do not have alternatives on lower-cost tiers. Our proposal to codify a maximum allowable cost sharing for the specialty tier equal to the cost sharing for the Defined Standard benefit plus the cost of any deductible would ensure Part D enrollees still pay no more than the Defined Standard cost sharing for high-cost drugs placed on a specialty tier.

Although we proposed to allow Part D sponsors to have up to two specialty tiers, we note that the currently available tier-model structures already allow Part D sponsors to negotiate rebates and distinguish their preferred, high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier. Such distinction could potentially drive the same rebates as two specialty tiers; however, Part D sponsors have told us they are reluctant to take such an approach because of the availability of tiering exceptions for the non-specialty tiers, which could increase costs in lower, non-specialty tiers in order to achieve actuarial equivalence. We believe this concern is addressed by our proposal (discussed in section IV.E.3. of this final rule) to permit Part D sponsors to exempt Part D drugs on either or both specialty tiers from tiering exceptions to non-specialty tiers.

Additionally, while we are sensitive to and trying to be responsive to the volatility of the specialty-tier drug market by proposing to allow Part D sponsors to have up to two specialty tiers, we remain concerned about whether our proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of two specialty tiers. As discussed in section IV.E.2 of this final rule, those stakeholders posit that permitting two specialty tiers will reduce Part D enrollee cost sharing for specialty Part D drugs. However, this would be true only for Part D drugs on the lower cost-sharing, preferred specialty tier, and only if the lower cost-sharing, preferred, specialty-tier cost sharing were set lower than 25/33 percent.

When requesting a second specialty tier, some Part D sponsors and PBMs have told us they would need to charge more than 25/33 percent for the higher cost-sharing, specialty tier. However, if we were to permit Part D sponsors to charge more than 25/33 percent for the higher cost-sharing, specialty tier, the cost sharing for drugs in the higher cost-sharing, specialty tier would likely be higher than if there were only one specialty tier. We appreciate that permitting Part D sponsors to increase cost sharing over current limits might lead to negotiations for better rebates, which could result in savings to Part D enrollees offered through, for instance, lower costs on some Part D drugs in the preferred specialty tier or lower premiums. However, in the absence of evidence to the contrary, it appears to us that if we were to permit Part D sponsors to charge higher percentages than is currently the case, Part D enrollees who need Part D drugs on the higher cost-sharing, specialty tier will pay more, and possibly significantly more, than they currently do for those drugs given that specialty tiers, by definition, consist of high-cost drugs. In other words, we remain concerned about Part D enrollee protections and do not want improved rebates on some Part D drugs to come at the expense of those Part D enrollees who could already be paying, as proposed, as much as a 33 percent coinsurance on the highest-costing drugs. Moreover, because Part D enrollees who use high-cost Part D drugs progress quickly through the benefit, some Part D enrollees' entry into the catastrophic phase of the benefit may be advanced faster if the higher cost-sharing, specialty tier were to have a maximum allowable cost sharing that is higher than 25/33 percent. Therefore, it is unclear to us, in the aggregate, how much a second specialty tier would save the government if the second specialty tier was allowed to have a higher cost sharing than the current 25/33 percent.

In addition, while a second specialty tier might improve Part D sponsors' ability to negotiate better rebates, we also have concerns regarding discriminatory plan designs with a second, higher cost-sharing, specialty tier with cost sharing higher than the 25/33 percent that is currently permitted. If we were to allow a maximum allowable cost sharing for the higher cost-sharing, specialty tier above the 25/33 percent that is currently permitted, some Part D enrollees whose Part D drugs are placed on the higher cost-sharing, specialty tier could see their out-of-pocket (OOP) costs increase above the Defined Standard cost-sharing amount. We are concerned that the disproportionate impact on Part D enrollees who take Part D drugs on the higher cost-sharing, specialty tier runs a greater risk of discriminatory plan design. Additionally, while it is generally allowable for plans to use tier placement to steer Part D enrollees toward preferred agents, we would have to develop additional formulary checks to prevent discrimination against those Part D enrollees who require Part D drugs on the higher cost-sharing, specialty tier, and those additional formulary checks would limit the ability of plans to negotiate for tier placement between the two specialty tiers.

We proposed to set a maximum allowable cost sharing for a single specialty tier or, in the case of a plan

with two specialty tiers, the higher cost-sharing, specialty tier as follows: (1) For plans with the full deductible provided for in the Defined Standard benefit, 25 percent coinsurance; (2) for plans with no deductible, 33 percent coinsurance; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided for in the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing that difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent. Shown mathematically, that is:

$$((ICL \times 0.33) - deductible)/(ICL - deductible)$$

We proposed to require that a plan's second specialty tier, if any, must have a maximum allowable cost sharing that is less than the maximum allowable cost sharing of the higher cost-sharing, specialty tier. For example, if a Part D sponsor establishes a cost sharing of 25 percent on its higher cost-sharing, specialty tier, the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 25 percent. Similarly, if a Part D sponsor establishes a cost sharing of 33 percent on its higher specialty tier (permitted if the plan has no deductible, as discussed earlier in this section of this final rule), the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 33 percent. To encourage flexibility, and with the belief that we might not be able to anticipate every variation Part D sponsors might plan, we did not propose to require a minimum difference between the cost-sharing levels of the higher cost-sharing, specialty tier and a lower cost-sharing, preferred specialty tier that would apply to Part D sponsors choosing to provide two specialty tiers. As we have generally seen, for example, in relation to our policy recommending a threshold of $20 for the generic tier and ''less than $20'' for the preferred generic tier,[58] we believe it would be unlikely that Part D sponsors would take the trouble to create two different tiers and then establish an inconsequential differential. With that, we would, of course, reexamine this policy if we find after finalizing this provision that not requiring a minimum difference between the cost-sharing levels of the two specialty tiers has created problems. Additionally, we solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier, including suggestions on requiring a minimum difference between the cost-sharing levels of the two specialty tiers that can provide maximum flexibility and anticipate varied approaches that Part D sponsors might take. Lastly, nothing in our proposal would prohibit Part D sponsors from offering less than the maximum allowable cost sharing on either tier as long as the preferred specialty tier has lower cost sharing than the higher cost-sharing, specialty tier.

As mentioned in section IV.E.3 of this final rule, we have ongoing concerns that offering a lower cost-sharing, preferred specialty tier below the current 25/33 percent maximum could, in theory, lead to increased costs in lower, non-specialty tiers in order to achieve actuarial equivalence. However, because these increases in costs would be spread across the overall plan design, we believe the overall impact on Part D enrollees, would be less than the increase on individual Part D enrollee cost sharing were we to permit a maximum allowable cost sharing for the specialty tier above what is currently permitted (25/33 percent). Although we are concerned about offsetting increases to lower, non-specialty tiers, the 25/33 percent maximum allowable cost sharing is based upon the Defined Standard benefit cost sharing and therefore would provide an important Part D enrollee protection to prevent discriminatory benefit structures. Consequently, we believe this approach strikes the appropriate balance between Part D sponsor flexibility and Part D enrollee access.

In summary, we proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D sponsor may maintain up to two specialty tiers. Further, we proposed to set a maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier by adding paragraphs (d)(2)(iv)(D)(*1*), (*2*), and (*3*) which provide: (1) 25 percent coinsurance for plans with the full deductible provided under the Defined Standard benefit; (2) 33 percent coinsurance for plans with no deductible; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is between 25 and 33 percent, determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL), dividing this difference by the difference between the ICL and the plan's deductible, then rounding to the nearest 1 percent.

We solicited comment on this approach. We were also interested in and solicited comments on plan benefit designs with two specialty tiers if we were to permit the higher cost-sharing, specialty tier to have a higher coinsurance than what we have proposed. Specifically, we were interested in comments that discuss whether permitting a coinsurance higher than 25/33 percent would be discriminatory.

Additionally, we note that the deductible applies to all tiers, and is not limited to, nor borne solely by, Part D enrollees taking Part D drugs on the specialty tier. Therefore, it is unclear that we should continue to differentiate the specialty tier from the other tiers on the basis of the deductible. Accordingly, we also considered adopting a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. We solicited comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible.

To summarize, we proposed to add a new paragraph at § 423.104(d)(2)(iv)(D) to: (1) Specify that a Part D plan may maintain up to two specialty tiers; and (2) set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. We also proposed to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier. Additionally, we solicited comment on actuarial equivalence and the potential for discriminatory effects plan designs with two specialty tiers if we were to permit: (1) The higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed; or (2) a maximum allowable cost sharing of 25 percent without regard to deductible. Finally, we also solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

We received 22 public comments concerning our proposal to set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. We received 23 public comments

[58] See page 212 of the Final 2020 Call Letter, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

concerning the alternative on which we solicited comment to permit the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed. We received 10 public comments concerning the alternative on which we solicited comment to permit a maximum allowable cost sharing of 25 percent without regard to deductible. We received 18 public comments concerning our proposal to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier; and 18 public comments concerning the alternative on which we solicited comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, policy institutes, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Most commenters supported CMS's proposals to set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier. A commenter asserted that under current policy, coinsurance for specialty tiers can be as high as 50 percent.

Response: We thank the commenters for their support. We are not clear on the commenters' assertion that coinsurance for the specialty tiers can be as high as 50 percent; it has been our longstanding policy—which we are codifying in this rule—that Part D sponsors may not charge more than 25/33 percent coinsurance, depending on the plan's deductible. We thank the commenter, and if the commenter has evidence to the contrary, we welcome further input on this matter.

Comment: Some commenters opposed CMS's proposal and supported the alternative on which CMS solicited comment to permit the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing CMS proposed. Some commenters suggested that CMS should keep the existing maximum allowable cost sharing for the lower cost-sharing, preferred specialty tier at 25/33 percent and establish the maximum allowable cost sharing for the higher cost-sharing, specialty tier with a range between 30 and 40 percent, inclusive, depending on the deductible. Other commenters suggested something of a hybrid approach between our proposal and the previous approach in which CMS would permit Part D sponsors to set the cost sharing for (1) the lower cost-sharing, preferred specialty tier *at any amount lower* than that of the other specialty tier *and* (2) the higher cost-sharing, specialty tier higher than the 25/33 percent maximum allowable cost sharing *as long as* the cost sharing between the two tiers averages, or is actuarially equivalent to, 25/33 percent. These latter commenters further suggested that CMS could set a maximum allowable cost sharing for the higher cost-sharing, specialty tier at 50 percent; however, they did not specify whether this 50 percent would be applied with regard to the deductible.

Response: We are not persuaded by commenters recommending that we permit Part D sponsors offering two specialty tiers to have coinsurance for the higher-cost sharing specialty tier that exceeds the 25/33 percent maximum we proposed. We continue to have significant concerns that allowing specialty-tier cost sharing to exceed 25/33 percent, especially when an enrollee may not be able to receive a tiering exception, could result in discriminatory plan designs, particularly for enrollees who take high-cost drugs that meet the specialty-tier cost threshold we are finalizing in this final rule. We remain concerned that, given the high cost of drugs that meet such specialty-tier cost threshold, increased cost-sharing could leave more Part D enrollees unable to afford what could be life-saving drugs. Moreover, as noted in section IV.E.2 of this final rule, our specialty-tier cost sharing maximum has historically been based on the Defined Standard benefit as a Part D enrollee protection, and the maximum allowable cost sharing of 25/33 percent that we proposed is dependent upon the plan's deductible. Commenters recommending higher cost sharing for the higher cost-sharing specialty tier offered no analysis or approach that would allow us to determine how the higher cost-sharing level would align with the Defined Standard benefit. For this reason, we similarly believe it is inappropriate to finalize a hybrid approach as some commenters suggested, as we would need more information and analysis before we could determine how such a hybrid approach would be structured. We can consider such a policy for future rulemaking, if warranted. We welcome further input from stakeholders, and we thank the commenters.

Comment: Most commenters preferred that the maximum allowable cost sharing for the specialty tiers continue to be expressed as a range, with a specific value for each plan that is dependent upon the plan's deductible. However, some commenters supported the alternative on which CMS solicited comment to permit a maximum allowable cost sharing of 25 percent without regard to deductible. A commenter agreed with this, in principle, but suggested that CMS should permit a maximum allowable cost sharing of 33 percent without regard to the deductible, and, some commenters suggested that plans should be permitted to establish the cost sharing for the specialty tier(s) at coinsurance greater than 25 percent if there is no deductible.

Response: Although we also solicited comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible, we did not receive any examples of this. We thank the commenters who expressed support or opposition to this alternative, but we were not persuaded to adopt a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. None of the comments persuaded us that the current policy, which we proposed to codify and are now adopting, is insufficient.

We note that under the current and proposed policies, Part D plans are permitted to establish the cost sharing for the specialty tier greater than 25 percent, up to and including 33 percent, if there is no deductible. As detailed earlier in this section of this final rule, we are concerned that, unlike our current maximum allowable cost sharing of 25/33 percent, establishing a maximum allowable cost sharing of 33 percent without regard to the deductible could be discriminatory.

Comment: Some commenters suggested that CMS should contemplate other changes to the non-preferred brand/drug tiers to address high Part D enrollee cost sharing. For example, some commenters suggested that a preliminary analysis indicates that, for plan benefit designs with coinsurance for the non-preferred brand/drug tiers, 75 percent of Part D enrollees receiving drugs on this tier pay more than, and some significantly more than, the corresponding amount for such tier when the plan uses copayments (for example, $100 for contract year 2021). These commenters suggested that CMS

should monitor this, particularly if enacting any changes to the specialty tiers.

Response: We thank the commenters for their comments, and welcome additional detail on this to consider it for future rulemaking.

Comment: Some commenters supported CMS's proposal to permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier, encouraging CMS to allow plans to innovate in this area. However, other commenters preferred the alternative on which CMS solicited comment to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier. Some commenters suggested that CMS establish a difference of 5 or 8 percent in cost sharing between the two specialty tiers; some commenters suggested that CMS establish the maximum allowable cost sharing for the lower cost-sharing, specialty tier at 15, 17, or 20 percent while maintaining the maximum allowable cost sharing of 25/33 percent for the higher cost-sharing, specialty tier. Some commenters encouraged CMS to give Part D sponsors the option set the cost sharing for their specialty tier(s) lower than the maximum allowable cost sharing CMS has specified.

Finally, a commenter suggested that CMS should provide by regulation that CMS will annually specify a minimum percentage differential that CMS determines will be likely to substantially incent utilization of the products on the preferred specialty tier over utilization of the products on the higher cost-sharing, specialty tier, and that minimum differential would be subtracted from the coinsurance for the plan's higher cost-sharing, specialty tier (in other words, between 25 and 33 percent, inclusive, depending on the plan's deductible) to result in the maximum allowable cost sharing for the lower cost-sharing, preferred specialty tier.

Response: While we appreciate the specific suggestions provided by commenters, we decline to adopt these suggestions. None of the commenters suggesting specific differentials provided any analysis to support those thresholds or reasonable extrapolation from the Defined Standard benefit (for example, the 25/33 percent).

Finally, while we are intrigued by the commenters' suggestion that we specify a minimum percentage differential that we determine will be likely to substantially incent utilization of the products on the preferred specialty tier versus those on the higher cost-sharing, specialty tier, we decline to adopt this approach. Because a Part D sponsor's decision to place a Part D drug on one tier versus another is multifactorial, it is unclear how we could determine a percentage that is ''likely to substantially incent utilization'' of the products on the preferred specialty tier versus those on the higher cost-sharing, specialty tier. However, we welcome additional information on this suggestion, and we thank the commenter.

After considering the comments, we are finalizing without modification our proposals to: (1) Add new paragraphs § 423.104(d)(2)(iv)(D)(*1*) through (*3*) to establish a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, for plans with two specialty tiers, the higher cost-sharing, specialty tier and (2) permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the other specialty tier.

5. Two Specialty Tiers and Tier Composition

A few commenters on the Draft 2020 Call Letter suggested that we should create a lower cost specialty tier for generic drugs and biosimilar biological products, and that such a tier should be limited to only such products. We declined to propose such a policy for this rule. First, we wish to provide maximum flexibility to Part D sponsors that might find, for instance, that a brand-name Part D drug costs less with a rebate than a generic equivalent or corresponding biosimilar biological product. Moreover, generic drugs and biosimilar biological products that meet the specialty-tier cost threshold may not always be the lowest-priced product. Second, nothing in our proposal would prohibit Part D sponsors from setting up such parameters should they choose (provided they meet all other requirements, including the proposed maximum allowable cost sharing). Therefore, in order to provide more flexibility for plans to generate potential savings through benefit design and manufacturer negotiations, we did not propose to prescribe which Part D drugs may go on either specialty tier. However, such placement will be subject to the requirements of our formulary review and approval process under § 423.120(b)(2). Additionally, consistent with our current policy, we will continue to evaluate formulary change requests involving biosimilar biological products on the specialty tiers on a case-by-case basis to ensure they continue to meet the requirements of our formulary review and approval process. (See § 423.120(b)(5).)

We solicited comment on whether Part D sponsors should restrict the lower cost-sharing, preferred specialty tier to only generic drugs and biosimilar biological products while also placing them along with any other Part D drugs meeting the specialty-tier cost threshold on the higher cost-sharing, specialty tier. In other words, either brand or generic drugs and biosimilar biological products would be placed on the higher cost-sharing, specialty tier, but only generic drugs and biosimilar biological products would be placed on the preferred specialty tier. We stated that we were particularly interested in comments that discuss what impact such a policy would have on non-specialty tiers.

We received 30 public comments concerning our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2); and 30 public comments concerning the alternative on which we solicited comment to require Part D sponsors to restrict the preferred specialty tier to only generic drugs and biosimilar biological products, while permitting Part D sponsors to have generic drugs, biosimilar biological products, and reference/originator drugs and biological products on the higher cost-sharing, specialty tier.

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, think tanks, and non-partisan Congressional agencies. A summary of the comments and our responses follow.

Comment: Most commenters supported CMS's proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds CMS proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2) and opposed the alternative on which CMS solicited comment to require Part D sponsors to restrict the preferred specialty tier to only generic drugs and biosimilar biological products, while permitting Part D sponsors to have generic drugs, biosimilar biological products, and reference/originator drugs and biological products on the higher cost-sharing, specialty tier.

Response: We thank the commenters for their support.

Comment: Several commenters opposed CMS's proposal. Some commenters asserted that CMS should require Part D sponsors to use their second specialty tier to encourage greater use of less-expensive biosimilar biological products and greater price competition for specialty-tier drugs, but did not provide suggestions on how to do so. Some commenters suggested that current formulary and tiering practices discourage utilization of generic specialty-tier drugs. Some commenters asserted that CMS should only allow brand products on the higher cost-sharing, specialty tier, and some commenters asserted that generic drugs and biosimilar biological products should be exempt from specialty tier placement altogether. Some commenters suggested permitting generic drugs and biosimilar biological products on the higher cost-sharing, non-specialty tier and/or the same tier as brand specialty-tier drugs and biological products would discourage the use of generic drugs and biosimilar biological products and hamper the research and development pipeline of such products. Conversely, some commenters asserted that current market incentives for generic drugs and biosimilar biological products are sufficient.

Response: We continue to strive to encourage the use of generic drugs and biosimilar biological products. However, we believe that our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2) is appropriate because restricting which types of products may be included on a particular specialty tier may result in fewer generic and biosimilar products being included on the formulary. Part D plans can frequently negotiate lower net prices for brand drugs than generic drugs and biosimilar biological products, and if we were to require preferred placement of a product that has the potential to be more expensive, Part D sponsors may elect not to include the generic drug or biosimilar biological product on their formulary at all. (We note that there currently are no interchangeable biological products on the market.)

Comment: Some commenters asserted that tier placement should have a clinical basis. Additionally, some commenters asked CMS to ensure that utilization management and prior authorization are not inappropriately imposed to prefer brand products over generic drugs and biosimilar biological products.

Response: We detailed the components of our annual formulary review and approval process in our May 2019 final rule (84 FR 23835). As part of this review and approval process, we perform multiple reviews related to the clinical appropriateness of both tier composition and utilization management strategies. For additional information, please also see section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.*

Comment: Some commenters, in expressing their opposition to CMS's proposal to permit Part D sponsors to maintain up to two specialty tiers: (1) Agreed with CMS's assertion that the currently available tier-model structures (which already allow Part D sponsors to negotiate rebates and distinguish their preferred, high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier) could potentially drive the same rebates as two specialty tiers; (2) suggested that Part D sponsors could place preferred, high-cost Part D drugs on the specialty tier and place less preferred agents on the non-preferred brand/drug tiers; and (3) suggested that, before implementing further changes to the specialty tiers, CMS needs to provide more detail on why the use of either of the aforementioned options (that is, (1) placing preferred, high-cost Part D drugs on the preferred brand tier while placing less preferred agents on the specialty tier, or, (2) placing preferred, high-cost Part D drugs on the specialty tier while placing less preferred agents on the non-preferred brand/drug tiers) is insufficient to achieve our stated policy goals for permitting Part D sponsors to maintain up two specialty tiers.

Response: While these options certainly are available, we do not foresee harm in finalizing our proposal to permit Part D sponsors to maintain up to two specialty tiers under the parameters we have established in this final rule while monitoring the uptake and outcomes associated with the use of a second specialty tier as Part D sponsors implement it. Conversely, as specialty-tier drugs play an increasingly important role in the prescription drug marketplace, limiting Part D sponsors to either of the aforementioned options could adversely impact the Medicare Part D marketplace. Currently, only 8 percent of Part D plans offer preferred brand tiers with coinsurance.

Limiting Part D sponsors to the option of placing preferred specialty-tier drugs on the preferred brand tier could lead to more plans adopting coinsurance for the preferred brand tier, which could significantly decrease competition among plans in the Part D marketplace as plan benefit designs become less varied and more like the Defined Standard benefit. Conversely, if Part D sponsors were limited to placing non-preferred, specialty-tier eligible drugs on the non-preferred brand/drug tiers, Part D enrollees whose specialty-tier eligible drugs are on this tier could face cost sharing of up to 50 percent coinsurance, which, given the high cost of specialty-tier eligible drugs, is substantially more than they would pay if the drug were on a specialty tier, with the maximum allowable cost sharing of 25/33 percent that we are finalizing in this final rule.

Comment: Some commenters believed that CMS's combined proposals (which would (1) permit Part D sponsors to maintain up to two specialty tiers and (2) give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds CMS proposed and the requirements of the CMS formulary review and approval process under § 423.120(b)(2)) are inextricably linked to problems concerning the role rebates play within Part D and, due to the high cost of specialty-tier drugs, will exacerbate the effect these problems have on costs incurred by Part D enrollees and the government.

Response: Because we are setting a maximum cost sharing for the higher cost-sharing, specialty tier at 25/33 percent, we do not believe that any Part D enrollee or the government will be worse off than today. Nonetheless, we intend to monitor the uptake of and outcomes associated with the use of a second specialty tier. Finally, we decline to adopt the recommendation that we require the preferred tier to reflect clinically appropriate therapeutic alternatives with the lower list price. Section 1860D–11(i) of the Act, otherwise known as the non-interference clause, prohibits us from (1) interfering with the negotiations between drug manufacturers and pharmacies and Part D sponsors, and (2) requiring a particular formulary or instituting a price structure for the reimbursement of covered Part D drugs. For additional information regarding noninterference, please see our rule titled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and

the Medicare Prescription Drug Benefit Programs'' (79 FR 29843) at 79 FR 29844, and 79 FR 29874–5.

Comment: Some commenters asserted that transitioning between biosimilar biological products, reference biological products, or both can jeopardize patient safety due to immunogenicity.

Response: We would refer commenters to the FDA regarding the safety and efficacy of biological products, including biosimilar biological products.

After considering the comments, we are finalizing without modification our proposal to give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the cost threshold we are finalizing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2).

6. Establishing and Increasing the Specialty-Tier Cost Threshold

To effectuate the specialty tier, it was necessary to determine which Part D drugs could be placed on a specialty tier. Consequently, we developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier. We have sought comment on both this methodology used to establish the specialty-tier cost threshold and the resultant value of the specialty-tier cost threshold when publishing the annual Draft Call Letter. Most recently, commenters on the Draft 2020 Call Letter were largely supportive of having a methodology in place to annually evaluate and adjust the specialty-tier cost threshold, as appropriate. While some commenters wanted to maintain the current level (and others wanted to eliminate the specialty tier or reduce its cost sharing), there was broad support to regularly increase the specialty-tier cost threshold. Some comments requested annual increases, while others wanted us to tie increases to the specialty-tier cost threshold to drug inflation, or benefit parameters. As we detail later in this discussion, we proposed to codify, with some modifications, the same outlier PDE analysis we have historically used. Our proposed annual methodology would account for rising drug costs, as well as any potential changes in utilization. By identifying the top 1 percent of 30-day equivalent PDEs, our proposal aims to create a specialty-tier cost threshold that is representative of outlier claims for the highest-cost drugs. By using PDEs, the proposed analysis would also reflect the fact that the numbers of Part D enrollees filling prescriptions for high-cost drugs as a percentage of all drug claims may vary from year to year. Given the general support for regular increases in the specialty-tier cost threshold, we proposed to make adjustments to the specialty-tier cost threshold based on a specific methodology, as discussed later in this section.

Beginning in 2007, we established the specialty-tier cost threshold at $500 per month [59] based on identifying outlier claims (that is, the top 1 percent of claims having the highest negotiated prices as reported on the PDE, adjusted, as described in this section of this final rule, for 30-day equivalent supplies) and increased the threshold to $600 beginning in contract year 2008. The specialty-tier cost threshold remained at $600 per month from contract years 2008 through 2016.[60] [61] In the 2016 analysis for contract year 2017 (using contract year 2015 PDE data), the number of claims for 30 day-equivalent supplies with negotiated prices meeting the existing $600 per-month cost threshold exceeded 1 percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment (in 2008), supported an increase in the specialty-tier cost threshold for contract year 2017. To adjust the specialty-tier cost threshold, we applied the annual percentage increase used in the Part D benefit parameter updates (that is, 11.75 percent for contract year 2017) to the $600 threshold. This increase in the specialty-tier cost threshold (that is, $70.50), rounded to the nearest $10 increment (that is, $70), was sufficient to reestablish the 1 percent outlier threshold for PDEs having negotiated prices for 30-day equivalent supplies greater than the threshold. Since contract year 2017, the specialty-tier cost threshold has been $670 per month.

In our April 2018 final rule, we defined specialty tier in regulation at § 423.560 to mean a formulary cost-sharing tier dedicated to very high-cost Part D drugs and biological products that exceed a cost threshold established by the Secretary (83 FR 16509). To improve transparency, we proposed to codify current methodologies for calculations relative to the specialty tier, with some changes. As noted in sections IV.E.3 and IV.E.4. of this final rule, it was necessary to establish the composition of a specialty tier in order to effectuate specialty tier exceptions and anti-discrimination policies. Under § 423.560, only very high-cost drugs and biological products that meet or exceed a cost threshold established by the Secretary may be placed on a plan's specialty tier (for example, a negotiated price of or exceeding $670 per month for coverage year 2020). Current guidance at section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual describes these high-cost drugs and biological products as those having Part D sponsor-negotiated prices that exceed a dollar-per-month amount we established in the annual Call Letter, which has noted the historical use of a threshold under which approximately 99 percent of monthly PDEs adjusted for 30-day equivalent supplies have been below the specialty-tier cost threshold.

In setting the specialty-tier cost threshold, we have historically analyzed PDE data for the plan year that ended 12 months before the applicable plan year (for example, we used contract year 2017 PDE data to determine the cost threshold for contract year 2019). First, we have calculated the number of 30-day equivalent supplies reported on each PDE. We have considered a 30-day equivalent supply to be any days' supply, as reported on each PDE, of less than or equal to 34 days. Thus, a PDE with a 34-days' supply has been considered one 30-day equivalent supply. (This reflects the fact that a full supply of medication for a Part D enrollee could equal less than a month's supply, or reflect manufacturer packaging. For instance, we did not want to triple the cost of a 10-day course of antibiotics to determine the 30-day equivalent supply because that would overstate the Part D enrollee's cost for the full prescription). If the days' supply on the PDE is greater than 34, the 30-day equivalent supply is equal to the PDE's days' supply divided by 30. Thus, for example, a PDE with a 90-day supply has been considered as three 30-day equivalent supplies. Similarly, a PDE with a drug that has been dispensed in a package containing a 45-days' supply has been considered as 1.5 30-day equivalent supplies. This includes long-acting drugs, including, but not limited to long-acting injections. For example, a single injection that is considered to be a 90-days' supply has been considered as three 30-day equivalent supplies.

After determining the number of 30-day equivalent supplies for each PDE, we have calculated the 30-day equivalent negotiated price for the PDE by dividing the PDE's negotiated price

[59] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/CY07FormularyGuidance.pdf.*

[60] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf.*

[61] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.*

by the number of 30-day equivalent supplies reflected on the PDE. Thus, for example, if the PDE is for a 90-days' supply and has a negotiated price of $810, that PDE contains three 30-day equivalent supplies, and the 30-day equivalent negotiated price is $270.

Next, taking into consideration the 30-day equivalent negotiated prices for all Part D drugs for which PDE data are available, we have identified the PDEs with 30-day equivalent negotiated prices that reflect the top 1 percent of 30 day-equivalent negotiated prices, and have maintained the specialty-tier cost threshold at an amount that corresponds to the lowest 30-day equivalent negotiated price that is within the top 1 percent of all 30-day equivalent negotiated prices.

We note that this process may result in dose specificity of eligibility for placement on the specialty tier, such that one strength of a Part D drug may be eligible but another strength may not. For example, suppose that Part D drug X is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. The 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold, are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

We believe our existing policy to set the specialty-tier cost threshold such that only the top 1 percent of 30-day equivalent negotiated prices would exceed it is consistent with the purpose of the specialty tier—that is, that only the highest-cost Part D drugs are eligible for placement on the specialty tier. For this reason, we proposed to codify a similar process to adjust and rank PDE data as the basis for determining the specialty-tier cost threshold, as described in this section of this final rule. Specifically, instead of 30-day equivalent negotiated prices, we proposed to determine the 30-day equivalent ingredient cost to set the specialty tier-cost threshold in the same manner as we have historically done, as described previously in this section.

In addition, to maintain stability in the specialty-tier cost threshold, we proposed to set the specialty-tier cost threshold for contract year 2021 to reflect the top 1 percent of 30-day equivalent ingredient costs, at an amount that corresponds to the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs. We also proposed to undertake an analysis of 30-day equivalent ingredient costs annually, and to increase the specialty-tier cost threshold for a plan year only if we determine that no less than a ten percent increase in the specialty-tier cost threshold, before rounding to the nearest $10 increment, is needed to reestablish the specialty-tier cost threshold that reflects the top 1 percent of 30-day equivalent ingredient costs.

As a hypothetical example, suppose that, in 2020, when analyzing contract year 2019 PDE data for contract year 2021, we find that more than 1 percent of PDEs have 30-day equivalent ingredient costs that exceed the contract year 2020 specialty-tier cost threshold of $670. Further, suppose that we find that 1 percent of the PDEs have 30-day equivalent ingredient costs that exceed $685. This $15 difference represents a 2.24 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, we would not increase the specialty-tier cost threshold for contract year 2021.

However, if we suppose that, instead of $685, we find that 1 percent of the PDEs have 30-day equivalent ingredient costs that exceed $753, then in this scenario, the $83 change represents a 12.39 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, because this would be a change of more than 10 percent, we would set the specialty-tier cost threshold for contract year 2021 at $750 which is the nearest $10 increment to $753.

We solicited comment on this proposal. Because rounding down, as in the previous example, would technically cause the new specialty-tier cost threshold to account for very slightly more than 1 percent of 30 day-equivalent ingredient costs, we also considered the alternative that we would always round *up* to the next $10 increment. Using the previous example, we would have set the threshold for contract year 2021 at $760 instead of $750. This alternative would: (a) Better ensure that the new specialty-tier cost threshold actually reflects the top 1 percent of claims adjusted for 30-day equivalent supplies, and (b) provide more stability to the specialty-tier cost threshold, that is to say, it will theoretically not need to be changed as frequently, because rounding down will always result in a specialty-tier cost threshold that would include more than the top 1 percent of 30-day equivalent ingredient costs. We do not expect that this alternative would significantly impact the number of Part D drugs that would meet our proposed specialty-tier cost threshold. We solicited comment on this alternative approach to rounding and stated that we could finalize an amended version of our proposed language at § 423.104(d)(2)(B) to reflect such alternative. We proposed to annually determine whether the adjustment would be triggered using the proposed methodology, and if it is, we would apply the proposed methodology to determine the new specialty-tier cost threshold, which we would announce via an HPMS memorandum or a comparable guidance document. Finally, we proposed for contract year 2021 that we would apply our proposed methodology to the contract year 2020 specialty-tier cost threshold of $670, and if a change to the methodology based on comments received on this final rule would result in a change to that threshold, we stated that we will announce the new specialty-tier cost threshold in this final rule.

We have concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point of sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. Consequently, as noted previously, we proposed to use the ingredient costs associated with 30-day equivalent supplies when we determine the specialty-tier cost threshold according to the methodology proposed earlier in this preamble. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price; however, this change to use the ingredient cost ensures that we are using the most predictable of all the components of the negotiated price upon which to base the specialty-tier cost threshold.

Using the methodology in this final rule and contract year 2019 PDE data that we have to date, the specialty-tier

cost threshold for contract year 2021 would be $780 as a 30-day equivalent ingredient cost. To determine this threshold, we analyzed 2.2 billion PDEs, and determined the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs to be $780, which did not require rounding. Therefore, we would increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). While this change will impact the specific dollar-threshold amount for specialty-tier eligibility, the specialty-tier cost threshold still accounts for the top 1 percent of all claims, as adjusted for 30-day equivalent supplies. Due to the increased costs of prescription drugs since the previous $670 specialty-tier cost threshold was set several years ago, the top 1 percent of all claims, as adjusted for 30-day equivalent supplies, cost more, on average. Moreover, we estimate that the change from using negotiated price to using ingredient cost only will result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have if we continued to use the 30-day equivalent negotiated price.

Additionally, consistent with current guidance in section 30.2.4 in Chapter 6 of the Medicare Prescription Drug Benefit Manual, we consider claims history in reviewing the placement of Part D drugs on Part D sponsors' specialty tiers. Consequently, we proposed to codify current guidance that a Part D drug will be eligible for placement on a specialty tier if the majority of a Part D sponsor's claims for that Part D drug, when adjusted for 30-day equivalent supplies, exceed the specialty-tier cost threshold. However, for Part D drugs newly approved by the FDA for which Part D sponsors would have little or no claims data because such drugs have only recently become available on the market, we proposed to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of their negotiated prices based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths. If, based on their estimated 30-day equivalent ingredient cost, the newly FDA-approved Part D drug is anticipated to exceed the specialty-tier cost threshold most of the time (that is, more than 50 percent of the time), we would allow Part D sponsors to place such drug on a specialty tier. Finally, such placement would be subject to our review and approval as part of our annual formulary review and approval process.

We proposed to add paragraphs (d)(2)(iv)(A), (B), and (C) to § 423.104 and to cross reference this section in our revised definition of specialty tiers, which we proposed to move to § 423.104, as described later in this section. Specifically, we proposed in paragraph (d)(2)(iv)(A) to described in paragraphs (d)(2)(iv)(A)(*1*) through (*4*) the manner by which we set the specialty-tier cost threshold, and further, to describe in paragraph (d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier. In paragraph (d)(2)(iv)(A)(*1*) we proposed to specify that we use PDE data, and further, use the ingredient cost reflected on the PDE to determine the ingredient costs in dollars for 30-day equivalent supplies of drugs. In paragraph (d)(2)(iv)(A)(*2*) we proposed to specify how we determine 30-day equivalent supplies from PDE data, such that if the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one, and if the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on the PDE divided by 30. We proposed that paragraph (d)(2)(iv)(A)(*3*) would specify that we then determine the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data. We proposed that paragraph (d)(2)(iv)(A)(*4*) would specify that, except as provided in paragraph (B), the amount determined in paragraph (d)(2)(iv)(A)(*3*) is the specialty-tier cost threshold for the plan year. Further, we proposed that paragraph (d)(2)(iv)(A)(*5*) would specify that, except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, we will approve the placement of a Part D drug on a specialty tiers when that Part D sponsor's claims data from the plan year that ended 12 months prior to the applicable plan year demonstrate that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies that exceed the specialty-tier cost threshold.

We proposed in paragraph (d)(2)(iv)(B) to describe the methodology we will use to increase the specialty-tier cost threshold. Specifically, we proposed to increase the specialty-tier cost threshold for a plan year only if the amount determined by paragraph (d)(2)(iv)(A)(*3*) for a plan year is at least ten percent above the specialty-tier cost threshold for the prior plan year. We proposed that if an increase is made, we would round the amount determined in proposed paragraph (d)(2)(iv)(A)(*3*) to the nearest $10. That amount would be the specialty-tier cost threshold for the applicable plan year.

Finally, we proposed paragraph (d)(2)(iv)(C) to specify that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

As mentioned in this section of this final rule, to align the definition of specialty tier with our proposal to allow Part D sponsors to have up to two specialty tiers, we first proposed to move the definition of specialty tier from § 423.560 to appear in § 423.104(d)(2)(iv) as part of a proposed new section on specialty tiers that also includes the methodology for determining the specialty-tier cost thresholds and maximum allowable cost sharing. (We also proposed to revise § 423.560 and § 423.578(a)(6)(iii) to cross reference the placement of that definition in § 423.104(d)(2)(iv).) Additionally, we proposed to amend the definition of specialty tier to reflect our proposal to allow Part D sponsors to have up to two specialty tiers. With respect to the phrase ''and biological products,'' for the reasons discussed in the section IV.E.3 of this final rule, (specifically, that biological products are already are included in the definition of a Part D drug at § 423.100), we also proposed a technical change to the definition of specialty tier to remove the phrase ''and biological products.'' Therefore, we proposed to define specialty tier at § 423.104(d)(2)(iv) to mean a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in § 423.104(d)(2)(iv)(A)(*2*)) that are greater than the specialty-tier cost threshold specified in § 423.104(d)(2)(iv)(A).

To summarize, we proposed to: (1) Amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); (3) add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty

tier; (4) add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold; and (5) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We solicited comment on specifying at the new § 423.104(d)(2)(iv)(B) that we would round *up* to the nearest $10 increment.

We received 8 public comments concerning our proposal to amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); and 8 public comments concerning our proposal to amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv). We received 10 public comments concerning our proposal to add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty tier. We received 12 public comments concerning our proposal to add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold; and 6 public comments concerning our proposal to add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We received 7 public comments concerning our proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*).

Although there was some overlap in stakeholder categories, all of the comments were from groups representing Part D sponsors, beneficiary advocates, manufacturers, providers, pharmacists and pharmacies, wholesale distributors, think tanks, and non-partisan Congressional agencies.

A summary of the comments on amending, moving, and cross-referencing the definition of specialty tier and data used to determine the specialty-tier cost threshold and our responses follow.

Comment: Most commenters supported CMS's proposals. We did not receive any comments on the alternative on which we solicited comment to specify at the new § 423.104(d)(2)(iv)(B) that we would round *up* to the nearest $10 increment. We received unanimous support of our proposals to (1) amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); and (3) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

Response: We thank the commenters for their support. We will not finalize the alternative on which we solicited comment to specify that we would round *up* to the nearest $10 increment at this time, but may consider it for future rulemaking. We will finalize without modification our proposal to add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. This provision will apply for coverage year 2022. We therefore are not finalizing our proposal to specify a specialty-tier cost threshold of $780 for 2021.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products.'' Additionally, paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

A summary of the comments on the methodology to determine the specialty-tier cost threshold and a Part D drug's eligibility for placement on the specialty tier and our responses follow.

Comment: Some commenters supported CMS's methodology to establish the specialty-tier cost threshold, but were opposed to the maximum dose being used to determine the specialty-tier eligibility for newly-FDA-approved drugs. Some commenters believed that: (1) The maximum dose should not be used to evaluate newly-approved drugs for specialty-tier eligibility; (2) for newly-FDA approved drugs, CMS should require Part D plans to estimate the 30-day equivalent ingredient cost for each drug product strength, package size, and formulation level, similar to how it is already done for already FDA-approved Part D drugs; and (3) CMS should also codify language at § 423.104 regarding dose specificity and dose optimization for all drugs.

Response: We thank the commenters for their perspective on the process for newly FDA-approved drugs. We agree that we need to provide more detail on what we meant in our preamble when we stated that we proposed to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of newly-FDA-approved drugs ''based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths.''

We did not mean to suggest that only maximum doses would qualify for the specialty tier. Rather, we would expect Part D sponsors to estimate the 30-day equivalent ingredient cost of a drug, taking into account dose optimization—which, based on the maximum FDA-approved dose of a medication, consolidates the Part D enrollee's dose into the fewest number of dose units (for example, tablets)—and dose specificity—which is based on the price applied to the particular strength and dosage form of the drug.

To illustrate that the process for determining a Part D drug's specialty-tier eligibility should take into account dose optimization and dose specificity for both already-FDA approved drugs (for which Part D sponsors would have claims history) and newly-FDA approved drugs (for which Part D sponsors would have little to no claims history), we clarify the example earlier in this section (section IV.E.6) of this final rule. We gave the example of ''Part D drug X'' that is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. Regarding dose specificity, the 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold,

are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

Regarding dose optimization, using the previous example, suppose ''Part D drug X'' is administered once daily, and the maximum dose is 30mg once daily. Suppose a Part D enrollee takes the maximum dose of 30mg once daily. The Part D enrollee could accomplish that by taking three 10mg tablets, one and a half 20mg tablets, or one 30mg tablet. However, because the 30mg tablets yield the fewest number of dose units for the Part D enrollee to achieve the required dose, dispensing 30, 30mg tablets for a 30-day supply is indicated to be ''dose optimized'' relative to the other options. Although prescriptions for 30 30mg tablets or 90 10mg tablets each cost $900, because the prescription for 90 10mg tablets is not dose optimized, it (still) does not qualify for the specialty-tier cost threshold.

Because our proposed language at (d)(2)(iv)(A)(*6*) applied to Part D drugs except those newly-approved by the FDA, in response to the comments, we wish to clarify the process for newly-FDA approved drugs. Therefore, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drug such that we will approve placement of a newly-FDA-approved Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated price for a 30-day equivalent supply is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to our review and approval as part of our annual formulary review and approval process.

While we appreciate the commenters' suggestion that we codify language at § 423.104 concerning dose specificity and dose optimization, we do not believe that we could effectively do so, given the myriad drugs, conditions, different doses for such conditions, dosage forms, package sizes, etc., that factor into these determinations, which can sometimes be quite complicated. We do not want to inadvertently exclude nuanced, but clinically relevant dose optimization strategies. Consequently, we will consider potential language for future notice and comment rulemaking.

Comment: Some commenters suggested that moving from negotiated price to ingredient cost may increase the number of drugs eligible for the specialty tier since negotiated prices may be lower than average wholesale price (AWP) and that CMS should ensure that the switch from negotiated price to ingredient cost tracks the medications captured by the current threshold. Some commenters suggested that if CMS finalizes this provision with 30-day equivalent negotiated price (instead of 30-day equivalent ingredient cost), CMS needs to clarify which definition of negotiated price.

Response: We estimate that the change from using negotiated price to using ingredient cost only would result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have met the threshold if we continued to use the 30-day equivalent negotiated price. In other words, in our preliminary analysis, moving from negotiated price to ingredient cost decreased the number of drugs eligible for the specialty tier. However, we will continue to monitor the uptake and outcomes associated with these proposals. We are finalizing the provision to establish a Part D drug's eligibility for placement on the specialty tier using the ingredient cost.

Comment: Some commenters requested clarity on why CMS is codifying the existing methodology while at the same time proposing a substantive change, and inquired why CMS does not simply propose the change. The commenters added that in proposing to move away from the negotiated price and use the ingredient cost that CMS has, in essence, removed the dispensing fee from the determination of a Part D drug's eligibility for specialty-tier placement, but that CMS has not specified if there is a specific issue with dispensing fees that would warrant removing them altogether from the calculation of the specialty tier cost threshold. These commenters then inquired if CMS had another definition for ingredient cost, and suggested that if so, CMS needs to spell this out.

Response: We proposed to codify our longstanding policy with certain changes to improve the transparency and consistency of the specialty tier cost threshold.

We have concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point of sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price.

Use of the ingredient cost in lieu of the negotiated price for purposes of determining the specialty-tier cost threshold does not remove the dispensing fee from the negotiated price. Rather, as previously noted, we are merely using the most stable portion of the negotiated price to determine the specialty tier cost threshold. Finally, by ingredient cost, we mean the ingredient cost that is reported on the PDE.

We are finalizing our proposal describing the methodology by which we set the specialty-tier cost threshold, and a Part D drug's eligibility for placement on the specialty tier with one modification. In response to comments, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

A summary of the comments on the methodology to increase the specialty-tier cost threshold and our responses follow.

Comment: Most commenters supported CMS's proposal describing the methodology CMS will use to increase the specialty-tier cost threshold.

Response: We thank the commenters for their support.

Comment: Some commenters opposed CMS's proposed 10 percent threshold for change for updating the specialty-tier cost threshold, and suggested that drugs that no longer meet the threshold should be removed from the specialty tier, regardless of the magnitude of the threshold's change. Some commenters were concerned about products not meeting the specialty-tier cost threshold from one year to the next, and consequently moving in and out of the specialty tier from one year to the next, which could cause Part D enrollee confusion. Some commenters noted a tension between tiering exceptions, use of the ingredient cost in lieu of the

negotiated price for purposes of determining the specialty-tier cost threshold, and increases to the specialty-tier cost threshold, noting that, as drugs no longer qualify for the specialty tier and are moved to a non-specialty, non-preferred brand/drug tier, Part D enrollees could potentially pay more for a preferred specialty tier drug than a non-specialty, non-preferred drug, even though the non-specialty, non-preferred drug is the less expensive product. Additionally, some commenters suggested that CMS should clarify how our proposal to revise the specialty-tier cost threshold could impact the distribution of generic drugs and biosimilar biological products that are able to be placed on the specialty tier. Finally, some commenters suggested that CMS should address sudden increases, perhaps due to a sudden increase in the utilization of specialty-tier drugs.

Response: We agree that the specialty tier should consist of only the highest-cost drugs. However, as the commenters noted, to decrease Part D enrollee confusion arising from year-to-year changes in the specialty-tier cost threshold, we must balance the limitation of the specialty tier to the highest-drugs with the need for stability in the specialty-tier cost threshold. Nonetheless, we wish to clarify that, even absent any increase in the specialty-tier cost threshold, if the price of a drug changes, and it no longer meets the specialty-tier cost threshold, it must be removed from the specialty tier at the beginning of the next plan year.

While we acknowledge the commenters' concerns about the tension between tiering exceptions, the specialty-tier cost threshold, tier composition (that is, as Part D drugs no longer meet the specialty-tier cost threshold and are potentially placed on other, non-specialty tiers), and Part D enrollee cost sharing, this dynamic exists today and our policy would not change this. We also note that if Part D drugs, including generic drugs and biosimilar biological products, were no longer eligible for specialty-tier placement and subsequently placed on a non-specialty, non-preferred tier in the following plan year, an enrollee could then request a tiering exception for that drug.

We also appreciate that the commenters' suggestion of sudden increases comes at a time of unprecedented uncertainty regarding the specialty tiers in light of COVID–19. However, we decline to adopt any new policies to address sudden price changes. Consistent with our guidance at section 30.3.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual and subject to the requirements of § 423.120(b)(5), we permit Part D sponsors to add drugs to and remove drugs from the formulary during the plan year.

Comment: Some commenters suggested that CMS should increase the specialty-tier cost threshold by the Annual Percentage Increase (API) or medical inflation with a periodic rebalancing when the specialty-tier cost threshold represents less than one percent of claims.

Response: We thank the commenters, but we decline to adopt this recommendation because we proposed a methodology that would keep specialty tier drugs at the top 1 percent.

We are finalizing without modification our proposed methodology to increase the specialty-tier cost threshold.

A summary of the comments on increasing the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*) and our responses follow.

Comment: Most commenters supported CMS's proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). A commenter asked what the cost threshold for higher cost-sharing, specialty tier would be, and if it will be set by the plan.

Response: We thank the commenters for their support. We are not finalizing this proposal. The specialty-tier cost threshold will apply to both specialty tiers, and while Part D sponsors would not set the threshold, Part D sponsors may choose which specialty-tier drugs go on which tier, subject to our annual formulary review and approval process. However, as we noted in our May 22, 2020 HPMS memorandum entitled, ''Updated Contract Year (CY) 2021 Final Part D Bidding Instructions,'' for coverage year 2021, we will maintain the specialty-tier cost threshold at $670, as a 30-day equivalent negotiated price. The methodology that is being finalized in this rulemaking will be in effect for coverage year 2022.

Comment: Some commenters asked whether CMS considered the effect of our proposal to increase the specialty-tier cost threshold in combination with our proposal to permit Part D sponsors to maintain up to two specialty tiers, overall, asserting that CMS may be reducing the benefits that a second specialty tier could bring to plans and Part D enrollees because a brand drug may continue to qualify for the specialty tier(s) while its generic equivalent may not.

Response: As discussed earlier in this section (section IV.E.6) of this final rule, we believe the specialty tier should consist of only the highest-cost drugs and therefore, that we should apply a methodology that takes into account rising drug costs and changes in utilization over time. There is a chance that a drug—including a generic drug—that no longer qualifies for placement on the specialty tier may be placed on a non-specialty, non-preferred brand/drug tier, which may have up to 50 percent coinsurance. We note however that this scenario exists today, where drugs are no longer eligible for specialty tier placement because they no longer meet the specialty-tier cost threshold, and Part D sponsors can choose to place them on formulary in a way that they deem best for their enrollees, provided they comply with the requirements of our formulary review and approval process under § 423.120(b). The dynamics around formulary placement of brand and generic drugs and the elements that drive those decisions are central to the core structure and function of the Part D benefit. We therefore do not believe this proposal exacerbates this issue. We also acknowledge in section IX.E.5. of this final rule that conflicting forces might limit the potential savings/benefits of this proposal. Moreover, it is important to note that drugs on a non-specialty, non-preferred brand/drug tier are subject to tiering exceptions.

Under the requirements of § 423.578(a)(6) and consistent with our guidance at section 40.5.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, non-preferred generic drugs are eligible for tiering exceptions to the lowest applicable cost sharing associated with alternatives that are either brand or generic drugs when the medical necessity criteria are met. This represents an important protection for Part D enrollees, particularly when paired with our benefit parameters that we establish on an annual basis. Under § 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs (meaning, actuarially equivalent standard, basic alternative, or enhanced alternative benefit designs) may not exceed levels (or cost sharing thresholds) that we annually determine to be discriminatory.

We are not finalizing our proposal to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent ingredient cost) for contract year 2021 from the previous $670 (as a 30-day

equivalent negotiated price). For CY 2021, we will maintain the specialty tier threshold at $670, as a 30-day equivalent negotiated price. However, as previously described, we are finalizing our proposed methodology to determine the specialty tier threshold each year, beginning with CY 2022.

In summary, we are finalizing without modification our proposals to:

- Add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers;
- Maintain the existing policy at § 423.578(c)(3)(ii), thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier;
- Add new paragraphs § 423.104(d)(2)(iv)(D)(*1*) through (*3*) to establish a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, for plans with two specialty tiers, the higher cost-sharing, specialty tier;
- Permit Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the other specialty tier;
- Give Part D sponsors the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the thresholds we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2);
- Amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv);
- Add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year;
- Add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the methodology by which we set the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier; and
- Add new paragraph (d)(2)(iv)(B), which describes the methodology we will use to increase the specialty-tier cost threshold.

In response to comments, we are also finalizing new paragraph (d)(2)(iv)(A)(*6*), which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drug.

These final policies will apply for coverage year 2022, and we will announce the specialty-tier cost threshold for coverage year 2022 prior to the contract year 2022 bidding deadline.

As discussed in section IV.E.2 and earlier in this section (section IV.E.6) of this final rule, to retain the policies in effect before coverage year 2022, we will:

- Amend the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022; and
- Amend § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products.'' Additionally, paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

F. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

1. Overview and Summary

Section 101 of the MMA requires the adoption of Part D e-prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. Prescribers and dispensers who electronically transmit and receive prescription and certain other information for Part D-covered drugs prescribed for Medicare Part D-eligible individuals, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

Section 119 of the Consolidated Appropriations Act requires that Part D plan sponsors implement a prescriber RTBT capable of integrating with clinicians' electronic prescribing and electronic health record systems for the real-time transmission of formulary, benefit, clinical alternative, cost sharing, and utilization management information specific to Part D plan enrollees. This requirement is to take effect once the Secretary names a prescriber RTBT standard, which has not yet occurred.

For a further discussion of the statutory basis for this final rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the February 4, 2005, Medicare Program; E-Prescribing and the Prescription Drug Program Proposed Rule (70 FR 6256).

In accordance with our regulations at § 423.160(b)(1), (2), and (5), CMS' Part D eRx program requires that Part D sponsors support the use of the adopted standards when electronically conveying prescription and formulary and benefit information regarding Part D-covered drugs prescribed to Part D-eligible individuals between plans, prescribers, and dispensers.

CMS utilized several rounds of rulemaking to update the Part D e-prescribing program. Most recently, in the May 2019 final rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Final Rule (84 FR 23832) (hereinafter referred to as the May 2019 final rule), we required that Part D plans support a prescriber electronic real-time benefit tool capable of integrating with at least one e-prescribing or electronic health record (EHR) system. The prescriber RTBT must provide its enrollees with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including enrollee cost sharing information formulary alternatives and utilization management requirements). This ''prescriber RTBT'' electronic transaction requirement will become effective January 1, 2021, and is expected to enhance medication adherence and lower overall drug costs by providing Part D prescribers information in real time when lower-cost alternative drugs are available.

The SCRIPT and the NCPDP Formulary and Benefits standards have already become critical components of the Part D program, and CMS believes that the recently finalized prescriber RTBT requirement at § 423.160(b)(7) will do the same by enhancing the electronic communication of prescription-related information between plans and prescribers under the Part D benefit program. In order to further enhance this communication, CMS has been monitoring the development of prescriber RTBT standards and will consider adoption of these standards in future rulemaking. While these requirements will empower prescribers, CMS also believes it is important to empower patients with

information like that which will be included in the prescriber RTBT and give them the ability to access this information either at their computer or using a mobile device.

In the February 2020 proposed rule, CMS proposed to adopt at § 423.128(d)(1)(vi), (d)(4) and (d)(5) a requirement that Part D sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, effective January 1, 2022, so as to allow both prescriber and patient to consider potential cost differences when choosing a medication that best meets the patient's medical and financial needs. CMS proposed to require that each system response value would need to present real-time values for the patient's cost-sharing information and clinically appropriate formulary alternatives, where appropriate. This requirement would include the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits, and prior authorization, applicable to each alternative medication. CMS also proposed to require that plans make this information available to enrollees via their customer service call center.

CMS received the following comments related to our proposal, in general. Our responses follow.

Comment: All commenters supported our proposal, citing the need to provide beneficiaries with actionable information about their prescription drug costs, so beneficiaries can make better informed decisions about treatment options.

Response: CMS thanks commenters for their support. CMS agrees that providing beneficiaries with information about prescription drug costs is important and that the beneficiary RTBT will help provide this information to Part D enrollees.

Comment: Some commenters requested that we delay the implementation date until January 1, 2023 to allow more time for testing the tool. Some of these commenters requested that we exercise enforcement discretion, should we choose not to delay the implementation date. Other commenters requested that we change the implementation date to January 1, 2021 so that beneficiaries can access the benefits of the tool more expeditiously.

Response: CMS understands both the desire to ensure that the tool functions properly and that Part D enrollees have access to information about prescription drug costs. However, in order to help ensure that Part D sponsors have adequate time to implement the tool properly so that beneficiaries can access accurate information as seamlessly as possible, we have decided to delay the implementation date until January 1, 2023.

Comment: A few commenters requested that CMS provide training tools on beneficiary RTBTs to help ensure that Part D enrollees are able to use the RTBTs properly. Other commenters requested that we provide the Part D sponsors with standard language to use on their beneficiary RTBTs to help ensure that Part D enrollees are able to understand the information.

Response: CMS believes that helping ensure that Part D enrollees can use the beneficiary RTBTs and understand the information within them is of utmost importance. However, CMS wants to help ensure that plans have sufficient flexibility when implementing this requirement, since most Part D sponsors have computer applications or portals in place and are more attuned to the needs of their enrollees. In addition, the RTBTs may differ slightly by plan, so we believe that Part D sponsors are better equipped to ensure that their enrollees understand how to use the tool and the language within it.

In order to help ensure that beneficiaries understand how to use this tool, CMS considered requiring that Part D sponsors provide training to their enrollees. However, we believe this would limit our strategy of maximal flexibility for Part D sponsors in implementing this new requirement. Part D sponsors are in the best position to gauge whether or not their enrollees would benefit from training about how to use beneficiary RTBTs. Furthermore, we expect these RTBTs to be similar to the computer applications or portals that most Part D sponsors already have in place, so we do not believe that Part D enrollees will require a training to use the new tool.

Comment: Commenters requested that we require Part D sponsors to include additional information unrelated to beneficiary drug costs in the beneficiary RTBT, such as beneficiary eligibility status, the notification that beneficiaries have the right to an appeal, an explanation of the difference between out of pocket costs and premiums, and a message letting beneficiaries know that assistance programs are available to beneficiaries to help them pay their out of pocket costs.

Response: Although CMS understands the importance of keeping beneficiaries informed about these important topics, we decline to adopt this suggestion. Beneficiaries can access this information from several sources, including upon enrollment in Medicare Part D, through the Medicare & You publication, and *Medicare.gov*. The purpose of the beneficiary RTBT is to better inform beneficiaries about alternative medications, rather than serve as a repository of information for Part D enrollees. As previously stated, CMS seeks to allow Part D sponsors flexibility in implementing this requirement. As a result, CMS is not requiring sponsors to include information that is not directly connected to the purpose of the RTBT. However, Part D sponsors can include additional information, if they deem it helpful to their enrollees.

2. Pricing Information for the Beneficiary RTBT

As previously noted, CMS proposed to require that Part D sponsors include beneficiary-specific cost information in their beneficiary RTBTs. We proposed this requirement since we believe that sharing this information would yield greater medication adherence. In our proposed rule, we cited evidence suggesting that reducing medication cost yields benefits in increased patient medication adherence. Evidence supports that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events.[62] Given that patient cost is such a determinant of adherence, including the patient in such discussions should improve medication adherence. Further, research shows that when patients play an active role in their health care decisions the result is increased patient knowledge, satisfaction, adherence with treatment and improved outcomes.[63] Although not all patients will choose to actively participate in treatment decisions, interactive discussions between patients and physicians are correlated with improved patient satisfaction with their health care provider.[64]

We believe that bringing all of these benefits to Part D enrollees is especially important, in light of the fact that the

[62] Impact of Type 2 Diabetes Medication Cost Sharing on Patient Outcomes and Health Plan Costs (2016), Julia Thornton Snider, Seth Seabury, et. Al.; The ''Cost'' of Medication NonAdherence: Consequences We Cannot Afford to Accept (2011), Marie A. Chisholm-Burns and Christina A. Spivey; Medication Non-adherence is Associated with Increased Medical Health Care Costs (2007), Sunanda Kane and Fadiya Shaya.

[63] See *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1855272/*.

[64] See *https://www.ncbi.nlm.nih.gov/pubmed/11021677/*.

Medicare population is becoming increasingly comfortable with technology. According to a 2017 Pew Research Center study, some groups of seniors report ''owning and using various technologies at rates similar to adults under the age of 65'' [65] and also characterized ''82% of 65- to 69-year-olds as internet users,'' and found that 40 percent of seniors now own smartphones, ''more than double the share that did so in 2013.'' As more seniors use computers and smart phones in their daily lives, it is likely that they will use electronic means to research information about their prescription medications. CMS believes that the Part D program must move to accommodate those enrollees by enhancing the way that digital technologies are currently used.

We also stated that we would consider it a best practice for beneficiary RTBTs to include cost-sharing amounts for medications if purchased at a pharmacy selected by the beneficiary, provided the pharmacy is in the plan's network. Sponsors would also be allowed to provide cost data for alternative pharmacies in the plan's network. However, due to concerns with enrollees being steered to different pharmacies, we did not propose to require that beneficiary RTBTs include pharmacy-specific cost sharing information.

In order to support maximum transparency, CMS also encouraged plans to show each drug's negotiated price (as defined in § 423.100) in the beneficiary RTBTs in addition to the requirement to reflect the beneficiary's out-of-pocket cost information at the beneficiary's currently chosen pharmacy. Alternatively, if the beneficiary RTBT does not show the negotiated price, we would encourage plans to provide additional cost data comparing the beneficiary and plan cost comparisons for each drug and its alternatives. For example, if Drug A has beneficiary cost sharing of $10 and the plan pays $100, and Drug B also has a beneficiary cost sharing of $10 but the plan only pays $90, the beneficiary RTBT would reflect a difference of $0 for cost sharing and −$10 in comparative plan cost for Drug B. Providing data such as negotiated price or comparative plan costs would provide beneficiaries with a better understanding of the price differences between alternative drugs and could help provide beneficiaries with information on potential clinically appropriate alternatives that could steer a discussion with their clinician and provide the biggest savings to the beneficiary and potentially lower Part D costs overall.

Although we encouraged the inclusion of the negotiated price and other comparative information in the beneficiary RTBT, we did not propose to require the inclusion of such information. We did not propose to require this because we do not have research that shows learning the payer's rate will affect beneficiary choice if there is no effect on their payment amount. However, we solicited comment on this issue.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. In the following pages, we summarize the comments received about the pricing data to be included in the beneficiary RTBT.

Comment: Some commenters requested that CMS require the inclusion of the negotiated and net prices of medications, which is the cost of the medication after all rebates and fees are subtracted. Other commenters requested that we refrain from even encouraging the inclusion of the negotiated price, as we did in our proposed rule.

Response: CMS understands that it may be helpful for some beneficiaries to see additional pricing information, including the negotiated and net prices. However, as stated in our November 2020 Transparency in Coverage final rule (85 FR 72158), which implements requirements for group health plans and health insurance issuers in the individual and group market to share participant cost sharing information and the negotiated price with the participant in the form of machine readable files and paper (upon request by the participant), CMS should aim to strike a balance between illuminating some of the factors that drive drug costs and not overwhelming consumers with information that is not directly relevant to their cost-sharing liability. In the case of the beneficiary RTBT, we believe this balance is best struck through alignment with the information in the prescriber RTBT, which does not require inclusion of the negotiated or net prices. Having the same information in both tools will not only help facilitate conversations between enrollees and their providers about different medications for the enrollee, but will give the prescriber the opportunity to explain the information in the beneficiary RTBT to enrollees. Providing enrollees information about the negotiated drug prices could easily overwhelm consumers with information, since the pricing information is updated in real time using test claims transmitted to the pharmacy in order to adequately gauge what the drug price is at the time the request is made.

By contrast, in our November 2020 final rule, the requirement for group health plans and private issuers is to compile information for consumers in a file outside of the prescriber RTBT. As a result, group health plans and private issuers are only required to provide this information once—through a machine-readable file or via paper. However, if we were to require Part D sponsors to provide the negotiated and net prices in the beneficiary RTBT, Part D sponsors would be required to transmit two different claims in order to facilitate these tools—one for the prescriber RTBT and one for the beneficiary RTBT. We believe that the benefit these enrollees derive from seeing the net and negotiated prices is outweighed by the burden for plans to calculate this cost and program it into the beneficiary RTBT.

Further, since most plans have similar beneficiary RTBTs in place, we believe that plans are in the best position to gauge what information is useful to their enrollees. We intend for our regulatory requirements to be a starting point for the beneficiary RTBTs and that plans will have the ability to add in additional information, if they believe it will helpful for their enrollees. The sole purpose of our regulatory requirements is to provide the minimum amount of information that must be included in the beneficiary RTBT, and we do not believe that including the net or negotiated prices is absolutely necessary in the beneficiary RTBTs. This approach differs from the approach in our November 2020 final rule, since Part D plans already have similar tools in place, whereas the group health plans and issuers in the private and group market do not.

Comment: Some commenters requested that CMS require Part D plans to include pharmacy and provider-specific data, so that beneficiaries can find the lowest possible price for their medications.

Response: CMS understands the importance of ensuring that beneficiaries have the appropriate tools to find the lowest price medications. However, CMS seeks to balance this desire with the desire to ensure that beneficiaries are not improperly steered away from their pharmacies and providers of choice. Since plans have

[65] Report is accessible at *https://www.pewinternet.org/2017/05/17/technology-use-among-seniors/.*

the most experience in working with enrollees, we seek to give plans flexibility in implementing the beneficiary RTBT. As a result, we will not prohibit plans from displaying pharmacy and provider-specific pricing. However, we will not require plans to show this information. Therefore, we decline to accept the suggestion that we mandate that plans include this information. Instead we are finalizing our proposal to require only that Part D sponsors include the enrollee cost sharing amount, rather than the negotiated or net price.

3. Beneficiary RTBT Formulary Data

In order to fully empower enrollees to select the most appropriate medications, we proposed to require Part D sponsors to review formulary medications to determine which alternatives exist and whether those alternatives may save their enrollees money through reduced cost sharing. The sponsors would then import that information into the beneficiary RTBT.

However, since we understand that most enrollees may not have the clinical background required to accurately discern the clinical appropriateness of all alternatives, we proposed a narrow exception to this requirement, to include for example certain antibiotics which are ''drugs of last resort'' that are typically reserved for instances in which the patient is found to have certain drug-resistant infections, or instances in which side-effects are such that a given prescription would not typically be selected in the absence of countervailing risks that would justify risking such side-effects, or instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug. In these and other clinically appropriate instances, we stated that it may be appropriate to omit certain drugs from what is presented to the user of a beneficiary RTBT. Thus, in order to address these and other clinically appropriate scenarios, we proposed that Part D sponsors would be permitted to have their Pharmacy and Therapeutics (P & T) committees evaluate whether certain medications should be excluded from the beneficiary RTBT. In order to help ensure that this exception is narrowly construed, we proposed to allow P & T committees to exclude medications from the beneficiary RTBT only in the following situations or instances: (1) The only formulary alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, (2) for cases where medications are considered to be ''drugs of last resort,'' (3) instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug, or (4) other clinically-appropriate instances.

We clarified that the data that we proposed to require be provided in the beneficiary RTBT must be patient-specific, clinically appropriate, timely, accurate, and devoid of commercial purposes that would adversely impact the intended functionality of promoting cost-effective beneficiary and prescriber selections of drugs. In the following pages, we summarize the comments and provide our responses and final decisions surrounding formulary data to be included in the beneficiary RTBT.

Comment: A number of commenters recommended that CMS remove the requirement for any formulary alternatives to be included on the beneficiary RTBT. These commenters expressed concern that listing these alternatives for Part D enrollees would lead to confusion among their enrollees, since beneficiaries would not be able to appropriately discern whether the medications are appropriate for them. Another commenter suggested that CMS require Part D sponsors to include alternatives that are not on plan formularies, in addition to the formulary alternatives, so that enrollees have a greater array of options.

Response: Part D sponsors are required to include medications on their formulary that provide beneficiaries with a broad range of medically appropriate drugs across an appropriate breadth of categories and classes that cover all disease states, and meet other classifications. CMS reviews these formularies annually to help ensure compliance. As a result, we believe that the medications listed on the Part D formularies should provide sufficient options for Part D enrollees without requiring alternative options for enrollees outside of the Part D formularies.

Although CMS shares commenters' concerns surrounding beneficiary confusion, we believe that limiting beneficiaries' choices to medications within their plan's formulary will help alleviate this concern. CMS believes that allowing beneficiaries the opportunity to choose from different medication alternatives within the plan's formulary strikes the right balance between ensuring that beneficiaries have adequate options for medications while not overwhelming beneficiaries with too many choices that may not be available to them. Although some enrollees may find these options overwhelming, we believe that the benefit of giving beneficiaries different medication options outweighs the risk that some beneficiaries may be overwhelmed by all the medication choices.

Comment: The majority of commenters disagreed with our proposal to allow plans to exclude formulary alternatives in clinically appropriate instances, citing the possibility that plans could use this exclusion as an opportunity to steer patients away from the most clinically appropriate medications, give rise to undue confusion in cases where the provider determines that an excluded drug is actually appropriate, or cause plans to erroneously omit certain medications from the RTBT. However, some commenters supported this exclusion, since they believed that Part D sponsors could benefit from the additional flexibility.

Response: After considering the information provided by the commenters, we are persuaded that the potential for misuse and confusion emanating from this exclusion outweighs the benefit of additional plan flexibility. CMS continues to believe that Part D sponsors should be granted flexibility when implementing the beneficiary RTBT. However, the harm that could be caused by the potential exclusion of appropriate medications outweighs the limited benefit of granting Part D sponsors this additional flexibility in this case. Therefore, we are removing this exclusion and finalizing our proposed requirement to include all formulary alternatives in the beneficiary RTBT.

4. Rewards and Incentives for Beneficiary RTBT

In order to encourage enrollees to use the beneficiary RTBT, we proposed to allow plans to offer rewards and incentives (RI) to their enrollees who use the tool. We proposed to define use, for purposes of permitted RI, to mean logging onto either the portal or application or calling the plan's call center to ask for this information, without regard to whether the enrollee engages in a discussion with his or her prescriber or obtains or switches to any medication in response to such use. In other words, we proposed that plans that choose to offer RI must offer it to all plan enrollees who use the tool or seek to access this information via phone and must not make RI contingent upon the medical diagnosis or the type of medication a beneficiary is taking, or upon the enrollee switching medications.

We proposed to prohibit any enrollee remuneration under the guise of RI, which includes waivers of copayments and deductible amounts and transfers of items or services for free. We also proposed to prohibit plans from offering any cash or monetary donations, under the guise of RI. However, we did propose to allow for the use of gift cards, as long as they are not cash equivalents and do not encourage enrollees to further patronize the plan or any of the plan's corporate affiliates. For purposes of this proposal, CMS proposed that gift cards that can be used like cash, for example, a VISA or Amazon gift card, to be a ''cash equivalent.'' Cash equivalents also may include, for example, instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards. This means that gas cards or restaurant gift cards would be permitted. However, a gift card that can be used for goods or services purchased from the plan would be prohibited, since that could incentivize enrollment in plans that could provide gift cards that enrollees could use at pharmacies or retail stores owned by their plan, rather than at a third-party establishment owned by a different company.

We also proposed that the RI be of nominal value, which Office of Inspector General (OIG) guidance specifies as no more than $15 per login or $75 in the aggregate annually, in accordance with OIG guidance.[66] We also proposed that the member can receive a RI for no more than one login per month. We also proposed that this expense would have to be included as an administrative expense in the bids of Part D sponsors, rather than it being considered a drug cost. We solicited comments on these limitations and on how we can ensure that these RIs will not be indirectly provided or funded by pharmaceutical manufacturers. We also solicited comments on safeguards to mitigate risks of fraud and abuse with respect to these incentives.

MA–PDs are already permitted to offer rewards and incentives for Part C benefits under our regulation at § 422.134, which permits plans to offer health-driven rewards and incentives that are designed to encourage enrollees to participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We propose to adopt Part C's ban at § 422.134(b) on discrimination for Part D RI that plans offer to encourage the use of the beneficiary RTBT. We therefore proposed to require that if a Part D plan sponsor offers RI, it must be available to all of the plan's enrollees that log into the plan's portal or call the plan's call center, without discrimination based on a prohibited basis; under applicable law, prohibited bases of discrimination include the enrollee's proficiency in English, race, color, national origin, sex, age, disability, chronic disease, health status, or other basis prohibited by law.

We proposed to add this provision to our regulations at § 423.128 by amending paragraph (d) to add paragraphs (4) and (5). Paragraph (4) would address the beneficiary RTBT and paragraph (5) would address the rewards and incentives for use of the beneficiary RTBT.

Because of the safeguards included in the aforementioned proposals, including requiring that the rewards and incentives be non-cash equivalents, we believe the RI presents a low risk of fraud and abuse and is unlikely to compromise the integrity of the program.

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters supported the use of rewards and incentives for this provision. However, some of these commenters requested that CMS allow use of Amazon gift cards for the beneficiary RTBT, since they are a popular incentive for beneficiaries. The commenters disagreed with our classification of Amazon gift cards as cash equivalents, since they can only be used when shopping on *Amazon.com* or in Whole Foods.

Response: CMS continues to believe that Amazon gift cards fall under the definition of cash equivalents. In their final rule entitled ''Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements,'' published on December 7, 2016, (81 FR 88393), the OIG states that items that can be used like cash (such as a general purpose debit card) constitute cash equivalents. In addition, we seek to help ensure consistency across CMS rulemaking, and CMS has previously defined cash equivalents to include Amazon gift cards. Please see final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' published on December 31, 2019.

Although we understand the desire to use incentives that enrich the lives of beneficiaries, CMS must balance this desire against the increased fraud and abuse risk that exists when cash equivalents, such as a general purpose debit card or Amazon gift card are offered. As a result, we prohibit the use of Amazon gift cards as an RI under the beneficiary RTBT.

However, we seek to empower Part D sponsors to ensure that beneficiaries are motivated to use the RTBT, especially given the aforementioned potential benefits of the RTBT, including medication adherence and improved patient satisfaction. As a result, we are not finalizing our proposed requirement that the rewards and incentives be nominal in value and thus be limited to $15/login and $75/year. Rather, we defer to the judgment of Part D sponsors as to what they consider to be a reasonable amount to offer their enrollees. As previously mentioned, we seek to grant flexibility to Part D sponsors as they are in the best position to judge the needs of their enrollees.

CMS understands that this standard differs from what is considered appropriate under the Part C rewards and incentives program. The goal of the Part C rewards and incentives program is to promote healthy behaviors. By contrast, the goal of the rewards and incentives program for the beneficiary RTBT is to promote use of the tool, which are intended to lead to the aforementioned potential benefits of the RTBT, including medication adherence and decreasing overall drug costs. Because these goals differ and the value of use of the tool cannot be easily quantified, the Part C limit on rewards and incentives, which requires that the value of the reward and incentive not exceed the value of the activity itself, is not appropriate in this context of the Part D beneficiary RTBT. As a result, CMS is finalizing the limit for the rewards and incentives to be the amount Part D sponsors believe to be reasonable, rather than the Part C limit on rewards and incentives or a nominal amount. The other aspects of the RTBT rewards and incentives program are being finalized as proposed.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at §§ 423.128(d)(4) and (5) with several modifications. First, we are adding a January 1, 2023 applicability date to the regulation text at paragraph (d)(4) to reflect that this

[66] Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries, Office of Inspector General (2016).

provision will not apply until that date. Second, because we are requiring that plans include all formulary medication alternatives, rather than only the alternatives that are clinically appropriate, we are modifying the language at § 423.128(d)(4)(ii) to require all formulary medication alternatives to be included. Since we will be allowing plans to determine what they believe to be reasonable in determining the dollar value of the rewards and incentives, we are modifying the language at 423.128(d)(5)(i) to replace the word ''nominal'' with ''reasonable'' to clarify that the new limit for the value of the rewards and incentives is what plans consider to be a reasonable value, rather than an amount that OIG has interpreted to be nominal. Because plans will be determining what they deem to be reasonable, rather than an amount that OIG has interpreted to be nominal, we are removing the limitation at § 423.128(d)(5)(ii) on offering rewards and incentives for only one login per month.

G. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts CMS enters into with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at § 423.514. We proposed to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements.

Collecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand how the measures are applied, whether uniformly or specific to pharmacy type. This effort may also explain if there is a pharmacy performance problem, as pharmacy price concessions (financial penalties incurred) after the POS have continued to grow annually. Knowledge of the industry's pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies. Once collected, we stated that CMS would publish the list of pharmacy performance measures reported to increase public transparency.

We encouraged the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We also solicited comment on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for instituting potential Part D Star Ratings metrics related to these measures. Finally, we solicited comment on the data elements, timeline, and method of submission for the reporting of pharmacy performance measures.

We received the following comments and our response follows:

Comment: The vast majority of comments were supportive of the proposal for CMS to establish a reporting requirement to collect pharmacy performance measures used by Part D sponsors in their network pharmacy contracts. Virtually all of the supportive comments shared the opinion that the current pharmacy performance measures and processes were either flawed, opaque or both. They believed the collection of this information would spur transparency and reveal the need for standardized measures via an industry driven consensus process facilitated by an experienced and neutral third-party.

Response: We appreciate the support for the proposal to establish a requirement for Part D sponsors to disclose pharmacy performance measures to CMS. We agree that the information should provide transparency and help industry stakeholders come to a consensus on measures.

Comment: A number of commenters believed that if CMS made the pharmacy performance measures used by Part D sponsors public it would result in a loss of leverage and flexibility for sponsors in their negotiations with network pharmacies. Other concerns were that it would stifle innovation and be harmful to market competition. A commenter requested that the measures only be shared with the involved parties. Another added that, if universal performance thresholds are applied, Part D sponsors would lose their ability to effectively negotiate performance programs with network pharmacies when true differences in performance may exist. Another believed the publication of performance measures without context could mislead patients about the performance of their pharmacies. A couple of commenters stated that the information was sensitive and that making it public would be harmful to market competition; believing it inappropriate to make sponsors' performance measure thresholds public.

Response: We remind commenters that in the proposed rule we did not propose universal performance thresholds, but rather proposed to collect plans' pharmacy performance measures as an additional reporting section of our Part D reporting requirements. Given the growing magnitude of pharmacy price concessions based on performance measures in Part D, we believe it is important to provide transparency to the public regarding the measures in use. In addition, we believe that publishing a list of currently used pharmacy performance measures will promote the development of consensus-built standards by the industry that are transparent and equitable across various pharmacy types and patient populations, and support value-based care. Creating a ''level playing field'' to measure pharmacy network performance should not pose an obstacle to flexibility, innovation or competitiveness. Rather, a fair, more accurate and transparent system of measuring the strengths or weaknesses of a plan's network pharmacies should encourage both plans and the pharmacies within their respective networks to be innovative, flexible and competitive in how they use the data collected. Accurately identifying poorly performing pharmacies and well-performing pharmacies should encourage, when practical, a sharing of top pharmacy best practices' throughout a plan's network that would ideally enhance a plan's competitiveness in the marketplace.

Comment: The large majority of commenters agreed with the reporting requirement proposal, but noted concerns related to industry burden, need for more industry input, that any elements or criteria be subject to rulemaking, and that a reasonable timeline for implementation be given.

Response: As stated in the proposed rule, we are dedicated to the involvement of the industry in the development of this requirement. After publication of this final rule to establish the requirement that sponsors disclose pharmacy performance measure information to CMS, any new elements added to the Part D reporting

requirements (OMB 0938–0992) to implement this requirement would result from industry feedback through 60- and 30-day public comment periods in the **Federal Register** and approval through the Office of Management and Budget (OMB) Paper Reduction Act (PRA) process. As with any new elements added to the Part D reporting requirements, we believe the opportunity to provide comment through the PRA process will allow adequate input from the public and the industry. We also agree that to implement this provision we need to ensure the timeline and burden are reasonable for all parties involved. We will take into consideration the feedback received in response to the proposed rule when putting forth a timeline for implementation and potential elements for public comment.

Comment: We received one comment that warned that implementing a standard set of performance measures held the potential of narrowing pharmacy networks, thereby impacting some pharmacies and the options available to beneficiaries. Other commenters, while expressing support for standardization of measures in principle, requested that sponsors not be locked into only specific measures.

Response: We did not propose to implement a standard set of performance measures nor did we make any proposals with respect to requiring the use of any particular measures. Rather, in the proposed rule, we encouraged industry to come to a consensus on a standard set of pharmacy performance measures.

Comment: A few commenters, while supportive of the industry standardizing pharmacy performance measures, cautioned against placing too many exacting limits on the performance measures, and stated that sponsors should retain the ability to use metrics beyond those decided by a third-party facilitator such as, but not limited to, the Pharmacy Quality Alliance (PQA), provided such measures are transparent to CMS and pharmacies.

Response: We thank the commenters for their comments. We reiterate that we did not propose to standardize pharmacy performance measures in the proposed rule. We would expect that if through an industry consensus a standard set of pharmacy performance measures is established, it would be through a similar transparent and consensus process that additional measures would be added. We note, however, that transparency is of little consequence if the measures or the corresponding thresholds for that measure are ill-suited for the type of pharmacy or patient population that is being evaluated.

Comment: We received a few comments regarding our request for feedback on recommendations on measures to consider for use in the Part D Star Ratings related to the uptake or evaluation of pharmacy performance measures. A commenter believed it premature to consider specific metrics for a Star Ratings program, and another opposed the idea, believing that the proposed use of Star Ratings for pharmacy performance would not be meaningful to Medicare beneficiaries who judge pharmacy performance on a highly personalized basis. Other commenters strongly supported our proposal with one asking the agency to follow its traditional approach when first introducing Star Ratings and report the results on the display page. We received a comment that requested that any future pharmacy performance measures be developed in a way that directly ties to the Part D Star Ratings program.

Response: We appreciate the comments received and will consider them for any potential future development of measures based on pharmacy performance measure information. We note that we believe it is not premature to discuss potential Star Ratings as there would be a natural outgrowth to the development of standardized pharmacy measures. While we agree with the commenter that the selection of a pharmacy by a Medicare beneficiary is often a highly personalized choice, we believe that creating a rating system that leverages this plan-reported data could offer the beneficiaries additional information about the performance of pharmacies in the sponsors' pharmacy network.

We agree with the commenter that requested we follow the regulatory process for the introduction of new Star Ratings measures. CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule (83 FR 16725 through 83 FR 16731), published in April 2018, for performance periods beginning with 2019; that final rule lays out the methodology for the 2021 Star Ratings and beyond. CMS will continue to solicit feedback on new measure concepts as well as updated measures through the process described for changes in, and adoption of, payment and risk adjustment policies in section 1853(b) of the Act. We will also continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. As specified at § 422.164(c)(2)–(4), § 423.184(c)(2)–(4), § 422.164(d)(2), and § 423.184(d)(2), new measures and measures with substantive specification changes must remain on the display page for at least 2 years prior to becoming a Star Ratings measure. We appreciate the comment that we develop any future pharmacy performance measures in a way that can be directly tied to the Part D Star Ratings program.

Comment: A few commenters responded to our solicitation for feedback regarding the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent and/or rural pharmacies. Most comments suggested that smaller pharmacies be exempt entirely from all performance measures or subject to a modified approach. A commenter indicated that a voluntary set of measures, or a custom measurement set that is more applicable and feasible for smaller pharmacies to report (for example, patient counseling, medication therapy management) be used.

Response: We thank the commenters for their recommendations and will take them into consideration.

Comment: A commenter stated that pharmacies should have the ability to appeal results of their performance measures.

Response: We appreciate the comment regarding appeal rights; however, we did not propose to adopt any performance measures, and therefore did not propose an appeals procedure.

Comment: In response to our solicitation for comments on the proposed list of potential data elements there were two primary objections made by commenters. Some commenters opposed the use of retrospective data that could include success/failure thresholds, and average scores or statistics that may reveal sensitive information regarding contractual arrangements. There were no comments supportive of the proposed rule specifically on the data elements.

Response: We appreciate the comments. In the proposed rule, we recommend and encourage industry to continue, through a neutral third-party facilitator, creating and testing potential pharmacy performance measures based on industry consensus. If an industry-wide consensus is reached on a set of standardized measures it follows that part of the process of reaching consensus will be determining what should and should not be reported retrospectively, and what would and would not be deemed sensitive

contractual information between a sponsor and its pharmacy network.

Based on these comments, we are finalizing our proposal to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements, with one modification to make the provision applicable starting January 1, 2022.

H. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

We proposed regulations for withdrawing or dismissing Part C organization determination and reconsideration requests and Part D coverage determination and redetermination requests. We also proposed regulations for withdrawing or dismissing Part C and Part D independent review entity (IRE) reconsiderations. We also proposed to apply these provisions to requests for integrated organization determinations and reconsiderations at §§ 422.631 and 422.633. The proposals specifically addressed under what circumstances it would be appropriate to dismiss a coverage request or appeal at the plan or IRE level. We also proposed rules for how a party may request to withdraw their coverage request or appeal at the plan or IRE level. A withdrawal of a request is when the party that initiated the request voluntarily decides that a decision on their request is no longer needed, and the party communicates that desire to the plan to stop consideration of the request for determination (or reconsideration). A dismissal of a request is when a plan decides to stop consideration of a request before issuing a decision. The effect of both a withdrawal and a dismissal is that the plan does not proceed with making a substantive decision on the merits of the coverage request.

Specifically, we proposed that:

• In new §§ 422.568(g), 422.631(e), and 423.568(i), we proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when any of the following apply—

++ The individual or entity making the request is not permitted to request an organization determination or coverage determination.

++ The plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination.

++ The enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; we explained in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ The individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan.

• In §§ 422.570(g) and 423.570(f), we proposed to permit a plan to dismiss an expedited organization determination or coverage determination, consistent with the proposed requirements at §§ 422.568 and 423.568, respectively. Applicability of these procedures to expedited integrated coverage determinations was proposed at § 422.631(e).

• In §§ 422.582(f), 422.633(h), and 423.582(e), we proposed to permit a plan to dismiss (either entirely or as to any stated issue) a request for the second plan level decision (that is, reconsideration, integrated reconsideration or redetermination) when any of the following apply —

++ The individual or entity making the request is not a proper party to the reconsideration, integrated reconsideration, or redetermination under the applicable regulation; we explained that this proposal would authorize dismissal when the individual or entity making the request is not permitted to request a reconsideration, integrated reconsideration, or redetermination.

++ When the plan determines the party failed to make a valid request for a reconsideration, an integrated reconsideration, or a redetermination that substantially complies with the applicable regulation for making a valid request for reconsideration or redetermination.

++ When the party fails to file the reconsideration, integrated reconsideration or redetermination request within the proper filing time frame in accordance with the applicable regulation.

++ When the enrollee dies while the reconsideration or redetermination is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration or redetermination. We explained in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ When the individual or entity submits a timely written request to withdraw their request for a reconsideration or redetermination.

• At new § 422.584(g), we proposed to permit a plan to dismiss an expedited reconsideration using virtually identical language as for the proposed requirements at § 422.582. At new § 423.584(f), we proposed to permit a plan to dismiss an expedited redetermination by cross referencing § 423.582. Applicability of these procedures to expedited integrated coverage determinations was described in proposed § 422.633(h).

• At new §§ 422.592(d) and 423.600(g), we proposed to permit the Part C and Part D IRE to dismiss a request when any of the following apply—

++ The individual or entity is not a proper party under § 422.578 in the case of a Part C reconsideration or is not permitted to request a reconsideration by the IRE under § 423.600(a) in the case of a Part D reconsideration.

++ The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation.

++ When the enrollee dies while the reconsideration request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration. We explained in the proposed rule that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage.

++ When the individual or entity submits with the independent review entity a timely written request for a withdrawal of the reconsideration.

• In §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) we proposed that a written notice of the dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action; this would include the

individual or entity who made the request. The notice must include certain information, as appropriate, including applicable appeal rights (that is, request to vacate dismissal, review of the dismissal).

- In §§ 422.568(i), 422.582(h), 422.592(f), 422.631(g), 422.633(j), 423.568(k), 423.582(g), and 423.600(i), we proposed that a dismissal may be vacated by the entity that issued the dismissal (that is, MA organizations, applicable integrated plans, Part D plan sponsors, and the IRE) if good cause for doing so is established within 6 months of the date of the dismissal.
- In §§ 422.568(j), 422.631(h), and 423.568(*l*), we proposed that the dismissal of the organization determination or coverage determination is binding unless it is modified or reversed by the MA organization, applicable integrated plan, or Part D plan sponsor, as applicable, upon reconsideration or vacated under the provisions we proposed for vacating dismissals.
- At new §§ 422.582(i), 422.633(k), and 423.582(h), we proposed that the dismissal of the reconsideration or redetermination is binding unless the enrollee or other valid party requests review by the IRE or the dismissal is vacated under the applicable regulation.
- At new §§ 422.592(g) and 423.600(j), we proposed that a dismissal by the IRE is binding and not subject to further review unless a party meets the amount in controversy threshold requirements necessary for the right to a review by an administrative law judge or attorney adjudicator and the party files a proper request for review with the Office of Medicare Hearings and Appeals as outlined in §§ 422.600, 422.602, and 423.600(j), as applicable.
- At new §§ 422.568(k), 422.592(h), 422.631(i), 422.633(g), 423.568(m), and 423.600(f), we proposed that a party that makes a request may withdraw its request at any time before the decision is issued by filing a written request for withdrawal. Each proposed regulation paragraph identifies the entity (that is, the MA organization, the applicable integrated plan, or the Part D plan) with which the request for withdrawal must be filed.

We also proposed a change that applies to Part C only, given that the current rules do not include a process for an enrollee or other party to request IRE review of an MA organization's reconsideration (because review by the IRE of an adverse reconsidered determination is automatic). Specifically, we proposed to add a new paragraph (i) (mistakenly identified as a new paragraph (h) in the preamble of the February 2020 proposed rule) to § 422.590 that would give the enrollee or another party to the reconsideration the right to request review by the independent entity of an MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g). In new paragraph (i) of § 422.590 we proposed that a request for review of such a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice. Under existing rules at § 422.590(a)(2), (b)(2), (c)(2), (d), (e)(5), and (g),[67] if the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination or fails to meet the timeframe for making a reconsidered determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a reconsideration (or no later than the expiration of an applicable extension). These regulations that require a case to be automatically sent to the independent entity do not apply in the case of a dismissal of a request for a reconsideration because the MA organization is not making a substantive decision on the merits of the request.

As a corollary to this proposal, we also proposed to revise paragraph (a) of § 422.592 to add that, consistent with proposed § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests. As noted earlier in this section of the preamble, this new paragraph (i) to § 422.590 was mistakenly identified as new paragraph (h) in the preamble of the February 2020 proposed rule; this incorrect citation at § 422.592(a) has been corrected in this final rule to correctly refer to § 422.590(i). Further, we proposed to add a new paragraph (i) at § 422.592 to state that the independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review. In this final rule, we add a reference to § 422.590 at § 422.592(i) to state if the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590.

We also proposed a change applying to Part D only, given that the current rules do not include a process for enrollees to request IRE review of plan sponsor dismissals of redetermination requests. We proposed to add a new paragraph (f) at § 423.582 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the Part D plan sponsor's dismissal of a request for a redetermination. As a corollary to this proposal, we also proposed to add paragraph (j) at § 423.590 to state that, consistent with proposed § 423.584(f), an enrollee can request review of a Part D plan sponsor's dismissal of a redetermination request by the independent entity. Finally, we proposed to add a new paragraph (k) at § 423.600 to state that if the independent entity determines that the Part D plan sponsor's dismissal was in error, the independent entity would reverse the dismissal and remand the case to the plan for a redetermination on the merits of the case.

We received the following comments on the proposals related to dismissal and withdrawal of Medicare Part C organization determination and reconsideration and Part D coverage determination and redetermination requests.

Comment: Numerous commenters opposed the proposed language that required a party to submit a written request in order to withdraw requests for organization determinations, coverage determinations, reconsiderations, and redeterminations. Commenters noted that this language indicated that verbal withdrawal requests would not be accepted. Commenters referenced CMS guidance that states, in the ''Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance'' (Effective January 2020), at section 40.14, that a plan may accept verbal requests to withdraw a request for an organization or coverage determination. Additionally, commenters noted the same guidance states, in section 50.4, that a plan may also accept verbal requests to withdraw a request for a reconsideration, provided that the plan mails a written confirmation of the withdrawal to the party within 3 calendar days from the date of the verbal request. Commenters recommended removing the requirement for a written request to withdraw appeal requests in order to maintain consistency with the sub-regulatory guidance and current industry practice, and to reduce burden

[67] We note that § 422.590 was extensively amended by the April 2019 final rule, effective January 1, 2020.

on enrollees and plans. Commenters supported the current practice of requiring a written confirmation be mailed to the party within three calendar days from the date of the verbal request.

Response: CMS thanks the commenters for their perspective and feedback. The proposed provisions were intended to generally model the current provisions regarding dismissal and withdrawal of requests for appeal codified in 42 CFR part 405, subpart I (see §§ 405.952 and 405.972) because under § 422.562(d)(1), unless subpart M provides otherwise, and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate. Part 405, subpart I states that a party may withdraw a request by filing a written and signed request for withdrawal (see, §§ 405.952 and 405.972). Accordingly, we proposed that a request for withdrawal be made in writing.

However, the primary goal of codifying dismissal and withdrawal processes in regulation is to codify what we believe to be the current practices related to dismissal and withdrawal of Part C organization determination and reconsideration requests and Part D coverage determination and reconsideration requests, including those applicable to the Part C and Part D IRE. As commenters pointed out, current guidance permits plans to accept a request for withdrawal that has been made verbally. Accordingly, in response to these comments, we are finalizing the regulation changes with revisions to permit verbal requests to withdraw requests for organization determinations, coverage determinations, reconsiderations, and redeterminations are permitted under this final rule.

In response to the comments asking that verbal dismissal and withdrawal requests not be prohibited by regulation, we are finalizing the proposed changes, with modifications, to permit withdrawal requests to be made verbally. Specifically, the word ''written'' is not being finalized in the following provisions in this final rule: §§ 422.568(g)(4), 422.568(k), 422.582(f)(5), 422.592(d)(4), 422.592(h), 422.631(e)(4), 422.631(i), 422.633(g), 422.633(h)(5), 423.568(i)(4), 423.568(m), 423.582(e)(5), 423.600(f), and 423.600(g)(5). Additionally, in this final rule we are finalizing revisions to §§ 422.582(e) and 423.582(d) to remove the word ''written'' from the current regulation text describing a withdrawal of a request for a reconsideration. While this is a variance from the fee-for-service rules at 42 CFR part 405, subpart I (see §§ 405.952 and 405.972) upon which these final rules are generally modeled, this approach is consistent with existing Parts C and D guidance on these processes which allow for verbal withdrawal requests for organization determinations, coverage determinations, reconsiderations, and redeterminations.

Comment: We received a number of comments on the proposals to require a plan to dismiss a request for organization determinations, coverage determinations, reconsiderations, and redeterminations when the individual or entity who requested the review submits a timely written request for withdrawal. Specifically, commenters were concerned about the requirements in §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) that would require plans to provide written notice to the parties of a dismissal, including instances where a party asks to withdraw their request for an organization determination, coverage determination or appeal. Commenters also noted that by considering a timely request for withdrawal as a circumstance under which a plan may dismiss a request, CMS is causing confusion between and conflation of withdrawals and dismissals. Commenters noted that the withdrawal process is different from the dismissal process and recommended that CMS exclude references to withdrawals in the list of circumstances under which a plan or IRE may dismiss a request for an organization determination, coverage determination or appeal under proposed §§ 422.568(g), 422.582(f), 422.592(d), 423.568(i), 423.582(e) and 423.600(g).

Response: CMS thanks the commenters for their perspective and feedback. The proposed provisions were intended to generally model the current provisions regarding dismissal and withdrawal of requests for appeal codified in part 405, subpart I (see §§ 405.952 and 405.972) because under § 422.562(d)(1), unless subpart M provides otherwise and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate.

The reasoning behind adopting the proposed provisions at §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) related to providing written notice to the parties of a dismissal, which are generally modeled on §§ 405.952 and 405.972, is to preserve the rights of other proper parties to the decision if one party submits a withdrawal request; other parties may wish to pursue the appeal. For example, a physician may file an organization determination request on behalf of the enrollee and then later decide to withdraw the request because the physician better understands the reason for denial after further research. The plan would then dismiss the physician's request and issue a dismissal notice to the physician and enrollee. The enrollee is still a party to the request for an organization determination and may have an interest in having that organization determination process continue so that the plan issues a complete decision in accordance with §§ 422.566 and 422.568 despite the physician's withdrawal of the physician's request. Under our proposed provisions, the enrollee could then file a request to review the dismissal at the next level and explain that he or she wants a decision to be reached and issued. CMS regulations do not require all parties to file a request for a determination or reconsideration in order for them to remain parties to the appeal; issuing a notice of dismissal to all parties when the dismissal is based on the withdrawal request from the party that initially filed a request acknowledges that involvement.

Commenters also stated that they believe the requirement to issue a notice of dismissal when a party requests a withdrawal may cause confusion from both a reporting standpoint and a notification standpoint. CMS does not believe this proposal will cause confusion. For reporting, purposes, withdrawals and dismissals will remain distinct categories. Further, a notice of dismissal must contain the reason for dismissal; accordingly, the reason for dismissal in such cases would be the withdrawal of the request for the organization determination, coverage determination, reconsideration, or redetermination by a proper party to the request. Further operational guidance will be issued by CMS, as necessary.

Comment: Several commenters noted that the circumstances for dismissal of a request for an organization determination, coverage determination, reconsideration, or redetermination listed in §§ 422.568(g), 422.570(g), 422.582(f), 422.584(g), 422.592(d), 422.631(e), 422.633(h), 423.568(i), 423.570(f), 423.582(e), 423.548(f), and 423.600(g) are permissive rather than mandatory, in that the word ''may'' is

used. The commenters noted that all of the circumstances listed in the regulation imply the party requesting the reconsideration is either not a proper party or no longer has a financial interest in pursuing the reconsideration. The commenters recommend that CMS make the dismissal due to these circumstances mandatory and not permissive.

Response: It was not CMS' intent that the proposed regulatory language related to dismissals for these reasons be permissive. In this final rule, we are finalizing the provisions at §§ 422.568(g), 422.570(g), 422.582(f), 422.584(g), 422.592(d), 422.631(e), 422.633(h), 423.568(i), 423.570(f), 423.582(e), 423.584(f), and 423.600(g) without the word ''may'' to be clear on this point and to better align these provisions with §§ 405.952(b) and 405.972(b).

Comment: Several commenters noted that, under the proposed provision, written notice of a dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action. The commenters requested further guidance from CMS regarding applicable timeframes that would apply to this notice as well as the template or information that must be included.

Response: With respect to the commenter's request for guidance regarding the timeframes applicable to a notice of dismissal, the existing regulatory timeframes for issuing a decision notice when a substantive decision is made on a request will also apply if a request is dismissed under these final rules. In other words, a decision to dismiss a request is a determination, albeit a procedural one, on the type of request that was made and is subject to the decision notice timeframes at §§ 422.568(b) and (c), 422.572(a), 422.590(a), (b), (c), and (e), 422.631(d)(2), 422.633(f), 423.568(b) and (c), 423.590(a), (b), and (d) and 423.600(d). As an example, if an enrollee requests a standard reconsideration for a medical item or service pursuant to § 422.582 and the plan dismisses the request under the provisions at § 422.582(f) set forth in this final rule, the enrollee must be notified of the dismissal no later than 30 calendar days from the date the plan receives the request for a standard reconsideration under the provisions at § 422.590(a). A model Notice of Dismissal of Appeal Request can be found in section 50.9 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective January 1, 2020). As necessary, additional operational guidance related to dismissal procedures will be issued by CMS. We note that the regulatory provisions we are finalizing regarding dismissals include specific provisions addressing the content of the notice of the dismissal (for example, §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h)); therefore, the current regulations governing the content of notices of substantive decisions on organization determinations, reconsiderations, integrated organization determinations, integrated reconsiderations, coverage determinations, and redeterminations and reconsiderations do not apply to dismissal notices. *We also note that the proposed provisions addressing the content of the notice of dismissal for integrated organization determinations at § 422.631(f) were inadvertently incomplete. In the final rule we have revised the proposed text of § 422.631(f) to align with the analogous provisions for non-integrated organization determinations at § 422.568(h).*

Comment: A commenter noted that CMS proposed that an MA plan may properly dismiss an organization determination if ''the individual or entity making the request is not permitted to request an organization determination under § 422.566(c).'' The commenter believes the referenced regulation, § 422.566(c), is too vague and this authority to dismiss a request on this basis will lead to beneficiaries being denied fair organization determinations. Specifically, the commenter noted that hospitals are often told by MA plans that a rehabilitation physician seeking to admit a patient to an inpatient rehabilitation hospital/unit cannot participate in organization determinations with MA plans. The commenter believes that the rehabilitation physicians that are precluded from participating are the same rehabilitation physicians required to perform the de facto prior authorization process required by Medicare. The commenter asked CMS to consider clarifying § 422.566(c) to allow any physician familiar with the patient's care needs, like a rehabilitation physician, to request an organization determination.

Response: CMS believes that the existing provisions at § 422.566(c) are sufficiently clear regarding who may request an organization determination, which include any provider that furnishes, or intends to furnish, services to the enrollee. As such, under the commenter's example, if a rehabilitation physician furnished or intended to furnish a service to an enrollee, the physician is permitted to request an organization determination pursuant to this regulation under §§ 422.568 and 422.570. Further, § 422.578 provides that a physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in § 422.582; a physician acting on behalf of an enrollee may also request an expedited reconsideration as described in § 422.584.

Comment: Several commenters requested that CMS structure the Part C and Part D regulatory text the same way where possible, for clarity. A commenter noted by example that in § 422.584 (Expediting certain reconsiderations) CMS repeats the rules from a different section while § 423.584 (Expediting certain redeterminations) cross refers to them.

Response: CMS strives for clarity in the structure of the Part C and Part D regulatory text. We are finalizing the amendment to § 422.584 using a cross reference to rules in § 422.582 as opposed to repeating regulation text related to dismissals that is also applicable to the dismissal of expedited requests. With this change, the structure of the Part C and Part D regulation text will be in parity.

Comment: Several commenters expressed concern that the proposed regulations allow dismissal or withdrawal of requests that are never valid in the first place. The commenters believe that requests that are invalid to begin with cannot be dismissed or withdrawn. The commenters believe CMS should not continue with the plan allowances to dismiss a case that should not have been started in the first place.

Response: CMS recognizes that there may be invalid requests. However, whether a request is initially valid or not is a determination a plan makes upon receiving and reviewing a request for an organization determination. When a plan receives a request for an organization determination that it believes to be invalid, the plan refuses to approve, provide or pay for the requested services. Such refusal is an action that is considered an organization determination under § 422.566(b). Parties to an organization determination may request that the determination be reviewed under § 422.578 and § 422.592. The scope of the 42 CFR part 422, subpart M regulations is, in part, to set forth the appeal process for MA enrollees with respect to organization determinations. Removing appeal rights from enrollees who receive an organization determination is antithetical to the purpose and scope of

these regulations. The very purpose of these provisions is to provide a process and procedure (that is, dismissal) for the plan to dispense with invalid cases by issuing a procedural decision while also preserving an enrollee's right of review to a plan decision.

Comment: Two commenters responded to our request for comments regarding whether the proposed rules would create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. The commenter noted that Medicare determination and coverage processes may be different than Medicaid, and therefore, if medical care or services are not covered by Medicare, but are covered by Medicaid, withdrawing the appeal is an effective way to minimize the administrative burden of appeals in Medicare.

Response: CMS thanks the commenters for their feedback. We agree that for non-integrated plans that operate separate Medicare and Medicaid appeals processes, if an appeal concerns an item or service that is only coverable by Medicaid, withdrawing a Medicare appeal can reduce administrative burden. However, for applicable integrated plans that will follow the unified process established in §§ 422.629–422.634, one single coverage determination and appeals process applies to all requests for Medicare and Medicaid items and services covered by the plan, making withdrawal or dismissal of an appeal of a coverage denial inappropriate when there may be Medicaid coverage available from the applicable integrated plan. Applicable integrated plans must take into account both Medicare and Medicaid coverage available under the plan when making an integrated organization determination or integrated reconsideration.

Comment: Several commenters noted that proposed § 422.590(i) states ''the enrollee or other party has the right to request review of the dismissal by the independent entity.'' The commenters suggested the language be clarified to reflect it is the enrollee or other ''proper party under § 422.578'' so as to be consistent with § 422.592, which allows dismissals of requests for reconsideration if the individual requesting the reconsideration is not a proper party.

Response: We are finalizing the amendment to § 422.590(i) and § 423.590(j) with revised text to clarify that only proper parties under § 422.578 and § 423.580, respectively, have the right to request review of the dismissal by the independent entity.

Comment: Several commenters noted that CMS proposed to permit a plan to dismiss a request for a coverage determination in four specifically listed situations (that is, when any of the following apply: The individual or entity making the request is not permitted to request an organization determination or coverage determination, the plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination, the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; or the individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan). The commenters requested clarification if this list is exhaustive or if there may be other scenarios under which a plan may dismiss a case.

Response: As noted above, we are clarifying in this final rule that a plan must dismiss a request for the reasons set forth at §§ 422.568(g), 422.582(f), 422.592(d), 423.568(i), 423.582(e) and 423.600(g). As explained in the proposed rule, we believe that codification of these procedures, including the scenarios in which a plan issues a dismissal, will reduce confusion and promote consistent and proper handling of withdrawals and dismissals. We do not believe there are other scenarios where it would be appropriate to require that a request be dismissed under these final rules. However, if program experience once these rules have been implemented reveals other appropriate scenarios for requiring that a request be dismissed, we will take that into consideration for future rulemaking.

Comment: Several commenters noted these proposed regulations have highlighted the confusing differences in terminology between the initial levels of appeal for the Fee-For-Service Medicare Program, MA organizations, and Part D plans appeals. The commenters recommended that CMS align the appeal terminologies to avoid provider confusion and burden. For example, the initial level of appeal should have the same name for all programs, rather than redetermination for Fee-for-service and Part D and reconsideration for MA appeals.

Response: CMS appreciates these comments. We note that the appeal terminologies mirror the terms set by statute, specifically Social Security Act section 1852(g)(2) for Part C appeals, Social Security Act section 1860D–4(g) for Part D, and Social Security Act section 1869(a)(3) for Parts A and B. It is beyond the scope of this final rule to revise terminology across the Fee-for-Service, Part C, and Part D program regulations.

Comment: A commenter noted that under proposed § 422.592(i), if the IRE determines that the plan's dismissal was in error, the dismissal would be vacated and remanded to the plan for reconsideration. The commenter further noted that there is no timeframe indicated by which the plan is required to issue a decision on the remanded appeal. To ensure consistent deadlines CMS should specify that the deadlines enumerated in § 422.590 apply to remanded appeals.

Response: CMS appreciates the comment. We have modified the regulation text at § 422.592(i) to clarify that if the independent entity vacates the dismissal and remands the case to the plan for reconsideration, the reconsideration must be conducted by the plan consistent with § 422.590, which includes applicable adjudication timeframes. Similarly, we have modified the regulation text at § 423.600(k) to clarify that if the independent entity vacates the dismissal and remands the case to the Part D plan sponsor, the reconsideration must be conducted by the plan sponsor consistent with § 423.590.

Comment: A commenter noted that CMS proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when the plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination. The commenter requested CMS clarify what is considered a 'valid' request.

Response: The regulations define what constitutes a valid request. For example, with respect to a request for a standard organization determination, a valid request would be one that substantially complies with § 422.568(a); the regulation we are finalizing at § 422.568(g)(2) cross references § 422.568(a) as establishing the standard for a request to be a valid one. Related guidance can be found in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective January 1, 2020).

Comment: A commenter noted that CMS proposed to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination. The commenter believed this is stating that a plan would dismiss a pre-service request if the enrollee dies, as it would no longer be valid, and requested further clarification.

Response: We clarify that these rules apply to a post-service request for payment as well as to pre-service requests for coverage. CMS proposed to permit a plan to dismiss a request for the initial plan level decision when the enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination. The death of the enrollee alone is not sufficient to dismiss a request. There must also be no remaining financial interest of the enrollee's spouse or estate in the case and no other individual or entity with a financial interest in the case that wishes to pursue the organization determination or coverage determination.

Comment: A commenter noted CMS proposed to permit the Part C and Part D IRE to dismiss a request when the independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation. The commenter requested CMS clarify who would be responsible for notification requirements when the IRE makes this determination.

Response: When the IRE makes a decision regarding a reconsideration, the IRE must comply with the notice requirements outlined in § 422.594 and § 423.602. This includes notifying the parties to the reconsideration of a dismissal.

Comment: A commenter noted that CMS proposed to add a new paragraph to § 422.590 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the MA organization's dismissal of a request for a reconsideration made under §§ 422.582(f) and 422.584(g). The commenter noted that the current process when a plan dismisses an appeal request is that the member has the right to go to the IRE to determine if the dismissal was correct. The commenter requested clarification on whether the proposed rule is stating the plan would send the case file to the IRE for all dismissals.

Response: This final rule codifies the current practice regarding dismissals, that the enrollee or other party to the reconsideration may file a request for review by the IRE of the plan's dismissal of a request for reconsideration. We believe that § 422.590(i), as proposed and finalized, is clear in establishing the regulatory authority for this request for IRE review in the MA context. We further clarify that this provision does not require MA plans to forward the case file to the IRE for all dismissals. MA plans and Part D plans must only forward the case file for a dismissal to the IRE when a proper party to the appeal requests IRE review of the dismissal under §§ 422.590(i) and 423.590(j). This is somewhat different than the process for Part C appeals under §§ 422.590 and 422.592, where the MA organization must gather and forward the relevant information to the IRE for an automatic review by the IRE of reconsidered determinations (standard or expedited) that are not completely favorable to the enrollee.

Comment: A commenter noted that in some sections of the proposal, CMS indicated that it intends these dismissal determinations to be binding, but also notes the plan must include information on available appeal rights in the written notice of the dismissal. The commenter questioned if this would prohibit the requesting party(s) from resubmitting a claim with additional or new information. The commenter would like CMS to ensure as part of the process that a request could be resubmitted should new information come to light or was inadvertently not included in the initial request.

Response: CMS only intends that dismissals be binding to the extent outlined in these provisions. For example, § 422.568(j) provides for a dismissal of a request for an organization determination to be binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under § 422.568(i) of this section. So, as applied to this example, new or additional information could be submitted with a party's request for reconsideration of a dismissal (which would be requested under §§ 422.582 or 422.584) or considered as part of the MA organization finding good cause to vacate its dismissal of a request for an organization determination under the provisions at § 422.568(i). Note we have also added language to what we proposed at § 422.633(k) regarding vacating dismissals of integrated reconsiderations. The additional language aligns with the analogous provision for reconsiderations at § 422.582(i).

Comment: A commenter questioned if CMS will modify the regulations concerning the withdrawal or dismissal of Part C and Part D determination requests, redetermination requests and IRE reconsiderations to better align with the regulations concerning limited English proficiency (LEP) communications.

Response: Entities that receive federal financial assistance, including Medicare Part C and D plans, must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency, in accordance with title VI of the Civil Rights Act of 1964 and section 1557 of the Affordable Care Act and implementing regulations (title VI and section 1557 respectively). Nothing in this final rule alters that requirement.

After consideration of the comments we received and for the reasons outlined in our responses and in the proposed rule, we are finalizing with modifications our proposed revisions to §§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600 to address withdrawals and dismissals by MA organizations, applicable integrated plans, and Part D plans. In addition to minor clarifications that are not substantive changes to our proposed regulations, we are also finalizing modifications compared to our proposals to clarify that plans are required to dismiss a request under the provisions of these final rules and to permit verbal withdrawal of requests for organization determinations, coverage determinations, reconsiderations, and redeterminations.

I. Methodology for Increasing Civil Money Penalties (CMPs) (§§ 422.760 and 423.760)

Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provide CMS with the ability to impose CMPs of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual

covered under the organization's contract. The current regulations mirror the statute with respect to the amount of the penalty that CMS may impose for a per determination (contract level) penalty. Additionally, as specified in §§ 422.760(b)(2) and 423.760(b)(2) CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency. CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually [68] for each affected enrollee or per determination, however CMS does not necessarily apply the maximum penalty amount authorized by the regulation.

CMS proposed to codify the methodology we would use to calculate the minimum penalty amounts that CMS would impose for certain types of program non-compliance by adding a new paragraph (b)(3) to §§ 422.760 and 423.760, and redesignating current paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

We proposed to update minimum penalty amounts no more often than every 3 years. CMS also proposed to increase the penalty amounts by including the increases that would have applied if CMS had multiplied the minimum penalty amounts by the cost-of-living multiplier released by the Office of Management and Budget (OMB) [69] each year during the preceding 3-year period. In addition, CMS proposed to track the yearly accrual of the penalty amounts and announce them on an annual basis.

Comment: We received one comment that supported our proposals. The commenter supported updating the minimum penalty amounts consistent with the three-year Part C and D organization audit cycle, and urged CMS to maintain the level of transparency afforded to the CMP methodology and updates.

Response: We thank the commenter for the support.

Comment: We also received one comment encouraging CMS to codify the process in which CMS notifies MA organizations and Part D sponsors of enforcement action referrals, including the opportunity to submit additional information before the final determination is made.

Response: We appreciate the comment, but it is beyond the scope of the proposed changes. However, we will consider it for future rulemaking. After consideration of the public comments received, we are finalizing this provision as proposed.

V. Codifying Existing Part C and D Program Policy

A. Plan Crosswalks for Medicare Advantage (MA) Organizations and Cost Plans (§§ 417.496 and 422.530)

We proposed to codify the current process and conditions under which MA organizations and 1876 cost plans can transfer their enrollees into the same plan from year to year when no other election has been made (this process is a ''plan crosswalk''), as well as when MA organizations and cost plans can transfer their enrollees to other plans offered by the same MA organization or cost plan (this is a ''crosswalk exception''). Our proposal was to define plan crosswalks, codify rules that protect a beneficiary's right to choose a plan, and specify the circumstances under which MA organizations and cost plans may transfer beneficiaries into another plan of the same type offered by the MA organization or, in the case of cost plans, transfer enrollees from that cost plan benefit package to another plan benefit package (PBP) under the same contract. In the proposed rule and this final rule, we generally use the terms ''plan'' and ''PBP'' interchangeably to refer to a specific plan offered under a contract. Specifically, the term PBP is used to describe the individual benefits packages that may be offered under a singular contract. Section 1851(c)(3)(B) of the Act provides for evergreen elections which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election, or the MA plan is discontinued or no longer serves the area in which the individual resides. In many cases, our crosswalk policy is a mechanism for operationalizing these evergreen elections.

Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. We proposed to codify existing policy regarding crosswalks and crosswalk exceptions using this authority and our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt standards and contract terms for MA organizations. In furtherance of the beneficiary's right to choose and implementing evergreen elections, we proposed to codify existing policy in new regulations at § 417.496 and § 422.530 to define plan crosswalks, implement rules that protect a beneficiary's right to choose a plan, and describe allowable circumstances under which MA organizations may transfer beneficiaries from one of its MA plans into another of its MA plans or a cost contract may transfer beneficiaries from one of its plans into another of its cost plans. With respect to cost plans, we proposed to codify existing enrollment policy related to the transfer of enrollees from one of an entity's PBPs to another PBP, under the authority of section 1876(i)(3)(D) of the Act, which requires that cost contracts shall contain such other terms and conditions, not inconsistent with the statute, as the Secretary may find necessary and appropriate. Our proposal and this final rule do not include rules for deeming enrollment from a cost plan to an MA plan under sections 1876(h)(5)(C) and 1851(c)(4) of the Act because the statute does not permit deeming of enrollees from cost plans to MA plans beyond contract year 2018.

We also proposed, at § 422.530(d), to codify the procedures that an MA organization must follow when submitting a crosswalk or a crosswalk exception request. An MA organization must submit all allowable crosswalks in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS. Through the bid submission process, the MA organization may indicate if a crosswalk exception request is needed at that time, but the MA organization must request a crosswalk exception later through the crosswalk exception functionality in HPMS by the deadline announced by CMS. CMS verifies the exception request and notifies the requesting MA organization of the approval or denial of the request after the crosswalk exception deadline has expired. These exceptions must be submitted by the

[68] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 CFR 422.760(b), 423.760(b), and 460.46(a)(4) will be published annually in 45 CFR part 102. Pursuant to § 417.500(c), the amounts of civil money penalties that can be imposed for Medicare Cost Plans are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422. Section 1876 solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[69] Per OMB Memoranda M–19–04, *Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,* published December 14, 2018, the cost of-living adjustment multiplier for 2019 is 1.02522.

MA organization to ensure that plan benefit package (PBP) enrollment is allocated appropriately.

CMS has developed extensive guidance addressing the transfer of enrollees from one PBP offered by an organization to another PBP offered by that organization under the same contract.[70] The guidance, applicable to MA organizations and cost plans, was developed in light of the ability of MA organizations and cost plans to revise their benefit offerings and PBPs from year to year. The transfer of enrollees from one PBP to another under these circumstances serves to facilitate evergreen elections. MA organizations frequently make business decisions resulting in changes to and in their MA plans offered for enrollment in the following contract year. Each year, through the bid process for plan design and an application process for service area changes, MA organizations submit changes in coverage and cost sharing design for their MA plans. In addition, MA organizations have the ability to terminate existing plans and apply to offer new plans. While cost plan organizations may not offer new cost plans, they also may make changes in their benefit and cost sharing design and seek service area changes through an annual process. CMS has issued annual sub-regulatory guidance related to changes of this type for MA and cost plans to address how MA organizations and cost plans may transition enrollees from a plan that is terminating or changing its service area to another plan offered by the same organization. These transitions are useful to preserve beneficiary enrollment and are subject to a number of beneficiary protections. We proposed to codify existing crosswalk policy to clearly identify the basic rules for plan crosswalks, including the parameters for allowable crosswalks, and formalize CMS's crosswalk exception review process. Crosswalk exceptions are specific circumstances where a crosswalk is not automatically authorized under our policies but CMS may permit MA organizations and cost plans to transfer beneficiaries into another plan of the same type offered by the MA organization or cost plan after a review, provided that certain requirements are met. The crosswalk exceptions process, as currently conducted and as proposed, allows CMS to review and validate the existence of an exception and then manually effectuate the transaction in our system. Crosswalk exceptions are not part of the standard, annual PBP renewal process. We proposed to codify these new regulations at §§ 417.496 and 422.530 to govern, respectively, cost plans and MA organizations.

We proposed, at §§ 417.496(a)(1) and 422.530(a)(1), to define a plan crosswalk as the movement of enrollees from one PBP to another PBP under the same contract between the MA or cost organization and CMS. MA and cost organizations complete these crosswalk transactions annually as part of the renewal process. Unlike MA plans, however, cost plans do not include different plan types such as PPOs, PFFS, and special needs plans, therefore proposed § 417.496(a)(2) did not specify that crosswalks from one plan type to another are prohibited while proposed § 422.530(a)(2) did.

In proposed § 422.530(a)(5), we defined the types of MA plans that are ''different plan types'' for purposes of crosswalk policy: Health maintenance organizations, provider-sponsored organizations, and regional and local preferred provider organizations coordinated care plans are different plan types, even though they are all coordinated care plans. Additionally, we noted that the segmented plans are not a ''type'' of plan in MA and that crosswalks are permitted between segmented and non-segmented plans. We did not include in the proposed cost plan crosswalk regulation provisions about contract transactions related to plan types and policies such as segmentation and continuation because they are specific to MA contract transactions. The majority of crosswalks involve moving enrollees from one contract year plan to the corresponding plan for the following contract year. Therefore, under our current policy and the proposal, enrollees are not required to make an enrollment election to remain enrolled in their chosen plan. In § 417.496(a)(2)(i), we proposed to codify the general rule that crosswalks are prohibited between different cost contracts, and in § 417.496(a)(2)(ii), we proposed to codify that crosswalks are prohibited between different cost plan IDs under a cost contract unless the crosswalk qualifies for an exception to this requirement. In § 417.496(c)(1)(i) and (ii) we proposed to codify the exception that cost contracts terminating PBPs with optional supplemental benefits may transfer enrollees to another PBP with or without optional benefits under the same cost contract as long as enrollees who have Part A and B benefits only are not transferred to a PBP that includes Part D. In § 417.496(c)(1)(iii)(A), (B), and (C), we proposed to codify the rule that an enrollee in a terminating PBP that includes Part D may only be moved to a PBP that does not include Part D if the enrollee is notified in writing that she/he is losing Part D coverage, the options for obtaining Part D, and the implications of not getting Part D through some other means. In § 422.530(a)(2), we proposed to codify the general rule that crosswalks are prohibited between different MA contracts or different plan types (for example, HMO to PPO), which means that crosswalks are only permitted between plans of the same type under the same contract. However, proposed § 422.530(c) specified the limited circumstances in which CMS would allow a crosswalk transaction that does not comply with this general prohibition on crosswalks to different contracts. We included in proposed § 422.530(a)(2) a reference to these ''exceptions'' permitted under paragraph (c). We explained that these exceptions in § 422.530(c) apply to MA plans only because they pertain to MA policies; therefore, we did not propose similar regulation text in § 417.496.

As most plan crosswalks are related to contract renewals and non-renewals, we proposed a general rule at § 422.530(a)(3) that would require MA organizations to comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to be eligible to complete plan crosswalks. In § 417.496(a)(3), we proposed that cost plan entities must comply with the renewal and non-renewals rule per §§ 417.490 and 417.492, in order to be eligible to complete plan crosswalks. In § 422.530(a)(4), we proposed that enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP as part of a crosswalk.

In §§ 422.530(b) and 417.496(b), we proposed to codify the existing crosswalk policy by specifying the circumstances under which a crosswalk is permitted so that an MA organization or cost plan may move enrollees into, respectively, another MA plan or cost plan. For MA plans, in paragraph (b)(1), we proposed permissible crosswalks for all plan types and in paragraph (b)(2), we proposed crosswalks that are permissible only for MA special needs plans (SNPs). We reminded readers that the MA plan types are identified in § 422.4; therefore, we specified in proposed § 422.530(a)(5) that the different types of coordinated care plans are considered different ''plan types'' for purposes of crosswalking policy. For cost plans, in proposed paragraph (b), we addressed permissible crosswalks for

[70] Chapter 16b of the Medicare Managed Care Manual and Process for Requesting an HPMS Crosswalk Exception for Contract Year (CY) 2020 (released annually).

cost plans. Each of these proposals was consistent with current policy.

1. Cost Plans and All MA Plan Types

a. Renewal Plan

Under existing program rules, an MA or cost organization may continue to offer, that is renew, a current PBP that retains all of the same service area for the following year; the renewing plan must retain the same PBP ID number as in the previous contract year. We proposed to codify moving the enrollees in the existing PBP to the PBP with the same ID number for the following year as a permissible crosswalk in paragraph (b)(1)(i) for MA plans and § 417.496(b)(1) for cost plans. Under the proposal, as with current policy, current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will transition all enrollees from the current PBP to the new PBP with the same PBP ID number for the following year. New enrollees must complete enrollment requests, and the MA or cost organization will submit enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 current MA and cost enrollees of a renewed PBP, respectively, must receive an Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

b. Consolidated Renewal Plan

Under existing program rules, MA and cost organizations may combine two or more PBPs offered under the same contract in the current contract year into a single renewal plan, as a plan consolidation. We explained that when the consolidation includes two or more complete PBPs being combined and no PBP being split among more than one PBP in the next contract year, the MA or cost organization is permitted to transition all enrollees in the combined plans under one PBP under that contract, with the same benefits in the following contract year; the resulting PBP must have the plan ID of one of the consolidated plans. We proposed to codify this as a permissible crosswalk in §§ 417.496(b)(2) and 422.530(b)(1)(ii) and explained that under the proposal (as with current policy), current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees. The renewal PBP ID is used to transition current enrollees of the plans being consolidated into the designated renewal plan. In operationalizing this crosswalk, the MA or cost organization may need to submit updated data to CMS for the enrollees affected by the consolidation. New enrollees in the consolidated renewal plan must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees in the consolidated renewal plan.

c. Renewal Plan With a Service Area Expansion (SAE)

Under existing program rules, an MA or cost organization may continue to offer the same cost plan or local MA plan but expand the service area to include one or more additional counties for the following contract year. We explained that to expand the service area of its plan(s), an MA or cost organization must submit a service area expansion (SAE) application to CMS for review and approval; CMS treats service area expansions as applications subject to the rules in part 422, subpart K, and § 417.402. Under our current policy an MA or cost organization renewing a plan with a SAE must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in that plan the following contract year; current enrollees of a PBP that is renewed with a SAE are not required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees but can transition all enrollees using a crosswalk from the current PBP to the new PBP with the same PBP ID number for the following year. We proposed to codify this as a permissible crosswalk in § 422.530(b)(1)(iii) for MA plans and § 417.496(b)(3) for cost plans. New enrollees must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees of a renewed PBP with a SAE.

d. Renewal Plan With a Service Area Reduction

Under existing program rules, an MA organization offering a local MA plan may reduce the service area of a current contract year PBP; similarly, a cost organization may reduce the service area of a cost plan. We explained that this service area reduction (SAR) means that enrollees who were in the part of the service area being reduced will generally not be eligible to remain in the plan because of the residence requirement in §§ 417.422(b), 422.50(a)(3), and 422.54. We addressed crosswalks that may occur in connection with a service area reduction in proposed §§ 422.530(b)(1)(iv) and 417.496(b)(4). Under our proposal (as in current practice), when there is a service area reduction for a plan, the MA organization or cost plan may only crosswalk the enrollees who reside in the remaining service area to the plan in the following contract year that links to a current contract year plan but only retains a portion of the prior service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area. MA organizations may have different options available to them in terms of notices and the ability to offer a continuation of enrollment under § 422.74(b)(3)(ii) depending on the other MA plans in the service area at the time of the service area reduction. We included regulation text in proposed § 422.530(b)(1)(iv)(A) and (B) to address the different scenarios.

We proposed in § 422.530(b)(1)(iv)(C), that enrollees that are no longer in the service area of the MA or cost plan will be disenrolled at the end of the contract year and will need to elect another plan (or default to original Medicare). The MA or cost organization must submit disenrollment transactions to CMS for these enrollees. In addition, the MA or cost plan organization must send a Medigap guaranteed issue rights to the affected enrollees and a non-renewal notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP). We proposed to codify at § 422.530(b)(1)(iv)(D) specific rules about what information may be provided by the MA organization about its other MA plan options in the area that will no longer be part of the service area of the continued plan. Per the marketing and communication regulations, at §§ 422.2263(a) and 423.2263(a) and discussed elsewhere in this final rule, marketing information about other MA plan options offered by the MA organization for the prospective plan year can begin October 1 of each year for the following contract year.

2. Special Needs Plans (SNPs)

Under our current crosswalk policies, MA Special Needs Plans (SNPs) follow the general rules, which we proposed to

codify in § 422.530(b)(1), and are permitted additional flexibility for crosswalks in specific situations. We proposed regulation text to identify the additional crosswalks permitted for SNPs in § 422.530(b)(2), which vary based on the type of SNP. In the proposed rule, we explained that MA organizations may not crosswalk enrollees from one SNP type to a different SNP type, as that would constitute crosswalking into a different type of plan, which is prohibited by § 422.530(a)(2). We clarify here as well that the rules in paragraph (a) all apply to the crosswalk authority for SNPs described in paragraph (b)(2) just as the rules in paragraph (a) apply to the crosswalk authority in paragraph (b)(1).

a. Chronic Condition SNPs (C–SNPs)

We proposed to codify four permissible crosswalks specific to C–SNPs at § 422.530(b)(2)(i)(A) through (D). C–SNPs serve and are limited to enrolling special needs individuals who have a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan. The MA organization offering the C–SNP may target one or more specific severe or disabling chronic conditions. When a C–SNP targets more than one severe or disabling chronic condition, we refer to that as a ''grouping'' and we have addressed groupings in guidance in Chapter 16b of the Medicare Managed Care Manual. We proposed that these permissible crosswalks reflect the limitations on eligibility for C–SNPs, as different C–SNPs serve different populations depending on the chronic condition(s) targeted for enrollment restriction.

- Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.
- Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

—Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from the grouping.

- Non-renewing C–SNP in a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior plan contained.

b. Institutional–SNPs

We proposed to codify five permissible crosswalks specific to I–SNPs at § 422.530(b)(2)(iii)(A) through (E). I–SNPs are limited to enrolling individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in§ 422.2. I–SNPs may limit their enrollment to either institutionalized or institutionalized-equivalent individuals or may enroll both categories of individuals. These permissible crosswalks reflect the enrollment limitations on I–SNPs.

- Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.
- Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.
- Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.
- Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.
- Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

c. Dual Eligible-SNPs (D–SNPs)

We did not propose to codify any permissible crosswalks specific to D–SNPs, which is consistent with our current crosswalk policy (which does not authorize additional crosswalk scenarios for D–SNPs outside of the crosswalk exceptions).

d. Exceptions

In some instances, crosswalk actions must be manually reviewed and entered by CMS staff. We call these *crosswalk exceptions.* We proposed to codify at § 422.530(c) when CMS will approve a request for a crosswalk exception and permit crosswalks in situations that are not specified in § 422.530(b). These exceptions address certain unusual circumstances involving specific types of plans or contract activities. Under our proposal, only an exception specified in § 422.530(c) would be approved and recognized as an additional circumstance when a crosswalk is permitted. We proposed to allow the following exceptions to the limits on the crosswalk process:

- When a non-network or partial network based private fee-for-service (PFFS) plan is transitioning to either a partial network or a full network PFFS plan, we would permit a crosswalk when CMS determines it is in the interest of beneficiaries. CMS will consider whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. We anticipate that granting these exceptions would be extremely rare since in the great majority of instances enrollees have choices of multiple MA plans or Original Medicare and are able to exercise their choice. We specifically proposed to restrict crosswalks between these network and non-network PFFS plans because the way enrollees will access health care services is significantly different in each of these plans. Section 1852(d)(5) of the Act establishes that in areas that are determined to be ''network areas'' PFFS plans can only operate by having a network of providers that meets CMS current network adequacy standards. The network based PFFS plan functions very much like a MA PPO plan in that there is a network of contracted providers through which enrollees can obtain Medicare covered services. In addition, an enrollee in a network based PFFS plan has the option of also going out-of-network for plan covered services though their cost sharing may be higher. However, in areas of the country that have determined to be non-network areas with respect to PFFS plans, the PFFS plan can operate without a network and enrollees must seek care from any willing provider under the non-network PFFS plan's terms and conditions of payment. Because these two types of PFFS plans function very differently for enrollees obtaining covered health care services, we do not believe crosswalks should be generally permitted between these two types of PFFS plans.
- When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts consolidated under one surviving contract, the enrollees from the consolidating plans may be moved to an MA plan under the surviving plan. As a result of the consolidation of contracts, enrollees from at least one of the PBPs are transitioned to another contract; therefore, CMS limits approval of these crosswalks to an exception because of the movement across different contracts. As part of reviewing a request for this crosswalk exception, CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).
- When a renewing D–SNP in a multi-state service area is reducing its service area to accommodate a state contract in part of the service area, we would permit enrollees who are no

longer in the service area to be moved into one or more new or renewing D–SNPs for which they are eligible, when CMS determines it is necessary to accommodate changes to D–SNP state contracts. We proposed to codify this crosswalk exception at § 422.530(c)(3).

• When an MA organization renews a D–SNP for the upcoming contract year with changes in the D–SNP eligibility criteria, has another available new or renewing D–SNP for the upcoming contract year, and the two D–SNPs are offered to different populations, we would permit a crosswalk exception if it is in the best interest to current enrollees who are no longer eligible for their non-renewing D–SNP. We proposed to codify this crosswalk exception at § 422.530(c)(4). An MA organization may change—or as part of state contracting, may be required to change—a D–SNP's eligibility criteria for the upcoming contract year. As a result, some current enrollees may no longer be eligible for their current D–SNP. However, the MA organization may have a new or renewing D–SNP in the same service area with eligibility requirements that can accommodate the enrollees who are no longer eligible for their current D–SNP.

• When a renewing C–SNP with a grouping of multiple conditions is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping. This crosswalk exception, which we proposed to codify at § 422.530(c)(5), differs from the allowable crosswalk in proposed § 422.530(b)(2)(i)(B) because it is a renewing C–SNP and not a non-renewing C–SNP. A crosswalk exception is required in order for CMS to identify which enrollees are moving from the renewing plan C–SNP to the other C–SNP. In a non-renewing C–SNP, all enrollees would be crosswalked to another plan or disenrolled.

In the proposed rule, CMS explained that the crosswalk policies we proposed to codify are designed to protect the rights of enrollees to make a choice about the plan from which they wish to receive Medicare benefits while facilitating how section 1851(c)(3)(B) of the Act requires evergreen elections. We proposed to codify policies and standards that CMS has implemented that allow MA and Cost organizations the flexibility to make business decisions about the benefit and cost sharing design of a plan while preserving the rights of beneficiaries to make informed choices about their health care coverage. We summarize the comments we received on these crosswalk proposals and our responses.

Comment: CMS received a comment specific to the crosswalk exceptions process for cost plans. The commenter expressed concern with CMS having an exception permitting cost organizations to move enrollees from one of its plans with Part D to a plan that does not have Part D. The commenter stated that enrollees might not be aware of the implications of losing Part D and, as a result, CMS should require that enrollees actively ''opt out'' of Part D before being enrolled by the cost organization into one of its non-Part D plans. The commenter acknowledged that we proposed that the cost organization be required to notify enrollees of the implications of losing Part D but expressed concern that this information could become lost in the barrage of advertising and other materials mailed during the annual enrollment period.

Response: We believe that the notice requirements proposed and finalized at § 417.496(c)(1)(iii) offer robust protections for enrollees. Cost enrollees with Part D may be crosswalked to a plan without Part D because, unlike MA plans, Part D can only be an optional supplemental benefit for cost enrollees. In addition to specific information on plan benefits and costs for the new plan, affected enrollees will receive information from the cost organization on the implications of losing creditable Part D coverage and options for acquiring Part D coverage. In addition, the enrollee will have the annual coordinated election period to choose another Part D plan or to elect coverage in another Medicare health plan that does offer Part D coverage. We also believe that the provision as proposed strikes the proper balance between protections for enrollees and flexibility for cost organizations. CMS is therefore finalizing § 417.496.

Comment: CMS received comments asking for a waiver of the requirement to provide an Annual Notice of Change (ANOC) document to enrollees who are crosswalked between SNP plans under the same legal entity if there are no substantive changes in premiums, benefits, and cost-sharing as a result of the transition.

Response: Under § 422.111, MA organizations are required to disclose key changes to coverage to all enrollees annually. This crosswalk regulation was not proposed to, and as finalized does not, supersede or circumvent those disclosure requirements. The ANOC requires any and all changes to premiums, benefits, and cost-sharing to be disclosed in the ANOC, not just substantive changes. In addition, the ANOC requires these plans to make it clear that if a beneficiary doesn't make a different choice, they will be automatically enrolled in the new plan. This helps preserve the beneficiary's right to make an informed choice about their health care coverage.

Comment: Commenters are seeking additional options to comply with the D–SNP integration requirements set forth in the BBA of 2018 and the implementing regulations. Several commenters suggested allowing D–SNP crosswalk exceptions to permit a non-renewing D–SNP plan benefit package (PBP) of one legal entity to crosswalk into a new or renewing D–SNP PBP of another legal entity within the same parent organization in cases where it would facilitate integration for dually eligible individuals in Medicare and Medicaid.

Response: We thank commenters for their suggestion. In our recent experience, contracting processes between D–SNPs and states to comply with provisions of the BBA of 2018 are raising new questions and challenges. In some cases, the current way a parent organization structures its MA contracts using different subsidiaries (so that the MA organizations on various contracts are different legal entities) may raise an impediment to achieving higher levels of integration between Medicare and Medicaid. Moving enrollees from one PBP to another PBP operated by the same parent organization but under a different legal entity, in some cases, could result in better experiences and outcomes for enrollees but may not always be permitted as a crosswalk under our proposal.

Under current rules, and without a crosswalk exception, there are two mechanisms for moving D–SNP members into another D–SNP operated by another MA organization under the same parent organization: (1) Consolidating contracts consistent with the change of ownership regulations (§§ 422.550 through 422.553), then crosswalking between plans in the next year; or (2) if approved by CMS, under the passive enrollment provisions at § 422.60(g). These mechanisms may be appropriate in some instances, but they may be more burdensome than we believe necessary in some types of within-parent-organization scenarios posed by commenters. The passive enrollment provision is also more narrowly targeted to enrollees already in an integrated D–SNP who would move to a fully integrated or highly integrated D–SNP, circumstances that would be most applicable when state Medicaid managed care contracting results in disruption of a current integrated care arrangement.

We proposed to permit two crosswalk exceptions for D–SNPs specifically at § 422.530(c)(3) and (c)(4). The first would allow an MA organization renewing a D–SNP in a multi-state service area that is reducing its service area to accommodate a state contract in part of the service area to crosswalk enrollees who are no longer in the service area to one or more new or renewing D–SNPs for which they are eligible, when CMS determines it is necessary to accommodate changes to D–SNP state contracts. The second would apply for an MA organization renewing a D–SNP for the upcoming contract year with changes in the D–SNP eligibility criteria, but which has another available new or renewing D–SNP for the upcoming contract year, where the two D–SNPs are offered to different populations. In this scenario, we proposed to permit a crosswalk exception if it is in the best interest to current enrollees who are no longer eligible for their D–SNP to allow such a crosswalk exception.

We agree with commenters that—where necessary to accommodate changes to D–SNP state contracts—we should permit crosswalk exceptions in additional scenarios. We are finalizing § 422.530(c)(3) in the final rule with two significant changes compared to the proposed rule. First, we are finalizing additional language applying this exception to multi-state regional PPOs (RPPOs). Our original proposal focused on service area reductions by multi-state D–SNPs. However, multi-state RPPOs cannot eliminate states from their service areas while remaining RPPOs. As finalized, § 422.530(c)(3) also allows a non-renewing D–SNP that is a MA regional plan (an RPPO) to crosswalk enrollees to D–SNPs in state-specific local PPOs. Second, we are finalizing additional language to allow crosswalking of members across D–SNPs within the same parent organization but across legal entities in these scenarios. This crosswalk exception in § 422.530(c)(3) only applies for D–SNPs with multi-state service areas, and we believe § 422.530(c)(3) as finalized with these changes will create additional opportunities to comply with state D–SNP contracting while promoting continuity of care for enrollees. We are declining, at this time, to extend this crosswalk exception to D–SNPs without multi-state service areas to allow us additional opportunity to assess the potential impacts of such a change. The D–SNP crosswalk exception we proposed and are finalizing at § 422.530(c)(4) does not require that the D–SNP service areas include multiple states and is not limited to accommodating changes to the contracts between the state(s) and the D–SNP under § 422.107; this other crosswalk exception addresses changes in the eligibility criteria for the current year D–SNP and permits moving enrollees to another D–SNP offered by the same MA organization where CMS determines it is the best interests of the enrollees to move to the other D–SNP for the new contract year in order to promote access to and continuity of care for the enrollees whose enrollment would be terminated from the D–SNP based on the change in eligibility criteria. We are declining, at this time, to extend this crosswalk exception at § 422.530(c)(4) to D–SNPs offered by different MA organizations, even if the parent organization is the same, to allow us additional opportunity to assess the potential impacts of such a change.

We will consider other potential crosswalk exceptions for future rulemaking.

After consideration of the public comments we received and for the reasons outlined in the responses to comments and the proposed rule, we are finalizing our proposal with the following modifications:

- Section 422.530(c)(1) is being finalized with additional text from the preamble of the proposed rule (85 FR 9091) to identify the factors considered by CMS in making a determination that moving enrollees from a non-network or partial network PFFS plan to a partial or full-network PFFS plan is in the interest of beneficiaries. The factors CMS will take into consideration are whether enrollees would be better served by being crosswalked to the new PFFS plan. Another consideration is if there are no other MA plans available where the enrollee resides (including whether there are a number of potentially more suitable MA plans available for the enrollee to select) and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. A PFFS plan requesting a crosswalk of enrollees from a non-network PFFS plan to a partial or full-network PFFS plan would need to include in their exception request an explanation of why the crosswalk would be in the best interest of the beneficiary (or beneficiaries) rather than the alternative of the enrollee(s) making an selection among available MA plans or Original Medicare during the Annual Election Period. This section also finalizes the requirement that CMS will not permit crosswalks from network based PFFS plans to non-network or partial network PFFS plans. As discussed in the proposed rule, CMS is finalizing this requirement because network based PFFS plans function very much like an MA PPO plan. In consequence, an enrollee in a network based PFFS plan crosswalked to a non-network or partial network PFFS plan would no longer have assured access to a network of contracted providers. Such a change in how their plan functions would be significant and potentially problematic for the enrollee in accessing their health care services.
- Section 422.530(c)(2) is being finalized with a slight revision to clarify that MA contracts, rather than MA plans, are consolidated. When MA contracts under two different MA organizations that share a parent organization are consolidated, the MA plans under the different contracts are then offered under the surviving MA contract. Some of the MA plans may also be consolidated under the surviving MA contract. The crosswalk exception permits the enrollees from the consolidated contracts to be crosswalked to an MA plan under the surviving contract.
- Section 422.530(c)(3) is being finalized as proposed to address multi-state D–SNPs and with additional text to address a crosswalk exception for non-renewing D–SNPs in multi-state RPPOs. In situations involving both types of D–SNPs, a crosswalk exception may be permitted in cases CMS determines it is necessary to accommodate changes to state contracts, as discussed in more detail in the response to the public comment. Section 422.530(c)(3) is also being finalized with additional text to clarify that the crosswalk exception permits moving enrollees to a different contract,
- Section 422.530(c)(4) is being finalized with additional text to clarify that the receiving D–SNP must be offered by the same MA organization and to specify that CMS would approve the crosswalk exception if the enrollees are eligible for the receiving D–SNP and CMS determines the crosswalk exception would be in the best interests of enrollees in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception.
- The crosswalk proposed at § 422.530(b)(2)(C) to permit a renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping is not being finalized because it was duplicative of proposed § 422.530(c)(5), which is being finalized. Under our current policy, an exception is not automatically granted in this situation. We believe that codifying our current

policy on this point is appropriate. What was proposed at § 422.530(b)(2)(D) is being finalized as § 422.530(b)(2)(C) instead.

• Finally, we are finalizing the regulation text at § 417.496(c)(1) and introductory text at § 422.530(c) using ''may permit'' instead of ''permits'' to clarify that CMS approval is not automatic for the crosswalk exceptions.

As finalized, § 422.530 also contains several non-substantive grammatical and technical changes to improve the clarity and readability of the regulation text.

B. Medicare Advantage (MA) Change of Ownership Limited to the Medicare Book of Business (§§ 422.550 and 423.551)

Section 1857 of the Act requires each MA organization to have a contract with CMS in order to offer an MA plan. Section 1857(e)(1) of the Act authorizes the adoption of additional contract terms that are consistent with the statute and that the Secretary finds are necessary and appropriate. Consistent with this authority, at the beginning of the Part C program we implemented contracting regulations in § 422.550 which provide for the novation of an MA contract in the event of a change of ownership involving an MA organization. (63 FR 35106) Under the regulations, codified at §§ 422.550 through 422.553, the execution of a novation agreement is required when an MA organization is acquired or when it wants to transfer its ownership to a different entity. When an MA organization is no longer able or willing to participate in the MA program, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to enrolled beneficiaries. In this instance, CMS has an interest in agreeing to a novation of the existing MA contract because it promotes the efficient and effective administration of the MA program.

We proposed to revise § 422.550 by adding a new paragraph at § 422.550(f) to restrict the situations in which CMS will agree to an MA contract novation to those transfers involving the selling of the organization's entire line of MA business, which would include all MA contracts held by the legal entity that is identified as the MA organization. It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights. We explained that the change codifies existing policy and also create more consistency in regulations between the Part D program, which has an explicit regulation requiring the sale of the entire book of Part D business at § 423.551(g), and the MA program.

In the proposed rule, we explained that this policy has not been applied in cases where contracts are transferred among subsidiaries of the same parent organization and we do not wish to interfere with an MA organization's (or parent organization's) ability to decide its corporate structure or contractual arrangements with its subsidiaries. Therefore, we also proposed, at § 422.550(f)(1), an exception to the proposed limit for changes of ownership to only when the entire MA book of business is being transferred; that exception would be when the sale or transfer is of a full contract between wholly owned subsidiaries of the same parent organization.

We proposed to codify explicitly in § 422.550(f)(2) that CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one MA contract if the organization holds more than one MA contract. We stated that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights as our primary rationale for this proposal.

We thank commenters for their input to help inform our final rule on changes of ownership. We received the following comments on this proposal, and our responses follow:

Comment: Some commenters were supportive of CMS's proposal and agreed that allowing a sale or transfer that consists solely of the sale or transfer of a cohort of beneficiaries/contracts, if the organization holds more than one MA contract, can have a negative impact on beneficiary election rights. Additionally, we received support on the exception to allow the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization.

Response: We thank commenters for their support of our proposal.

Comment: A commenter suggested that CMS's proposal would remove a viable option for an organization to transfer a contract with minimal disruption to enrollees because the enrollee would move with the contract and the move would be invisible to the enrollee. They explained that this limitation would require an organization to retain a contract that is not working and force them to exit the MA market entirely in order to close an underperforming contract.

Response: Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. Additionally, section 1851(c)(3)(B)(ii) of the Act provides for evergreen elections, which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election or the MA plan is discontinued or no longer serves the area in which the individual resides. Both of these statutes protect an enrollee's right to choose and remain in an MA plan of their choosing. We believe that allowing the sale or transfer of contracts, without the entire line of business, does not support the enrollee's right to choose their MA plan under the statute because a plan offered and administered by a specific MA organization is necessarily different than a plan, even with the same benefits coverage and cost sharing, offered and administered by a different organization. A different parent organization is likely to have different administrative policies and processes, such as appeals processing, medical necessity policies, or customer service functions, which an enrollee should be able to consider before electing to enroll in a plan. An individual that has elected coverage in a plan offered by one entity is necessarily choosing not to be in a plan offered by a different entity; the sale of a single contract frustrates those choices. We distinguish this from the sale or transfer of the entire line of business to another MA organization, where the seller/transferor is choosing to leave the market entirely and the buyer/transferee is taking on all responsibilities and obligations to continue providing benefits to all enrollees without interruption. Also, we disagree that this limitation would require a plan to retain a contract that is not working and force them to exit the MA market entirely in order to close an underperforming contract. MA organizations retain the right to non-renew a contract for any reason, provided it meets the timeframes for

doing so at § 422.506, and may continue to operate other existing MA contracts without interruption.

Comment: A commenter requested that CMS clarify whether the divestiture of an MA organization's business would allow the blending of contracts by virtue of a novation.

Response: By ''blending'' we understand the commenter to be referring to combination of transferring a contract to a new MA organization and consolidating the contracts at the same time. The divestiture of an MA organization's entire line of business does not allow those transferred contracts to be consolidated with the acquiring MA organization's existing contracts in the same year. In other words, the plans in the acquired contract must continue to operate under their given contract number. After the acquisition is complete and during the next bidding cycle, the MA organization may follow crosswalk rules finalized at § 422.530 in order to consolidate contracts into a single contract.

Comment: Two commenters recommended that CMS allow flexibilities to transfer or sell plans or contracts under certain, additional conditions through specific exceptions to the ''entire line of business'' rule. One commenter recommended that we create an exception based on certain geographies or markets. Another commenter recommended an exception based on special circumstances, such as one involving the sale of an I–SNP. The commenter suggested that the sale of an I–SNP would benefit the Medicare program and beneficiaries because the acquiring MA organization could better serve that population and would likely be a better solution to maintain appropriate coverage for the impacted beneficiaries over terminating the contract.

Response: It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line of business, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights, particularly where an exception is based on a decision that a specific plan or MA organization is ''better for'' enrollees. The same policy is in place in the Part D program, in § 423.551(g). We do not believe that allowing an exception based on ''special circumstances'', either because of a product type (for example, I–SNP) or characteristics of a region or marketplace, outweighs the importance of upholding an enrollee's right to elect a plan of their choosing. Additionally, commenters did not provide specific information about which markets or geographic regions would benefit from this type of exception and why an exception for specific areas is necessary for us to evaluate in more detail. We may monitor issues like this and consider specific exceptions to this policy in future rulemaking.

Comment: A commenter recommended that we consider special circumstances permitting an MA organization to transfer one PBP to another legal entity within the same parent organization in cases where it would facilitate D–SNP integration. The commenter explained that an MA organization may need to shift a D–SNP PBP to an H-contract affiliated with a different legal entity to meet federal requirements that FIDE plans be on the same legal entity as the corresponding Medicaid product.

Response: We do not agree that adding explicit regulatory text to permit an organization to transfer one PBP in a contract to another legal entity (even if limited to transfers within the same parent organization) in cases where it would facilitate D–SNP integration is necessary. The regulatory text, as proposed and finalized, permits the sale or transfer of a single contract (that is not the full book of business) where both MA organizations (the seller and the buyer) are wholly owned subsidiaries of the same parent organization, regardless of the plan types under the contract. Additionally, MA organizations will be able to use crosswalk exceptions discussed in section V.A of this final rule to facilitate D–SNP integration with § 422.107. As we discuss in Section V.A of this final rule, we are permitting, at § 422.530(c)(3), an MA organization to crosswalk enrollees from one PBP to a PBP of another legal entity within the same parent organization in certain cases where it is necessary to accommodate changes to the D–SNP state contracts required under § 422.107. We believe these crosswalk exceptions, as finalized, will provide MA organizations with any additional flexibility needed to accommodate D–SNP integration.

Comment: One commenter recommended that we consider special circumstances allowing an MA organization to buy or sell a single PBP when the intent is to promote integration for dual eligible beneficiaries. The commenter explained that the ability to sell a D–SNP PBP to an existing, incoming, or re-procured Medicaid organization will prevent disruption that otherwise would occur when a D–SNP must exit a market (unless authority for Medicare passive enrollment is expanded).

Response: We do not agree that adding explicit regulation text to permit an organization to buy or sell one PBP to another legal entity to facilitate D–SNP integration is necessary. The regulation text, as proposed and finalized, permits the sale or transfer of a single contract (that is not the full book of business) where both MA organizations (the seller and the buyer) are wholly owned subsidiaries of the same parent organization, regardless of the plan types under the contract. In accordance with § 422.552(a)(3)(iii), which has been in place for several years, the successor organization must meet the requirements to qualify as an MA organization under part 422, subpart K; this means that all of the requirements to offer a SNP must also be met if the contract includes PBPs that are SNPs. We do not believe carving out a specific PBP from a contract, even if that PBP is a D–SNP, to sell the PBP would serve MA program purposes and goals. In addition, we do not believe that an expansion of the passive enrollment authority for the MA program is within the scope of this rulemaking.

Comment: One commenter recommended that the last part of the sentence in § 422.550(f)(2)—''or one contract if the organization holds more than one MA contract''—be removed because it contradicts § 422.550(f)(1) which explicitly allows an exception for one contract when it is owned within the same parent organization. They also recommended that the corresponding language in the Part D regulation at § 423.551(g)(2)) be revised.

Response: We agree with the commenter and believe the removal of ''or one contract if the organization holds more than one MA contract'' would reduce potential confusion. We also agree that the same change should be made to the Part D regulation at § 423.551(g)(2), since the proposed language at § 422.550(f)(2) was meant to mirror the language in § 423.551(g)(2). Therefore, we are modifying the regulation at § 422.550(f)(2) and § 423.551(g)(2) to remove ''or one contract if the organization holds more than one MA contract.'' We emphasize that the prohibition on transfers or sales of single contracts, is prohibited under the first sentence of § 422.550(f)(1) and 423.551(g)(1): CMS will not recognize the sale of anything less than an MA organization or PDP sponsor's book of business except for the limited situation

where the sale or transfer of a full contract is between wholly owned subsidiaries of the same parent organization. Further, CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the comments, we are finalizing the proposed changes to § 422.550(f) without the phrase ''or one contract if the organization holds more than one MA contract'' in § 422.522(f)(2). We are also finalizing a change to § 423.551(g)(2) to remove ''or one contract if the organization holds more than one MA contract.''

C. Supplemental Benefit Requirements (§§ 422.100)

CMS has released guidance on supplemental benefits several times since April 2, 2018, including the 2019 Call Letter [71] and a subsequent HPMS memo,[72] concerning the definition of 'primarily health related' with respect to supplemental benefits. Under a longstanding interpretation of the MA statute and regulations, CMS defines a mandatory or optional supplemental health care benefit as an item or service (1) not covered by original Medicare, (2) that is primarily health related, and (3) for which the plan must incur a non-zero direct medical cost. Only an item or service that meets all three conditions could be proposed and covered as a supplemental benefit in a plan's PBP. We proposed to codify this policy at § 422.100(c)(2)(ii) by setting forth these criteria as requirements that supplemental benefits must meet.

The current regulation text at § 422.100(c)(2) focuses on distinguishing between mandatory supplemental benefits and optional supplemental benefits. We proposed to re-designate the substance of that current regulation text as new paragraphs (c)(2)(i)(A) and (B). We proposed to codify our longstanding definition of supplemental benefits as three requirements that must be met by a supplemental benefit at paragraph (c)(2)(ii). In paragraph (c)(2)(ii)(A), we proposed to codify that a supplemental benefit must be primarily health related, using a standard discussed in more detail in this section of this final rule and with specific text to address SSBCI. In paragraph (c)(2)(ii)(B), we proposed to codify that a MA organization must incur a non-zero direct medical cost in furnishing or covering the supplemental benefit to verify that the benefit is medically related, with specific text to address special supplemental benefits for the chronically ill (SSBCI), discussed in more detail in section II.A of the proposed rule and section II.A of the final rule titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program,'' which appeared in the **Federal Register** on June 2, 2020 (''June 2020 Final Rule'') (85 FR 33796, 33800 through 33805). Finally, in paragraph (c)(2)(ii)(C), we proposed to codify the requirement that the supplemental benefit is not covered by Medicare. The portion of a benefit where coverage is more generous or greater coverage of a Medicare Part A or Part B benefit—such as coverage of more inpatient days or coverage with lower cost sharing compared to Medicare—is a supplemental benefit. However, an MA plan may not cover a Part D drug or reduce Part D cost sharing as an MA supplemental benefit. Under § 422.500, an MA plan that covers any Part D benefit must comply with the Part D regulations in part 423 and, therefore, must be a Part D sponsor of a Part D plan. In addition, § 422.266(b)(1) provides that an MA plan may use its rebates to buy down a Part D premium, including the premium for supplemental drug coverage described at § 423.104(f)(1)(ii).

1. Primarily Health Related

We explained in the proposed rule that, as discussed in the 2019 Call Letter and an April 2018 HPMS memo, CMS currently interprets ''primarily health related'' as meaning that the item or service is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. We are clarifying in this final rule that the current interpretation is that in order for a service or item to be ''primarily health related'', it must *diagnose, prevent, or treat an illness or injury,* compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization; these key words (''diagnose, prevent, or treat an illness or injury'') were inadvertently left out of the proposed rule. Using this interpretation, CMS has provided MA plans with flexibility in designing and offering supplemental benefits that may enhance beneficiaries' quality of life and improve health outcomes. We proposed to codify that supplemental benefits must be primarily health related, with this definition, at § 422.100(c)(2)(ii)(A).

Examples of supplemental benefits include: Dental, vision, adult day health services, home-based palliative care, in-home support services, support for caregivers of enrollees, stand-alone memory fitness, expanded home and bathroom safety devices and modifications, wearable items such as compression garments and fitness trackers, over-the-counter items, and expanded transportation for medical purposes. A supplemental benefit is not primarily health related under this definition if it is an item or service that is solely, or primarily used for cosmetic, comfort, general use, or social determinant purposes. Also, to be primarily health related, the benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a care plan, if not directly provided by one. Enrollees are not currently required to get physician orders for supplemental benefits (for example, OTC items), and requiring it now would impose new restrictions on MA plans and potentially cause large administrative burden and interruptions in care. Therefore, our proposal included continued use of the ''recommended'' standard as part of interpreting and applying this component of the definition of supplemental benefit. We note that supplemental benefits must also be medically appropriate to be primarily health related; if a service or item is not medically appropriate, it is not primarily health related. This is consistent as well with our longstanding guidance in Chapter 4, section 30.2, of the Medicare Managed Care Manual that supplemental benefits must be medically necessary. We will continue our current interpretations and guidance in codifying existing policy on this issue.

We noted in the proposed rule that the BBA of 2018 amended section 1852(a)(3) of the Act to permit MA plans to offer additional supplemental benefits that are not primarily health related for chronically ill enrollees, beginning January 1, 2020. In section II.A of the proposed rule, we proposed a regulation, to be codified at § 422.102(f), to set standards for special supplemental benefits for chronically ill enrollees (SSBCI); we finalized that

[71] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[72] *https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011202/HPMS%20Memo%20Primarily%20Health%20Related%204-27-18.pdf.*

regulation largely as proposed in the June 2020 Final Rule. We explained that the expansion of supplemental benefits for chronically ill enrollees would not affect our proposed definition of ''primarily health related'' and how it applied to traditional supplemental benefits under our proposal at § 422.100(c)(2)(ii), but we proposed to exclude SSBCI from compliance with the requirement that supplemental benefits be primarily health related at § 422.100(c)(2)(ii)(A). We also explained that the standard that supplemental benefits be primarily health related was a higher standard than the requirement that have reasonable expectation of improving overall health.

2. Uniformity Requirements

We also proposed to codify an existing policy regarding the requirement that benefits covered by an MA plan be uniform for all enrollees in the plan. There are several MA regulations that address uniformity, including the definition of MA plan at § 422.2, the requirement at § 422.100(d), and the bidding and premium requirements at §§ 422.254(b) and 422.262(c). As explained in the final rule, published in April 2018, titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, (''April 2018 final rule'') (83 FR 16440, 16480–85), CMS has determined that providing access to supplemental benefits that are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA program. We solicited comments on this reinterpretation and finalized it in that prior rulemaking. In response to those comments and based on our further consideration of this issue, we provided guidance to MA organizations in both the April 2018 final rule and a subsequent HPMS memo [73] released April 27, 2018. We proposed to codify this reinterpretation specifically in regulation text at § 422.100(d)(2).

The regulations on MA uniform benefits implement both section 1852(d) of the Act, which requires that benefits under the MA plan are available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In 2018, in issuing a final rule and guidance for contract year 2019, we determined that these statutory provisions and the regulation at § 422.100(d) meant that we had the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, *all* enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same. We explained this in the proposed rule and that our interpretation means that there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state. We proposed to redesignate paragraph (d)(2) as (d)(2)(i) and add new paragraph (d)(2)(ii) to specifically state that MA organizations may reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same and that there is some nexus between the health status or disease state and the tailored benefits. We explained in the proposed rule that we review MA benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations; this review applies various standards in addition to the uniformity requirements.

We thank commenters for helping inform CMS' policy on supplement benefit requirements. We received approximately 27 comments on this proposal; we summarize them and our responses follow:

Comment: Many commenters supported this proposal.

Response: We thank commenters for their feedback.

Comment: A few commenters requested CMS provide greater detail on allowable supplemental benefits and confirm examples. Additionally, commenters requested that CMS update the Medicare Managed Care Manual to include these new policies.

Response: We believe that our discussion in the proposed rule explaining the proposal we are finalizing provides sufficient guidance for MA organizations on this topic in this context. The proposal was to codify existing guidance. In addition to the CY2019 Call Letter (specifically about the expanded definition of ''primarily health related'') and the April 2018 HPMS memo on the Reinterpretation of ''Primarily Health Related'' for Supplemental Benefits, Chapter 4 of the Medicare Managed Care Manual provides extensive guidance about basic benefits and supplemental benefits offered by MA plans. Specifically, section 30 of Chapter 4 discusses a number of examples. Additionally, CMS will consider additional subregulatory guidance, including manual updates, as necessary in implementing and administering the legal standards for MA benefits.

Comment: Some commenters stated concern that recent changes to the Medicare Communications and Marketing Guidelines (MCMG) could also increase confusion about supplemental benefits among enrollees.

Response: As stated in the April 2018 HPMS memo on primarily health related supplemental benefits, MA plans are responsible for clearly identifying what will and will not be covered in the plan's Evidence of Coverage (EOC). Any limitations on coverage should be clearly noted in the EOC. Organizations are encouraged to provide explanations to establish how a supplemental benefit, particularly a new or novel benefit, is primarily health related or how coverage of an item or service will be limited to when it is primarily health related. Activities and materials that mention benefits are considered marketing (as defined under §§ 422.2260 and 423.2260) and are subject to the requirements at §§ 422.2263 and 423.2263 (General marketing requirements). Please refer to section V.E. of this final rule, where we address proposals to codify our current policies for marketing and communications by MA and Part D plans. We believe that our requirements for how MA plans market their benefits and how the scope and rules for coverage must be disclosed annually to enrollees ensure that confusion is minimized for enrollees. As we monitor the MA program and complaints (submitted to 1–800-Medicare and otherwise), we will consider if additional guidance or rulemaking is necessary to address unforeseen confusion among beneficiaries.

Comment: Some commenters expressed concern that original Medicare beneficiaries do not have access to supplemental benefits. One commenter stated that MA plan premiums for supplemental benefits may pose a barrier to the receipt of supplemental benefits. One commenter

[73] *https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011207/HPMS%20Memo%20Uniformity%20Requirements%204-27-18.pdf.*

suggested CMS introduce models that allow original Medicare beneficiaries access to supplemental benefits.

Response: Comments regarding Original Medicare beneficiaries' access to MA plans supplemental benefits are out of scope for this regulation. As to the comment about MA premiums, sections 1853 and 1854 of the Act address how MA plan premiums are defined and charged. Further, section 1852 of the Act explicitly authorizes MA organizations to offer supplemental benefits to their enrollees and section 1854 of the Act addresses how MA plans that bid below the payment benchmark for their service area may use a portion of the amount by which the benchmark exceeds the bid to pay the premiums for supplemental benefits. Information about premiums and supplemental benefits is available during the annual coordinated election period for beneficiaries to use in making enrollment decisions.

Comment: A commenter suggested CMS allow MA plans the ability to offer supplemental benefits at a county level within a multi-county service area plan.

Response: Plans segments are county-level portions of a plan's overall service area. As discussed in the April 2018 Final Rule (83 FR 16486), § 422.262(c)(2) permits MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment so long as the supplemental benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. MA plan segments currently may be composed of one or more counties within the service area.

Comment: A few commenters expressed concern that supplemental benefits are not visible in the MPF.

Response: We will take this recommendation under consideration as we continue to refine the MPF tool.

Comment: A commenter expressed concern about the lack of community-based providers available to provide supplemental benefits.

Response: CMS is prohibited from requiring MA plans to contract with specific providers under section 1854(a)(6)(B)(iii) of the Act and § 422.256(a)(2)(i), but so long as they comply with the standards established for provider contracting in part 422, subpart E, MA organizations may contract with community-based providers. Further, § 422.112(b)(3) provides for coordinated care MA plans to include community-based services in their plans for coordination and continuity of care for enrollees. In addition, § 422.112(b)(3) specifically states that MA coordinated care plans are required to ''coordinate MA benefits with community and social services generally available in the area served by the MA plan.'' MA plans may contract with community-based organizations to provide supplemental benefits that are compliant with the statutory and regulatory requirements. For example, an MA plan could elect to offer a meals or food/produce supplemental benefit (so long as the benefit is primarily health related and the plan incurs a non-zero direct medical cost consistent with § 422.100(c)(2)) and pay a community-based organization for furnishing the covered benefit. We understand that in some areas there may be a limited number of community-based providers and hope that the increased supplemental benefit flexibilities discussed in this rule encourage increased opportunities for community provider participation.

Comment: A commenter requested CMS provide additional guidance on how plans can make sure that supplemental benefits meet the ''primarily health related'' requirement.

Response: We suggest plans review the April 27, 2018 memo titled ''Reinterpretation of ''Primarily Health Related'' for Supplemental Benefits''. In addition, Chapter 4 of the Medicare Managed Care Manual contains guidance on permissible supplemental benefits, which gives MA organizations and the public an understanding of which benefits we have previously determined to meet this standard. The standard we are finalizing at § 422.100(c)(2)(ii)(A) provides that to be primarily health related, a benefit must—as a primary matter—diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization. A supplemental health benefit proposed by an MA organization must be reasonably and rationally encompassed by this standard and may not have a primary purpose that is outside of this standard. The primary purpose of an item or service is determined by national typical usages of most people using the item or service and by community patterns of care. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee's healthcare needs and be medically appropriate for the enrollee. While we do not require that the physician or health care professional prescribe or order an item or service for it to be considered primarily health care, we believe that recommendation by a licensed provider as part of a care plan is an important sign that an item or service meets this standard. We cannot provide an exhaustive list of items and services that potentially are primarily health related. We consider this sufficient general guidance for plans to make sure that supplemental benefits meet the ''primarily health related'' requirement.

Comment: In light of COVID–19, one commenter suggested CMS provide additional flexibility to provide supplemental benefits for high-risk populations that must remain in their homes. This commenter suggested CMS allow plans to provide home delivered meals, grocery, produce, and non-medical transportation for this population.

Response: We are not finalizing a change to the proposed standards for defining supplemental benefits to specifically address the COVID–19 public health emergency. Earlier in 2020, CMS issued guidance [74] to MA plans, in response to the unique circumstances resulting from the outbreak of COVID–19. CMS exercised its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements that was adopted in a 2008 final rule (73 FR 43628); CMS allowed MA plans to implement additional or expanded benefits that address medical needs and access to healthcare raised by the COVID–19 outbreak, such as covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID–19 public health emergency. For CY2021, CMS issued additional guidance on December 28, 2020 titled ''Contract Year 2021 Coronavirus Disease 2019 (COVID–19) Permissive Actions FAQ'' stating that we will continue this use of enforcement discretion in connection with the prohibition on mid-year benefit enhancements.

Comment: A commenter requested that CMS provide additional clarity around what is intended by CMS's statement in the preamble and referenced guidance that a primarily health related benefit should be recommended by a licensed medical professional as part of a care plan and to clarify what is acceptable when the supplemental benefit is not directly provided by a licensed medical professional and the enrollee does not receive case management services and an individual care plan.

[74] *https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf.*

Response: A medical professional does not have to be the individual or entity furnishing the supplemental item or service. We recognize that there are scenarios in which a medical professional would not be furnishing a service (for example, meals). However, the item or service must still meet the regulatory criteria for a supplemental benefit at § 422.100(c)(2)(ii)(A) being finalized here, that is to be primarily health related, a benefit must benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health. Recommendation by a medical professional, even if not part of a formal care management or care coordination plan, is an important indicator that a particular item or service is being furnished for primarily health-related purposes but is not necessarily the only indication. The primary purpose of an item or service is determined by national typical usages of most people using the item or service and by community patterns of care and/or by established research or medical compendia and journals about such item or service. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee's healthcare needs and must be medically appropriate for the enrollee. We expect MA plans to have procedures and processes in place to ensure a reasonable determination is made that the covered benefit is medically appropriate for the enrollee in the event that it is not practical for a medical professional to make a specific recommendation or evaluation.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, substantively as proposed but with clarifications, the proposed amendments to § 422.100(c) to restructure the regulation text and add the three requirements for an item or benefit to be a supplemental benefit and to § 422.100(d)(2) to restructure the regulation text and add a provision explicitly addressing how supplemental benefits that are tied to disease state or health status may meet the uniformity requirement and be offered as supplemental benefits. Although we are finalizing this provision as applicable beginning January 1, 2022 (2022 calendar/contract year), it effectively applies to 2022 bids and all plan materials and activities affecting or in furtherance of facilitating enrollment for the 2022 contract year. Therefore, the final rule will govern most plan communication and marketing activities and materials during the second half of 2021. Furthermore, it codifies current policies so we encourage MA organizations to take this final rule into account immediately.

In addition, we are finalizing § 422.100(c)(2)(ii)(A) with clarifying changes. First, we are adding the phrase ''prevent, or treat an illness or injury,'' which was mistakenly left out of the proposed rule but is part of the current policy we are codifying. Second, we are finalizing the regulation text in this paragraph with semi-colons between each phrase to make it clear that fulfilling one of the listed functions as the primary function is sufficient for an item or service to be considered primarily health related under this final rule. Third, we are adding text to clarity that supplemental benefits must not be items and services covered by Parts A, B or D; to further clarify this point, we added the words ''Parts A, B, and D'' in parenthesis next to the word Medicare in paragraph (c)(2)(ii)(C). The proposal was to codify already existing guidance and practices and we stated that it is not expected to have additional impact above current operating expenses; this final rule is the same on this point.

D. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

As noted in the February 2020 proposed rule, based on CMS' authority under sections 1856(b)(1) and 1857(e)(1) of the Act, CMS, in 2014, authorized MA organizations, including those offering a Medicare Medical Savings Account (MSA) plan option, to offer rewards and incentives (R&I) programs (79 FR 29956, May 23, 2014). We adopted this regulation that authorized Part C R&I programs for a number of reasons. In some cases, MA organizations wished to extend rewards and incentives already offered to their commercial members to their Medicare enrollees. Many MA organizations wished to sustain their current R&I programs as well as stay competitive with other MA organizations with comparable offerings. Additionally, there is evidence suggesting that health-driven reward and incentive programs may lead to meaningful and sustained improvement in enrollee health behaviors and outcomes.

Our experience has shown that most R&I programs offered by MA plans fall into the following four areas:

(i) Specified use of plan benefits such as rewards provided for obtaining preventive benefits at specified intervals;

(ii) Following a specified program that promotes exercise and/or good nutrition;

(iii) Participating in specified programs that educate on health matters and/or self-management of nutrition and exercise;

(iv) Specified utilization of plan resources such as hotlines, patient portals, and similar items that facilitate promotion of health.

In the February 2020 proposed rule, CMS proposed to amend § 422.134 to codify the guidance we have given since adopting the regulation in 2014, unify principles governing MA rewards and incentive programs, clarify the requirements of the regulation, and clarify flexibilities available to MA organizations under the regulation. Readers are directed to the proposed rule for a detailed discussion of the proposal (85 FR 9204 through 9108) as we are not fully repeating our proposal here.

In this final rule, CMS is re-organizing the regulation at 42 CFR 422.134 to clarify and codify existing guidance that reflects how we have addressed inquiries about the R&I program over the past 5 years. The reorganization of 42 CFR 422.134 is outlined as follows: (a) Definitions, (b) the option for an MA plan to offer an R&I program subject to the requirements of this section, (c) the requirements and prohibitions for target activities, (d) requirements and prohibitions on the offering of reward items, (e) marketing requirements, (f) disclosure requirements, and (g) miscellaneous requirements, for example, bids, sanctions, and grievances. As finalized, § 422.134 is substantially reorganized compared to the current regulation. The finalized policy presented here differs from the NPRM in the following areas: We have:

(i) Further clarified the definition of qualifying individual at paragraph (a),

(ii) Moved the requirements of uniformity of the target activity and provision of accommodations from paragraphs (c)(2)(iii)(A) and (B) to paragraphs (c)(1)(iv) and (v),

(iii) Modified the requirement of providing accommodations (moved from paragraph (c)(2)(iii)(B) to paragraph (c)(1)((v)) to respond to commenter concerns,

(iv) Reworded the requirement of uniformity in the reward item at paragraph (d)(1)(i),

(v) Removed the prohibition of midyear changes at paragraph (g)(iv) and,

(vi) Although not changing the regulatory text, clarified in the preamble the requirements at paragraph (d)(1)(iii).

The details of these changes including comments and responses and the rationale for the changes are provided in their respective discussions below.

We are not specifically addressing here those aspects of our proposal that were merely moving a provision currently in § 422.134 to a different paragraph and on which we did not receive substantive comments. See Table E6 for a comparison of the current regulation text with the regulation text we are finalizing in this rule.

We now discuss the new requirements proposed in the February 2020 proposed rule, the comments received, and our decision about finalization.

Definitions. We proposed to codify various definitions at § 422.134(a), including ''target activity,'' ''reward item,'' ''incentive item,'' and ''reward and incentive program.'' Along with a proposed definition, we also introduced the term ''qualifying individual'' as a way to refer to the individual who could be eligible for or earn a reward; we proposed that a qualifying individual, in the context of a plan-covered health benefit, means any plan enrollee who would qualify for coverage of the benefit and satisfies the plan criteria to participate in the target activity; in the context of a non-plan-covered health benefit, a qualifying individual means any plan enrollee who satisfies the plan criteria to participate in the target activity.

As we considered the proposed rule, we believe that the definition of ''qualifying individual'' can and should be refined even though no commenter specifically raised the issue. To avoid any confusion about the limitations plans may set regarding who may participate in target activities, we are finalizing the definition with modifications from the proposal. In the context of a plan-covered health benefit (whether an Original Medicare benefit, an SSBCI, or other supplemental benefit), qualifying individual refers to any individual meeting coverage criteria. We introduced this definition to communicate how MA plans should offer reward uniformly and without discrimination to all enrollees and to avoid problems with uniformity discussed in detail below. For example, it is not a violation of uniformity if a plan offers rewards and incentives for any qualifying individual who gets a mammogram. While it is true that many men and some women do not qualify for mammograms, the plan is not violating uniformity in this example since we now define uniformity as requiring plans offer R&I to ''all qualifying individuals'' which in the case of plan-covered benefits is different than ''all enrollees.'' CMS' intention in the proposed rule was to codify current CMS reward and incentive policy, not to add new criteria for program participants to qualify for participation in an R&I program or to earn a reward. The proposed definition, by including references to satisfying the MA plan's criteria for participating in the activity, suggested that MA plans could limit participation in R&I programs in a broader manner than we intended.

We received no comments on the proposed definitions in paragraph (a) itself and are finalizing paragraph (a) substantially as proposed for the reasons provided in the proposed rule. We also are finalizing edits in the definition of qualifying individual so that it is clearer in setting forth how enrollees are to be offered access to reward programs: *Qualifying individual* in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Direct involvement of enrollee. At § 422.134(c)(1)(i), we proposed to codify our existing guidance requiring that target activities must directly involve the qualifying individual and performance by the qualifying individual. Under our proposal, the completion of activities by caregivers would not qualify for a reward item.

We received no comments on this provision and are finalizing it as proposed for the reasons provided in the proposed rule.

Level of completion requirements. At § 422.134(c)(1)(ii), we proposed to clarify that target activities must be specified (by the MA organization) in detail as to the level of completion needed in order to qualify for a reward item. We explained in the proposed rule how this was based on current § 422.134(c)(1)(i), which requires a reward to be offered in connection with an entire service or activity, and our current guidance, which provided flexibility for MA organizations to identify ''an entire service or activity.'' Our proposal was essentially to codify our current guidance, which permitted MA organizations to offer and furnish rewards for completion of components of a multi-part activity so long as the MA organization reasonably defined the scope of the entire activity. For example, an MA organization may offer an eight-session weight management class; under this example, the MA organization may offer and provide a reward for either completion of all eight sessions of this eight-session weight management class or for attendance at each individual session of the weight loss class that the enrollee attends. Both of these scenarios are permissible as long as the plan (or R&I program) defines the target activity that will be rewarded.

Comment: A few commenters requested that CMS allow provision of the entire incentive upfront, rather than after the incentivized benefit has been utilized, to capitalize on humans' innate tendency toward loss aversion.

Response: We thank the commenters for their interest in incentivizing enrollees. We however are not adopting the recommended change. The R&I program, although not a benefit, is an expense to the Medicare Advantage program. Certain safeguards, such as a requirement of actual completion of activities to receive the reward, therefore, are necessary to avoid inappropriate use of Medicare dollars. In addition, we are mindful of how section 1851(h)(4) of the Act requires the adoption of standards that prohibit MA organizations from providing for cash, gifts, prizes, or other monetary rebates as an inducement for enrollment *or otherwise;* providing the reward in advance of the performance of the health related activity could create the appearance that MA plans are providing items of value as a prohibited inducement.

We are finalizing this provision as proposed for the reasons provided in the proposed rule and indicated in the response to comments.

Health related activity requirements. At § 422.134(c)(1)(iii), we proposed to move the standard stated in the current regulations that R&I programs reward enrollees ''in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources.'' We proposed to move this requirement to § 422.134(c)(1)(iii) to more clearly outline that target activities must be health-related by doing at least one of the following: promoting improved health, preventing injuries and illness, or promoting the efficient use of health care resources.

Comment: Some commenters praised the clarity in the enumeration at § 422.134(c)(1)(iii).

Response: We thank the commenters for their support. We take this opportunity to clarify that we interpret the reference to the efficient use of health care resources in the final regulatory text as capable of being determined from either the perspective of the plan or the beneficiary. We are finalizing this provision as proposed.

Uniformity: To achieve greater clarity and to address issues raised by commenters, we are finalizing § 422.134(c) with several changes from the NPRM in connection with uniformity and non-discrimination requirements.

The requirements of uniformity and provision of accommodations (that is, that rewards must be offered uniformly to all qualifying individuals and that accommodations must be provided to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity. for target activities) were proposed to be codified at § 422.134(c)(2)(ii) as standards to ensure that anti-discrimination requirements were met. We are finalizing these concepts as part of the standards for target activities, at § 422.134(c)(1)(iv) and (v). Upon reflection and based on the comments requesting clarification related to these concepts, we believe that uniformity and provision of accommodations are positive statements and best classified as requirements for target activities at § 422.134(c)(1) rather than as part of demonstrating compliance with a prohibition against discrimination. We believe these standards serve purposes in addition to anti-discrimination, such as encouraging participation in health related activities in the broadest way possible even if limiting access to a reward would not necessarily be based on a prohibited basis like health status, race or sex. This reorganization of how these standards apply provides greater clarity and transparency for the application of § 422.134.

We now discuss each of these requirements separately by presenting the comments we received on them.

Uniformity: We are finalizing the requirement that a target activity must uniformly offer any qualifying individual the opportunity to participate in the target activity at § 422.134(c)(1)(iv). This means that target activities must be designed so that they are uniformly offered to all qualifying individuals, as that term is defined in paragraph (a). For example, regarding an R&I program that provides a reward for obtaining a mammogram, providing rewards only to those enrollees who have never before obtained a mammogram would violate the uniformity requirement as it would leave out members who have previously obtained a mammogram but are otherwise qualifying individuals. We believe that this uniformity requirement is key to preventing discrimination against different groups of enrollees and consistent with our current guidance in section 100 of Chapter 4 of the Medicare Managed Care Manual. This requirement ensures that reward programs encourage all enrollees to be actively engaged in their health care and activities that ultimately improve and sustain their overall health and well-being.

The purpose of CMS implementing the R&I program requirements this way is to incentivize all individuals to engage in target activities that will meet one of three health-related goals. Enrollees who have previously taken steps to care for their health should be incentivized to continue to do so as much as individuals who are taking such steps for the first time.

Comment: Some commenters suggested we allow R&I programs to target a beneficiary's clinical status, for example, those who would most benefit from the incentivized intervention or those who are not using a benefit. Another commenter wanted to reward women who had not had mammograms in three years with a higher reward to encourage them to get mammograms more regularly by providing a higher reward. These commenters noted that recent legislative and regulatory activities have permitted Medicare Advantage plans to tailor health benefits to targeted populations, ensuring they meet the unique needs of specified groups of beneficiaries based on diagnosed conditions or diseases. The commenters indicated that, in the same way, CMS should explore permitting Medicare Advantage plans to tailor R&I programs for beneficiaries to meet the needs of clearly defined groups of beneficiaries. The commenters believed this could improve participation in care and improve outcomes by incentivizing compliance in clinical recommendations such as attending office visits or participating in wellness programs tailored to their needs.

Response: We thank the commenters for raising these issues. In response to the suggestion that we allow R&I programs to target those who are not using a benefit, we note that this would not be allowed because it would not be offered uniformly to all qualifying individuals and, as explained above, goes against the goal of R&I programs. In response to the suggestion that CMS allow an R&I program to reward women who had not had mammograms in three years with a higher reward, we note that, as worded by the commenter, this violates the general non-discrimination provision at 42 CFR 422.134(g)(1) because the reward would only go to women. If the target activity had instead been formulated by the commenter as targeting any qualifying individual who has not had a mammogram in three years, this would still not be allowed since it does not offer the target activity uniformly to all qualifying individuals but only to those individuals who have not had a mammogram in three years. Providing different rewards to those completing a mammogram based on their past history of mammogram services would violate the uniformity of reward requirement at 42 CFR 422.134(d)(1)(i), which is discussed further below.

We believe the reference to recent legislative and regulatory activity refers to Special Supplemental Benefits for the Chronically Ill (SSBCI) recently codified in CMS–4190–F1. We are not persuaded that the same approach is necessary for R&I programs because SSBCI is a benefit but rewards and incentives are not benefits. In the case of SSBCI, these special types of benefits are allowed to be targeted to enrollees who specifically need them while enrollees who do not need SSBCI are not allowed these items; contrastively, R&I is beneficial for all enrollees irrespective of their past since both those who are currently using benefits as well as those who are not currently using benefits can be incentivized to either start using the benefit or continue using the benefit. CMS believes the intent of R&I programs to incentivize all enrollees to engage in healthy behaviors to improve health outcomes applies universally. Maximizing access to R&I programs by enrollees will result in broader benefits and broader engagement in health related activities. Further, ensuring broad access by any qualifying enrollee to the target activity (and therefore access to earning the reward) ensures that a beneficiary will not be persuaded to enroll in a particular plan based on the reward program and subsequently learn that he or she is not able to participate in the reward program because the target activity is limited to enrollees who have never engaged in it.

However, an MA plan may design an R&I program that could effectively target enrollees with a specific condition or disease state and for those who would benefit most from the incentivized interventions (as suggested by commenters) without violating the non-discrimination or uniformity requirements being finalized in § 422.134. Plans may do this by rewarding qualifying individuals for participating in target activities that are covered benefit items and services as these benefits must be medically necessary, or for SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee,

for an individual to obtain. As finalized, § 422.134 does not require a plan to cover an item or service when it is not medically necessary, even if getting that particular covered benefit is the target activity for an R&I program. Therefore, these types of target activities are already tailored to the qualifying individual's needs based on a specific condition or disease state and would be available to those who would benefit most from the incentivized intervention. For example, an R&I program designed to offer rewards to any qualifying individual for using glucose test strips would likely help an MA plan reach their diabetic enrollee population, as glucose test strips are generally only considered medically necessary if an enrollee is diabetic, while also allowing other members, in rare instances, who may need glucose test strips an opportunity to be rewarded for engaging in the healthy behavior as well.

We are finalizing the uniformity requirement for target activities at paragraph (c)(1)(iv) as proposed (with the move from paragraph (c)(2)(iii)(A) to paragraph (c)(1)(iv) discussed above) for the reasons provided in the proposed rule and our discussion in this final rule.

Accommodations: We next discuss the requirement of providing accommodations at § 422.134(c)(1)(v) (moved from § 422.134(c)(2)(iii)(B)) and comments received on this requirement. Proposed paragraph (c)(1)((v) stated a requirement for an MA organization to provide accommodations to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

Comment: Comments on our proposal that MA organizations provide accommodations to qualifying individuals were generally supportive. The commenters generally stated that providing accommodations to those who wish to participate, but are without the means to do so, will allow the benefits of these R&I programs to positively impact the health of a broader population of members. However, a commenter pointed out that an accommodation should not be permitted if such an accommodation would contradict the purpose of the target activity. This commenter agreed that as a general matter plans should accommodate members without internet access wherever possible to offer an alternative offline activity consistent with the purpose of the target activity. For example, a plan that rewards members who report their exercise online can accommodate a member without internet access by allowing that member to verbally report their exercise to a call center. In this example, rewarding the alternative activity serves the purpose of the original target health activity. However, where the target activity is intended to promote the efficient use of resources, such as agreeing to electronic delivery of documents, the commenter statutes that it would not reasonable to require plans to offer an offline alternative, as an offline activity would not promote the efficient use of resources and would be directly contrary to the reward's purpose.

Response: We appreciate the support for the requirement that MA organizations provide accommodations. As stated previously, we believe that this requirement will ensure that R&I programs are broadly based and encourage enrollees to be actively engaged in their health care and, ultimately, improve and sustain their overall health and well-being. We agree with the commenter's concern and are therefore finalizing the requirement for accommodations with additional text to provide that the required accommodation be consistent with the goal of the target activity. We encourage MA organizations to take into account the resources, abilities, and characteristics of its enrolled population in devising R&I programs and in identifying target activities. As noted above, we believe moving the accommodation requirements from paragraph (c)(2)(iii)(B) to paragraph (c)(1)(v) provides greater clarity and transparency in imposing this as an affirmative standard for all target activities. It also removes any implied limitation that accommodations are only necessary to ensure that a prohibited basis for discrimination (such as race, ethnicity, sex or health status) is not being used. As illustrated in our example in the proposed rule and our current guidance in section 100.2 of Chapter 4 of the Medicare Managed Care Manual, the requirement for accommodations is broadly interpreted in order to ensure access for all qualifying individuals.

Part D target activities. We proposed, at § 422.134(c)(2)(i), to prohibit target activities that are related to Part D benefits because the provisions in Part 422 pertain to Medicare Advantage Part C and not to Part D. This is consistent with our subregulatory guidance in Chapter 4 of the Managed Care Manual as well as with responses to comments in the 2014 rule which initially authorized MA plans to use R&I programs (79 FR 29917). Should a Part D R&I program be developed, it will be a separate provision from this one, with regulatory language added to Part 423. We note that in section IV.F of this final rule, we are finalizing a narrow reward program provision for Part D plans.

Comment: We received several comments from stakeholders urging CMS to allow Part D sponsors to offer rewards for target activities related to Part D benefits, such as beneficiary adherence to a medication regimen(s). Commenters generally believed that such an allowance could benefit enrollees by improving compliance. One commenter noted that the specific application of R&I for healthy prescription drug behaviors of enrollees of MA–PD plans is being tested by CMMI in the MA VBID model. An initial evaluation based on the first year of experience found that plans were able to drive more appropriate use of medical services by providing rewards and incentives. Beginning in plan year 2019, plan sponsors were able to include R&I for prescription drugs as well; however, these programs have not yet been evaluated. Commenters recommended allowing Part D R&I programs for both MA–PD plans as well as stand-alone prescription drug plans.

Response: We thank the commenters for their recommendations and the citations of similar programs offered elsewhere. CMS regularly reviews the various models being tested by the Center for Medicare and Medicaid Services Innovation Center to ascertain what works and what can be incorporated into our general programs. An example of CMS's commitment to new ideas may be found in Section IV.F of this final rule which creates a limited R&I program for the real time benefit tool. We note that Section IIIC of this final rule presents a comment similar to the comment just cited, requesting that R&I be used to incentivize return of unused opioids. However, as noted in Section IIIC and as noted above, it is out of scope of § 422.134 to allow a Part D R&I program. CMS did not propose a regulation to authorize general Part D reward and incentive programs and therefore is not finalizing such a new regulation.

We are therefore finalizing § 422.134(c)(2)(i) as proposed and reiterate that it does not authorize rewards or incentives tied to Part D benefits, either by MA organizations that offer MA–PD plans or by other Part D sponsors that offer stand-alone Part D plans.

Non-Discrimination and Health Status. R&I programs must not be discriminatory; there is a general prohibition about that proposed and finalized at § 422.134(g)(1). At § 422.134(c)(2)(ii), we proposed to revise

and clarify the non-discrimination requirements in the current regulation and codify our current guidance on those requirements. Proposed at paragraph § 422.134(c)(2)(ii)(C) and finalized at § 422.134(c)(2)(ii), this regulation generally prohibits target activities from discriminating against enrollees and requires specifically that MA organizations comply with § 422.134(g)(1) and not design a reward program that is based on the achievement of a health status measurement. Current sub-regulatory guidance provides that non-discrimination, which is part of the current regulation at § 422.134(c)(1)(ii), requires in part that a target activity not consist of the achievement of a specific health status or measurement or outcome as this would be discrimination based on health status. For example, an MA organization would be prohibited from creating a target activity that stipulates achieving a certain weight, or achieving a certain Body Mass Index (BMI) score. However, a target activity could consist of some combination or all of the following: Maintaining an exercise program, eating nutritious meals (with ''nutritious'' being further defined by the plan), and taking weight measurements at periodic intervals. Similarly, an MA organization would be prohibited from creating a target activity that stipulates achieving a blood pressure reading in a certain range but a permissible target activity could consist of taking blood pressure measurements at periodic intervals.

We did not receive any comments that specifically discussed this part of the proposed rule. We are finalizing the provisions at § 422.134(c)(2)(ii) as proposed for the reasons provided in the proposed rule.

Offered Uniformly. We proposed at new paragraph (d)(1)(i) to require reward items to be offered uniformly to any qualifying individual who performs the target activity. In the proposed rule, we explained that this would codify our current subregulatory guidance, which ties the standard to the non-discrimination requirement in the current version of § 422.134(b)(2) that reward programs must be designed so that all enrollees are able to earn rewards.

We did not receive any comments specific to the proposed requirement proposed in paragraph (d)(1)(i) that reward items be offered uniformly to qualifying individuals. However, in order to avoid conflating this requirement with the uniformity requirement we are finalizing at paragraph (c)(1)(iv) regarding target activities, we are finalizing paragraph (d)(1)(i) as a requirement that reward items must be offered identically to any qualifying individual who performs the target activity. This requirement is to ensure that each enrollee has access to the same reward items (or same choice among reward items if applicable). While related to the uniformity requirement for target activities, it is designed to address the potential that some enrollees would receive different, potentially more valuable, reward items compared to other enrollees. This requirement is a reflection of the non-discrimination principles underlying several other requirements being finalized in § 422.134. We believe that this additional standard is necessary to ensure that R&I programs are operated in an equitable way and that the use of different reward items does not result in more incentive being offered by the MA plan to certain enrollees. As discussed previously, R&I programs should be broadly based and operated for the benefit of all enrollees or as many enrollees as possible; using identical rewards for each qualifying individual who performs the same target activity contributes to that goal.

Note that throughout § 422.134 we use the term ''perform'' or ''performance.'' However at paragraph (c)(1)(ii) we refer to the ''level of completion needed in order to qualify for the reward.'' We therefore clarify that our use of ''perform'' refers to the performance of the entire health related activity. At paragraph (c)(1)(ii) we refer to the ''level of completion needed'' because rewards must be earned by completing an entire service or activity (or combination of services/activities), as established by the MA plan, and may not be offered for completion of less than any/all required component(s) of the eligible service or activity. This requirement allows CMS and MA plans to interpret the value of a reward or incentive in relation to the service or activity for which it is being offered. Plans are expected to reasonably define the scope of a health related service or activity within their RI Program design and assign a value of the reward accordingly. For example, a plan may decide to offer rewards and/or incentives for participation in a smoking cessation program. The plan may decide to give smaller rewards for each class or counseling session attended or may offer a single, larger reward for completing a pre-determined number of classes or counseling sessions.

We did not receive any comments that specifically discussed this part of the proposed rule. We are finalizing the provisions at § 422.134(d)(2) as proposed for the reasons provided in the proposed rule and.

Direct and Tangible. At § 422.134(d)(1)(ii), we proposed, consistent with current guidance, to require that reward items be direct and tangible. For example, a reward item cannot consist of a charitable donation.

We received no comments on this provision and are finalizing it as proposed for the reasons provided in the proposed rule.

Transfer of ownership. At § 422.134(d)(1)(iii), we proposed to require that the reward item must be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless if the enrollee is likely to use the reward item after the contract year.

Comment: Several commenters pointed out that this provision may pose operational concerns. For example, in late December an enrollee may complete a target activity that the plan finds out about at the beginning of the next plan year, which is outside of the time the enrollee could claim the reward as the guidance currently states.

Response: We agree with the commenters' concerns. We believe the language in the NPRM did not adequately communicate our intent that the R&I program be based on activities completed during the contract year. As stated in the NPRM, we believe that MA plans should not be able erase a gift card provided as a reward or invalidate the reward in the next contract year after the enrollee has completed the target activity. We believe that this is an important beneficiary protection to ensure that rewards are timely provided to the enrollee and that the enrollee retain the rights to use the reward whenever he or she wants. (85 FR 9107) While we acknowledge that the preamble explanation introduced the idea of ''timely provision to the enrollee,'' that was not part of the proposed regulation text. Our regulatory text was intended to require that the reward item be provided to the enrollee, such as through transfer of ownership or delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year. The intended criterion was that the reward-item be delivered based on a target activity completed in the contract year during which this R&I program was offered.

We are finalizing paragraph (d)(2)(ii) with modifications such that the regulation requires delivery based on the completion of the target activity during the contract year. Under this final rule, delivery of the reward item in

the next contract year, such as after administrative activities associated with the reward program are performed, is permissible. However, the qualifying individual cannot be required to continue activities into the next contract year to retain or gain the reward earned during a prior contract year.

Reward Items. At § 422.134(d)(2)(i), we proposed to reorganize existing provisions and codify existing guidance to set forth clearer regulation text about what items could not be offered as rewards. Currently, § 422.134(c)(2) prohibits rewards from being offered in the form of cash or monetary rebates and our subregulatory guidance explains that this includes reductions in cost sharing or premiums and gift cards that are redeemable for cash. We proposed regulation text explicitly to prohibit reward items from being offered in the form of cash, cash equivalent or other monetary rebates (including reduced cost sharing or premiums). We also proposed regulation text to set forth that an item is considered cash or cash equivalent if it: (A) Is convertible to cash (such as a check); or (B) Can be used like cash (such as a general purpose debit card). In addition, the proposed rule prohibited reward items that involve elements of chance or have a value that exceeds the value of the target activity itself.

We also proposed, at paragraph (d)(3), to list examples of permissible reward items for a target activity, specifically that reward items may: (i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items; and (ii) be offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services. Like the prohibition on using items that involve an element of chance, the examples of permissible reward items were based on our guidance and responses to questions since § 422.134 was first adopted.

Comment: We received many comments on these provisions. Commenters advocated for authority to use general debit cards as a reward item, specifically arguing that targeted gift cards can be burdensome and confusing. A commenter advocated for the provision of incentives in the form of monetary credits toward monthly premiums or cost sharing requirements.

Response: Section 1851(h)(4) and 1854(d)(1) of the Act both prohibit an MA organization from giving enrollees cash or monetary rebates as an inducement for enrollment *or otherwise.* Since the statute prohibits cash or monetary rebates, we proposed, consistent with the statute, to prohibit reductions in cost-sharing from being used as a reward. Since the statute prohibits cash, we proposed to prohibit giving a reward for anything that can be used as cash or cash equivalent such as checks or general debit cards. In arriving at this conclusion, we saw the primary attribute of cash as its universal use to purchase. For this reason, we proposed to prohibit general debit cards which can be used universally but to allow, at paragraph (d)(3)(ii), a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services. We similarly prohibited checks which are easily converted to cash and then can be used universally.

As to the suggestion that using that targeted gift cards can be burdensome and confusing and therefore CMS should permit the use of general debit cards as rewards, we note that the use of any gift card as a reward item is optional. If a plan finds that beneficiaries are confused or burdened by targeted gift cards, the MA plan may choose to use another form of reward. As explained above, we view general debit cards as the equivalent of cash and believe that § 422.134 must be consistent with the statutory prohibition on MA organizations providing cash as an inducement. Our experience with the program suggests that many stakeholders implement R&I with multiple gift cards. While it would be more convenient to have just one gift card, we do not believe it correct to say that multiple gift cards are burdensome and cumbersome since in practice plans are already using this vehicle for rewards, implying that their enrollees find the benefits of multiple gift cards outweigh the burdensomeness. As to the minor inconvenience of multiple gift cards, minor inconvenience is not a sufficient reason to override a statutory prohibition. Further, we note that providing a choice among equal value gift cards, so long as all qualifying individuals are offered the identical choice consistent with § 422.134(d)(1)(i) as finalized here, is also permitted.

We are finalizing these provisions as proposed for the reasons outlined in the proposed rule and our responses to comments.

Marketing. As part of the reorganization of § 422.134, we proposed at paragraph (e) a provision requiring compliance with all marketing and communications requirements in Part 422, Subpart V rather than specifically adopting marketing and communication requirements for reward programs in § 422.134. Section VI.H of the proposed rule and section V.E of this final rule discuss the marketing and communications requirements for MA organizations, including provisions specific to reward programs.

Comment: Commenters expressed concern that while CMS has proposed that R&I programs be subject to the marketing requirements, they are only communications and not subject to marketing requirements.

Response: As proposed (and finalized) in § 422.134(g)(3), and as indicated in CMS' subregulatory guidance in Chapter 4, R&I are classified as non-benefits. Consequently, R&I are not subject to inclusion in the Annual Notice of Change (ANOC) or Evidence of Coverage (EOC). Nevertheless, CMS believes treating materials about R&I programs offered by MA plans as subject to the marketing and communications requirements and standards in Part 422, Subpart V is appropriate. As proposed and finalized in Section V.E of this final rule, the definition of marketing (§§ 422.2260 and 423.2260) includes content regarding rewards and incentives; we believe that this is appropriate because the availability of R&I programs and rewards may influence the decision of a beneficiary to enroll or stay enrolled in a particular MA plan. The beneficiary protections, review standards and prohibitions that apply to marketing materials and activities (as well as those that apply to communications) will apply to materials and activities about rewards and incentives when those materials and activities are intended to (i) draw a beneficiary's attention to an MA plan or plans or (ii) influence a beneficiary's enrollment decision(s). We also direct readers to section V.E of this final rule for additional discussion of the definition of marketing and the standards and requirements that apply to marketing and communications materials.

We are finalizing paragraph (e) as proposed for the reasons outlined in the proposed rule and our responses to comments.

Reporting requirements. At § 422.134(f), we proposed regulation text to require an MA organization to make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

Comment: We received comments on this proposal. A commenter supported a reporting requirement to ensure that plans are implementing any reward programs fairly and without discrimination. Another commenter believed it sufficient for the purpose of monitoring and oversight that MAOs provide information upon request

without the additional burden of a specific reporting format.

Response: We thank the commenters for their interest in oversight and fairness and support for a reporting requirement. Currently, § 422.134(c)(3) includes a reporting requirement in connection with R&I programs and our proposal carried over that provision verbatim to the proposed revision at 422.134(f). The policy itself was not originally proposed in this rulemaking; what is finalized in this rule is the change of location from paragraph (c)(3) to paragraph (f). Based on the current regulation, CMS has had for several years annual reporting requirements for R&I programs. These reporting requirements are accessible at *https://www.cms.gov/files/document/cy2020-part-c-reporting-requirements 04222020.pdf.* Thus far, CMS has found these reporting requirements sufficient for its oversight needs.

Miscellaneous. At § 422.134(g)(2), we proposed regulation text to clarify that plan failure to comply with R&I program requirements may result in a violation of one or more of the bases for imposing sanctions at § 422.752(a). At § 422.134(g)(3), we proposed regulation text to codify existing guidance that the reward and incentive program is classified as a non-benefit expense in the plan bid and that disputes on rewards and incentives must be treated as a grievance under 422.564.

Comment: A few commenters supported our codification at paragraph (g)(3) that R&I programs are classified as a non-benefit expense.

Response: We thank the commenters for their supportive comments.

We received no other comments on these provisions and are finalizing as proposed for the reasons provided in the proposed rule.

Midyear changes. At § 422.134(g)(4), we proposed regulation text to prohibit mid-year changes to reward and incentive programs. We explained in the proposed rule that this new provision was based on how the reward and incentive program must be included in the plan bid each year and that we considered it an important beneficiary protection.

Comment: We received numerous comments with diverse perspectives on our proposal to prohibit mid-year changes in R&I programs. Some commenters were supportive: They were aware of the issue of the integrity of the bid and also believed that mid-year R&I program changes would be confusing to enrollees. By contrast, some commenters wanted the flexibility to respond mid-year to low utilization of plan resources and benefits by designing rewards targeted to those populations. Other commenters suggested a compromise: Allow additions of R&I mid-year (positive changes) but prohibit negative changes (removal of R&I).

Response: We thank all commenters for their insights. In reviewing these comments, we also considered that reward and incentives are not classified as benefits and therefore are not subject to the same prohibition on mid-year changes in benefits that we adopted in 2008 (73 FR 43628). Historically, we have permitted changes in administrative rules or policies for other things that are not benefits; non-benefit changes midyear are governed by the requirements relating to mid-year plan rule changes presented at 42 CFR 422.111(d), which ensures that enrollees are notified of the changes at least 30 days before the effective date of the change. We believe that these considerations resolve the concerns underlying our proposal to prohibit mid-year changes in reward and incentive programs. Consequently, we are not finalizing the proposed regulatory change to prohibit midyear changes to R&I.

After consideration of the comments we received on proposed § 422.134 and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed regulation with some limited changes from the proposal. Specifically, we are finalizing minor technical and grammatical changes throughout the regulation and several substantive changes. The substantive changes include: (1) Changes in the codification and application of the uniformity and accommodation policies finalized in paragraphs (c)(1)(iv) and (v) but that were proposed in paragraphs (c)(2)(ii)(A) and (B); (2) clarifying changes in paragraph (d)(1)(i) regarding how all qualifying individuals must be offered the same rewards for the particular target activity; (3) clarifying changes in the definition of qualifying individual; and (4) clarifying changes in paragraph (d)(1)(iii) to address delivery of a reward. In addition, we are not finalizing paragraph (g)(4). Because § 422.134 as finalized here substantially reorganizes the existing regulation while maintaining most of the current requirements, Table E6 summarizes where existing provisions have been moved and where we are codifying existing guidance.

TABLE E6—COMPARISON OF FINALIZED CFR REGULATIONS WITH CURRENT CFR REGULATIONS

§ 422.134, CMS–4190–F2 (as finalized)	Brief summary	Current provision
(a) Definitions	Provide definitions of R&I, reward item, target activity etc.	Codifies terms and concepts used in the regulation consistent with current guidance.
(b) Offering an R&I program	Plans may offer an R&I Program	Current 422.134(a).
(c) Target Activities	One comprehensive list of all requirements and prohibitions (Details are provided in the following rows).	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(c)(1)	Requires that the level of completion of the target activity be specified.	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(c)(1)(i)	Specifies that the target activity must directly involve the qualifying individual.	Codifies existing guidance.
(c)(1)(ii)	The target activity must be specified, in detail, as to the level of completion needed in order to qualify for the reward item.	Clarification and restatement of current § 422.134(c)(1)(i) and codifies existing guidance.
(c)(1)(iii)	The target activity must be health related	Currently § 422.134(a) and in existing guidance.
(c)(1)(iv)	The target activity is required to be uniformly offered to all qualifying enrollees.	Current § 422.134(b)(2).
(c) (1) (v)	Accommodations are required for those unable to do the target activity but otherwise qualify.	Codifies existing guidance related to the non-discrimination requirement in current § 422.134(1)(1)(ii).

TABLE E6—COMPARISON OF FINALIZED CFR REGULATIONS WITH CURRENT CFR REGULATIONS—Continued

§ 422.134, CMS–4190–F2 (as finalized)	Brief summary	Current provision
(c)(2)	Prohibitions on target activities	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(c)(2)(i)	The target activity shall not be related to Part D benefits.	Codifies existing guidance and the interpretation adopted in the 2014 final rule.
(c)(2)(ii)	The target activity shall not be discriminatory	Current § 422.134(b)(1) prohibits discrimination in the R&I program generally.
(c)(2)(ii)(A)	Not reward a health status measurement	Codifies existing guidance related to the non-discrimination requirement in current § 422.134(1)(1)(ii).
(d) Reward items	List of requirements, prohibitions, and permissions	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(d)(1)	Requirements that must be met for reward items	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(d)(1)(i)	Reward items must be identically offered to all qualifying enrollees completing the target activity.	Current § 422.134(b)(2) and codifies current guidance.
(d)(1)(ii)	Reward is direct and tangible	Codifies existing guidance.
(d)(1)(iii)	Ownership transfer of reward items for target activities completed within the contract year during which this R&I program was offered.	Codifies and clarifies existing guidance.
(d)(2)	Prohibitions on reward items	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(d)(2)(i)	Prohibition of cash and monetary rebates	Current § 422.134(c)(2)(i).
(d)(2)(i)(A) and (B)	Definition of cash, cash equivalents or other monetary rebates.	New provision to clarify terms.
(d)(2)(ii)	Value of reward item does not exceed value of target activity.	Current § 422.14(c)(1)(iii).
(d)(3)	Reward not based on elements of chance	Codifies existing guidance.
(d)(3)	Allowance of i) tokens and ii) specified gift cards	Codifies existing guidance.
(e) Marketing Requirements	Makes marketing requirements as found in Subpart V of 42 CFR 422 applicable to this section 422.134.	Current § 422.134(c)(2)(ii) prohibits targeting new enrollees; marketing requirements are otherwise not in current § 422.134.
(f) R&I Disclosure	Disclose information and provide reports on request to CMS.	Current § 422.134(c)(3).
(g) Miscellaneous	Items not directly about requirements of reward item, target activity, marketing, or disclosure.	Requirements and prohibitions are currently scattered throughout current § 422.134 and codifies existing guidance.
(g)(1)	Compliance with other laws (anti-kickback, fraud, etc.)	Current § 422.134 (c)(1)(iv).
(g)(2)	Possible sanctions for violation	Current § 422.134(b)(3).
(g)(3)	Non-benefit expense in bid	Codifies current guidance about application of bidding regulations at §§ 422.254 and 422.256.

E. Requirements for Medicare Communications and Marketing (§§ 422.2260–422.2274; 423.2260–423.2274)

Sections 1851(h) and (j) of the Act provide a structural framework for how Medicare Advantage (MA) organizations may market to beneficiaries and direct CMS to adopt standards related to the review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(*l*) of the Act applies certain prohibitions under section 1851(h) to Part D sponsors in the same manner as such provisions apply to MA organizations. CMS has adopted regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in § 422.111; 42 CFR part 422, subpart V; § 423.128; and 42 CFR part 423, subpart V; these regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under § 417.428, most marketing requirements in Subpart V of part 422 apply also to section 1876 cost plans. CMS has long provided further interpretation and guidance for these regulations in the form of a marketing manual titled the Medicare Communications & Marketing Guidelines (MCMG), previously known as the Medicare Marketing Guidelines. Because the proposal and this final rule are applicable to MA organizations, Part D plan sponsors, and cost plans, we refer to each of these regulated entities as a ''plan.''

In the February 2020 proposed rule, CMS proposed to codify guidance contained in the MCMG by integrating it with the existing regulations. To incorporate the guidance, we proposed to reorganize and redesignate the existing and proposed provisions according to the topics included in the MCMG; we explained that this order and organization was familiar to the Medicare Advantage, cost, and Part D plans that are subject to the rules. As a result, the proposed regulatory provisions reflected some changes to the current regulations, even though CMS did not propose to substantively change much of the policy. To be clear, the policies we proposed to codify are not new; they are in the MCMG and were

developed over time in concurrence with stakeholder feedback to implement and administer the current regulations.

The first of the policies that CMS proposed to codify, in §§ 422.2260 and 423.2260, is the guidance related to the definitions of ''marketing'' and ''communications,'' as well as additional definitions from the MCMG. As explained in the February 2020 proposed rule, CMS has amended the marketing regulations for both the MA and the Part D programs at 42 CFR parts 422 and 423, subparts V, respectively, since their original implementation, and provided sub-regulatory guidance in the MCMG each time to ensure beneficiaries receive the necessary information to make informed choices. Recently, in the April 2018 final rule, we established new definitions for communications materials and activities and marketing materials and activities in 42 CFR 422.2260 and 423.2260, which set out the scope of materials and activities subject to the regulations. In the 2019 MCMG, we clarified these definitions based on our interpretation of the regulatory terms ''intent'' and ''content'' as the deciding factors for when a communication activity or material is marketing.

We proposed to codify the MCMG guidance and revise the regulation text at §§ 422.2260 and 423.2260 to align more closely with the interpretation explained in our guidance. Specifically, we proposed that ''marketing'' means communications materials and activities that meet certain standards for intent and content that were enumerated in the proposed regulation text. For the *intent* standard, we proposed the same intent language that is in the current regulation, with a technical change to separately list out two different intent standards (paragraphs (1)(i)(B) and (C) in the proposed definition of marketing) that are in one paragraph (paragraph (3)) in the current definition of marketing at §§ 422.2260 and 423.2260. We note that a typographical error appeared in the description of this technical change in the preamble to the February 2020 proposed rule, which incorrectly stated that the two separate intent standards described here appeared at paragraphs (1)(ii) and (iii) of the proposed rule's definition of marketing (whereas this text actually appeared in paragraphs (1)(i)(B) and (C) of the proposed rule), and that these standards appear in one paragraph (paragraph (3)) of the current definition of marketing materials at §§ 422.2260 and 423.2260 (whereas these standards currently appear in paragraph (3) of the current definition of marketing in the same regulations). We explained in the February 2020 proposed rule that, when evaluating the intent of an activity or material, we intended, consistent with our current practice and guidance, to consider objective and contextual information (for example, audience, timing, etc.) in applying the proposed definition. Under our proposal, CMS would not be limited by the plan's statements about its intent.

In the content standard, we proposed that the regulation state affirmatively what must be included for a communications activity or material to be a marketing activity or material, rather than stating what is excluded (as the current regulation does). We explained that the first two types of content listed (paragraphs (2)(i) and (ii)) in the proposed definition of marketing are derived from the current regulation (although we explained that ''premiums'' was also included, consistent with the MCMG). We proposed to codify a third type of content in the definition (information on rewards and incentives programs), as we wanted to be clear that while rewards and incentives themselves are not a benefit, they are used as a means of prompting a beneficiary to use a specific benefit, and therefore our policy has been that information on rewards and incentives fall within the definition of marketing. We explained that our proposal would avoid any confusion and ensure that plans continue to be aware that when providing any information on rewards and incentives, they must follow the same requirements as for other marketing. We also proposed to streamline the definitions by removing the list in the current regulation of examples of materials (for example, brochures or posters) and explained that we did not believe this list of examples is necessary, as we evaluate whether a material is marketing based on intent and content rather than its particular form. Additionally, we proposed to combine the definitions for ''communications'' and ''communications materials,'' as well as ''marketing'' and ''marketing materials'' to streamline the definitions section. We also explained that this would be consistent with how we have interpreted the current regulations that both activities and materials are subject to the same intent and content standards. We also proposed that the regulatory definition of ''communications'' state that communications activities and use of materials are those ''created or administered by the MA organization or any downstream entity.''

Finally, we proposed to codify at §§ 422.2260 and 423.2260 additional definitions that apply to plan marketing. Specifically, we proposed to add definitions of ''advertisement (ad),'' ''alternate format,'' ''banner,'' ''banner-like advertisements,'' and ''Outdoor Advertising (ODA).'' We explained that these familiar terms have been defined and used throughout the MCMG. Our proposed definitions of these terms included some technical and clean-up edits but were substantively consistent with current policy and guidance. We explained that in codifying much of the MCMG, we believed it was paramount that we codify these definitions which are used throughout the MCMG and in our proposed regulations.

We next proposed to codify, at §§ 422.2261 and 423.2261, requirements for plans to submit certain materials to CMS for review, the process for CMS review, and the standards by which CMS will perform the review. These requirements are currently found in §§ 422.2262, 422.2264, 423.2622, and 423.2264, as well as in section 90 of the MCMG, which builds upon those sections and includes detailed operational instructions to plans regarding submission, review, and distribution of marketing materials (including election forms). In particular, we proposed at §§ 422.2261(a)(1) and 423.2261(a)(1) that the Health Plan Management System (HPMS) would be the primary system of record and the mechanism by which CMS would collect and store submitted plan materials for review and evaluation. Additionally, we proposed to codify, at §§ 422.2261(a)(2) and 423.2261(a)(2), our current policy that only plans can submit materials to CMS for review and approval for use and to specify that this policy prohibits third parties/downstream entities from submitting materials directly to CMS. Additionally, in new §§ 422.2261(d) and 423.2261(d), we proposed to codify that CMS would review submitted materials for compliance with all applicable requirements in §§ 422.2260 through 422.2267 and §§ 423.2260 through 423.2267 and that the benefit and cost information accurately reflects the plan's bid. We explained the proposed standards are consistent with our current policy and how we review marketing materials.

We next proposed to codify general standards for plan communications, including requirements related to product endorsements and testimonials and standardization of certain materials (specifically, certain telephone numbers and material IDs) at §§ 422.2262 and 423.2262. These standards are currently found in §§ 422.2268(a) and 423.2268(a), which also include examples of what plans may not do.

While the proposed regulations included the current general standards prohibiting MA plans from misleading, confusing, or providing inaccurate information to current or potential enrollees, we proposed to include additional examples of what plans may not do (in paragraph (a)(1)) and to incorporate examples of what plans may do (in paragraph (a)(2)), consistent with section 30 of the MCMG.

We also proposed to codify, at §§ 422.2262(b)(2) and 423.2262(b)(2), requirements regarding endorsements and testimonials that are in the policy currently found in section 30.8 of the MCMG. We proposed in §§ 422.2262(b)(1) and 423.2262(b)(1) that, consistent with our current policy, product endorsements and testimonials may take different forms. We also proposed to codify at §§ 422.2262(c) and 423.2262(c) requirements currently found in section 30 of the MCMG related to including telephone numbers (specifically, customer service numbers and 1–800–MEDICARE) in materials. We explained that these additional parameters for how telephone numbers are communicated in communications and marketing ensure that beneficiaries get useful and accurate information. Finally, we proposed to codify at §§ 422.2262(d) and 423.2262(d) requirements related to standardized material identification, currently found in section 90.1 of the MCMG.

We proposed to codify at §§ 422.2263 and 423.2263 requirements related to how plans may conduct marketing, which is specified as a subset of communications and therefore also subject to the requirements proposed in §§ 422.2262 and 423.2262. First, we proposed to clarify, at §§ 422.2263(a) and 423.2263(a), that October 1 is the date plans may begin marketing for the upcoming plan year. This is consistent with longstanding guidance, but the current rule lacks specificity and context. We also proposed to codify at §§ 422.2263(b) and 423.2263(b) examples of what plans may not do in marketing. As explained in the February 2020 proposed rule, this list reflects current policy in existing §§ 422.2268(b), 423.2268(b) and section 40.1 of the MCMG, with some technical edits. As our proposal was to codify all current requirements and guidance on marketing and communications, we explained that a number of the prohibitions that are currently stated in §§ 422.2268(b) and 423.2268(b) would be codified elsewhere in our proposed regulations, where the provisions would topically belong under the new regulatory structure. Although not discussed in the preamble to the February 2020 proposed rule, §§ 422.2263(b)(2) and 423.2263(b)(2) included a provision specific to the prohibition on providing gifts unless they are of a nominal value; the proposed regulation provided that we would defer to guidance from the HHS Office of the Inspector General (OIG) to determine what dollar threshold to use to determine if a gift is of nominal value. Under current CMS guidance in the MCMG, section 40.4 applies the current regulation prohibiting gifts other than nominal gifts to set a cost threshold of $15 per gift and $75 aggregated, per person per year, which are the amounts that the HHS OIG identified as nominal amounts in its current applicable guidance, dated December 7, 2016 and available on-line here: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2006053221-hi-oigpolicystatementgiftsofnominalvalue.pdf.* Proposed §§ 422.2263(b)(2) and 423.2263(b)(2) provided that a determination of nominal value would be governed by guidance published by the HHS OIG in order for §§ 422.2263(b)(2) and 423.2263(b)(2) to remain in alignment with OIG guidance and policy about nominal gifts going forward. We note here that achieving alignment on this issue provides clearer and more consistent direction from the government to regulated plans and provider greater consistency in overall monitoring and enforcement. Finally, at § 422.2263(c), we proposed to codify requirements related to marketing of Star Ratings currently located in section 40.6 of the MCMG.

We next proposed to codify, at 42 CFR 422.2264 and 423.2264, requirements related to plan contact with Medicare beneficiaries and a beneficiary's caregivers. Our proposed regulation text used the term ''beneficiary contact'' to include all outreach activities to a beneficiary or a beneficiary's caregivers by the plan or its agents and brokers. First, in 42 CFR 422.2264(a)(1) and 423.2264(a)(1), we proposed to codify the policy for when unsolicited contact is permitted, including direct mail and email which are currently found in the MCMG. Under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we proposed to codify the rules for when unsolicited direct contact with beneficiaries is and is not permitted. Currently, §§ 422.2268(b)(13) and 423.2268(b)(13) explicitly prohibit plans from soliciting door-to-door or engaging in other unsolicited contact and our guidance in section 40.2 of the MCMG applies and interprets this prohibition in specific contexts, with additional detail about activities we consider (and do not consider) unsolicited contact. Additionally, under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we also proposed to codify the current policy that unsolicited direct messages from social media platforms are also prohibited, as currently addressed in section 30.6 of the MCMG. We also proposed to clarify that plans may contact their current members (including those individuals enrolled in commercial plans who are becoming eligible for Medicare) regarding plan business, which is consistent with our current policy in the MCMG in section 40.3. Finally, in §§ 422.2264(c) and 423.2264(c), we proposed to codify requirements regarding events (such as meetings) with beneficiaries, currently found in section 50 of the MCMG. As explained in the February 2020 proposed rule, the proposed regulation text included specific provisions that are consistent with our current policies of what plans may do. Our proposed revisions to §§ 422.2267 and 423.2267 would incorporate the policy currently in §§ 422.2264 and 423.2264, ''Guidelines for CMS Review,'' with more detail. We explained that whereas the current §§ 422.2264 and 423.2264 provide general guidance on important information that plans must provide to a beneficiary interested in enrolling, proposed §§ 422.2267 and 423.2267 would include more detailed standards and requirements on the specific materials or content that a plan must produce. The proposed rule explained that, collectively, the required materials and content outlined in proposed §§ 422.2267 and 423.2267 account for the requirements in the current §§ 422.2264 and 423.2264.

We next proposed to codify requirements for plan websites at new §§ 422.2265 and 423.2265. As explained in the February 2020 proposed rule, the current regulations at §§ 422.111(h)(2) and 423.128(d)(2) establish the requirement for Part C and Part D plans to have an internet website and include requirements regarding content that must be posted on the website and the MCMG has historically provided additional detail on required website content, including the dates by which plan content was required to be posted annually. Proposed §§ 422.2265 and 423.2265 would restate the requirement to have a website and codify the additional requirements and guidance currently in section 70 of the MCMG.

We next proposed to codify at §§ 422.2266 and 423.2266 requirements plans must follow for activities in a healthcare setting, including requirements for provider-initiated

activities, plan-initiated provider activities, and plan activities. We explained that proposed §§ 422.2266 and 423.2266 would include requirements currently located in §§ 422.2268(b)(7) and 423.2268(b)(7) and codify policies interpreting those requirements in section 60 of the MCMG.

We next proposed to codify, at new §§ 422.2267 and 423.2267, instructions for how plans should submit required materials to CMS for review. Specifically, we proposed to codify the guidance for standardizing and monitoring the production of required documents, including a listing of these required documents, currently found in section 100 and Appendices 2, 3, 4, and 5 of the MCMG. As we explained in the February 2020 proposed rule, some of these required materials are addressed in current regulations (for example, the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC)) while others are only described in the MCMG (for example, the Summary of Benefits (SB)). Therefore, we proposed to specify all of the required materials and content in §§ 422.2267(e) and 423.2267(e). In doing so, we refer to current established regulatory authority when relevant. We did not propose any changes to §§ 422.2272 and 423.2272, which address licensure of marketing representatives and confirmation of marketing resources.

Finally, we proposed to consolidate, at §§ 422.2274 and 423.2274, requirements related to plan compensation to agents, brokers and other third parties currently found at §§ 422.2272, 422.2274, 423.2272, and 423.2274, and section 110 of the MCMG. We explained in the February 2020 proposed rule how our proposed revised and consolidated text generally would not change the policies currently laid out in the existing regulations and guidance, but that significant technical and organizational edits were used to improve clarity and reduce duplication in the proposed regulation text. We proposed to codify our method for calculating fair market value for agent/broker compensation, as current regulations limit compensation to fair market value but do not further define it or provide the methodology CMS uses for calculating it. As we explained in the February 2020 proposed rule, CMS first developed the Fair Market Value (FMV) calculation used for regulating plan compensation paid to agents and brokers for contract year 2009 and published these rates in an HPMS memo on December 24, 2008. To develop the FMV, we requested that plans submit the fees they paid in 2006 and 2007, as well those planned for 2009; plans submitted approximately 19,000 records that we analyzed based on geographic location and organization type. Following this analysis, we developed the FMV for MA plans, 1876 cost plans and Part D plans. The MA FMV rates for enrolling a single beneficiary were established at a national rate of $400, with exceptions for Connecticut, Pennsylvania, and DC ($450), and California and New Jersey ($500), based on higher rates being reported in those geographic areas. The PDP rate was set at $50 for a single enrollment nationally. For years after contract year 2009, we calculated the FMV based on the National Per Capita MA Growth Rate for aged and disabled beneficiaries for Part C and 1876 Cost plans and the Annual Percentage Increase for Part D, using the following formula: Current Year FMV + (Current Year FMV * National Per Capita MA Growth Rate for aged and disabled beneficiaries) for MA and 1876 cost plans and Current Year FMV + (Current Year FMV * Annual Percentage Increase for Part D) for PDP plans. Our proposal for §§ 422.2274 and 423.2274 would codify a definition of FMV with this formula. Based on this formula, the FMV for 2022 would be the FMV for CY 2021 + (CY2021 FMV * National Per Capita Growth Rate for aged and disabled beneficiaries). We issued an HPMS memo on May 29, 2020 with the FMV amounts for 2021. For CY2021, the FMV rates for MA and 1876 Cost Plans are: National FMV is $539, FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, FMV for California and New Jersey is $672 and the FMV for U.S. Virgin Islands and Puerto Rico is $370. For CY2021, the FMV rate for all Prescription Drug Plans is $81.

Additionally, we noted that section 110.7.1 of the MCMG currently clarifies when the regulations at §§ 422.2274(b)(2) and 423.2274(b)(2), which require recovery of agent compensation when a newly-enrolled individual disenrolls within the first 3 months of enrollment (rapid disenrollment), do not apply. We proposed to codify that guidance at §§ 422.2274 and 423.2274; although the preamble of the February 2020 proposed rule identified this policy as being codified in proposed paragraph (g)(2)(ii)(C), our proposed regulation text addressed exceptions to the requirement for plans to recover agent compensation at paragraph (d)(5)(iii). In addition, we refer readers to section IV.C. of this final rule, which addresses our proposal regarding referral and finder's fees for agents and brokers.

In summary, our proposal was for new and revised regulatory sections in Subpart V as follows:

- Sections 422.2260 and 423.2260 revise and streamline the current definitions of ''communications'' and ''marketing,'' and codify definitions for additional key terms from the MCMG used throughout the proposed regulations.
- Sections 422.2261 and 423.2261 contain requirements for plans to submit certain materials to CMS for review, the process for CMS review and the standards by which CMS will perform the review, taken from current §§ 422.2262, 422.2264, 423.2622, and 423.2264 and section 90 of the MCMG.
- Sections 422.2262 and 423.2262 specify the general standards for plan communications materials and activities, including endorsements and testimonials, and examples of what plans may and may not do. These sections also contain requirements related to standardization of certain key elements of communications materials (specifically, telephone numbers and material IDs). These sections include policies currently articulated in current §§ 422.2268 and 423.2268, as well as sections 30 and 90.1 of the MCMG.
- Sections 422.2263 and 423.2263 contain requirements for how plans must conduct marketing. These sections will incorporate requirements currently in §§ 422.2268 and 423.2268, as well as additional guidance from section 40 of the MCMG.
- Sections 422.2264 and 423.2264 address the rules for plan contact with Medicare beneficiaries. These sections include requirements and standards currently in §§ 422.2268 and 423.2268, and further expanded upon in sections 40 and 50 of the MCMG.
- Sections 422.2265 and 423.2265 explain the requirements for plans to have a website as well as what must, may, and must not be on the website. These sections include material currently in section 70 of the MCMG.
- Sections 422.2266 and 423.2266 contain the requirements plans must follow for activities in a healthcare setting. These sections include material from current §§ 422.2268 and 423.2268, and from section 60 of the MCMG.
- Sections 422.2267 and 423.2267 provide instructions on materials and content that CMS requires plans to deliver or make available to beneficiaries, including required disclaimers. These sections include material from section 100 and Appendices 2, 3, 4, and 5 of the MCMG.
- Sections 422.2274 and 423.2274 consolidate requirements from §§ 422.2272, 422.2274, 423.2272, and

423.2274, and section 110 of the MCMG regarding agents, brokers, and compensation to third parties.

Finally, we requested comment on how CMS should implement prohibitions related to plan marketing during the open enrollment period (OEP). Section 1851(e)(2)(G)(iv) of the Act, as added by section 17005 of the Cures Act, prohibits marketing during the open enrollment period (OEP). The current regulations implementing the statutory prohibition on plan marketing during the OEP are at §§ 422.2268(b)(10) and 423.2268(b)(10). We explained in the February 2020 proposed rule that the MCMG includes additional guidance about what activities fall within this prohibition including, specifically, that plans are prohibited from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period (AEP), and leveraging agent/broker activities that target the OEP as a way to make further sales.

We received the following comments on our proposal and our responses follow:

Comment: Several commenters expressed support for CMS codifying the various requirements traditionally found in the MCMG. Many of these commenters questioned if CMS still intended to produce an MCMG after these regulations are adopted as final. Similarly, other commenters specifically requested that CMS continue to produce the MCMG in tandem with the requirements found in the final rule.

Response: CMS appreciates the favorable response to the codification of the many requirements typically found in the MCMG. While the agency believes it would be duplicative to continue to produce the MCMG in its current form, we do intend to continue producing sub-regulatory guidance to provide operational instruction to plans. We believe that the regulations we are finalizing in parts 422 and 423, subparts V are clear and succinct.

Comment: A commenter expressed concern that beneficiaries could be negatively impacted by CMS's decision to stop collecting co-branded relationship data in the Health Plan Management System (HPMS).

Response: CMS notes that the decision to no longer collect this data through the HPMS Marketing Module predates this rulemaking. Although CMS no longer collects co-branding information through the HPMS Marketing Module, the co-branding relationship data is collected elsewhere in HPMS, making the need to collect it twice in one system duplicative. In addition, plans continue to be responsible for all materials and activities, including those that they create or carry out in conjunction with any co-branded entities. All regulatory requirements pertaining to communications and marketing still apply to co-branded materials, including the requirement to submit all marketing materials to CMS. As a result, we do not believe that the negative impact on beneficiaries as contemplated by the commenter is likely.

Comment: A commenter suggested that CMS eliminate the requirement that plans and sponsors prorate agent/broker commissions. The commenter noted the amount of work to enroll an individual does not change if the enrollment takes place in November or in January, so the requirements related to prorating payments do not make sense and are unfair to Medicare-certified health insurance agents.

Response: CMS thanks the commenter for their input. Prorated payments of agent/broker commissions are a necessary component of the compensation requirements finalized in this rule because we believe that providing a full year payment to an agent, rather than a prorated amount, might incentivize agents and brokers to encourage beneficiaries to switch plans during the coverage year in order for the agent or broker to receive a full year of compensation, thus resulting in the unnecessary churning of beneficiaries from one plan to another. Section 1851(j)(2)(D) of the Act specifically directs the Secretary to establish limitations on compensation for agents and brokers to ensure payments create incentives for agents and brokers to enroll beneficiaries into the plan that best meets the beneficiary's needs. Providing a prorated amount incentivizes the agent or broker to find the plan that is the best fit for the beneficiary so that the beneficiary will remain enrolled throughout the year, rather than changing plans due to dissatisfaction with the coverage or feeling as though they were misled. The prorated compensation also provides an incentive for the agent or broker to continue to service the beneficiary's needs after the sale.

Comment: A commenter was in favor of CMS codifying the rules for agent/broker compensation, noting that the transparency is helpful for plans as well as agents and brokers.

Response: CMS appreciates the comment.

Comment: A few comments suggested that CMS provide more examples of specific materials that would fall under the definition of communication or marketing in §§ 422.2260 and 423.2260 of the regulation.

Response: CMS understands that examples can aid plans in better understanding the definitions of communications and marketing, but we do not believe that including examples in the regulation text are the best manner in which to achieve this objective. Given the more static structure of regulations as compared to the dynamic nature of communications and marketing, we believe that sub-regulatory guidance and training is the more appropriate manner by which to apply the regulatory definitions and standards to particular facts in order to identify and convey our requirements. With the finalization of the proposed amendments to §§ 422.2260 and 423.2260, CMS will gauge need for examples and provide them as required. With that said, we note the definitions codified in this final rule are consistent with our current practice and the current regulations, as we discussed in the February 2020 proposed rule; therefore the examples in section 20.1 of the MCMG dated September 5, 2018, and available online here: *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf,* remain applicable. In addition, we note that the extensive list of standardized and model materials in §§ 422.2267(e) and 423.2267(e) generally specifies which materials are communication materials and which are marketing materials.

Comment: A commenter suggested that definitions in §§ 422.2260 and 423.2260 such as ''alternate format,'' ''banner,'' ''banner-like advertisements,'' and ''outdoor advertising'' should be considered marketing activities because these types of materials are also evaluated on intent and content and not on their particular form.

Response: We agree that ''alternate format,'' ''banner,'' ''banner-like advertisements,'' and ''outdoor advertising'' are evaluated based on their intent and content. We clarify, however, that such materials are not automatically considered marketing under the definitions we proposed and are finalizing here at §§ 422.2260 and 423.2260, as specific materials in these formats could meet either the definition of communications or of marketing based on their intent and content. For example, a billboard (outdoor advertising) that says ''Super Medicare Advantage—a new choice in Medicare for 2022'' is not marketing as it does not

include or address the content outlined in paragraph (2) of the definition of ''marketing'' under §§ 422.2260 and 423.2260. Based on the possibility of these items being communications or marketing depending on the particular facts or circumstances, CMS is not changing the definitions.

Comment: A commenter suggested that CMS should consider establishing a separate pre-release review process for communications, given their importance for beneficiaries. The commenter specifically cited CMS required materials that are communications. The commenter strongly urged that in cases where CMS identifies inaccuracies or misleading information through a post-release review, CMS allow affected beneficiaries to have a special enrollment period, in order to mitigate consequences of decisions based on inaccurate or misleading information.

Response: We agree that appropriate oversight of communication materials is an important beneficiary protection. We believe that our current oversight processes ensure the appropriate level of beneficiary protection. CMS currently collects certain CMS required materials, such as the Evidence of Coverage making them subject to retrospective reviews. In addition, CMS reviews the accuracy of CMS required materials outside of the formal material submission process, for example provider directory reviews have been conducted outside of the formal HPMS material submission process for several years.

In this final rule, CMS is also maintaining authority (currently in §§ 422.2262(d) and 423.2262(d) and codified here at §§ 422.2261(c)(1) and 423.2261(c)(1)) to collect, prior to use by plans, certain designated communications materials that are critical to beneficiaries and plan enrollees understanding plan options or accessing their benefits; the final regulation text provides an example of a communications material that meets this standard: The Evidence of Coverage (EOC). CMS may also retrospectively collect any communications materials for subsequent review under §§ 422.504(f)(2)(vii) and 423.505(f)(2)(viii). In addition, CMS can collect data on communications materials through beneficiary complaints, and communication and marketing surveillance activities. In this final rule, we have included §§ 422.2261(c)(2) and 423.2261(c)(2) to ensure that CMS has the authority to require additional communications materials be submitted, or submitted and reviewed, prior to use based identified as a concern based on errors identified through the methods outlined above.

These regulatory authorities allow CMS to focus more closely on those materials that have the potential to have the greatest impact on beneficiary enrollment decision-making, without the need for a more burdensome process of collecting and reviewing all communication materials that have little impact on beneficiary choice.

In addition, in the proposed rule under §§ 422.2262(c) and 423.2262(c), we said that ''CMS does not generally require *submission and approval* of communications materials prior to use . . .'', which unintentionally did not accurately depict the current processes for material collection through the HPMS Marketing Module. In general, there are two ways that designated materials are submitted to CMS through the HPMS Marketing Module. The ''path'' a material takes is predetermined by CMS. One submission path includes when plans submit materials to HPMS, but these materials are not reviewed prospectively by CMS, but are subject to a retrospective review. An example of a material that would fall under this pathway is the EOC. A second submission pathway includes when plans submit materials to HPMS that CMS must review and approve prospectively and prior to their distribution. To clarify these requirements regarding the submission of materials, in this final rule we are editing §§ 422.2262(c) and 423.2262(c) to say that CMS does not generally require *submission, or submission and approval,* of communications materials prior to use.

With regard to the comment that CMS grant a special enrollment period based on receipt of inaccurate or misleading information, CMS has the ability to grant SEPs under §§ 422.62(b)(3)(ii) and 423.38(c)(8)(iii) when a plan or its agent, representative, or plan provider materially misrepresented the plan's provisions in communications as outlined in Subpart V of this part. Such actions are made on a case-by-case basis.

Comment: A commenter offered support of the codification of ''intent'' and ''content'' standards currently in the Medicare Communications and Marketing Guidelines. Specifically, the commenter supported CMS' proposal to provide a list of what must be included for a communication material or activity to be considered marketing, believing it eases the interpretation of the previous definition under §§ 422.2260 and 423.2260.

Response: We thank the commenter for their support.

Comment: A commenter voiced concern regarding the use of the word ''address'' as part of the definition of marketing under §§ 422.2260(2) and 423.2260(2). The commenter stated that the term was too expansive and vague and overly broadens the definition of marketing.

Response: CMS believes that since we changed the definition of marketing in the final rule ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' published in the **Federal Register** on April 16, 2018 (the April 2018 final rule), we have gained valuable experience through two ''marketing cycles'' applying and using the new definition. During this time, we have observed plans using marketing tactics that skirted the definition of marketing by addressing marketing content, such as benefits, premiums, or plan comparisons, without explicitly including the content that are specified in the definition of ''marketing'' that we proposed and are finalizing in §§ 422.2260 and 423.2260. For example, a plan advertisement that says ''Plan X monthly premiums are lower than your current Medicare Advantage plan'' would be marketing under our new definition but is not clearly within the scope of marketing materials in the current regulatory definition and guidance. While the advertisement doesn't list the premium or a specific ranking standard, it addresses both of these concepts and is clearly designed to draw a beneficiary's attention to a plan and to influence the beneficiary's enrollment decision. By using the term ''address'' in the definition we have proposed and are finalizing, we ensure our review of materials such as this example would be marketing under the revised definition adopted in this final rule. The revised definition that we are finalizing provides an important safeguard for Medicare beneficiaries.

Comment: A commenter expressed displeasure with the ''benefits disclaimer'' not being included in §§ 422.2267 and 423.2267 of the regulation. Prior to August 6, 2019, the MCMG required plans to include on marketing materials that list ten or more benefits the following disclaimer: ''this is not a complete description of benefits. Call [insert customer service phone number/TTY] for more information.''

Response: We proposed to codify our current policy as the decision to no longer require this specific benefits disclaimer predates this rulemaking. As plans must provide a Summary of

Benefits (SB) and the Pre-Enrollment Checklist (PECL) with an enrollment form, we believe the benefits disclaimer is no longer necessary. The SB outlines key benefits, and also provides information on how to access the Evidence of Coverage (EOC) for a comprehensive list of all benefits. The PECL prompts the beneficiary to review important information before making an enrollment decision, including reviewing the EOC. We believe these documents adequately put beneficiaries on notice that the EOC is the complete list of benefits and that the other documents are merely summaries. Therefore, we did not propose and are not finalizing a requirement to use the benefits disclaimer used in the past.

Comment: One commenter noted an error in § 422.2266(b). The commenter pointed out that the sentence should be fixed to say ''. . . including but not limited to,'' rather than ''. . . including, are not limited to . . .''

Response: We agree with the commenter and are correcting the sentence by replacing ''including, are not limited to'' with ''including'' in § 422.2266(b). However, we are not inserting the remainder of the text suggested by the commenter (''but not limited to''), as it is an accepted practice to interpret ''including'' as meaning ''including but not limited to.'' For consistency, we will apply these changes to § 423.2266(b).

Comment: A commenter expressed concern that we did not include the requirement that Plans/Part D Sponsors may only advertise in their defined service area, unless unavoidable.

Response: We note the decision to no longer restrict marketing outside of a plan's designated service area predates this rulemaking. This decision was made because it is self-policing, as CMS believes that MA Plans and Part D sponsors have little incentive to advertise outside of their service area since beneficiaries must live in the service area to be enrolled in the plan. In addition, CMS believes that there is no negative outcome should a beneficiary view marketing for a specific plan that is not available in their service area, with the exception of marketing about Star Ratings; with Star Ratings, a beneficiary might be misled of confused about the rating of specific plan availing in one area that is offered by a company with a higher rated plan in a different service area. We are finalizing, in 42 CFR 422.2263(c)(5) and 423.2263(c)(5), the current prohibition on marketing Star Ratings outside of a service area that is discussed in the MCMG, section 40.6 (applying the prohibition on misleading marketing and communications) unless the marketing is conveying overall the organization's performance. If the Star Ratings are used in marketing that is distributed outside of the specific service area, the plan must do so in a way that is not confusing or misleading. CMS's current policy is to limit Star Rating marketing to the service area in which the rating is applicable. This policy is to ensure that beneficiaries are not mislead into believing that a Star Rating earned by ''Plan A'' applies to ''Plan B's'' service area. However, we recognize that organizations that are expanding into new service areas would not necessarily have received Star Ratings. We believe that an organization entering a new area should be able to demonstrate the quality of their plan when marketing, provided it is not misleading or confusing. Therefore, we are modifying our current policy to permit the marketing of Star Ratings outside of the service area if done in a way to convey overall organization performance without being misleading or confusing. This is consistent with the overall policy of permitting marketing to occur outside of a plan's service area.

Comment: A few commenters requested that we expand the Annual Notice of Change (ANOC) to include notice to enrollees when providers seen by that enrollee during the past year are no longer in the plan's network (focusing on Primary Care Providers and specialists).

Response: The ANOC is a document geared for mass distribution to all enrollees. Adding specific beneficiary information of this type to the ANOC would not be feasible or advisable given the limitations of current technology, the effort such an addition would require, and the possibility of inaccurate data being provided to enrollees given the fluid nature of provider networks and contracting. Moreover, adding this information to the ANOC would duplicate an existing requirement at 42 CFR 422.111(e) that plans notify their enrollees when a provider the enrollee regularly sees will no longer be in the plan's network.

Comment: A commenter stated that the prohibition on robocalling is implied in §§ 422.2264 and 423.2264. The commenter requested that CMS list robocalling as a prohibited activity.

Response: We appreciate the comment and agree that the prohibition on unsolicited telephone calls includes robocalling. We are finalizing the regulation text at §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv) with the addition of robocalls to the list of prohibited activities to eliminate any chance of ambiguity when it comes to robocalls being considered an unsolicited telephone call. We note as well that any other type of telephone solicitation would be prohibited even if not specifically listed because the regulation prohibits all unsolicited telephone solicitation, not merely calls from a live person.

Comment: A commenter requested that CMS prohibit MA plans and Part D sponsors from contacting enrollees based on plan business if the enrollee has an external agent of record. The commenter expressed concern that plans could reach out to a member who was enrolled by an agent, and through a process such as upselling, enroll the member into a different plan, which could result in the agent no longer receiving renewal compensation.

Response: We understand the concern, but believe that this concern — regarding changes in enrollment directly solicited by the plan that lead to changes in agent compensation — is a matter that should be addressed in the contract between plans and brokers. We reiterate that cost plans, in addition to MA organizations and Part D sponsors, must comply with the marketing and communications standards that we are finalizing here based on existing § 417.428, which requires cost plans to comply with part 422, subpart V, with the exception of § 422.2276. In applying those provisions, references to MA organizations should be read as references to HMOs and CMPs, that is cost plans in part 417.

Comment: A commenter noted differences in the wording between the February 2020 proposed rule in §§ 422.2264(a)(4) and 423.2264(a)(4) (''MA organizations are responsible for ensuring sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including, but not limited to, do not call requirements,'') and section 110.3 of the MCMG (Plan/Part D sponsor Oversight) (''Plans/Part D sponsors must oversee downstream entities to ensure agents/brokers abide by all applicable state and federal laws, regulations, and requirements.''). The commenter expressed concern that the wording might result in states requiring that MA plans and Part D sponsors be subject to a multiplicity of state laws that are expressly preempted by federal law.

Response: Existing regulations at §§ 422.504(i) and 423.505(i) regulate the relationship between plans and their first tier, downstream, and related entities and require plans to maintain oversight and monitoring of these entities and that the related entity, contractor, or subcontractor must comply with all applicable Medicare

laws, regulations, and CMS instruction. Therefore, we believe that there are adequate standards in place to ensure that the beneficiary protections and marketing and communications rules we are adopting here will apply to related entities, contractors and subcontractors that market on a plan's behalf. In addition, section 1851(h)(7)(A) provides that agents and brokers must be licensed and appointed for the states where they sell and we believe the regulation is consistent with that statutory requirement. Based on this, CMS is not including the provision in proposed §§ 422.2264(a)(4) and 423.2264(a)(4) in the final rule.

Comment: A commenter requested CMS expand the requirement at §§ 422.2274(c)(8) and 423.2274(c)(8) to state that plans must oversee first tier, downstream, and related entities to ensure agents and brokers do not charge beneficiaries a marketing fee.

Response: CMS shares the commenter's concern about charging beneficiaries marketing fees. This final rule governs MA organizations, Part D sponsors, and their first tier, downstream, and related entities (including agents and brokers). As required under §§ 422.504(i) and 423.505(i), MA organizations and Part D sponsors are ultimately responsible for their downstream entities. Therefore, CMS could take compliance action against the MA organization or Part D sponsor for the individual's behavior if they are affiliated with, or acting on behalf of the organization, plan, or sponsor. To clarify this point further, we are finalizing §§ 422.2274(c)(8) and 423.2274(c)(8) with revisions to prohibit marketing consulting fees from being charged when a beneficiary is considering enrollment in a plan. The marketing and communications regulations finalized here also apply to cost plans based on § 417.428; although there are no explicit regulatory provisions in Part 417 regarding the downstream entities and subcontractors of cost plans, cost plans must comply with the requirement that the plan ensure that beneficiaries are not charged marketing consulting fees; we therefore expect that cost plans will instruct and contract with their subcontractors accordingly to ensure that beneficiaries are not charged these fees.

Comment: Several commenters suggested that CMS do more to protect dually eligible beneficiaries from misleading marketing practices. The commenters suggested that CMS require when an agent/broker disenrolls a beneficiary from an integrated product that the agent/broker provide the beneficiary a clear explanation of the product from which the beneficiary is disenrolling, including explaining how the beneficiary's disenrollment from an integrated product to a non-integrated product might impact their health care service delivery. Commenters also suggested that outbound enrollment verification calls by plans and sponsors include similar information. Commenters also suggested that CMS should require actual contact with the beneficiary during these verification calls.

Response: CMS believes the requirements under § 422.2262(a)(1)(xv), (xvi), (xvii), and (xviii) (and the parallel provisions in Part 423 applicable to Part D plans) function to protect dually eligible beneficiaries from misleading marketing practices. Before additional requirements are considered, CMS will continue to monitor how MA plans and Part D sponsors market to dually eligible beneficiaries to determine if additional requirements are needed. CMS believes that the general requirements set forth in Subpart V of this rule establish the framework necessary for the agency to pursue additional oversight activities to apply the standards in this final rule to specific factual circumstances without further rulemaking. We will also explore changes to agent/broker training and testing to address this.

Regarding outbound enrollment verification, as reflected in the requirement in current §§ 422.2272(b) and 423.2272(b) (which are not being amended in this final rule), plans are no longer limited to verifying enrollment by only phone calls. We now permit plans to confirm enrollment by letter through the mail because our experience has demonstrated that it is virtually impossible for plans to guarantee actual beneficiary contact by phone. Moreover, a hardcopy letter gives the beneficiary a detailed record that can be saved and provided to others, including the State Health Insurance Assistance Program (SHIP), for help and guidance, if needed.

Comment: Several commenters offered support for the requirement at §§ 422.2262(a)(1)(xv)–(xviii) and 423.2262(a)(1)(xiv)–(xvii) prohibiting MA plans marketing non-D–SNPs as if they were designed for dually eligible beneficiaries or claiming that they have a relationship with the state Medicaid agency.

Response: We thank the commenters for their support.

Comment: A commenter voiced concern that the language found in §§ 422.2262(a)(1)(xvi), stating that plans may not market a non-dual eligible special needs plan as if it were a dual eligible special needs plan, was too vague and ambiguous. The commenter noted that the language goes beyond the language found in the current MCMG and that existing objective limitations are already incorporated in the other subparagraphs under § 422.2262(a)(1).

Response: We disagree with the commenter that the language is vague and ambiguous. Through our experience of investigating complaints concerning D–SNP look-alikes, we have found many examples of plans mimicking the look and language used by D–SNPs in a manner that is confusing or misleading to the beneficiary. While we agree that other provisions in this rule, for example § 422.2262(a)(1)(i), generally protect against misleading materials, given the vulnerability of the dually eligible population, we believe that the requirements as written are warranted and are finalizing these prohibitions as proposed.

Comment: A commenter noted that the guidance regarding dual look-alike plans in the MCMG prohibits ''targeting marketing efforts exclusively to dual eligible individuals . . .'', whereas, the requirement in the February 2020 proposed rule prohibits ''targeting marketing efforts primarily to dual eligible individuals . . . .'' The commenter suggested that the final rule use the ''exclusively'' standard from the MCMG.

Response: We respectfully disagree. In our experience investigating complaints concerning the marketing of D–SNP look-alikes, the current MCMG language of ''exclusively'' has allowed look-alike plan materials to include content that is targeted almost exclusively towards dually eligible beneficiaries with the exception of one or a few sentences noting that the plan was open to all Medicare eligible individuals. Based on this experience, combined with the vulnerability of the dually eligible population, we believe it is important to bolster the language to include those materials that are primarily focused at the dually eligible individuals. As such, we will finalize the language under § 422.2262(a)(1)(xvii) as proposed.

Comment: A commenter was concerned that the language proposed in §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) was too vague. The proposal requires the agent/broker to provide an opportunity for the beneficiary to determine if they want to continue to a marketing event directly following an educational event. The commenter stated this was too vague, resulting in the agent/broker determining if the beneficiary has given consent.

Response: We agree with this concern in part and have strengthened the language at §§ 422.2264(c)(2)(i) and

423.2264(c)(2)(i) that requires agents and brokers make the beneficiary aware of a change in meeting type from educational to marketing and to provide the opportunity for beneficiaries to leave prior to the start of the marketing event. With this change from the proposed rule, we do not believe that the regulation text is vague or requires the agent, broker or other plan representative to guess whether a beneficiary wishes to remain for the marketing event. We also note that agents and brokers, as downstream entities of plans, must abide by the requirements in Subpart V of this rule, including §§ 422.2262(a)(1)(iii) and 423.2262(a)(1)(iii), which prohibits them from engaging in activities that could mislead or confuse Medicare beneficiaries.

Comment: A commenter expressed concern that the revisions found in §§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii) of the February 2020 proposed rule will allow agents or brokers to set up marketing appointments directly following educational events. The commenter stated that ''it appears that an agent or broker could immediately step out of the room, so to speak, and conduct a sales event.'' Similarly, another commenter questioned why a previous sub-regulatory requirement regarding separation of the time and place of marketing and educational events was not included in the February 2020 proposed rule.

Response: The policy decision to allow marketing and educational events to occur in a close physical and time proximity predates this rulemaking, as reflected in CMS's August 6, 2019 Medicare Communications and Marketing Guidelines Update Memorandum (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly*). We made this change because it can be burdensome for beneficiaries to travel to events. If the beneficiary attends an educational event and wants to hear more plan specific information via a sales event, we believe it should be allowed to happen around the same time, rather than requiring the beneficiary to return on a different day or to a different venue. We, however, share the concern regarding the meeting type switching without the beneficiary being aware. As such, we are further strengthening the language proposed at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), to require that a beneficiary be made aware of a change from educational event to marketing event and given the opportunity to leave prior to the event beginning.

In addition, if a beneficiary is attending a personal marketing appointment with a plan representative, the representative would need to have the beneficiary complete a scope of appointment (SOA) form prior to any discussion as required under §§ 422.2274(b)(3) and 423.2274(b)(3). Finally, current beneficiary protections, such as the requirements under §§ 422.2262 and 423.2262 that plans may not engage in activities that could mislead or confuse Medicare beneficiaries or misrepresent the plan (or the entity offering the plan, such as the MA organization, cost plans, or Part D sponsor), remain in place under the regulations we are finalizing here.

Comment: Several commenters noted that in an HPMS memo released on August 6, 2019 titled ''Medicare Communications and Marketing Guidelines,'' CMS deleted the requirement to include the hours of operations from the MCMG (section 30.4 of the 2019 MCMG) when listing the customer service telephone number from materials.

Response: CMS thanks the commenters for identifying this issue. Our intention in the HPMS memo was to eliminate the listing of the hours of operation for telesales telephone numbers and not to eliminate the need for including the customer service hours of operation when the customer service call center is mentioned. CMS inadvertently removed section 30.4 entirely. We believe enrollees (or prospective enrollees) should know when they can reach their plan. As proposed and finalized, the substance of §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) remains largely the same: when a plan includes its customer service number, the hours of operation for the call center must be prominently included at least once. However, we are finalizing changes from the proposed regulation text (which addressed the first time the customer service number appears) to focus on ensuring that the information is provided in a useful way to beneficiaries by finalizing a requirement that the hours of operation be prominently included at least once. In addition, we note that we are finalizing a similar change in §§ 422.2262(c)(1)(iii) and 423.2262(c)(1)(iii) regarding inclusion of the hours of operation for 1–800–MEDICARE; we proposed that the hours of operation be included each time the 1–800–MEDICARE telephone number or Medicare TTY appears but are finalizing a requirement that the hours of operation be prominently included at least once on the material that includes the 1–800–MEDICARE telephone number or Medicare TTY. These provisions will ensure that beneficiaries have sufficient information to know how and when to reach the customer service call center.

Comment: A commenter requested that CMS consider updating §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) to say that the hours of operation must be listed ''at least once'' instead of ''the first time'' as it was in the February 2020 proposed rule. The commenter stated that changing the requirement would provide flexibility regarding where the hours of operation are placed on materials, resulting in a more beneficiary-friendly location.

Response: We agree that allowing flexibility in where the hours of operation for the customer service call center is listed could result in more beneficiary-friendly materials. We are, however, concerned that updating the requirement to say ''listed at least once'' may allow the hours of operation to be placed in a way that would obscure this information from beneficiary view or make it difficult for beneficiaries to find how to contact the plan call center. To address this concern, we are finalizing §§ 422.2262(c)(1)(i) and 423.2262(c)(1)(i) with the standard that the plan must prominently include the hours of operation at least once when including its customer service number.

Comment: Two commenters suggested that CMS should not include rewards and incentives (R&I) as a part of the content that is considered marketing in paragraph (2)(iii) of the marketing definition in proposed § 422.2260(2)(iii). The commenters claimed that the inclusion of reward and incentive (R&I) would consider this to be programmatic content and more appropriately treated as Communications, not subject to the same submission and review requirements. In addition, one commenter said that are two kinds of R&I related content that are communicated to beneficiaries. The commenter referred to them as promotional and programmatic. The commenter said that information plans may include in their open enrollment materials regarding R&I is intended to influence a beneficiary's decision-making process when making a MA plan selection and would be promotional, and rightly characterized as marketing and subject to submission and review requirements. The commenter went on to make the distinction that R&I program content that does not discuss or mention benefits, does discuss and mention healthcare services, but it does not promote or communicate cost-sharing,

available network providers, or other benefit details should not be considered marketing. The commenters also noted that a blanket classification of R&I materials as marketing materials, subject to regulatory requirements, would create additional administrative burden and could lead to member confusion.

Response: We respectfully disagree with these comments. For marketing purposes, we view such information as analogous to benefits in the beneficiary's view even though R&I are not benefits *per se.* We believe marketing of rewards and incentives or R&I programs could influence a beneficiary's decision making process when making a plan selection. As such, we believe that its inclusion in the content part of the definition of marketing fits with the overall definition of marketing. We note to the commenter that, for an activity or material to be considered marketing, it must meet both *intent* and *content.* To that point, an activity or material that includes or addresses content about R&I, but does not meet the intent standard specified in the definition at § 422.2260 would not be considered marketing under this final rule. Instead, this activity or material would be considered communications and generally not require submission to CMS. For example, a plan sending R&I information to a current member as a means of influencing the member to get a flu shot would not be considered marketing because the information does not meet the intentions provided under paragraph (1) of the definition of ''marketing'' under §§ 422.2260 and 423.2260. Conversely, a plan marketing to a prospective member with an advertisement stating ''Members of Plan X receive a $15 coupon book by simply getting their flu shot'' would be considered marketing as the clearly communicated intent is to use the R&I as a means of influencing the beneficiary's decision-making process when making a plan selection. CMS considers information about Rewards & Incentives to be marketing content and therefore, if the intent standard in the new definition is met, is subject to all the review and requirements applied to communications and marketing content.

Comment: A commenter expressed concern that CMS did not include specific reward and incentives (R&I) communication and marketing requirements as was done in section 40.8 of the MCMG. The commenter noted this means plans can market such programs independently, without context of overall plan benefits to allow individuals to do cost-benefit analyses regarding whether such incentives are worth it.

Response: The decision to remove certain marketing requirements directly targeting to R&I programs from CMS marketing and communication oversight predates this rulemaking. In the MCMG prior to August 6, 2019, plans were directed to provide R&I information in conjunction with information about plan benefits and include information about all R&I programs offered by the MA Plan. We determined that these requirements were overly prescriptive. For example, if a beneficiary requested information about a specific reward or incentive, we determined it unnecessary for a plan to include information about all rewards and incentives. The additional requirements previously addressed in the MCMG, specifically that the rewards not be used in exchange for enrollment and be provided to all potential enrollees without discrimination, are duplicative of other requirements found in this final rule. We direct readers to section D. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V) of this final rule for discussion of requirements for R&I programs. We proposed, and are finalizing, inclusion of information about R&I as part of the content measure for the definition of marketing under § 422.2260. This means that the marketing of R&I (and materials that discuss R&I) must comply with all, in some cases more stringent, marketing requirements set forth in Subpart V, except where otherwise noted.

Comment: A commenter expressed concern that CMS removed the language used in the 2019 MCMG that required plans to support any comparisons with other plans ''by studies or statistical data.'' The commenter acknowledged that the February 2020 proposed rule, at §§ 422.2263(b)(5) and 423.2263(b)(5), includes the requirement that such comparisons be not misleading, which was also in the MCMG.

Response: CMS believes the final rule addresses the commenter's concerns. Under §§ 422.2263(b)(5) and 423.2263(b)(5), as proposed and finalized, plans may not make plan comparisons unless the information is accurate, is not misleading, and can be supported by the plan making the comparison. By using the term ''accurate'', CMS expects that any plan comparison can be substantiated, including by the use of studies or statistical data or other information. In addition, the paragraph (2)(ii) of the definition of marketing, at §§ 422.2260 and 423.2260, again as proposed and finalized, makes it clear that plan comparisons are content that is considered marketing, and thus resulting in a greater level of oversight.

Comment: A commenter recommended that CMS develop marketing materials for beneficiaries and providers to educate them on the different types of integrated products and benefits of being in an integrated product. The commenter also stated that CMS should consider requiring agents and brokers that use CMS developed materials to educate all dually-eligible individuals on the availability of highly integrated products in their market and to use beneficiary education materials that include a description of the benefits of integrated product offerings.

Response: We appreciate the comment, but do not believe that additional actions are needed at this time. Extensive information about plan options is available to beneficiaries through Medicare.gov, the Medicare & You booklet and Medicare Plan Finder website. To date, CMS, in partnership with states, has developed standardized, state-specific model materials for MMPs that factually describe the benefits received from Medicare and Medicaid in one plan. In addition, SHIPs play a non-biased educational role in providing information to beneficiaries about their Medicare choices as well. We also note that states play a role in educating beneficiaries regarding integrated products, such as Health Care Options (*https://www.healthcareoptions.dhcs.ca.gov/need-help-choosing-program*) which is a beneficiary-focused website sponsored by the state of California. We will continue to evaluate the need for additional communications. Finally, we note that plans may continue to market how their plan benefits structure and organization are beneficial to enrollees, including providing information about access to integrated Medicare and Medicaid benefits. We do not believe that additional action by CMS is necessary at this time.

Comment: A commenter requested that the requirement under §§ 422.2262(a)(1)(x) and 423.2262(a)(1)(x) to include the plan type at the end of the plan name should not be required every time the plan name is mentioned. The commenter noted that such a requirement is not reader-friendly to beneficiaries and seemed unnecessary.

Response: We agree with this comment and are finalizing the regulation at §§ 422.2262(a)(1)(x) and 423.2262(a)(1)(x) with additional text to clarify that plans are not required to repeat the plan type when the plan

name is used multiple times in a material.

Comment: A commenter requested that CMS add the word ''materially'' in front of ''inaccurate'' in §§ 422.2262 and 423.2262 so it would read ''MA organizations may not mislead, confuse or provide materially inaccurate information to current or potential enrollees.'' The commenter noted that doing so would mirror current guidance standards (presumably 30.7 of the MCMG and § 422.2264 of the current regulation).

Response: As explained in the February 2020 proposed rule, our intent with the revisions to §§ 422.2262 and 423.2262 was to redesignate and reorganize requirements in the current regulations and to codify existing guidance. As current §§ 422.2264(d) and 423.2264(d) and section 30.7 of the MCMG use ''materially'' in setting forth the requirement, we agree that the revisions finalized here for §§ 422.2262 and 423.2262 should preserve that standard. We are finalizing §§ 422.2262 and 423.2262 to prohibit plans from misleading, confusing or providing materially-inaccurate information to current or potential enrollees.

Comment: In addition to the ''mail by'' dates provided for various required materials and content under §§ 422.2267(e) and 423.2267(e), one commenter suggested that CMS also codify the earliest date health plans may release this information. The commenter suggested that doing so would simplify the process and allow health plans to prepare for the mailing.

Response: We agree with this comment and that setting earliest date that a plan may begin sending materials for a plan year will help minimize potential confusion for beneficiaries. Therefore, we are finalizing §§ 422.2267(e) and 423.2267(e) with additional text to permit plans to send required materials once a fully executed contract is in place but no later than the due dates listed in §§ 422.2267(e) and 423.2267(e) for each material. Use of the date that the contract is executed for a particular year ensures that enrollees and potential enrollees are not furnished materials for an upcoming plan year before both the plan and CMS have committed to the plan being offered. We note that only required materials that do not meet the definition of marketing may be sent once a fully executed contract is in place. Any material that meets the definition of marketing, unless otherwise noted or instructed by CMS, may not be distributed until October 1 of each year as required under §§ 422.2263(a) and 423.2263(a).

Comment: A commenter pointed out a typo in §§ 422.2267(e) and 423.2267(e) with the words ''or perspective.''

Response: We appreciate the commenter catching the typographical error. We are finalizing §§ 422.2267(e) and 423.2267(e) with corrections, to read, ''. . . must be provided to current and prospective enrollees. . . .''

Comment: A commenter requested that CMS also exclude envelopes, ID cards, and call scripts from the requirement to provide the Federal Contracting Statement under §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii). The commenter noted that these materials were excluded from requiring the Federal Contracting Statement in Appendix 2 of the MCMG.

Response: We agree with the commenter in part because, as explained in the February 2020 proposed rule, our intent, with a few exceptions, with the revisions to Subpart V was to redesignate and reorganize requirements in the current regulations and to codify existing guidance. We are finalizing §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii) with an additional exclusion for envelopes. We are not finalizing an exclusion of this required statement from ID cards or call scripts related to sales and enrollment. Sections 1851(d) and 1860D–1(c) of the Act require CMS to provide for activities to disclose the potential for termination of MA and Part D plans to promote informed choice by enrollees; requiring plans to include the Federal Contracting Statement is consistent with the statute. First, ID cards are issued after a beneficiary had made an informed choice and are already excluded from the Federal Contracting Statement requirement. Second, while appendix 2 of the MCMG did exclude disclaimers (including the Federal Contracting Statement) from call scripts, the Federal Contracting Statement is only required to be a part of materials and information furnished to beneficiaries in connection with information promoting informed choice regarding enrollment into a plan. Consistent with this, we are requiring that any call scripts which meet the definition of marketing, such as sales scripts and enrollment scripts, include this statement. Under this final rule, the Federal Contracting Statement must be verbally conveyed along with the other content of the script.

Comment: A commenter requested that the exceptions that apply to §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii), the Federal Contracting Statement, apply to all disclaimers specified in §§ 422.2267(e) and 423.2267(e).

Response: We respectfully disagree with this comment. Unlike the Federal Contracting Statement that, with few exceptions, is required on all marketing materials, the other disclaimers listed in §§ 422.2267(e) and 423.2267(e), by design, are limited by their application (for example, when inviting beneficiaries to an event), or are triggered based on specific material content (for example, the Star Ratings disclaimer). Therefore, we do not believe that the general exclusions in §§ 422.2267(e)(30)(ii) and 423.2267(e)(32)(ii) are appropriate for the other required disclaimers and notices.

Comment: A commenter asked if CMS intentionally omitted the requirements found in 60.4.1 of the MCMG (Special Guidance for Institutional Special Needs Plans (I–SNPs) Serving Long-Term Care Facility Residents). The commenter noted that the additional flexibility afforded to I–SNPs is important and should either be added to the final rule or incorporated into sub-regulatory guidance.

Response: We appreciate the feedback. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included an intent to incorporate 60.4.1 of the MCMG into the codified requirements. CMS inadvertently excluded the marketing restrictions for I–SNPs from the proposed regulation text; the preamble of the proposed rule, 85 FR 9110–9111, however, did make clear that we intended to include all of the policies regarding marketing in a health care setting in section 60 of the MCMG in these updated regulations. We agree with the commenter that this guidance is important to plans, beneficiaries, and caregivers. We are finalizing § 422.2266 with an additional paragraph (f) to codify the current policy addressing how I–SNPs may market in the context of a long term care facility. We note that the requirements in § 422.2266(f) apply to I–SNPs that are contracted with long term care (LTC) facilities as well as those I–SNPs that have an ownership stake in the LTC facility. This new regulation text, combined with the other requirements proposed and finalized in § 422.2266, includes the substance of our existing I–SNP guidance for MA plans. We note that 42 CFR part 423 regulates the marketing of Part D and we are not finalizing similar regulation text for Part D sponsors. Part D only plans should not be marketing I–SNPs because Part D

plans do not provide the medical services and thus would not have contracts with I–SNPs; further, while I–SNPs must be MA–PDs (see § 422.2 definition of specialized MA plans for special needs individuals), compliance with the marketing and communications requirements in § 422.2266(f) will necessarily include materials and activities related to the I–SNP's Part D coverage.

In addition, we also finalizing an additional provision at §§ 422.2264(c)(3)(iv) and 423.2264(c)(3)(iv), to provide that plans may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent/broker is considered unsolicited door-to-door marketing and therefore prohibited.

Comment: A commenter expressed strong support of CMS's proposal to prohibit marketing activities and distribution of marketing materials in dialysis facilities.

Response: We thank the commenter for the support. Stemming from section 1851(j)(1)(D)(i) of the Act, CMS has had a longstanding policy and requirements that limit marketing in healthcare settings. We would like to clarify that our rules have always allowed for marketing activities in common areas. We clarify that the prohibition on marketing activities and the provision of materials in treatment areas, where patients interact with a provider or the clinical team, does not include a prohibition of marketing activities or the provision of marketing materials in common areas. We are including an edit in sections 422.2266(a)(3) and 423.2266(a)(3) to clarify that, to the extent that dialysis facilities actually do have such common areas, that the same limitations would apply to them as to other healthcare settings. It is not our intent to prohibit marketing for every single area in a facility/health care provider's location and this change in policy for dialysis facilities would mirror the policy as it has been applied previously for all other provider locations.

Comment: A commenter urged CMS to not include the prohibition on providers being compensated for marketing or enrollment activities in the final rule. The commenter noted that, the section 70.5.1 of the Medicare Marketing Guidelines (MMG) issued on 7/20/17 (available here online: *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines_Final072017.pdf*), only restricted compensation based on enrollment activities. The commenter stated that the language could be read to prohibit plans and providers from sharing the costs of otherwise permissible provider affiliation activities and advertising.

Response: We respectfully disagree with this comment. The steps taken by CMS to restrict compensation to providers for marketing activities are rooted in ensuring the provider is a neutral party who is offering guidance to patients based solely on what is best for the patient. We note that the decision to preclude plans from compensating providers for marketing activities predates this rulemaking and has been in section 60.2 of the MCMG since it was first released on July 20, 2018. Additionally, the MMG issued in July 2017, under section 70.5.1, still precluded providers from mailing marketing materials on behalf of Plans/Part D sponsors. Under our current policies, affiliation announcements (a provider announcing that they are now [or continue to be in] a plan's network) are communications if limited to that information, and thus would be allowed. However, if a plan is using such an announcement as a veiled means of provider-based marketing, it would be precluded by this rule, as it would under the MCMG since the July 2018 version. For example, an affiliation announcement that says Dr. Smith is now accepting Medicare Advantage X, then goes on to say that Medicare Advantage X offers $0 copays, and $0 monthly premiums, and that Dr. Smith thinks Medicare Advantage X is the greatest Medicare Advantage Plan would be prohibited by this rule, as well as the current rule, as interpreted in the MCMG.

Comment: Several commenters urged CMS to add specific provisions in the marketing and communications regulations regarding MA special supplemental benefits for the chronically ill (SSBCI) and how plans may market them.

Response: In general, CMS respectfully disagrees that additional regulatory requirements specific to communications and marketing related to SSBCI are necessary. The requirements in Subpart V establish standards and requirements to address a wide range of issues and contexts, rather than having standards for individual benefits, items, issues, and services. This allows CMS to be more dynamic with regard to the ever changing communications and marketing environment. The regulations that we proposed and finalized are as applicable to SSBCI as they are to other benefits covered and offered by an MA plan. However, we recognize that beneficiaries should be aware that SSBCI are not available to all plan enrollees and that the eligibility for these benefits is limited by section 1852(a)(3)(D) of the Act and § 422.102(f); ensuring a clear statement of these limitations guards against beneficiary confusion or misunderstanding the scope of these new benefits. To that end, a new requirement for a disclaimer to be used when SSBCIs are mentioned is being finalized at § 422.2267(e)(32).

Comment: A few commenters expressed concern that marketing SSBCI would lead to inappropriate steering or targeting of beneficiaries. Similar to other comments, the commenters urged CMS to implement specific requirements under Subpart V of the regulation to guard against such predatory sales tactics. A commenter feared that brokers may ask individuals about their health status and use that information to steer them toward specific plans in violation of anti-discrimination rules.

Response: CMS respectfully disagrees that additional requirements for communications and marketing related to SSBCI should be placed under Subpart V. The requirements, as written in this rule, allow CMS to pursue any marketing or sales tactics that are misleading or confusing to the beneficiary, regardless of whether the violation is tied to specific benefits (like SSBCI). In addition, although CMS understands the concern expressed about agents and brokers asking individuals about their health status, when done appropriately, such activities can be an important part to identifying the best plan for a beneficiary and addressing eligibility for SNPs that serve individuals with severe or disabling chronic conditions. CMS has requirements in place in this rule to ensure plans (including agents and brokers, as downstream entities of plans) act appropriately when it comes to health status, namely §§ 422.2262(a)(1)(vi) and 422.2264(c)(2)(iii)(B).

Comment: Several commenters requested that CMS provide more examples pertaining to the restrictions of marketing during the OEP in §§ 422.2263(b)(7) and 423.2263(b)(7).

Response: We agree that providing more examples and illustrations of how the regulatory standards apply in specific factual situations can be helpful. However, we believe that sub-regulatory guidance is the best location for providing additional examples.

Comment: Another commenter also expressed the need for examples.

However, the commenter also cited the need for CMS to more closely monitor marketing activities during the OEP. The commenter noted that if the consequences of marketing during the OEP are not explicit or consistent, it defeats the purpose of prohibiting plans to market during this time.

Response: We agree with the commenter that appropriate oversight is necessary for effective regulatory guidance. The Medicare Advantage OEP was added to section 1851(e)(2)(G) of the Act by the 21st Century Cures Act with a prohibition on unsolicited marketing or marketing materials being sent to Medicare beneficiaries during the OEP and, in the April 2018 final rule, we adopted the specific prohibition in current §§ 422.2268(b)(10) and 423.2268(b)(10) that is being redesignated with additional provisions at §§ 422.2263(b)(7) and 423.2263(b)(7) in this final rule. Since the April 2018 final rule, CMS has fielded several questions from plans concerning what can and cannot be done during the OEP. In addition, CMS has also investigated complaints received concerning plans the complainant felt were not in compliance with the prohibitions of marketing during the OEP. CMS has used this experience to shape the requirements in this final rule, which includes specific provisions regarding prohibited conduct (such as sending unsolicited materials that advertise the availability of this enrollment period and calling former enrollees to solicit reenrollments) and permitted conduct (such as responding to beneficiary requests for sales meetings) in addition to the general prohibition on knowingly targeting or sending unsolicited materials during the OEP. CMS will continue to monitor compliance with the prohibition of knowingly marketing to beneficiaries during the opportunity afforded by the OEP, and take appropriate compliance or enforcement action when necessary. CMS encourages beneficiaries to report any abusive, confusing or misleading marketing practices by plans, agents and brokers by contacting contact 1–800–Medicare. In addition, we encourage reports of potential violations of this requirement.

Comment: A commenter requested that CMS consider lifting the restriction on marketing to beneficiaries during the OEP. The commenter believed information about the OEP should be shared proactively with beneficiaries so that they are aware of the option to switch MA plans if the enrollee's MA plan is not a good fit. The commenter noted that beneficiaries may be losing out on an enrollment opportunity and forced to stay with their existing plan until the next AEP to make a change because CMS prohibits plans from proactively marketing information about the OEP.

Response: The prohibition of marketing during the OEP is statutorily required so we do not have authority to eliminate it. Further, CMS believes that the intent of Congress was to allow beneficiaries to make an enrollment decision during the OEP, without creating a second opportunity for plans to proactively persuade or attempt to persuade beneficiaries to switch MA plans. Neither the statute nor regulation restricts a plan from providing educational materials or marketing materials if and when the beneficiary proactively reaches out looking for help during or regarding the OEP.

Comment: A commenter agreed with CMS that marketing and advertisements should be restricted during the MA OEP. The commenter noted that during the MA OEP, excessive marketing can be confusing to seniors and leads people to unnecessarily believe that they need to make a plan change. The commenter additionally stated that the OEP should be a time to help seniors process necessary changes that are based on real issues; not those who have been influenced by excessive marketing.

Response: We agree with the commenter and believe the requirements proposed and finalized at §§ 422.2263(b)(7) and 423.2263(b)(7) implement the statutory prohibition and provide the appropriate beneficiary protections.

Comment: A commenter requested that CMS include language in §§ 422.2263(b)(7) and 423.2263(b)(7)(i) to allow general information on websites, as currently permitted in section 40.7 of the MCMG.

Response: We agree with this comment. We are finalizing the §§ 422.2263(b)(7)(i) and 423.2263(b)(7)(i) with an additional paragraph (E) that permits plans to include educational information, excluding marketing, on the plan's website about the existence of the OEP.

Comment: A commenter stated that the language at §§ 422.2263(b)(7)(ii)(C) and 423.2263(b)(7)(ii)(C) stating plans ''must not engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales . . .'' was vague and overbroad, as it suggests the intent of the activity alone may determine whether it is compliant.

Response: We respectfully disagree with the comment. Our goal, as when the prohibition on marketing during the OEP was originally codified in the April 2018 final rule, is to implement the statute in a manner that protects beneficiaries without creating undue burden on plans. To accomplish this, we consider the intent of marketing materials or activities. If CMS focused only on the content of materials or activities, bad actors would be able to evade oversight by simply excluding certain words, while using materials or conducting activities with the same overall focus and intended outcome. We also believe that plans are well equipped to determine if materials or activities are intended to be used or are being used to target beneficiaries during the OEP.

Comment: A commenter requested that CMS revise the regulatory text pertaining to non-renewal notices at § 422.2267(e)(10) to address the earliest date that health plans may release this information. The commenter noted that section 100.4 of the MCMG states information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS.

Response: CMS agrees with this comment. Section 100.4 of the MCMG provides that information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance. As such, we are finalizing §§ 422.2267(e)(10)(i) and 423.2267(e)(13)(i) with additional text to permit release of non-renewal notices after CMS provides notification to the plan. We note that §§ 422.506(a)(2)(ii) and 423.507(a)(2)(ii) state the beneficiary must receive notice by mail at least 90 calendar days before the date on which the nonrenewal is effective; we are not changing or limiting that timeframe in this final rule.

Comment: A commenter suggested that CMS reclassify payments to third parties, addressed in §§ 422.2274(e) and 423.2274(e), as ''payments other than compensation.'' The commenter explained that the change would not only account for payments to third parties, but also for payments to agents/brokers that are not considered compensation. The commenter gave the example that payment to an agent for completion of health risk assessments is a payment other than compensation because the payment is not for the sale or renewal of a policy.

Response: CMS agrees with the commenter that additional clarification

is necessary. We are finalizing §§ 422.2274(e) and 423.2274(e) as a provision identifying payments that are not compensation but are administrative payments. We are finalizing the scope of these payments as proposed, meaning payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, assistance with completion of health risk assessments), but without the limitation that the payments be made to a third party. As proposed and finalized, all payments of this type must not exceed the value of those services in the marketplace. This standard is intended to ensure that plans do not use these administrative payments as a means to circumvent the limits on compensation to agents and brokers. Plans must limit these payments to the amounts that would be fairly negotiated on the open market for the administrative services being performed and should be able to demonstrate that the administrative payments were made for actual performance when necessary. We are finalizing paragraph (e)(2) as proposed but without limiting the provision to payments to third parties.

Comment: A commenter voiced the concern that permitting plans to contact beneficiaries in another line of business could lead to an onslaught of unsolicited marketing. The commenter was especially concerned about unsolicited marketing to dually eligible beneficiaries. The commenter urged CMS to limit plan outreach/marketing to once a quarter, a limitation that corresponds with the LIS special enrollment periods.

Response: CMS understands the commenter's concern. However, CMS does not believe that outreach for plan business has harmed beneficiaries. CMS uses the Complaints Tracking Module to log concerns from beneficiaries and others who call 1–800-Meducare. We have not received complaints related to inappropriate outreach to enrollees regarding plan business. In addition, §§ 422.564 and 423.564 provide beneficiaries who feel they are being overly bothered by such calls the option of filing a grievance with the plan under the part C and D grievance rules. The intent of allowing contact for plan business is to ensure CMS's rules are not a barrier to a beneficiary gaining access to helpful plan information, rather than exposing the enrollee to unsolicited burdensome contact. We do not agree with adopting the remedy suggested by commenters of limiting contact to once per quarter because doing so may unintentionally limit what could be wanted or needed communication for the enrollee. Instead, we are finalizing a requirement that the plan offer an opt-out when contacting a beneficiary for plan business at §§ 422.2264(b)(2) and 423.2264(b)(2). As a result, plans must respect requests from enrollees to cease calls to enrollees about plan business. We encourage plans to develop opt-out procedures and policies that provide the enrollees the ability to limit calls to particular topics or timeframes as well as opting out of all future calls. We believe this remedy, as opposed to an arbitrary cap on calls, provides enrollees with the means to stop calls should they wish.

Comment: A commenter offered support to CMS's bifurcation of provider activities under §§ 422.2266(c)–(d) and 423.2266(c)–(d). The commenter noted that §§ 422.2266(c) and 423.2266(c) allowed providers to provide fact-based guidance to their patients on MA plans.

Response: CMS thanks the commenter for the support.

Comment: A commenter expressed concern that the language used for the review of communications materials under §§ 422.2261(c) and 423.2261(c) implies that the EOC would require filing, as well as CMS review and approval, before it could be used. The commenter stated that it was not feasible for plans to get an EOC completed after annual bid approval, printed for member requests by 10/15 and accessibility-processed for website availability by 10/15, if plans have to wait for CMS to review and approve the EOC. The commenter also noted that currently CMS requires plans to file the EOC, but it gets ''NM'' status and is available for use immediately after filing in HPMS.

Response: CMS is not changing the process for the submission and review of the EOC. The EOC is a standardized material, meaning plans must use the language provided by CMS with no modification. As such, the potential for a beneficiary to be misled by an EOC is low, and therefore, the EOC is not prospectively reviewed. Plans are required to submit the EOC to CMS for retrospective review, and plans must provide CMS with ready access to the EOC should CMS receive a beneficiary complaint about the EOC.

Comment: A commenter requested that the CMS final rule include the qualification under section 30.7 of the MCMG that unsubstantiated absolute and/or qualified superlatives may be used in logos and taglines.

Response: CMS agrees with this comment. As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included an intent to incorporate 30.7 of the MCMG into the codified requirements. This exception to the unsubstantiated statement requirement was unintentionally not included in the proposed rule. We are finalizing additional text at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to allow unsubstantiated statements, which could be in the form of superlatives or pejoratives, in logos or taglines. We note that plans are permitted to use unsubstantiated statements only in taglines and logos, which means that plans may not include unsubstantiated statements in larger or longer marketing materials. We further note that it may be possible for some superlatives or pejoratives to qualify as substantiated statements.

Comment: A commenter, citing proposed §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), requested that CMS provide specific guidance in one place on the requirements in the notice for electronic delivery of materials and requested clarification whether plans would be permitted to create their own notice.

Response: Paragraphs (D) and (E) of §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i) outline the content requirements for the notice. In addition, paragraphs (A), (B), (C), and (F) provide additional requirements for a plan to use the flexibility of notice of electronic access to the EOC, Provider and Pharmacy Directories and Formulary without prior authorization from the enrollee. Provided the requirements under §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i) are followed, plans are permitted to create their own notice.

Comment: A commenter expressed concern that listing the SB as a model material in §§ 422.2267(e)(5) and 423.2267(e)(4) of the February 2020 proposed rule was going to result in the required use of a model. The commenter expressed concern that doing so would impact a plan's freedom to design the SB and explain benefits as they currently can under Appendix 5 of the MCMG.

Response: As proposed and finalized, the requirements for the SB are consistent with the current policy in the MCMG, including Appendix 5 of the MCMG. We clarify here that the term standardized materials, which are specified in §§ 422.2267(b) and 423.2267(b) must be used in the form and manner provided by CMS. Model materials, which are specified in §§ 422.2267(c) and 423.2267(c) are created by CMS is an example of how to convey beneficiary information. As with current policy and practice, plans

may customize the SB so long as all required content is included and are not required to use the CMS model SB without customization.

Comment: A commenter noted that the MCMG requires the PECL to be included with the SB, whereas §§ 422.2267(e)(4) and 423.2267(e)(3) of the February 2020 proposed rule would require the PECL be included with the SB and the enrollment form. The commenter explained that while typically the SB and an enrollment form are provided together in a pre-enrollment packet, if a prospective enrollee elects to access plan marketing materials on the plan's website, the individual will access the SB and enrollment form separately. The commenter recommended that CMS allow the checklist to continue to only be included with the SB as required in current guidance.

Response: We agree with this comment in part. We agree that it is unnecessary to require the PECL be included with the SB and the enrollment form. However, the PECL was originally developed as a tool to help beneficiaries consider important questions about their needs and coverage choices and we have always intended it to be reviewed prior to making an enrollment decision. As such, we believe it best to require the PECL with the enrollment form as opposed to the SB. Plans may include the PECL with other materials, if they choose. We are finalizing §§ 422.2267(e)(4) and 423.2267(e)(3) to require that the PECL be provided with the enrollment form. As finalized, these regulations do not require the PECL to be included with the SB but we encourage plans to do so when it is appropriate and helpful to potential enrollees.

Comment: A commenter pointed out an error to the requirement for mailing statements at § 423.2267(e)(36)(i).

Response: CMS appreciates the commenter bringing this error to its attention. CMS is finalizing § 423.2267(e)(35)(i) (proposed § 423.2267(e)(36)(i)) with a correction to include the same language as proposed and finalized at § 422.2267(e)(34)(i). These regulations require MA plans, cost plans and Part D plans to include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

Comment: A commenter requested that CMS clarify that, consistent with current policy, the ''Important plan information'' mailing statement would only be required for current member mailings, as indicated in Appendix 2 of the MCMG.

Response: CMS confirms that the commenter is correct. Under §§ 422.2267(e)(34)(i) and 423.2267(e)(35)(i), as finalized, plans must include the statement when mailing information about the ''enrollee's'' current plan, which is synonymous with ''current member.''

Comment: A commenter requested that CMS re-evaluate the HPMS timing and submission of the Star Ratings Document to remove the 5-day waiting period. The commenter stated that, because the document is automatically generated from HPMS, there is no value in requiring plans to resubmit the Star Ratings Document back into HPMS as a file and use material, which requires a 5-day waiting period before the document can be used. The commenter requested that CMS apply the same guidance to the Star Ratings document as the Annual Notice of Change (ANOC).

Response: Based on the regulatory definition of marketing under §§ 422.2260 and 423.2260, CMS has determined the Star Ratings Document is a marketing material. Because the collection of marketing materials is required under section 1851(h)(1) of the Act, the Star Ratings Document, as a marketing material, must continue to be submitted via the HPMS Marketing Module under the defined process. CMS is finalizing the requirement that the Star Ratings documents are subject to the 5-day waiting period. This period will provide an opportunity for CMS to ensure that organizations do not alter the document as that document is a key piece required with an enrollment form.

Comment: Two commenters requested that CMS remove the requirement for the Availability of Non-English Translations disclaimer under proposed §§ 422.2267(e)(32) and 423.2267(e)(34). Both commenters referenced the requirement tied to section 1557 of the Affordable Care Act (ACA) as having duplicative requirements. The commenters stated that the Availability of a Non-English Translations disclaimer would result in beneficiaries receiving the disclaimer language multiple times within the same mailing.

Response: CMS understands the concern with duplication. As of this final regulation, the Office for Civil Rights (OCR) finalized the regulations implementing section 1557 of the ACA without requiring disclaimers. Acknowledging OCR's finalized regulations did not include language-based disclaimers, CMS will not finalize the proposed Availability of Non-English Translation disclaimer, proposed §§ 422.2267(e)(32) and 423.2267(e)(34), in this final rule. To clarify, there would be no requirement in this regulation for the Availability of Non-English Translation disclaimer; however, plans must still abide by OCR's current or future requirements on this topic as they have the authority to impose such requirements. As such, CMS believes future rulemaking regarding non-English disclaimers, if appropriate, is best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. In addition, we note that the other paragraphs in §§ 422.2267(e) and 423.2267(e) will be renumbered as compared to the proposed rule as a result.

Comment: Several commenters provided support for CMS including non-English language disclaimers in the proposed regulation.

Response: CMS appreciates the support but has made the decision not to finalize proposed at §§ 422.2267(e)(32) and 423.2267(e)(34) in this final rule and to defer to OCR for possible future rulemaking. CMS has determined that deferring to OCR's oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program.

Comment: Several commenters requested that CMS remind plans about their obligations to comply with section 1557 notice requirements, including ''taglines'' or disclaimers in the top 15 languages and to conduct enforcement and oversight when appropriate.

Response: We appreciate the comments. We believe it is important for plans to be cognizant of obligations as they relate to applicable rules and regulations that require interpreter services, translation of materials, and associated notices or disclaimers and have included the requirement in this final rule under §§ 422.2267(a)(3) and 423.2267(a)(3).

Comment: Two commenters urged CMS to take this opportunity to revisit §§ 422.2267(a)(2) and 423.2267(a)(2) and require using a threshold of five percent or 1,000 people in the service area, whichever is lower, of a population speaking a language other than English to trigger translations for vital documents.

Response: CMS respectfully disagrees with this comment. CMS previously considered a similar standard when translation requirements were first added to §§ 422.2264 and 423.2264 in the final rule, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and

Other Changes,'' published in the **Federal Register** on April 15, 2011. (73 FR 21423, 21512 through 21514) At that time, CMS stated that use of a standard of the lesser of 5 percent or 500 people would result in all PDPs and nearly all MAOs providing translated materials in all languages captured in the ACS data, which would result in a significant increase in the number of plans required to translate and the number of languages required for translation. Absent definitive evidence to support the sharp increase, this would result in insupportable costs and burden. Although the commenter was suggesting a five percent or 1,000 people in the service area, CMS believes the reasons identified by final rule cited above still apply and that raising the alternative minimum standard to 1,000 people from 500 would not significantly reduce the potential burden. As such, CMS will is finalizing as proposed the provision at §§ 422.2267(a)(2) and 423.2267(a)(c) setting the translation standard at five percent of the individuals in a plan benefit package (PBP) service area.

Comment: A commenter requested that CMS allow the Scope of Appointment (SOA) provision found at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to be satisfied by a simple question on the coverage application, with additional paperwork only required if the appointment topic shifts beyond the scope of Medicare.

Response: Section 1851(j)(2)(A) of the Act requires the Secretary to establish limitations to require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement, which must be in writing if the marketing appointment is in person; section 1860D–4(*l*) imposes the same requirements in the Part D program. The regulations proposed, and finalized, at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), implement these statutory requirements. We believe that using the enrollment form, typically a document that is used at the end of a personal marketing appointment, would not be consistent with the statute. Therefore, we are finalizing these provisions.

Comment: A commenter requested that CMS clarify what is meant by ''use of a previous post'' as stated in §§ 422.2262(b)(1)(iv) and 423.2262(b)(1)(iv). The commenter stated that it is unclear what types of social media ads would be considered product endorsements or testimonials.

Response: The phrase ''previous post'' refers to a social media post that had been made in the past or prior to its use, sharing, or posting by a different user. For example, a plan enrollee tweets that they were able to quit smoking thanks to a smoking cessation program offered by Super Duper Medicare; if Super Duper Medicare shares (by retweeting or otherwise) that tweet with their followers, it would be considered a use of a previous post. Under §§ 422.2262(b)(1)(iv) and 423.2262(b)(1)(iv), as proposed and finalized, this use of the previous post is a product endorsement or testimonial. We will provide additional examples as necessary through sub-regulatory guidance and training.

Comment: A commenter requested that CMS consider changing the training and testing standards at §§ 422.2274(b)(2) and 423.2274(b)(2) to relax the requirements for more seasoned (5 years or longer) agents and brokers. The commenter stated doing so would encourage longevity and stability among private Medicare agents and brokers.

Response: CMS appreciates the comment and will consider this in future rulemaking, but believes further analysis and consideration is necessary before adopting such a policy. This policy would potentially increase the complexity of agent and broker oversight. Further, we believe we should analyze the cost implications, including potential additional costs (or savings) of implementing a tiered approach to agent and broker training and testing.

Comment: A commenter requested CMS clarify that ''applicable disclaimers,'' as used in §§ 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii), are those disclaimers required by CMS.

Response: Sections 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii) refer to notices, statements, disclosures, and disclaimers required for plan use under other statutes or regulations, such as (but not necessarily limited to) the disclaimers required under §§ 422.2267(e) and 423.2267(e). To clarify this point, we have updated the language at 422.2265(a)(1)(iii) and 423.2265(a)(1)(iii) to include notices, statements, disclosures in addition to disclaimers.

Comment: A commenter requested that CMS limit the requirement at § 422.2265(a)(1)(iv) regarding the need to update websites with the most current information within 30 days to only updates to the website that are material changes.

Response: CMS agrees with this comment as it would be overly burdensome to require plans to update non-material changes, such as a new company mascot, within 30 days. Moreover, non-materials changes are not impactful to a beneficiary's ability to have access to the information needed to make an educated enrollment decision. CMS is finalizing §§ 422.2265(a)(1)(iv) and 423.2265(a)(1)(iv) with revisions to limit the requirement to update the website to material changes. CMS is finalizing the remaining substance of the regulation as proposed.

Comment: One commenter requested that CMS complete a thorough review of the website requirements to ensure consistency with current guidance as well as inclusion of any requirements outside of the MCMG. The commenter provided two examples. They noted that the Final Rule published on February 12, 2015 (CMS–4159) required plans to post their disaster and emergency policy annually on the website and the CY 2014 Final Call Letter required plans to have a dedicated Medication Therapy Management MTM program linked from their plan website and it be accessible by clicking through a maximum of two links.

Response: We agree with this commenter and confirm the two requirements noted. We are finalizing § 422.2265(b) with a modification to include a requirement to post disaster and emergency policy annually as outlined under § 422.100(m)(5)(iii). We are finalizing § 423.2265(b) with a modification to include the most recent MTM program website requirements. While CMS strives to list all website requirements under §§ 422.2265 and 423.2265, we note that the lack of a requirement in these sections does not remove plan responsibility for compliance if requirements are adopted elsewhere.

Comment: A commenter recommended CMS align Provider Directory PDF web posting requirements with MCMG section 70.2 (Searchable Formularies and Directories), which indicates that a searchable tool (for example, search engine/database) may be a substitute for downloadable PDF directories as long as all instructions and template information are provided.

Response: CMS respectfully disagrees with this comment. Currently, the regulation at § 422.111(h)(2)(ii) requires the MA plan's website to have information (names, addresses, phone numbers, and specialty) about network providers. Our current guidance, in MCMG section 70.2, provides that organizations that have a searchable directory on their website are not required to have a downloadable directory on their website. However, regulations at §§ 422.111(h)(2)(ii) and 423.128(d)(3) still require organizations

to provide materials in hard copy when requested. Therefore, the provision of hard copies of provider and pharmacy directories is currently a requirement for plans. In addition, now that a greater number of materials may be made available electronically under §§ 422.2267(d)(2) and 423.2267(d)(2), we believe that it is even more important for beneficiaries to have access to a PDF of the compete directory or formulary; this is especially true for the provider directories because prior consent from the enrollee is not required for a plan to use electronic delivery instead of mailing hard copies for provider directories. Our electronic delivery regulations permit organizations to notify individuals that certain materials can be accessed via a website or other method. These materials, unless requested by the beneficiary, will not be mailed in hard copy. As proposed and finalized, §§ 422.2265(b)(3) and 423.2265(b)(3) require plans to post a pdf or copy of a printable version of their provider and pharmacy directories on their website. Even though there is great value in making available on the website a tool or functionality that allows the beneficiary to search for a specific provider or drug based on set criteria, searchable formularies or directories do not allow a beneficiary the ability to view or download the directory or formulary as they would if it had been mailed. For that reason, we believe searchable directories and downloadable PDF documents are distinctly different and are not equivalent in their utility to a beneficiary.

Comment: A commenter inquired about the elimination of the requirement that plans use CMS standard icons when marketing a plan's Star Rating. The commenter noted that, previously, plans were not permitted to create their own gold star icon or any other icon of distinction, however, under the revision of the MCMG, plans could create their own gold star icon (or any other icon of distinction) so long as the icon is not misleading or confusing to beneficiaries. The commenter then stated that it was unclear to them how CMS would determine whether a plan-created icon was misleading or confusing.

Response: As explained in the February 2020 proposed rule, we intended to redesignate and reorganize requirements in the current regulations in Subpart V and to codify existing guidance; that included the ability for plans to create their own star icon, which we proposed at §§ 422.2263(c)(6)(ii) and 423.2263(c)(6)(ii) and are finalizing here. The revision to the MCMG, section 40.6.1, to permit such plans to create their own Star Ratings icons was announced in an HPMS memo updating the MCMG on August 6, 2019 and predates this rulemaking. If warranted, CMS may examine the effects of allowing plans to use their own icons to denote CMS 5 Star Ratings. CMS will take appropriate action against any plan that uses icons that are misleading or confusing to beneficiaries and we intend to use information such as, but not limited to, beneficiary complaints, CMS marketing reviews, and CMS surveillance activities to identify violations of the prohibitions on misleading or confusing beneficiaries. At this time, we believe that providing plans with this flexibility, while also continuing to prohibit misleading marketing and communications, is appropriate. We note that we proposed and are finalizing the longstanding requirement that low performing plans use the specific CMS-created Low Performing Icon, state what that icon means, and may not attempt to refute or minimize their Low Performing Status, as stated in §§ 422.2263(c)(7) and 423.2263(c)(7). In situations where a plan has been assigned the Low Performing Icon, there is a greater incentive for a plan to mischaracterize its Star Ratings; therefore, by requiring use of the CMS-created icon in those situations, we are sufficiently guarding against the negative consequences of allowing plans to create and use their own Star Ratings icons. Additionally, we will continue to rely on the practices we have developed, discussed in prior responses, for determining whether marketing language and methods are misleading or confusing, including the use of plan-created icons.

Comment: A commenter was concerned about the limited enforcement in the marketplace regarding marketing and referral fees. The commenter suggested that instead of making changes to the requirements, CMS should improve its coordination with state departments of insurance to enforce existing regulations.

Response: CMS has mechanisms in place to monitor agent and broker behavior in the marketplace, including prospective and retrospective marketing reviews, CMS regional office account manager oversight, ad hoc review by CMS Central Office staff, notification by peers (that is, other health plans), and notification through 1–800–MEDICARE (via the Complaints Tracking Module (CTM)) on a case-by-case basis. Additionally, CMS reviews agent/broker payment data in the HPMS agent/broker payment database for anomalies. CMS has a memorandum of understanding (MOU) with all states to facilitate coordination with state Departments of Insurance in order to share information and work with these departments as appropriate. CMS also may take compliance or enforcement action if it determines plans are not adhering to CMS' requirements, including the requirements at §§ 422.504(i) and 423.505(i) for the oversight of first tier, downstream, and related entities, which includes for agents and brokers.

Comment: A commenter suggested that individuals not discuss benefits with beneficiaries in any Medicare plan unless they are licensed and certified.

Response: CMS believes beneficiaries need to understand their benefits and to require a beneficiary to only speak to a licensed and certified agent about the benefits in a plan would be burdensome to both the beneficiary as well as the plan. For example, CMS does not require a customer service representative (CSR) to be licensed and certified to answer a beneficiary calling to determine what the co-pay would be for a medical procedure. The requirements in §§ 422.2272 and 423.2272 are designed to ensure that an individual conducting marketing activities (that is selling) and enrolling individuals into a plan are licensed and certified. CMS also has rules in place at §§ 422.503(b)(4)(vi)(F), 422.504(i)(3)(iii), 423.504(b)(4)(vi)(F), and 423.505(i)(3)(iv) requiring that MA organizations and Part D plans contractually require downstream and first tier entities to comply with Medicare rules when doing Medicare business. We believe these requirements appropriately safeguard the beneficiary without the need for additional restrictions.

After careful consideration of all the comments we received, and for the reasons set forth in the February 2020 proposed rule and in our responses to the comments, we are finalizing the proposed changes to amend part 422, Subpart V (§§ 422.2260 through 422.2274) and part 423, Subpart V (§§ 423.2260 through 423.2274), with some modifications. Some comments alerted us to typographical errors in either the preamble or regulatory text of the proposed rule; we are finalizing the regulation text with those necessary corrections. Some comments requested immediate clarification of our intentions or semantics, which we have provided as appropriate. Some comments were ultimately requests for clarifications or for additional guidance and, in most cases as noted in our responses to those comments, we intend to update our sub-regulatory guidance to clarify those

instructions. There were some comments that caused us to rethink the nature of our proposed changes. We have also made technical and grammatical changes to some provisions without changing the substance of the proposed policy. Finally, we are finalizing the following substantive changes compared to the proposed provisions in addition to the substantive changes discussed in our responses to comment (*e.g.,* the revision to §§ 422.2264(c)(3) and 422.2264(c)(3) regarding appointments with residents of long-term care facilities).

We are making four changes that are not specifically based on comments. First is with regard to how required content (disclaimers) outlined under §§ 422.2267(e) and 422.2267(e) are classified as either standardized under §§ 422.2267(b) and 423.2267(b), or as model under §§ 422.2267(c) and 423.2267(c). We have reconsidered some of those classifications to provide for more flexibility for certain disclaimers by changing them from standardized to model content. This change will give plans the option to adjust the language used to convey the required message (that is, the disclaimer) in a manner that is both understandable and consistent with other plan-based communications. Aside from providing more flexibility, the requirement for when the noted content must be used, as well as the beneficiary protections afforded by the substantive message the content is conveying, remains the same.

The following required content is changing from standardized to model:

- §§ 422.2267(e)(31) and 423.2267(e)(33), Star Ratings disclaimer
- §§ 422.2267(e)(33) and 423.2267(e)(34), accommodations disclaimer
- §§ 422.2267(e)(36) and 423.2267(e)(37), provider co-branding disclaimer
- § 422.2267(e)(37), out of network non-contracted provider disclaimer
- § 422.2267(e)(38), NCQA SNP approval statement

We remind plans that, as required under §§ 422.2262 and 423.2262, the language used for required content may not mislead, confuse, or provide materially inaccurate information.

Second change, we are finalizing §§ 422.2261(a)(2) and 423.2261(a)(2), with the heading *Submission, review, and distribution of materials,* with modifications from the proposal. In the February 2020 proposed rule, we proposed that materials must be submitted to the HPMS directly by the MA organization and that third party and downstream entities are not permitted to submit materials directly to CMS. This provision was, in part, based on technological limitations of the HPMS Marketing Module that did not have a means for third parties to submit materials directly to CMS. During the time between publishing the NPRM and this final rule, we have begun updating the HPMS Marketing Module. As a part of this update, we are considering changes that may allow third parties, with the appropriate safeguards, to submit materials on behalf of a plan or plans. As such, we are updating the final rule to include §§ 422.2261(a)(3) and 423.2261(a)(3) which state that unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS. This added flexibility will give the agency the ability to grant third party access in the future.

Third, we are finalizing a change to remove ambiguity from the prohibition on providing gifts unless they are of a nominal value under §§ 422.2263(b)(2) and 423.2263(b)(2) by clearly indicating the provision is applicable to all beneficiaries, that is both current and potential enrollees. In the February 2020 proposed rule, we proposed edits to the language in the existing regulations (§§ 422.2268(b)(2) and 423.2268(b)(2)) to cite the HHS OIG guidance governing nominal gifts for Medicare beneficiaries. In doing so, our intention was for this requirement to apply to both current and potential enrollees (that is those eligible for Medicare), as is the case with the OIG's requirements as well as our current requirements found under section 40.4 of the MCMG. Sections 1851(j)(2) and 1860D–04(l)(2) of the Act effectively prohibit gifts unless they are nominal gifts to prospective enrollees by requiring that limitation to be included in marketing standards established for the Part C and Part D programs. In addition, section 1856(b) authorizes CMS to adopt standards to implement the statute and section 1857(e)(1) of the Act authorizes the adoption of additional contract terms that the agency determines are necessary and appropriate and not inconsistent with the Medicare statute. Similar authority in connection with the Part D program is in section 1860D–12(b)(3) of the Act. Under this authority, we are finalizing the prohibition on gifts to any beneficiary, except for nominal gifts that are within the value set in the OIG guidance that are offered to all beneficiaries. This is consistent with our current policy. CMS has historically viewed prohibitions on gift giving to apply to both prospective and current plan members and Medicare beneficiaries are prospective enrollees. This prohibition protects beneficiaries from making an adverse enrollment decision because they were influenced by the receipt of a plan gift. It also protects those beneficiaries who may have been persuaded to remain enrolled in a particular plan based on receiving a plan gift. We are also finalizing a change in §§ 422.2268(b)(2) and 423.2268(b)(2) of the regulation to say that nominal gifts must be provided to ''similarly situated'' beneficiaries as opposed to the current wording of ''all beneficiaries''. We are making this change to allow plans to provide nominal gifts as a part of attending an event without obligating the plan to provide that gift to all current and prospective members regardless of event attendance.

Fourth, we failed to list the Part D EOB under § 423.2267(e) (CMS required materials and content), even though we did list the Part C EOB under § 422.2267(e)(2). (For additional information on the Part C EOB, please see § 422.111(k) of this final rule.) This was an oversight when we published the proposed rule. It is important to note that the Part D EOB is already required under § 423.128(e) and its inclusion in the list at § 423.2267(e)(2) is to make it easier for users of the regulation to identify the various materials and content required as a Part D sponsor. We have also renumbered this section accordingly to account for the addition.

CMS is finalizing these provisions as applicable for coverage beginning January 1, 2022, so these regulations will cover marketing and mandatory disclosures made in 2021 for enrollments made for effective dates in 2022. Additionally, this final rule largely reorganizes current regulations and codifies current policies. As such, CMS encourages MA organizations to take this final rule into account immediately.

F. Past Performance (§§ 422.502 and 423.503)

Since the publication of the first Medicare Advantage (MA) and Part D program regulations in 2005, CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Part D sponsor contract if that organization has failed to comply with the requirements of a previous MA or Part D contract. In the April 2011 final rule, we completed rulemaking that placed limits on the period of contract performance CMS would review (that is, 14 months

preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance (75 FR 19684 through 19686). In the April 2018 final rule, we reduced the review period to 12 months (83 FR 16638 through 16639).

In the proposed rule, CMS sought to add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance by identifying in the regulation text the criteria we will use to make a determination to deny an application based on prior contract performance. This approach will replace the past performance methodology that CMS developed and issued annually through sub-regulatory guidance.

CMS' overall policy with respect to past performance remains the same. We have an obligation to make certain that MA organizations and Part D sponsors can fully manage their current contracts and books of business before further expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees. Accordingly, we proposed to adopt three factors, each of which, on its own, represents significant non-compliance with an MA or Part D contract, as bases for denying an MA or Part D application: (A) The imposition of civil money penalties or intermediate sanctions, (B) low Star Ratings scores, and (C) the failure to maintain a fiscally sound operation. We proposed that the presence of any one of these factors in an applicant's record (with the exception of intermediate sanctions imposed on dual eligible special needs plans (D–SNPs) under § 422.752(d)) during the past performance review period could subject it to the denial of its MA or Part D application. Once finalized, these three bases would be added to our already codified authority and may be used to deny an application based on CMS' termination of an applicant's previous contract under § § 422.502(b)(3) and 423.503(b)(3). We note that while in the June 2020 (85 FR 33796) final rule we adopted § 422.116(a)(1)(ii), which states that CMS will not deny an application on the basis of an evaluation of the applicant's contracted provider network, we also stated in the preamble to the final rule at 85 FR 33866 that CMS would still consider intermediate sanctions or CMPs imposed based on non-compliance with network requirements as bases for the denial of an application based on failure to comply with a current or previous contract. Also, we decline to consider an application from an organization still covered by the 2-year period during which it had agreed, pursuant to § § 422.508(c) and 423.508(e), not to submit applications for new MA or Part D contracts as part of a mutual termination agreement entered into with CMS pursuant to § § 422.508(a) and 423.508(a).

For one of these proposed bases for application denial to be considered, we proposed that the relevant non-compliance must be documented by CMS (through the issuance of a letter, report, or other publication) during the 12-month review period established at §§ 422.502(b)(1) and 423.503(b)(1). Thus, CMS may include in our analysis conduct that occurred prior to the 12-month past performance review period but either did not come to light, or was not documented, until sometime during the review period.

In evaluating applications submitted by organizations with no recent MA or Part D contracting history, we proposed to consider the performance of contracts held by the applicant's parent organization or another organization controlled by the same parent and ascribe that performance to the applicant. Specifically, we proposed to identify applying organizations with no recent prior contracting history with CMS (that is, a legal entity brand new to the Medicare program, or one with prior Medicare contract experience that precedes the 12-month review period). We would then determine whether that entity is held by a parent of other MA organizations or Part D sponsors or otherwise shares common control with another contracting organization. In these instances, it is reasonable in the absence of any recent actual contract performance by the applicant due to a lack of recent Part C or Part D participation, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. Should one or more of the sibling organizations meet one of the bases for denial stated in (b)(1)(i), the application from the new legal entity would be denied.

We proposed to codify the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(A)—low Star Ratings, (b)(1)(i)(B)—intermediate sanction or CMP, and (b)(1)(i)(C)—failure to maintain fiscally sound operation under §§ 422.502 and 423.503. The provision governing the consideration of applicant's parent organizations or sibling entities will be stated at §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).

Comment: A commenter noted that the proposed regulatory provision as it applies to Part D is stated in error. The revisions should have been made to § 423.503, not § 423.502.

Response: We have revised the regulation language to be consistent with our discussion in the preamble to the proposed rule, so that the modification is made to § 423.503.

Comment: Several commenters objected to the use of CMPs as a sole basis for denying an application based on past performance. Some commenters noted that CMPs are imposed in a wide range of dollar amounts and for a wide range of instances of non-compliance. They maintain that often CMPs are not issued based on what could be considered substantial failures to meet MA or Part D program requirements. Also, CMPs are frequently based on performance information resulting from a routine CMS program audit. Commenters stated that, since CMS audits only a portion of all MA or Part D sponsors in a given year, using CMPs as a basis for evaluating past performance is unfair since organizations are not uniformly at risk of earning a CMP and thus being subject to an application denial based on past performance. As a result, some commenters recommended the elimination of CMPs altogether as a basis for denial. Others suggested that CMS count only CMPs above a certain threshold dollar amount.

Response: We appreciate these comments and acknowledge that, while all CMPs are based on significant non-compliance, the wide range of dollar amounts of CMPs imposed each year reflects a variation in the severity of conduct upon which they are based. It is worth considering whether all CMPs warrant treatment as a basis for determining that an applicant's past Medicare contract performance warrants denial of their MA or Part D contract qualification application. Therefore, we will strike CMPs from the regulation as a basis for an application denial based on past performance. We may consider in a future rule whether we should establish thresholds in dollar amounts or types of non-compliance that would warrant denial.

Comment: Several commenters expressed opposition to the use of just one year of low Star Ratings as a basis for denying an application based on poor past performance. Generally, they stated that one year of Star Ratings was not necessarily a true reflection of an

organization's performance and that consideration of a three-year period of ratings was a better basis for making a determination of poor past performance. Adopting this approach would be consistent with the standard used to identify contracts with the low performing icon (LPI) on the Medicare Plan Finder (MPF). Commenters also contend that one year's performance might be an outlier for an organization that otherwise has consistently good ratings. This is a particular concern given the uncertainty surrounding the potential impact of the COVID–19 pandemic on quality measures. Finally, one commenter suggested that we adopt overall scores as opposed to summary scores as the Star Ratings basis for denial for MA–PD organizations since the overall score reflects the full range of operations of those organizations.

Response: The regulations at §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x) already establish our authority to terminate an MA or Part D sponsor contract in the event that it fails for three consecutive years to achieve at least one summary rating score of at least three stars. Also, for 38 months following such a termination, CMS may deny a contract qualification application submitted by the terminated organization or one of its related entities, per §§ 422.502(b)(3) and (4) and 423.503(b)(3) and (4).

After reviewing comments and reconsidering, we are persuaded that 1 year of low ratings may be considered a contract compliance failure, but not a substantial failure on par with the other two denial bases being finalized in this rule (that is, sanctions and financial solvency). By regulation, we have already established that 3 years of low ratings is a substantial failure, justifying termination. In comparison, enrollment sanctions are almost always based on substantial compliance failures. Also, financial solvency issues by definition pose a significant risk to a contracting organization's ability to substantially comply with a contract. Therefore, those two topics continue to warrant adoption as bases for application denial based on poor past contract performance. Accordingly, in the final rule, we are removing low Star Ratings from the list of bases for an application denial. We note, however, that low Star Ratings remain a basis for the denial of an application during the three years following the CMS termination of a contract based on three consecutive years of low ratings, pursuant to §§ 422.52(b)(3) and 423.503(b)(3).

Comment: Several commenters recommended that a determination to deny an application based on past performance should be based on multiple factors, not the presence of any one of the bases (that is, sanction/CMP, low Star Ratings, or financial risk). This approach would be modeled more like our previous approach to making past performance determinations, where we used a published methodology that described 11 elements we would consider, along with point values assigned to each and established point total thresholds for denying an application. Commenters believe that, by allowing denial based on the presence of any one of our three proposed bases, our approach does not allow for a comprehensive review of the applicant's true performance.

Response: The two bases for an application denial that we adopt through this rule (enrollment sanctions and financial solvency) each by their nature already capture significant and comprehensive information about an applicant's past contract performance. Therefore, it is appropriate for CMS to rely on the presence of either of the bases to support a determination to deny an application.

CMS may impose enrollment sanctions in instances where it has found that an organization has substantially failed to comply with the terms of its Medicare contract. In our experience, such a determination may be based on a systemic failure of the organization that produces non-compliance across a range of requirements or a comprehensive failure to properly administer a critical MA or Part D plan function. Either way, the information that would support an enrollment sanction would in all instances paint a detailed enough portrait of the organization's performance to warrant the application denial.

Financial solvency goes to the heart of any organization's ability to meet all of its obligations as an MA organization or Part D sponsor. For an organization that cannot meet the programs' solvency requirements, no further analysis of its capacity to take on additional Medicare business is necessary, since this type of non-compliance places in jeopardy the organization's ability to even meet its current contractual requirements.

Comment: Several commenters recommended that CMS should afford applicants the opportunity to correct the performance that would form the basis for a determination that they failed to comply with a current contract before CMS makes a final decision to deny the application.

Response: We believe that a ''curing opportunity'' is inconsistent with the purpose of the past performance review. In effect, through the past performance denial authority, CMS takes a snapshot of an applicant's performance during a specific period of time and uses that information as a kind of credit report to evaluate whether the applicant should reasonably be entrusted with a new or expanded Medicare contract. In that kind of analysis, the only relevant information is the actual history of significant non-compliance that has occurred during the review period. The fact that the non-compliance occurred in the first place speaks to recent gaps in the applicant's ability to manage its current Medicare business. An applicant curing non-compliance during the review period reassures CMS that the organization should continue to administer its current contract, but a more sustained period of compliance is appropriate to demonstrate that its operations are stable enough to warrant eligibility for new Medicare business.

We also note that the past performance provision has its own built-in cure period in the form of the 12-month review period. By operation of the regulation, CMS reviews a new 12-month period during each annual application review cycle. As a result, past non-compliance does not stay on an applicant's record for a sustained period of time, and an applicant that might have been denied based on past performance in one application cycle can find itself eligible for approval in the very next cycle if it has taken effective corrective action.

Comment: Some commenters recommended that the regulation be revised to exclude intermediate sanctions as a basis when the organization has cured the relevant non-compliance and the sanction has been lifted during the review period. The commenters maintain that the lifting of the sanction is evidence that the organization has restored its ability to successfully manage its current operations and therefore should be eligible to apply for additional contracts.

Response: For the purposes of assessing qualification for a new MA or Part D contract, we believe that we should consider all instances of failure to comply described in the regulation that occurred throughout the twelve-month review period. While, of course, CMS expects all sanctioned organizations to move promptly to complete the necessary corrective action to have a sanction removed, we believe that in any instance, the fact that a sanction had to be imposed at all speaks to the stability of the organization and is relevant to whether it should be approved for a new contract. The

applying organization will receive credit for resolving the non-compliance that warranted the sanction during the next past performance review period, when, presumably, the organization will not have an active sanction in place at any time during the applicable 12-month review period.

Comment: A commenter advocated that our past performance authority should not be applied to applications where the purpose is not for the applicant to qualify for a new contract or a current contract with an expanded service area, but for a parent organization to restructure their existing set of MA or Part D sponsor contracts. The commenter noted that parent organizations periodically restructure their Medicare managed care business without taking on new Medicare business. Often this is done through one affiliate of the parent applying to qualify as an MA organization so that it may assume responsibility, through novation, of a contract held by another of the parent's affiliates or through consolidation of two current contracts. The commenter is concerned that our proposed policy would preclude parent organizations from making legitimate reorganizations of their business arrangements. Therefore, the commenter urges us to adopt an exception to our use of poor past performance as a basis for denying MA and Part D applications when they are part of a parent organization's plan to reorganize its contracting arrangements

Response: We note that under the regulation, parent organizations are not precluded from reorganizing their business arrangements. CMS conducts the past performance analysis at the level of the contracting entity. Parent organizations looking to have other entities take over one of their subsidiary's Medicare contracts can select an entity that already has an MA or Part D sponsor contract for that purpose. Assuming that the experienced entity does not meet any of the bases for a past performance-based denial, the entity would be eligible for approval to take over the contract held by its sibling company.

The only instance where CMS considers the past performance of an entity other than the applicant is when the applicant does not currently hold an MA or Part D sponsor contract but is related to a parent organization that has at least one subsidiary that is an MAO or Part D sponsor. In that instance, if one of the parent's subsidiaries met the criteria for a past performance-based application denial, we would deny the application from the ''inexperienced'' entity. While the application approval would not necessarily result in additional or expanded Medicare business for the parent organization, allowing another contracting entity with no Medicare experience of its own but related to an entity with demonstrated compliance issues does not promote the effective administration of the Medicare program. Even if the parent organization is seeking only to rearrange the contracting entities holding its Medicare contracts, and not to expand its number of contracts, plan offerings, or enrollees, it still would be looking to add to its roster of qualified contracting entities at a time when its efforts should be focused on bringing all of its current contracting entities into compliance with their contracts. In effect, the parent organization would be attempting to expand its Medicare business capability without focusing attention on resolving existing weaknesses in its operations. We do not believe that parent organizations should be permitted to evade our past performance review authority in that manner.

Comment: A commenter stated that organizations that acquire poor performing contracts should not have the performance of the acquired contract counted as part of the parent organization's past performance. The commenter noted that the acquiring organization should have time to focus on improving the performance of the newly acquired contract, for which it had no responsibility, without having to jeopardize its opportunity to pursue other MA or Part D lines of business.

Response: We agree with this comment. The commenter is in effect requesting that we codify the ''grace period'' policy we had previously included in the Past Performance Methodology. Specifically, when an organization acquired a contract with a record of issues related to non-compliance, under the Methodology, the purchasing parent was afforded a two-year period, calculated from the date of closing, before any negative performance by the purchased entity or contract would be imputed to the parent's existing entities. We adopted this policy in recognition of the fact that the enrollees in the non-compliant plans, as well as CMS, can benefit from a stronger organization taking over responsibility for a poor performing contract. The acquisition of a Medicare contract by a competent contracting organization is much less disruptive to plan enrollees than termination or non-renewal, which would require enrollees to obtain different Medicare coverage, often resulting in different benefit plans and providers. We believe, in the context of the evaluation of contract qualification applications, that it is important to the administration of the MA and Part D programs that qualified organizations not be discouraged from pursuing acquisitions that could resolve issues created by non-compliant contracting organizations and result in uninterrupted access to benefits and providers for the affected enrollees. To ensure that our past performance policy supports that goal, we are amending the regulation to exempt organizations for two years following the completion of an acquisition from the provision that applies the past performance record of other subsidiaries of a parent to an applicant from the same parent with no Medicare contracts. This provision will remove any concerns an acquiring organization might have that taking on a poor performing contract would compromise its ability to submit a successful contract qualification application.

Comment: A commenter recommends that we provide clarification regarding our use of the term, ''may'' in the regulation text for this provision. Specifically, the commenter notes that language at § 422.502(b)(1)(i) stating that, ''An applicant *may* be considered to have failed to comply with a contract . . .'' [emphasis added] conveys the message that CMS may or may not deny an application from an organization that meets at least one of the proposed criteria. The commenter also states that such an interpretation means that applicants meeting the criteria should have the opportunity to present information about extenuating circumstances. The commenter asks that if CMS intends that there be no flexibility in the application of our denial authority, we should make that explicit in the regulation text.

Response: As we stated in the preamble to the proposed rule, by adopting these new past performance review criteria, we sought to ''add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance.'' Accordingly, we proposed to establish three clear bases for denial, each of which on its own is sufficient to establish conclusively that an applicant has failed in a significant way to comply with MA or Part D requirements. This streamlined approach differed from our previous approach of publishing an annual Past Performance Methodology, through which we would announce the scoring of the multiple performance elements we would consider and how we would score applicants' past performance, including setting point thresholds to identify those whose application would be denied. In

establishing all of our review criteria in regulation and streamlining the number of factors to be considered, we intended to convey to applicants that CMS will deny any applicant that meets any of the new bases for a denial based on past performance. Therefore, organizations should expect that we will not consider requests that we exercise flexibility in the application of the new criteria and grant an approval to an application that meets the denial criteria.

With respect to requesting an opportunity to provide information about extenuating circumstances to CMS for consideration, we note that our regulations still provide the opportunity for denied applicants to request a review by a CMS hearing officer, and if unsuccessful there, by the Administrator. More significantly, enrollment sanctions have their own reconsideration process through which an organization may assert that extenuating circumstances justify a CMS decision to decline to impose the sanction.

Comment: A commenter urged that the past performance review should not include contracts that the applicant has already non-renewed or terminated for the upcoming contract year.

Response: We believe that the past performance analysis must be based on an applicant's actual performance history, which should not be subject to revision after the fact. An organization that non-renews a particular contract for an upcoming contract year has already established its performance history through its operation of that contract. The non-renewal does not change the fact that there is record of performance for CMS to review and consider in evaluating whether that entity deserves a new or expanded MA or Part D contract. Moreover, we would be concerned that adopting the commenter's policy would create the wrong set of incentives for contracting organizations. They should be encouraged to improve the performance of their existing contract rather than abandon the contract, and its enrollees, for the opportunity to seek to operate a new set of plans under a new contract.

Comment: A commenter questioned us to clarify that the analysis of past performance under this provision is to be done of the contracting organization and not of all contracts controlled by its parent organization. The commenter believed that our previous application of the past performance authority was done at the parent organization level and unfairly punished large parent organizations that controlled an extensive number of Medicare contracts.

Response: The new provisions we adopt in this rule continue our general policy of evaluating the past performance of the contracting organizations that have submitted applications, not their parent organizations. We have codified here the exception to that policy that we established under the previous Past Performance Methodology. That is, when an organization that does not hold an MA or Part D sponsor contract but is related to a parent organization that does hold at least one contract itself or through another subsidiary, we do apply the past performance record of the experienced subsidiary to the new applicant.

Comment: A commenter expressed support for our decision to exclude enrollment sanctions imposed against D–SNP organizations from consideration as a sanction that would form the basis for a past performance-based application denial.

Response: We appreciate the commenter's expression of support.

Comment: One commenter agreed with our proposal not to penalize an MA organization based on non-compliance with integration standards at the plan level. They suggested that CMS provide an initial enforcement safe harbor from enrollment sanctions for D–SNPs who have made a good faith effort to negotiate SMAC contracts with states. They stated that imposing these sanctions on D–SNPs while implementing look-alike standards could mean that beneficiaries could lack access to transition into otherwise compliant D–SNPs.

Response: We appreciate the support for excluding D–SNP intermediate sanctions for failure to implement the BBA of 2018 D–SNP requirements from past performance. However, changes to the D–SNP intermediate sanction policy are out of scope for this regulation.

Comment: A commenter questioned CMS to clarify whether an enrollment prohibition imposed pursuant to §§ 422.2410(c) and 423.2410(c) against an organization that failed for three consecutive years to meet the minimum medical loss ratio (MLR) threshold would count as an enrollment sanction for the purposes of a past performance-based application denial.

Response: We intended to include all enrollment sanctions, including those based on the failure to meet the minimum MLR, as a basis for application denial based on past performance, with the exception of those related to the failure of D–SNPs to integrate Medicare and Medicaid benefits, which we specifically excluded. The failure to reference the MLR sanctions in the proposed rule was simply a drafting oversight since that sanction authority resides in a different part of the MA and Part D regulations than Subpart O of Parts 422 and 423 where the general enrollment sanction authority resides. Accordingly, we are revising § 422.502(b)(1)(A) to add, ''an enrollment sanction imposed pursuant to § 422.2410(c)'' and § 423.503(b)(1)(A) to add ''an enrollment sanction imposed pursuant to § 423.2410(c)'' to the statement of enforcement-related bases for CMS to deny an application based on poor past performance to make explicit the imposition of an MLR sanction as a basis for application denial.

Congress established the significance of the MLR requirement by mandating as part of the MA statute at section 1857(e)(4)(B) of the Act and incorporating by reference into the Part D statute through1860D–12(b)(3)(D) of the Act that organizations that consistently fail to meet the 85 percent threshold should be prohibited from accepting new enrollments until they can demonstrate that they comply with the MLR requirement. Since the failure to meet the MLR requirement for three consecutive years is subject to the same penalty that may be applied to all other forms of substantial compliance failures, it follows that we include the MLR failure among the bases for an application denial based on poor past performance.

Comment: A commenter maintained that contracts with low enrollment or a large portion of plan enrollees of low socioeconomic status (SES) should not be subject to application denials based on poor past performance.

Response: The commenter provided no explanation of why, specifically, organizations that operate plans with low enrollment or with a large portion of beneficiaries with low SES should be excluded from the past performance review standard. These characteristics should have no bearing at all on two of the new bases for denial, financial solvency and intermediate sanctions.

No matter the level of a Medicare plan sponsor's enrollment or its proportion of beneficiaries with low SES, it must have sufficient financial resources to meet adequately its obligations to provide health care and prescription drug benefits to its members. Also, the required level of financial resources varies at least in part based on an organization's enrollment, so those with low enrollment should not be uniquely adversely affected by the financial solvency bases for application denial.

An MA organization or Part D sponsor must comply with the requirements of

the Part C and D programs, regardless of their level of enrollment or proportion of beneficiaries with low SES. Enrollees in low enrollment plans are not entitled to any lesser level of access to Medicare services, nor should CMS expect weaker Medicare contract administration from organizations offering such plans. Therefore, again, organizations with low enrollment are not uniquely in jeopardy of being unfairly subject to an intermediate sanction. Also, as with any sanctioned organization, a low enrollment organization may always challenge the imposition of the sanction through the appeals process stated in subpart O of Part D 422 and 423. Similarly, enrollees with low SES should receive the same level of Medicare services as all other enrollees, and should receive these services from organizations with sufficient resources to provide them.

Comment: A commenter questioned that CMS continue to produce the Past Performance Outlier report that CMS previously issued every six months to provide contracting organizations information concerning their past performance record.

Response: We will discontinue publishing the Past Performance Outlier report. CMS had adopted the report as a tool to assist organizations in tracking their scores as it was calculated under the multi-factor Past Performance Methodology. Such a report was useful when an organization's performance was assessed various point values and denial was based on those points meeting certain thresholds. However, given the simplicity of the new method for determining whether an applicant will be denied based on past performance, all organizations can track their past performance status for themselves, and no CMS report is needed.

After consideration of these comments, we are finalizing the proposal with the following modifications:

(1) We are removing from §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) references to CMPs as a basis for a determination that an applicant has failed to comply with a previous Medicare contract;

(2) We are removing the references to Star Ratings as a basis for denial at paragraph (B) of §§ 422.502(b)(1)(i) and 423.503(b)(1)(i) and re-labeling the proposed paragraph (C) concerning fiscal solvency as the new paragraph (B).

(3) We are adding language to §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii) to provide parent organizations that acquire poor performing contracts a two-year grace period during which the performance of the acquired contract will not be considered as part of our evaluation of an application submitted by a new subsidiary of the parent;

(4) We are adding language to §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) clarifying that enrollment sanctions imposed for failure to comply with MLR requirements for three consecutive years will be considered among the sanctions that qualify for a determination that the applicant failed to comply with a previous Medicare contract; and

(5) We are making the technical correction to make the relevant Part D modifications at § 423.503, not § 423.502.

G. Prescription Drug Plan Limits (§ 423.265)

Section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, provides CMS with the authority to establish additional contract terms, not inconsistent with Part D, that CMS finds ''necessary and appropriate.'' Section 1860D–11(d)(2)(B) of the Act provides CMS with the authority to negotiate bids and benefits that is ''similar to'' the statutory authority given to the Office of Personnel Management (OPM) in negotiating health benefit plans. We interpreted this authority to mean that we can negotiate a plan's administrative costs, aggregate costs, benefit structure and plan management (70 FR 4296). CMS regulations at §§ 423.272(a) and 423.272(b) require Part D sponsors to submit bids and benefit plans for CMS approval. As stated in § 423.272(b), CMS approves the plan only if the plan's offerings comply with all applicable Part D requirements. Similarly, regulations at § 423.265(b)(2) require that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to beneficiary out-of-pocket costs or formulary structures.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plans that PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. CMS has declined to approve more than three stand-alone prescription drug plans offered by a Part D sponsor in a PDP region—one basic plan and (at most) two enhanced plans. A basic plan consists of the following: (1) Standard deductible and cost-sharing amounts (or actuarial equivalents), (2) an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year, (3) a coverage gap phase, and (4) a catastrophic coverage phase that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. An enhanced plan is an optional plan offering, which provides additional value to beneficiaries in the form of reduced deductibles, reduced cost sharing, additional coverage of some or all drugs while the beneficiary is in the gap phase of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100, or some combination of those features. Section 423.104(f)(2) prohibits a Part D sponsor (as defined in § 423.4) from offering enhanced alternative coverage in a service area unless the sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

Prior to adopting regulations requiring meaningful differences between each plan sponsor's plan offerings in a PDP Region, our guidance allowed sponsors to offer additional basic plans in the same region as long as they were actuarially equivalent to the basic plan structure described in statute. However, under § 423.265(b)(2), PDP sponsors are no longer permitted to offer two basic plans in a PDP Region because Part D sponsors cannot demonstrate a meaningful difference between two basic plans and still satisfy statutory actuarial equivalence requirements. In addition, we believe that allowing more than one basic plan could result in sponsor behaviors that adversely affect the program, such as the creation of plan options designed solely to engage in risk segmentation whereby one basic plan would target enrollment of the LIS beneficiaries and the second basic plan would target a lower risk population. As it stands, healthier beneficiaries are increasingly being incentivized to enroll in low premium enhanced plans, leading to a higher risk pool in the basic plans. Permitting a sponsor to offer two basic plans in a region could ultimately result in increasing bids and premiums for basic plans, given that LIS auto-enrollment is limited to basic plans. Total government costs would likely increase because CMS pays most of the premium for LIS beneficiaries.

Since the beginning of the Part D program, CMS has consistently tried to ensure that Part D sponsors only market the number and type of PBPs necessary to offer beneficiaries meaningfully different plan options and allow them to carefully examine all of the plan offerings. However, we were persuaded

by the argument that allowing sponsors to offer enhanced prescription drug plan offerings that are not meaningfully different with respect to beneficiary out-of-pocket costs could lead to more innovation and provide sponsors with added flexibility to offer health care options that can be tailored to different beneficiary choices with a portfolio of plan options with different benefits, pharmacy networks, and premiums. As such CMS eliminated the meaningful difference requirement between a plan sponsor's enhanced alternative benefit offerings effective for contract year 2019. As a result of eliminating this requirement, we have seen a greater number of enhanced plan offerings.

CMS has examined Part D plan payment data in cases and markets with different numbers of enhanced plans. When looking at this data, we noted that markets with a greater number of enhanced plans have higher costs than basic plans. This was true even when controlling for other factors, such as population health and age. In these cases, the basic component of enhanced plans' bids was found to trend higher than basic plan bids themselves. Given the upward impact to program costs, CMS proposed to codify our policy of limiting the total number of allowed plan offerings by a Part D sponsor in a PDP region to offering no more than three prescription drug plans (one basic and up to two enhanced) per PDP region by adding a new paragraph at § 423.265(b)(2). Since this change would codify our existing practice, this change would not alter any existing processes or procedures within the Part D bid submission and approval process.

We solicited stakeholder input as to the impact of limiting the number of enhanced plan offerings to two. In addition, we sought information on what type of impact expanding the number of enhanced plan alternatives would have and whether there is any need for more than two standalone enhanced plan options per PDP sponsor per PDP region.

We received 15 comments on this proposal, which we have summarized below, and our responses follow:

Comment: Most commenters supported our proposal, citing the benefit of helping ensure that beneficiaries are able to choose from among meaningfully different plan offerings and the harm of risk segmentation. The few commenters that disagreed with the proposal stated their belief that the plan limit unnecessarily hinders sponsors from offering a broader range of more innovative plan designs.

Response: We appreciate commenters support for this proposal as well as the concern that was raised by the commenters that opposed it. Based on our annual review of Part D sponsors plan benefit packages, we believe that the current policy gives plans sufficient ability to innovate. In addition, we believe that the potential negative consequences of permitting sponsors to offer more than one basic plan and two enhanced plans per PDP region, those consequences including risk segmentation leading to additional costs to the government coupled with the risk that there may not be meaningful differences between plans offerings, outweigh any minimal benefit that may occur from allowing Part D sponsors the ability to administer additional plan offerings.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in this response to comments, we are finalizing the proposed changes to § 423.265(b)(2) without modification. However, we recognize that this regulatory provision is closely intertwined with our policy for crosswalking of enrollees, under varying circumstances, within a plan sponsor's benefit offerings. In the event that we decide to reexamine that policy, we may revisit this limitation on the number of PDP plans offered in a region. Although we are finalizing this provision as applicable beginning January 1, 2022, it codifies current policies so we encourage Part D sponsors to take this final rule into account immediately.

H. Definition of a Parent Organization (§§ 422.2 and 423.4)

Pursuant to our authority under sections 1856(b) and 1860D–12(f)(1) of the Act, we proposed to codify our definition of parent organization for purposes of the MA and Part D programs as the legal entity exercising controlling interest in an MA organization or Part D sponsor. We proposed adding a definition for the term ''parent organization'' to § 422.2 in part 422, subpart A, and § 423.4 in part 423, subpart A, to reflect this understanding.

We proposed the codification to ensure that the MA and Part D programs apply a consistent definition of parent organization. CMS uses the identity of an MA organization's or Part D sponsor's parent organization in a variety of operational contexts, including, but not limited to:

—Determining whether an individual can be deemed to have elected enrollment in a D–SNP based in part on his enrollment in an affiliated Medicaid managed care plan (§ 422.66(c)(2));
—Accounting for contract consolidations in assigning Star Ratings under the Quality Rating System for health and/or drug services of the same plan type under the same parent organization (§§ 422.162 and 423.182);
—Determining whether a new MA contract constitutes a new MA plan for calculation of Star Ratings, benchmarks, quality bonus payments, and beneficiary rebates, (§ 422.252).
—Recognizing an individual's appointment as an MA organization's or Part D sponsor's compliance officer based on his or her status as an employee of the organization, its parent organization, or a corporate affiliate (§§ 422.503(b)(4)(vi)(B)(*1*) and 423.504(b)(4)(vi)(B)(*1*));
—Determining whether an applicant for a new PDP contract is eligible to receive a contract in a particular service area (§ 423.503(a)(3)) after evaluating whether the approval of an application would result in a parent organization, directly or through its subsidiaries, holding more than one PDP contract in a PDP region;
—Determining whether to administer an essential operations test to a Part D contract applicant new to the Part D program (§§ 423.503(c)(4) and 423.505(b)(27), taking into account the exemption from the essential operations test for subsidiaries of parent organizations that have existing Part D business;
—Releasing summary Part D reconciliation payment data at the parent organization level (§ 423.505(o)); and
—Determining whether CMS will recognize the sale or transfer of an organization's PDP line of business, where CMS regulations require the transfer of all PDP contracts held by the selling or transferring sponsor unless the sale or transfer is between wholly owned subsidiaries of the same parent organization (§ 423.551(g)).

We currently define the term ''parent organization'' for purposes of applying the prohibition against approving an application that would result in a parent organization holding more than one PDP sponsor contract in a region as an entity that exercises a controlling interest in the sponsor. (See § 423.503(a)(3)). In conjunction with the proposal to codify a more detailed definition that would apply throughout the MA and Part D programs, we proposed to delete that language in § 423.503(a)(3).

Under the proposed definition, a parent organization is the legal entity that holds a controlling interest in the

MA organization or Part D sponsor, whether it holds that interest directly or through other subsidiaries. The controlling interest can be represented by share ownership, the power to appoint voting board members, or other means. Control of the appointment of board members is particularly relevant with respect to not-for-profit organizations, where there is often no direct corollary to the ownership of corporate shares in for-profit organizations. We recognize that the many ways that one legal entity may have a controlling interest in another legal entity are varied and could take many forms too numerous for us to create an exhaustive list. Therefore, we proposed a definition that includes the ability for us to look at other means of control to be exercised or established.

We further specified that the parent organization cannot itself be a subsidiary of another entity. This ensures that each MA organization or Part D sponsor has a single parent organization for purposes of the MA and Part D programs. For example, if Company A owns 80 percent of Company B, which in turn owns 100 percent of an MA organization, Company A would be the parent organization of the MA organization under the proposed definition.

We explained that the proposed definition codifies current policy and ensures continued consistency throughout the MA and Part D programs. We note that this definition of parent organization will apply in implementing the proposed change to § 422.550 regarding the type of change of ownership that CMS would permit for MA contracts; we discuss that proposal in section V.D. of this final rule.

Comment: A commenter suggested that we further clarify what we mean by ''controlling interest'' by specifying that it means ownership of a ''majority'' of shares, appointment of a ''majority'' of voting board members, and/or by being a sole member.

Response: We do not believe this clarification is necessary or appropriate. We also believe it may unnecessarily narrow the definition of ''controlling interest'' to one that simply counts shares of stock when organizations may adopt other criteria for allocating board membership and voting rights. For example, two organizations may own equal shares in a legal entity, so that neither holds a majority of shares, but the articles of incorporation or other organizational documents may specify that one of them has the power to cast the deciding vote when they disagree. In such a situation, CMS may determine that the organization with the power to make decisions in case of dispute is the parent despite there not being a single majority shareholder. Conversely, if two organizations owned equal shares of a legal entity and appointed equal numbers of board members and the organizational documents specified that decisions must be made jointly, CMS might determine that neither organization is the parent; additional factual information might be necessary to identify the organization that owns a controlling interest in the particular entity.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the provision as proposed without modification. Although we are finalizing this provision as applicable to coverage beginning January 1, 2022, it codifies current policies so we anticipate that there will be no change in operations or administration of the MA and Part D programs and encourage MA organizations and Part D sponsors to take this final rule into account immediately.

I. Call Center Requirements (§§ 422.111 and 423.128)

In implementing sections 1851(d) and 1860D–4(a)(3) of the Act, CMS established, at §§ 422.111(h) and 423.128(d), that MA organizations and Part D sponsors are required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees, and, for a Part D plan, to pharmacies in the plan network, upon request. One of these enumerated mechanisms includes operating a toll-free customer service call center.

In this final rule, CMS is adding greater specificity and clarity to our requirements for MA and Part D plans by delineating more explicit minimum performance standards for MA and Part D customer service call centers, as well as ensuring greater protections for beneficiaries. We proposed changes to §§ 422.111(h) and 423.128(d) for this purpose and explained in the proposed rule our goals of providing plans clear standards under which to operate their customer service call centers and eliminating uncertainty with regard to CMS's expectations. Customer service call centers include call centers operated for current enrollees, prospective enrollees, and for pharmacies in plans' networks that are seeking information on drug coverage for customers enrolled in a particular plan. For the most part, we proposed, and are finalizing, amendments to §§ 422.111(h) and 423.128(d) to codify existing guidance and CMS's overall policy with respect to operating a toll-free customer service call center remains largely the same. We have always expected MA organizations and Part D sponsors to operate customer service call centers in a way that ensures beneficiaries and pharmacies have timely and accurate access to information about benefits in a manner that they can understand and use. Providing specific performance standards in regulation text clearly lays out the performance requirements and our expectations for customer service call centers. Additionally, beneficiaries will benefit from CMS holding plans to clearly defined call center standards. As we explained in the proposed rule, failure to comply with the more specific minimum requirements finalized in this rule would represent significant deviation from acceptable call center operational practices and a significant risk to beneficiaries' well-being under our enforcement policies and applicable regulations.

In §§ 422.111(h)(1)(i) and 423.128(d)(1)(i), we proposed that customer service call centers must be open from at least 8:00 a.m. to 8:00 p.m., local time, in all service areas and regions served by the MA or Part D plan, and for Part D plans, that any call center serving network pharmacies or pharmacists employed by those pharmacies must be open any time a pharmacy in the plan service area is open. We reminded stakeholders that MA–PD plans are Part D plans that must comply with Part 423 requirements. We proposed these timeframe standards to lend greater specificity to the current regulation text, which only requires a call center to be open during ''normal business hours.'' We explained that 8:00 a.m.–8:00 p.m. constitutes normal business hours for beneficiary access, based both on our knowledge of industry-wide practices and our experience with MA and Part D plans' call center operations in particular. Codifying the requirement for call centers serving network pharmacies to be open any time a pharmacy in that network in the plan's service area is open reflects the need to resolve questions about benefits and coverage promptly at the point of sale. The vast majority of current MA and Part D plans meet these standards. We explained that by requiring plans to be open for calls from current and prospective enrollees from 8:00 a.m. to 8:00 p.m. in all service areas or regions served by that Part C or D plan, our proposal would ensure that in instances in which plans operate in

service areas that straddle multiple time zones, all beneficiaries and pharmacists have equal access to call center services.

We proposed in §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) a series of minimum requirements that define specific operational requirements for customer service call centers. In §§ 422.111(h)(1)(ii)(A) and 423.128(d)(1)(ii)(A), we proposed to codify the requirement that the average hold time be 2 minutes or less, with specific text to explain when the two-minute count starts to ensure consistent application of the metric by defining the hold time as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person. In §§ 422.111(h)(1)(ii)(B) and 423.128(d)(1)ii)(B), we proposed to codify the requirements that the call center answer 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction. In §§ 422.111(h)(1)(ii)(C) and 423.128(d)(i)(ii)(C), CMS proposed to codify the requirement that 5 percent or less of incoming call calls be disconnected or unexpectedly dropped by the plan customer call center. These standards both ensure that beneficiaries can consistently access call centers in a timely manner and set thresholds that plans can reasonably attain. We explained that data gathered from our call center monitoring studies indicates that 90 percent of MA organizations and Part D sponsors have average hold times of less than 2 minutes, 87 percent answer 80 percent incoming calls within 30 seconds, and 82 percent have disconnect rates of less than 5 percent. As we further explained, longstanding CMS policy interpreting the current regulatory requirement for the call center to meet standard business practices requires call centers to answer calls within 30 seconds and plans overwhelmingly comply with this requirement.

CMS also proposed to amend §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to further delineate accessibility requirements for non-English speaking and limited English proficient (LEP) individuals. Plans have always been required to provide interpreters when necessary to ensure meaningful access to limited English proficient individuals, as that is consistent with existing civil rights laws. In addition, it ensures meaningful access to Medicare beneficiaries to Medicare-covered benefits. We proposed to further require that interpreters be available within 8 minutes of reaching the customer service representative and that the interpreter be available at no cost to the caller. These requirements are consistent with our interpretation of the requirement for call centers to meet standard business practices and performance is measured against this standard in our current monitoring and oversight activities. We explained that data from our call center monitoring indicates that 95% of plans already meet this standard.

CMS proposed to add §§ 422.111(h)(1)(iv) and 423.128(d)(1)(v), explicitly requiring that call centers respond to TTY-to-TTY calls, consistent with standards established under existing law governing access for individuals with disabilities at 47 CFR part 604, subpart F. Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act already require the provision of appropriate auxiliary aids and services for individuals with disabilities, such as deaf or hard-of-hearing individuals. We also proposed, at §§ 422.111(h)(1)(v) and 423.128(d)(1)(v), that when using automated-attendant systems, MA and Part D plans must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay systems. See 28 CFR 35.161, 36.303(d). We explicitly clarified that the requirements proposed at §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii)—regarding the average hold time, average answer time, and disconnect rate—also apply to TTY calls. CMS will hold plans accountable for complying with the requirements of §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) when receiving TTY calls. We explained in the proposed rule how the proposed standards are consistent with current CMS interpretation and implementation of the requirement that plans have a call center that meets standard business practices and how. We explained that CMS data shows that 91 percent of plans currently respond to TTY calls within 7 minutes. We solicited comments on adopting the 7-minute response time as a TTY standard.

We proposed to codify our existing interpretations and policies regarding MA and Part D plan call centers as explicit requirements for operating a toll-free customer service call center in §§ 422.111(h) and 423.128(d). We proposed this codification to ensure transparency and stability for plans about the performance standards they must meet.

In this section of this rule, we summarize the comments we received and provide our responses and final decisions.

Comment: Several commenters requested that we clarify whether the requirements for customer service call centers apply to call centers operated primarily for sales and marketing to prospective enrollees. The August 6, 2019 HPMS memo issuing the updated Medicare Communication and Marketing Guidelines permitted plans to operate telephone lines designated solely for marketing activities, such as sales and enrollment, under different business hours than customer service call centers for current and prospective enrollees. The guidelines required that sales lines adhere to all other requirements for customer service call centers. Some commenters requested that CMS revise the proposed rule to reflect that guidance permitting sales and enrollment telephone lines to operate during different business hours than customer service call centers for current and prospective enrollees.

Response: Once applicable, the provisions of this final rule will supersede prior, inconsistent call center guidance in the Medicare Communications and Marketing Guidelines. While we proposed to codify existing guidance, we did not include a provision permitting call centers operated for the MA plan to have different business hours based on specific functions. Sections 422.111(h) and 423.128(d) require the call centers to be a mechanism for providing the information described in those regulations to current and prospective enrollees. Using a separate call center for prospective enrollees is not consistent with the current regulation or the proposed revisions. We have therefore reconsidered that prior guidance and will not be using it going forward. Specifically, the policies included in this final rule apply the same requirements applicable to all customer service call centers for current and prospective enrollees, including those used for sales and enrollment. This includes the requirements related to hours of operation.

The guidance issued in in August 2019 to permit separate standards for a sales-only call center has proved difficult for CMS to enforce and confusing for some plans to adhere to. Specifically, plans have expressed confusion about the distinction between sales call centers and customer service call centers for prospective enrollees. CMS discovered that some plans were inappropriately using their automated answering system to direct calls from

numbers not known to be associated with plan enrollees to sales lines, making it difficult for both current enrollees and prospective enrollees to reach the customer service call center they were attempting to call and compromising the ability of current and prospective enrollees to get access to the information specified in §§ 422.111 and 423.128. That information addresses topics and specifics that beneficiaries should have, such as information about benefits (including cost sharing and out of network coverage), access, and enrollment procedures, to make an enrollment election. Returning to a clearer and uniform approach to interpreting and implementing the call center requirements is important to ensure consistency and clarity. We also do not believe that this increases burden on plans, as even after the August 2019 guidance plans were required to continue operating call centers for current and prospective enrollees from 8 a.m. to 8 p.m. Under this final rule, all plan call centers must comply with the regulation standards.

Comment: Some commenters wrote in approval of what they perceived to be stricter requirements for customer service call centers than CMS previously applied. For example, a commenter noted that the proposed rule would require call centers to connect callers with LEP to an interpreter within 8 minutes 100 percent of the time. A few requested that CMS apply more stringent standards than proposed and currently used, including requiring that all customer service call centers be open 24 hours a day, 7 days a week.

Response: CMS appreciates the support. Our intention in codifying the current policy on customer service call center is to provide a uniform standard for customer service call centers, including call centers for current and prospective enrollees. We were explicit that under our proposal, CMS's overall policy with respect to operating a toll-free customer service call center would remain largely the same and did not describe our proposals as creating more stringent specific standards. We do not believe that the requirements of the final rule represent a significantly more stringent standard than that which we expected under earlier guidance. In particular, it was not our intention to apply a stricter standard for interpreter availability or call center hours of operation than is described in current guidance. To clarify this, we are finalizing §§ 422.111(h)(1)(iii)(B) and 423.128(d)(1)(iii)(B) with a change from the proposal to reflect the current compliance standard we used evaluating interpreter availability—80 percent of calls being connected to an interpreter within 8 minutes. We note that plans already largely comply with this requirement of the final rule because 95 percent of plans already meet this standard and, in addition, the 80 percent threshold is consistent with the thresholds codified with respect to the speed of answer.

We are also finalizing, at §§ 422.111(h)(1)(i)(B) and 423.128(d)(1)(i)(A), the proposed standards for operating hours, with a change to clarify that we are not expanding the hours of operation required for customer call centers compared to current practice (except to the extent we are discontinuing the allowance for sales and enrollment call centers to be open for shorter hours than customer service call centers for current and prospective enrollees). Not only do we not believe that customer service call centers for current and prospective enrollees need to be open 24 hours a day, 7 days a week without exception to ensure adequate service to Medicare beneficiaries, we do not believe it is necessary to expand the current policy in section 80 of the Medicare Communications and Marketing Guidelines, which permits call centers to be closed most Federal holidays and on weekends from April 1 through September 30. Therefore, we are finalizing our proposal for hours of operation with the addition of the same exceptions that have been outlined in the Medicare Communication and Marketing Guidelines for several years:

—From October 1 through March 31 of the following year, call centers may be closed on Thanksgiving Day and Christmas Day, so long as the interactive voice response system or similar technology records messages from incoming callers on those holidays and such messages are returned in one (1) business day. This time period encompasses both the MA and Part D Annual Enrollment Period and the MA Open Enrollment period. Plans must not close their call centers for any other days during this period because of the need for both current and prospective enrollees to reach plans during these generally applicable enrollment periods in order to make informed decisions about their plan choices.

—From April 1 through September 30, call centers may be closed on any Federal Holiday and on any Saturday or Sunday, so long as the interactive voice response system or similar technology records messages from incoming callers and such messages are returned in one (1) business day.

These exceptions have been in place for many years and that there has been no indication that allowing call centers to close on these days has negatively impacted beneficiaries' ability to reach and obtain services and information from plans.

Comment: Some commenters expressed approval of CMS codifying performance standards in the regulation.

Response: CMS appreciates commenters' support for the proposed rule. In this final rule, we are organizing and structuring the addition of these more specific, minimum standards for plan call centers to §§ 422.111(h)(1) and 423.128(d)(1) in a different way than proposed. Instead of replacing the existing regulation text with the more specific standards, we are maintaining the current regulation text that requires plan call centers to be open during usual business hours, provide customer telephone service in accordance with standard business practices, and provide interpreters for non-English speaking and limited English proficient (LEP) individuals. These general performance requirements remain applicable to plan call centers and are not changed by this final rule. Rather, this final rule adds the new specific standards with additional language to clarify how these specific standards will be applicable for coverage beginning on and after January 1, 2022. This means that these standards will apply to call center operations made in 2021 for enrollments made for contract year 2022 (*e.g.,* for call center activities during the Annual Election Period for 2022 that takes place in fall 2021). This clarifies how these specific standards are minimum performance thresholds for plan call centers and illustrates CMS' expectation that plan call centers operate consistent with standard business practices to provide information and assistance to current and prospective enrollees. Regardless of whether there is a specific, minimum quantitative standard in our regulations, plans should ensure that their call centers provide high quality customer service, at a minimum consistent with usual and standard business practices. The regulations at §§ 422.111(h) and 423.128(d) are clear that call centers are one of several mechanisms by which plans must provide specific information on a timely basis to current and prospective enrollees upon request. By adding certain specific minimum standards, we do not intend to dilute or lower that requirement.

Comment: A few commenters requested that CMS apply the standards for pharmacy call centers to call centers for other health care providers, such as

physicians and hospitals. The commenter explained that health care providers also operate 24 hours, 7 days a week and may therefore need real time access to plan representatives to determine coverage for services.

Response: CMS appreciates the suggestion. We understand that hospitals, physicians, and other non-pharmacy providers often operate 24 hours a day, 7 days a week and may wish to have real time access to plan representatives at all times. However, unlike pharmacies, physicians and hospitals do not administer a point of sale benefit. Rather, they bill retrospectively. Therefore, immediate access to the plan through the call center does not appear to be necessary to ensure access to medically necessary covered health care. While CMS is open to considering future rulemaking in this area, we need to gather more evidence and stakeholder input to determine whether it is appropriate or necessary to require plans to operate 24-hour, 7-day-a-week call centers for non-pharmacy providers.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the amendments to §§ 422.111(h) and 423.128(d) regarding call centers as proposed, with five modifications.

Two of the modifications address concerns explicitly raised by commenters. We are finalizing the proposed standards for interpreter availability with the addition that 80 percent of calls requiring an interpreter must be connected to an interpreter within the proposed 8 minutes, rather than simply requiring all such calls to be connected within 8 minutes. In addition, CMS is finalizing the proposed hours of operation requirements with modifications to provide exceptions for certain federal holidays and on certain weekends so long as callers can leave messages and those messages are returned within one business day. These modifications reflect CMS's intention to largely codify existing policy in this rule.

The third modification that we are finalizing is similar to these two changes. CMS requested comment on whether to adopt the 7-minute TTY response time in the regulation. We received no comments on this issue and have decided to finalize the rule with a requirement that 80 percent of TTY calls be connected to an operator within 7 minutes. As discussed in the February 2020 proposed rule, this reflects current performance by plans (91 percent connect calls within the required time frame) and is consistent with the thresholds codified with respect to speed of answer and interpreter availability.

Fourth, it has come to CMS's attention that 47 CFR, part 64, subpart F applies to state-operated TTY relay systems and not to plan call centers. The proposed rule would have, at 42 CFR 422.111(h)(1)(iv) and 423.128(d)(1)(v)(A), required plan call centers to comply with these standards. However, neither CMS nor plans have authority over state-operated relay systems and Medicare plan call centers do not perform the same function as state relay systems. Therefore, CMS is not finalizing those provisions and is designating the remaining regulation text accordingly.

Finally, we are finalizing the proposed additions to §§ 422.111(h) and 423.128(d) with a slightly different structure to be consistent with how this final rule is adding specific minimum standards and is generally applicable beginning with coverage for 2022.

Although we are finalizing these changes to §§ 422.111(h)(1) and 423.128(d)(1) regarding call centers, with the modifications described above, as applicable with coverage beginning on and after January 1, 2022, it codifies current policies so we encourage MA organizations and Part D sponsors to take this final rule into account immediately.

VI. Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

The intent of this final rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states. The proposals addressed reassessments, service delivery requests, appeals, participant rights, required services, excluded services, interdisciplinary team requirements, medical record documentation, access to data and records, safeguarding communications, and service delivery requirements. The finalized changes would reduce unnecessary burden on PACE organizations, provide more detail about CMS expectations and provide more transparent guidance.

A. Service Determination Request Processes Under PACE (§§ 460.104 and 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We issued regulations on grievances at § 460.120, and we issued regulations on appeals at § 460.122. Additionally, CMS created a process under § 460.104(d)(2) to allow participants or their designated representatives to request that the interdisciplinary team (IDT) conduct a reassessment, when the participant or designated representative believes the participant needs to initiate, eliminate or continue a service. The process under § 460.104(d)(2) is commonly referred to by CMS and industry as the service delivery request process. This process serves as an important participant protection, as it allows a participant to advocate for services. As we stated in the Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions final rule (hereinafter referred to as the 2006 PACE final rule), ''[t]he provisions for reassessment at the request of a participant [were] intended to serve as the first stage of the appeals process.'' (71 FR 71292). Section 460.104(d)(2) currently sets out the responsibilities of a PACE organization in processing each request. Currently, a participant or their designated representative initiates a service delivery request when they request to initiate, eliminate, or continue a service. Once the IDT receives the request, the appropriate members of the IDT, as identified by the IDT, must conduct a reassessment. The IDT member(s) may conduct the reassessment via remote technology when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or their designated representative agrees to the use of remote technology. However, the appropriate member(s) of the IDT must perform an in-person reassessment when the participant or their designated representative declines the use of remote technology, or before a PACE organization can deny a service request. Following the reassessment, the IDT must notify the participant or designated representative of its decision to approve or deny the request as expeditiously as the participant's condition requires, but generally no later than 72 hours from the date of the

request for reassessment. If the request is denied, the PACE organization is responsible for explaining the denial to the participant or the participant's designated representative both orally and in writing. The PACE organization is also responsible for informing the participant of his or her right to appeal the decision, including the right to request an expedited appeal, as specified in § 460.122. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised plan of care, the failure constitutes an adverse decision and the participant's request must be automatically processed as an appeal in accordance with § 460.122.

While this section provides an important participant protection, we have heard from stakeholders that the language in § 460.104(d)(2) is overly broad as written, and that even simple requests to initiate a service require a reassessment and a full review of the request by the PACE organization's IDT. Stakeholders have also noted that addressing the service delivery request process in the section of the regulation governing participant assessments undercuts the importance of the requirements for processing these requests. Additionally, through CMS oversight and monitoring, we have identified a need to better define what constitutes a service delivery request and create clearer guidance on how PACE organizations must identify and process these requests.

We proposed moving the requirements for service delivery requests at § 460.104(d)(2) to a new section of the regulations at § 460.121, titled ''Service Delivery Requests.'' We used the term ''service delivery request'' because that is the term typically used by industry and CMS to describe these actions, however, we solicited comments on whether we should utilize this term or consider something different. For example, the initial decision to cover a drug in Part D is a coverage determination (§ 423.566), and the initial decision to cover an item or service in Part C is an organization determination (§ 422.566). We requested feedback on whether a term other than ''Service Delivery Request,'' such as ''PACE Organization Determination,'' ''Coverage Determination,'' or ''Service Determination,'' would be preferable.

In addition to proposing that the requirements for processing service delivery requests would be moved from § 460.104(d)(2) into a new section, we also proposed to modify these requirements based on industry feedback and lessons learned through our experience operating the PACE program and monitoring PACE organizations. First, we proposed to reorganize the requirements for clarity and to better align them with the appeals regulations in subpart M of parts 422 and 423, for Medicare Advantage (MA) and Part D respectively, while also ensuring the requirements address the specific features of the PACE program, which is a unique combination of payer and direct care provider. We believe aligning the layout of the regulation and the notification requirements of the initial determination processes in PACE, MA, and Part D would allow us to minimize confusion for participants, who are often familiar with the initial determination and appeals processes in the Parts C and D programs, and would also increase transparency for PACE organizations regarding CMS' expectations.

While the current regulation at § 460.104(d)(2) begins with the requirements for processing a request for reassessment, we added § 460.121(a) to require that a PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of § 460.121. We believe it is important to ensure that PACE organizations develop internal processes and procedures to properly implement this process.

At § 460.121(b), we define what constitutes a service delivery request and what does not. We define what constitutes a service delivery request at § 460.121(b)(1). Currently, the process in § 460.104(d)(2) is triggered if the participant (or his or her designated representative) believes the participant needs to initiate, eliminate, or continue a particular service. At § 460.121(b)(1), we specify that the process for service delivery requests would apply to 3 distinct types of service delivery requests, specifically, a request to (1) initiate, (2) modify, or (3) continue a service.

We note that the term ''services'' is already defined at 460.6 to include ''items,'' and we proposed, as discussed in section VI.I. of this final rule, to make explicit that this definition is meant to reflect the full scope of the PACE benefit package, and thus also includes ''items'' and ''drugs.'' Therefore, our use of ''service'' or ''services'' throughout § 460.121 always includes any type of PACE-covered services, items, or drugs, and participants have the right to advocate with respect to all types of PACE-covered services, items, or drugs that they believe may be necessary. The language at § 460.121(b)(1) would retain the existing concepts of ''initiating'' and ''continuing'' services but would replace the term ''eliminate'' with the term ''modify.''

In § 460.121(b)(1)(i) that the first type of service delivery request would be a request to initiate a service. This first type of request is based on the existing language at § 460.104(d)(2). In § 460.121(b)(1)(ii) that the second type of service delivery request would be a request to modify an existing service. We specify that requests to modify an existing service include requests to increase, reduce, eliminate, or otherwise change a particular service. We believe that defining service delivery requests to include requests to modify an existing service is an important protection, as participants may believe that the services they are currently receiving are not sufficient to meet their needs. For example, a participant may request to increase their home care from 3 hours a week to 6 hours a week because they believe that they are becoming less steady in their gait and they are afraid to be alone for long periods.

The third type of service delivery request at § 460.121(b)(1)(iii), is a request to continue a service that the PACE organization is recommending be discontinued or reduced. This type of request would apply to circumstances where the PACE organization is recommending to discontinue or reduce a service that the participant is already receiving, and the participant wishes to continue receiving that service. An example of this type of request would be a participant that is attending the PACE center 5 days a week and the PACE organization decides to reduce attendance to 4 days a week. If the participant requests to continue attending the center 5 days a week, this request must be processed as a service delivery request under our proposal. Another example would be if a participant is receiving a specific drug, and the IDT makes a decision to stop providing that drug. Under the proposal, the participant's request to continue receiving the drug would be processed as a service delivery request. Through our monitoring of PACE organizations, we have identified instances where a participant requests to continue receiving a service that has been reduced or discontinued, and the PACE organization provides the participant appeal rights under § 460.122 instead of conducting a reassessment as required under the current § 460.104(d)(2). We would include requests to continue coverage of a service in part to ensure that PACE organizations understand that they must process a service delivery request for these situations before

processing an appeal under § 460.122. Our revisions to this section, as well as our revisions to the appeals regulation discussed in section VI.B. of this final rule, would establish that the service delivery request process is the first level of the appeals process, and requests to continue a service must first be processed under the service delivery request process prior to an appeal being initiated under § 460.122. We discuss the scope of the appeals process in greater depth in our discussion of the updates to the appeals process in section VI.B. of this final rule. We also proposed that participants would be allowed to make this type of service delivery request before a service was actually discontinued, to permit the participant to advocate for a continuation of the service. This requirement is reflected in the language we proposed for § 460.121(b)(1)(iii), where we emphasize that this provision relates to a service that the PACE organization is recommending be discontinued or reduced. We believe by wording this requirement in this way, we would make clear that the participant could make a service delivery request as soon as a PACE organization recommends reducing or discontinuing a service. For example, if the IDT was recommending reducing center attendance from three days a week to two days a week, and the participant wanted to continue coming to the center three days a week, the participant could request a service delivery request once the IDT recommended the reduction, even if the reduction in days had not yet been implemented.

We recognize that our proposal defined what constitutes a service delivery request broadly. We also understand that there are circumstances that are unique to PACE where a request may not constitute a service delivery request based on the role of a PACE organization as a direct care provider that is responsible for coordinating and delivering care. Therefore, we proposed an exception to the definition of a service delivery request. In paragraph (b)(2) we specify that certain requests to initiate, modify, or continue a service would not constitute a service delivery request, even if the request would otherwise meet the definition of a service delivery request under (b)(1). Specifically, at § 460.121(b)(2) if a request is made prior to the development of the initial care plan the request would not constitute a service delivery request. This exemption would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased). We believe this approach would be beneficial to the participant and the PACE organization as the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. For example, if the PACE organization is developing the initial plan of care and actively considering how many home care hours the participant should receive, and the participant makes a request for a particular number of home care hours, that request would not be a service delivery request because the IDT was actively considering that question in developing the plan of care. Once the initial plan of care is developed, if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service delivery request at that time.

While drafting the proposal, we considered other ways to potentially limit the application of the service delivery request process to account for situations where it is possible to adequately address a request without undertaking the full service delivery request process. First, we considered excluding requests for services made during the course of a treatment discussion with a member of the IDT from the service delivery request process, so long as the IDT member is able to immediately approve the service. Ultimately we decided these situations should constitute service delivery requests, in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service delivery requests and those that do not. However, in an effort to reduce burden, we determined that it would be appropriate to process service delivery requests that an IDT member is able to approve in full at the time the request is made in a more streamlined manner than other service delivery requests. We discuss our proposals on this point in more detail in the section relating to § 460.121(e)(2) in this final rule.

We also considered whether we could exclude other types of requests from the service delivery request process. For example, we have received questions from PACE organizations about requests that do not relate to health care or to a participant's medical, physical, emotional, and social needs, such as a participant requesting lemons in their water, or a participant requesting a particular condiment at lunch. We considered proposing to exclude requests that are not related to health care or to the participant's medical, physical, emotional, and social needs, and therefore would not constitute a service delivery request. We strongly believe that any time a service may be necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, that request should be processed as a service delivery request. We similarly understand that some requests are completely unrelated to the participant's health care or condition. However, we believe that adding a provision to address this relatively insignificant issue would potentially cause confusion for PACE organizations and participants and therefore we did not propose such a provision at this time. We solicited comments on whether specifying that requests unrelated to a participant's medical, physical, emotional, and social needs need not be processed using the service delivery request process would benefit PACE organizations without restricting participants' ability to advocate for any service they believe may be necessary, regardless of whether that is meals, transportation, drugs, home care, or other services provided as part of the PACE benefit, and if so, how we should word such a provision.

We also proposed at § 460.121(c) to specify the individuals who can make a service delivery request. Under the current requirements in § 460.104(d)(2), only the participant or the participant's designated representative may request to initiate, eliminate, or continue a particular service. This proposal would expand the number of individuals who can make a service delivery request on behalf of a PACE participant to include the participant, the participant's designated representative, or the participant's caregivers. We believe that the proposal would be consistent with the current practice of most PACE organizations, in part because caregivers are often also participants' designated representatives; however, it would affirmatively state in regulation that these individuals may make service delivery requests. We believe this would provide an important safeguard for participants, as caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For example, if a PACE participant's wife believes that the participant needs more home care to assist with toileting, bathing and dressing, she would be able to make a service delivery request to the PACE organization and advocate for that service delivery request, regardless of

whether she is her spouse's designated representative. The proposal also aligned with current care plan regulations (§ 460.106(e)) which state that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. Because caregivers are involved in the care planning process and determining what care may be necessary, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant, regardless of whether these service delivery requests result in changes to the plan of care. While a designated representative or caregiver such as a family member may initiate the service delivery request process, the PACE organization remains responsible for issuing a decision based on the individual needs of the participant regardless of the party that initiated the request. We solicited comments on this proposal to expand the number of individuals who can make a service delivery request on behalf of a PACE participant. In addition, we solicited comment regarding whether or not there are other individuals that should be allowed to make service delivery requests on behalf of a participant. For example, in MA and Part D, providers or prescribers can initiate a request for coverage (either coverage determination or organization determination) on behalf of a beneficiary, which allows prescribers or other providers to advocate for drugs or services that are unique to their discipline or scope of practice. In PACE, this would mean that if a participant went to a contracted specialist, that specialist would be allowed to advocate or request a service specific to their discipline. We specifically solicited comments on whether we should specify that prescribers or providers, outside of the IDT, can make a service delivery request on behalf of a participant in PACE.

We also proposed at § 460.121(d) to specify how a service delivery request may be made. The current regulation at § 460.104(d)(2) is silent regarding how a participant or his or her designated representative may request to initiate, eliminate, or continue a particular service. We proposed at § 460.121(d)(1) to permit service delivery requests to be made either orally or in writing. We believe this is consistent with current practice for all PACE organizations. The right to request an initial determination either orally or in writing is provided as an enrollee safeguard in both MA and Part D (see §§ 422.568(a)(1), 422.570(b), 423.568(a)(1), and 423.570(b)), and given the vulnerability of the PACE population, we believe it is important that PACE participants also have the ability to submit service delivery requests in either form. We also proposed at § 460.121(d)(2) that service delivery requests may be made to any individual who provides direct care to a participant on behalf of the PACE organization, whether as an employee or a contractor. All employees and contractors that provide direct participant care should be trained to recognize and document these requests when they are made by a participant pursuant to § 460.71. Because of the comprehensive nature of the PACE program and the requirement that PACE organizations provide care across all care settings, participants may not know whom they should communicate with when making a service delivery request. For example, certain participants may not attend the PACE center on a routine basis and a home care aide may be the only representative of the PACE organization the participant has contact with frequently. Under this proposal, the participant could make service delivery requests to the home care aide, and those requests would be considered to have been made to the PACE organization. All individuals providing direct care to participants, whether contractors or employees, should be trained to recognize service delivery requests and ensure such requests are documented appropriately and brought to the IDT as part of the training employees and contractors receive under § 460.71(a)(1). While we require that all contractors and employees that provide direct care be able to receive service delivery requests from participants, we solicited comment on whether this requirement should be limited to a smaller subset of individuals. For example, we solicited comment on whether we should instead require only those contractors or employees who provide direct participant care in the participant's residence, the PACE center, or while transporting participants to receive service delivery requests.

We would establish new requirements at § 460.121(e) specifying how service delivery requests must be processed. In § 460.121(e)(1) all service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the request was made. The existing requirement at § 460.104(d)(2)(iii) specifies that the IDT must generally notify the participant or designated representative of its decision in regard to a request to initiate, eliminate, or continue a particular service no later than 72 hours after the date the IDT receives the request for reassessment. Stakeholders have requested that CMS explain if the current 72-hour timeframe begins when any member of the IDT receives the service delivery request, or when the full IDT receives the request. In order to avoid similar questions about the new service delivery request process we proposed, we also established two distinct timeframes. Specifically, an initial timeframe for the PACE organization to bring a service delivery request to the IDT, and a second timeframe for the IDT to make a decision and provide notice of the decision to the participant. We would include this second timeframe at § 460.121(i), and discuss in more detail later in this section. We believe that creating these distinct timeframes would benefit both PACE organizations and participants. We also believe it is necessary to ensure that once a service delivery request is made, it is brought to the IDT for processing as expeditiously as the participant's condition requires but no later than 3 calendar days from when the request was actually made. In monitoring PACE organizations, we have seen organizations take a week or longer after a request was first made to bring the request to the IDT for consideration. By establishing a requirement that service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires but no later than 3 calendar days from the time the request is made, we believe this would ensure participant requests are handled expeditiously while still ensuring the IDT has sufficient time to process the service delivery request and consider all relevant information when making a decision. We solicited comments on this proposal to establish a new timeframe for PACE organizations to bring service delivery requests to the IDT.

We also proposed at § 460.121(e)(2) to specify an exception to the processing requirements for service delivery requests. Specifically, if a member of the IDT receives a service delivery request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. We understand that PACE organizations, as direct care providers, routinely interact with participants when providing care and services. These interactions often include treatment discussions between an IDT member and a participant about what care may or may not be appropriate for

the participant to receive. During these discussions, a participant may request a service that the IDT member receiving the request is able to immediately approve as requested based on their knowledge of the participant and the participant's condition. For example, during a physical therapy session, a participant may request a walker to assist in his or her daily activities. If the physical therapist, who is a member of the IDT, determines that the item is necessary and can approve the walker at the time the participant requests it, then the request would not need to be processed as a normal service delivery request. The exception would not apply if the IDT member cannot approve exactly what is requested. For example, if a participant requested 20 hours per week of home care but the IDT member is only willing to approve 15 hours per week, the exception would not apply because the participant's request would be partially denied. Specifically, at § 460.121(e)(2)(i) would require that when a member of the IDT can approve a service delivery request in full at the time the request is made, the PACE organization must fulfill only the requirements in paragraphs (j)(1), (k), and (m). These paragraphs are discussed in more detail later in this section, and generally relate to notice of a decision to approve a service delivery request, effectuation requirements, and record keeping. We also proposed at § 460.121(e)(2)(ii) that PACE organizations would not be required to process these particular service delivery request in accordance with paragraphs (f) through (i), paragraph (j)(2), or paragraph (*l*) of this new section, all of which are discussed in more detail in this section of this final rule.

This exception to how a service delivery request is processed based on feedback from stakeholders that IDT members often have treatment discussions with participants about modifying services and make decisions to accommodate the participants' requests in full at the time the requests are made. Additionally, we have seen situations where a caregiver requests an item or service that an IDT member is able to immediately approve at the time the request is made. In these situations, it is important that the decision to approve the service is communicated to the participant or the requestor at the time the request is made so that the participant/requestor understands the outcome of their request. If a decision to approve a requested service cannot be made in full at the time of the request, the PACE organization must fully process the service delivery request in accordance with all relevant paragraphs of this new section. If an IDT member can quickly approve a service as being necessary for the participant, we do not believe that it would benefit the participant or the organization to have to fully process a service delivery request, since the participant or requestor has already been successful in advocating for the service. Instead, the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires. We want to note that pursuant to our proposal in § 460.121(d)(2), a service delivery request may be made to any contractor or employee who provides direct care to a participant, and that all individuals providing direct care to participants, whether contractors or employees, should be trained to recognize and receive service delivery requests pursuant to § 460.71(a)(1). However, to specifically limit the exception in § 460.121(e)(2) to requests made to IDT members, where the receiving member of the IDT is able to approve the service delivery request in full at the time the request is made. This will ensure that the IDT remains responsible for determining the benefits a participant should receive, and that contractors or employees, such as a home care aide, are not authorizing services without the IDT's review.

We also believe this exception at § 460.121(e)(2) would reduce the current burden on PACE organizations in three primary ways. First, PACE organizations would not have to bring requests that can be quickly approved by one IDT member to the full IDT for consideration and discussion, which would allow the IDT to use that time for other purposes, including to focus on requests that require in-depth consideration. Second, because the IDT would not have to conduct a reassessment in each case, we expect that this change would improve the overall speed with which PACE organizations are able to provide necessary services. Third, the IDT would not have to provide separate notification to the participant because the IDT member would inform the participant or requestor that the request was approved in the initial discussion.

Currently the IDT is required to process requests for reassessments from participants and/or designated representatives under § 460.104(d)(2). The IDT is responsible for selecting the appropriate IDT members to conduct the reassessment under § 460.104(d)(2), and for issuing a decision to approve or deny a request under § 460.104(d)(2)(iii). At § 460.121(f), we would require that all service delivery requests, other than those under § 460.121(e)(2), must be brought to the full IDT for review and discussion before the IDT makes a determination to approve, deny or partially deny the request. As required by § 460.102(b), each PACE organization's IDT must, at a minimum, be composed of members qualified to fill the roles of 11 disciplines, each of which offers a unique perspective on the participant's condition. CMS commonly refers to this group as the full IDT. Because service delivery requests not processed under § 460.121(e)(2) are processed only for services that cannot be approved in full at the time the request is received, we believe that it is important that the IDT, as a whole, discuss the service delivery request in order to determine whether the request should be approved or denied. A discussion by the full IDT would allow each discipline to offer their perspective on the participant's condition as it relates to the requested service, and ensure that the IDT is best equipped to determine what services are necessary to improve or maintain the participant's health status. As previously discussed, service delivery requests that are approved in full by a member of the IDT at the time the request is made would not have to be brought to the full IDT for review.

In § 460.121(g) we would require that the IDT must consider all relevant information when evaluating a service delivery request. Currently, the regulation is silent on what the IDT must consider when making a decision under § 460.104(d)(2). The IDT must consider, at a minimum, the findings and results of any reassessment(s) conducted in response to a service delivery request, as well as the criteria used to determine required services specified in § 460.92(b), as discussed in section VI.C. of this final rule. We have seen through our monitoring efforts that certain IDTs do not always consider the reassessments conducted in response to a service delivery request when making a decision. For example, a physical therapist and occupational therapist may both indicate in their discipline-specific reassessments that a participant would benefit from additional home care hours, but the IDT might deny the request without explaining why the recommendations resulting from those reassessments were not followed. We believe it is important that an IDT is able to demonstrate that it took any reassessments performed in the process of reviewing a service delivery request into consideration when making a decision on that service delivery

request. Additionally, we believe that IDT decision making for service delivery requests should be aligned with the IDT's decision making for what constitutes a required service under § 460.92(b). Specifically, we believe that a decision by the IDT to provide or deny services must be based on an evaluation of the participant that takes into account the participant's medical, physical, emotional and social needs. We have encountered situations where the IDT made its decision based on one aspect of the participant's condition, for example, their physical health related to their ability to perform activities of daily living, but disregarded other aspects of the participant's condition, such as their medical, emotional, and social needs. We believe that the IDT must consider all aspects of the participant's condition in order to make an appropriate decision. For example, if the participant is requesting to attend the PACE center on additional days due to feelings of social isolation and depression, it would be inappropriate for the IDT to make a decision based on the participant's physical needs without considering their emotional and social needs. Additionally, under the modifications in § 460.92, we would also expect PACE organizations to utilize current clinical practice guidelines and professional standards of care when rendering decisions, as applicable to a requested service. We discuss this decision making process and use of these guidelines in more detail in section VI.C. of this final rule.

Based on feedback from PACE organizations and advocacy groups, at § 460.121(h) we proposed to require an in-person reassessment only prior to an IDT's decision to deny or partially deny a service delivery request. Currently, the IDT must perform a reassessment as part of its consideration of any request to initiate, eliminate, or continue a service under § 460.104(d)(2), regardless of whether the request is approved or denied. We modified the requirements related to conducting reassessments in response to a participant or designated representative's request to initiate, eliminate, or continue a service in the 2019 PACE Final Rule (84 FR 25644 through 25646). The regulations now permit the IDT to conduct that reassessment via remote technology if certain requirements are met, but the IDT must conduct an in-person reassessment prior to denying a request. However, since that rule was published on June 3, 2019, we have continued to receive feedback from PACE organizations requesting further action to address the burden of conducting reassessments in response to service delivery requests, specifically when the IDT can approve a request without performing a reassessment. Under our proposal, if a service delivery request is brought to the full IDT and the IDT determines that it can approve the request based on the information available, the IDT would not be required to conduct a reassessment of the participant prior to making a decision to approve the service delivery request. We understand that many IDTs have frequent interactions with PACE participants and may be able to make a decision to approve a request without having to conduct another reassessment based on internal consultation and knowledge of the participant. As we indicated in our discussion for § 460.121(e)(2), we do not believe that delaying the provision of a requested service the IDT has determined is necessary, in order to conduct a reassessment, benefits the PACE organization or the participant. We believe the IDT, with its knowledge of the participant, is in the best position to determine if a reassessment is necessary prior to approving a service delivery request. Therefore, CMS would only require a reassessment prior to the IDT denying or partially denying a request under this proposal.

If, after consideration of all available information, the full IDT expects to make a decision to deny or partially deny a service delivery request, the IDT would be required to perform an unscheduled in-person reassessment pursuant to § 460.121(h)(1), prior to making a final decision. We would consider a request denied or partially denied whenever the IDT makes a decision that does not fully approve the service delivery request as originally requested. For example, if a participant requested 3 hours of home care a week, and the IDT made a decision that the participant only required 2.5 hours of home care each week, such a decision by the IDT would constitute a partial denial because the request was not fully approved as requested by the participant. In other words, any decision to offer a compromise, an alternative service, or to grant only a portion of the request would constitute a partial denial. The in-person reassessment must be conducted by the appropriate members of the IDT, as identified by the IDT, in order to align with the current requirement under § 460.104(d)(2) that the IDT is responsible for identifying the appropriate members to conduct the reassessment. We believe this change would strike an appropriate balance between protecting participants and ensuring that the process for handling service delivery requests is not overly burdensome for PACE organizations.

We also proposed in § 460.121(h)(1) to require that any reassessment conducted for a service delivery request must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs in a manner consistent with § 460.92, and the revisions we proposed to those provisions. We have seen through our monitoring efforts that in conducting reassessments as a result of requests to initiate, eliminate or continue particular services, the IDTs are not always evaluating whether the requested service would actually improve or maintain the participant's condition, taking into account all relevant aspects of the participant's condition, including assessing the participant's medical, physical, emotional and/or social needs as applicable. We believe this information is vital, and must be considered by the full IDT in making its decision. For example, if a participant is requesting more days at the PACE center for social reasons, the IDT should ensure that the appropriate members of the IDT conduct the reassessment in order to evaluate the participant's social needs, and whether additional center days are necessary to meet the participant's needs, including improving the participant's social condition. We discuss our proposed modifications for § 460.92 in greater detail in section VI.C. of this final rule.

In accordance with our belief that the IDT is in the best position to determine if a reassessment is necessary prior to approving a service delivery request, at § 460.121(h)(2) we proposed that the IDT may choose to conduct a reassessment (via either remote technology or in-person) before approving a service delivery request, but we do not believe we should require one as part of the process for approving service delivery requests. If the IDT determines a reassessment should be conducted prior to approving the request, the IDT would still be responsible for processing the service delivery request, and notifying the participant, in the timeframe specified at § 460.121(i).

In paragraph (i) we would establish a time frame in which the IDT must make its determinations regarding service delivery requests and provide notification of its decisions. The current requirement under § 460.104(d)(2)(iii) states that the IDT must notify the participant or designated representative of its decision to approve or deny a service delivery request as expeditiously

as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request, unless the IDT extends the timeframe. CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states ''72 hours from the date'' and thus requires that the timeframe starts on the day received. We proposed a similar timeframe at § 460.121(i), to require that the IDT make its determination and notify the participant or their designated representative of the determination as expeditiously as the participant's health condition requires, but no later than 3 calendar days after the date the IDT receives the request. We continue to believe this is a reasonable timeframe for the IDT to discuss the request, conduct reassessments when required, and make a decision.

The IDT is currently allowed to extend the timeframe for notifying a participant or their designated representative by no more than 5 additional days under § 460.104(d)(2)(iv). Extensions are currently permitted when the participant or designated representative requests an extension, or when the IDT documents its need for additional information and how the delay is in the interest of the participant. In § 460.121(i)(1) we proposed to include a similar provision for extensions, which would allow the IDT to extend the timeframe for review by up to 5 calendar days beyond the original deadline in certain circumstances. In § 460.121(i)(1)(i) we proposed that the IDT may extend the timeline for review and notification if the participant or other requestor listed in § 460.121(c)(2) or (3) requests the extension. We would change designated representative to requestor to account for the change we made in § 460.121(c) regarding who can make a service delivery request, and including caregivers in situations where that person may not already be a designated representative. We believe that the participant or other requestor should be able to request an extension. For example, the participant may be out of town and the caregiver may request the IDT to take an extension in order for the participant to be in-person for the reassessment related to the request. Under proposed § 460.121(i)(1)(ii) the IDT could extend the timeframe for review and notification when the extension is in the best interest of the participant due to the IDT's need to obtain additional information from an individual who is not directly employed by the PACE organization, and that information may change the IDT's decision to deny a service. We believe it is important that the IDT does not routinely take extensions when the participant or other requestor has not asked for an extension. We understand that when the IDT has to obtain information from individuals not employed directly by the organization, it may be difficult to get timely responses. We also understand that obtaining this information is beneficial for the IDT and the participant in order to ensure that the IDT has sufficient information to make a decision on whether or not a service should be approved. For example, if the IDT is considering a request for dentures, information from the participant's dentist would be relevant to the review, and the IDT may need to take an extension if the dentist does not respond within the initial 3 calendar days. However, we believe it is important that PACE organizations develop processes to ensure prompt decisions about service delivery requests, and that IDTs do not routinely or unnecessarily rely on extensions of the notification timeframe, such as when information can be obtained from an employee of the PACE organization. We also proposed, for extensions based on the need for additional information, to apply the requirements currently in § 460.104(d)(2)(iv)(B) which require the IDT to document the circumstances that led to the extension and to demonstrate why the extension is in the participant's interest. We would add a new requirement at § 460.121(i)(2) to require the IDT to notify the participant or the designated representative in writing, as expeditiously as the participant's condition requires but no later than 24 hours after the IDT extends the timeframe, and to explain the reason(s) for the delay. We would require that the notification of the extension must occur within 24 hours from the time the IDT makes the decision to extend the timeframe because we believe it is important that participants or their designated representatives understand that a decision may be delayed and why, especially if the extension was taken by the IDT.

In addition, we proposed adding requirements at § 460.121(j) related to notifying the participant or the designated representative of the IDT's decision to approve, deny, or partially deny a service delivery request. Currently, IDTs are required to notify the participant or their designated representative of the decision to approve or deny a request under § 460.104(d)(2)(iii). As we previously discussed, in relation to our proposals under § 460.121(c), we proposed to expand the number of individuals who can make a service delivery request. However, we did not change the individuals whom the IDT would notify of its decision to approve or deny the service delivery request. We believe that in all circumstances, the participant (or designated representative) should receive the notification of the IDT's decision to approve or deny the service delivery request. In the rare situation where a caregiver, such as a family member, is not the designated representative, notification of the service delivery request would be sent to either the participant or designated representative, and not the family member. As always, under current § 460.102(f), the PACE organization remains responsible for establishing, implementing and maintaining documented internal procedures that govern the exchange of information between participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e). We would expect that PACE organizations, as a part of that documented process, have a method for determining when notification should go to the participant versus a representative (including a caregiver).

In paragraph (j)(1) we would specify the notification requirements when the IDT approves a service delivery request. Specifically, we would require the IDT to notify the participant or the designated representative of that decision either orally or in writing. We proposed that the notification must explain any conditions for the approval in understandable language, including when the participant may expect to receive the approved service. We believe it is important that the IDT explain to the participant or their designated representative any conditions that may apply whenever the IDT approves a service delivery request. For example, if the IDT is approving a service delivery request for home care, the IDT should indicate the days and hours that are being approved and when the home care would start.

For service delivery requests that can be approved in full at the time the request is made under § 460.121(e)(2), the IDT member who approves the request would be responsible for ensuring that the notification satisfies the requirements in new § 460.121(j)(1). Because a request must be able to be approved in full at the time the participant makes the request under this provision, the IDT member who

approves the service would be responsible for providing notification, and ensuring that the conditions of the approval (if any) are explained to the participant. While we allow for the IDT to provide approval notification either orally or in writing, because decisions under § 460.121(e)(2) are made in real time, and communicated to the participant at the time the request is made, we do not believe written notification would be necessary in these instances; however, a PACE organization may always choose to send written notification following the oral notification in order to memorialize any conditions of the approval.

We also proposed at § 460.121(j)(2) provisions similar to those currently set forth in § 460.104(d)(2)(v), to require that PACE organizations must notify participants or the designated representative of a decision to deny or partially deny a service delivery request both orally and in writing. We believe that the requirement to notify the participant or their designated representative both orally and in writing should be maintained to ensure participants or their designated representatives receive and understand the denial. We also proposed to expand upon the specific requirements for what a denial notice must contain. At § 460.121(j)(2)(i) we require that the IDT state the specific reasons for the denial, including an explanation of why the service is not necessary to improve or maintain the participant's overall health status. Under what we proposed, the rationale for the denial would have to be specific to the participant, taking the participant's medical, physical, emotional, and social needs into account, and it would include the results of any reassessment(s) conducted by the PACE organization. The rationale would have to be stated in understandable language so that the participant or designated representative can comprehend why the request was denied. We believe that it is important to continue to require that the IDT provide the specific reasons for a denial. However, based on our experiences monitoring PACE organizations, we believe we needed to propose more detailed requirements about what the explanation of the specific reason(s) for the denial should include. Providing this explanation for a denial would allow the participant or their designated representative to more fully understand why the IDT determined a requested service was not necessary. This would also allow a participant or designated representative to better understand what information they may need to provide if they appeal the denial.

At § 460.121(j)(2)(ii) and (iii), we would retain the requirements currently codified in § 460.104(d)(2)(v)(A) and (B) that the PACE organization inform the participant or designated representative of the right to appeal any denied service delivery request as specified in § 460.122; and that the PACE organization must also describe the process for both standard and expedited appeals, and the conditions for obtaining an expedited appeal. Additionally, with minor modifications, we would retain a requirement similar to current § 460.104(d)(2)(v)(C): the PACE organization would be required to notify Medicaid participants about their right to, and the conditions for, continuing to receive a disputed service through the duration of the appeal. Medicaid participants include all participants that are enrolled in Medicaid only or both Medicaid and Medicare (dually eligible). Currently, § 460.104(d)(2)(v)(C) cross-references all of § 460.122(e), but we believe that a more tailored reference to § 460.122(e) would be preferable. Therefore, we proposed to cross-reference only § 460.122(e)(1) at § 460.121(j)(2)(iv), because the information provided in § 460.122(e)(2) relates to the PACE organization's continued responsibility to continue to furnish to participants all required services other than the disputed service, and is not specifically about continuing to receive the disputed service. We do not believe we need to require that the IDT include information from § 460.122(e)(2) in a service delivery request denial notification because this concept is widely understood and could potentially confuse participants if they received notification of that requirement. However, we solicited comments on whether it would be preferable to retain a cross-reference to all of § 460.122(e).

In § 460.121(k) we proposed to specify the timeframe in which the PACE organization must provide services approved, in whole or in part, through the service delivery request process. We would require the PACE organization to provide the requested service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. We did not propose a specific timeframe due to the many varying types of services that PACE organizations provide. However, we expect PACE organizations to develop processes to help them identify how quickly they need to provide a service based on the participant's condition. For example, we would generally expect that a drug used to treat a participant's diabetes would be provided much more quickly than we would expect a dental cleaning to be provided. That is because a treatment for diabetes may require a more immediate response, whereas a dental cleaning may not be as urgent. We recognize that not all services can be physically provided in a rapid timeframe, however, we do expect that the PACE organization take prompt action to ensure the approved service is provided as expeditiously as needed. Additionally, for services that can be approved under § 460.121(e)(2), while we require that the IDT member be able to approve the request in full at the time the request is made, we do not require that the approved service be physically provided at the time the request is made. Instead, those approved service delivery requests must also be effectuated under the requirements in this section.

The current requirement at § 460.104(d)(2)(vi) states that the PACE organization must automatically process a participant's request as an appeal when the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care. We would retain this requirement, unaltered, at § 460.121(*l*). We continue to believe that this is an important safeguard for participants to ensure they have access to the appeals process, even when a PACE organization does not adhere to the processing requirements under the rules of this part.

In paragraph (m) we would add requirements that would address record keeping for service delivery requests. While PACE organizations are currently required to document all assessments under § 460.104(f), we believe that it would be important to have a separate section in the new § 460.121 that more specifically addresses the record keeping requirements, to help ensure that PACE organizations accurately document and track all service delivery requests and have a complete and accurate record of each request and how it was resolved. In § 460.121(m) PACE organizations must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests. We would specify that PACE organizations must account for, and document, requests received both orally and in writing. PACE participants often call PACE organizations and request a service over the phone, and it is important for the PACE organization to have an

established process to accurately document and track those verbal requests, along with requests submitted to the organization in writing. Once a PACE organization receives a service delivery request, the PACE organization would be responsible for documenting, tracking and maintaining all records that relate to the processing of the service delivery request, including but not limited to, the IDT discussion, any reassessments conducted, all notification that was provided to the participant or designated representative, and the provision of the approved service, when applicable. These documentation requirements would apply to all service delivery requests, including service delivery requests that can be approved in full at the time the request is made per § 460.121(e)(2). Additionally, as we mention in our discussion of § 460.200(d) at section VI.E. of this final rule, we would require that documentation be safeguarded against alteration, and that written requests for services must be maintained in their original form. We also proposed to require that these records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

Because we proposed toe define the requirements for service delivery requests in the new § 460.121, we also proposed to remove all requirements relating to service delivery requests from the current § 460.104(d)(2). Specifically, we are removing § 460.104(d)(2)(i) through (v) and we would modify the existing language in § 460.104(d)(2) to reiterate that the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request. Additionally, as we discussed in § 460.121(h)(2), the IDT may conduct a reassessment as determined necessary for services it intends to approve. We would modify language in § 460.104(d)(2) to direct readers to the new § 460.121(h) for the requirements regarding conducting reassessments in response to service delivery requests.

We summarize the comments received on the proposals related to service delivery requests and provide our responses to those comments below.

Comment: All commenters that addressed this proposal were supportive of moving the requirements for service delivery requests from § 460.104(d)(2) to a new section of the regulations in § 460.121. A few commenters were generally supportive of the provisions related to service delivery requests.

Response: We thank the commenters for their support of the provisions related to service delivery requests.

Comment: A few commenters offered suggestions related to the proposed use of the term ''service delivery request''. Most suggested that CMS use ''service determinations'' rather than ''service delivery request'' because it is more consistent with the objective of this process which is to determine whether a PACE organization should initiate, modify, or continue a service in response to a request from a participant, designated representative, or caregiver. Another commenter recommended using the term ''service request'' as it is consistent with past practice and suggested that it was easier for participants to understand.

Response: We appreciate the commenters' response to our request for feedback and we are persuaded to make changes to the regulation text and incorporate both of the recommended terms to use the term ''service determination request'' rather than ''service delivery request'' for requests that are processed under proposed § 460.121. We anticipate that such a change will help participants and PACE organizations to understand that this process is ultimately about the determination of whether to initiate, modify, or continue a service. After consideration of the comments received, we recognize that there are two actions that largely make up the proposed service delivery request process; the request itself and the determination made by the PACE organization. In order to maximize clarity regarding the process, we are revising the title of new section § 460.121 from ''Service delivery requests'' to ''Service determination process.'' We believe that this modified title better reflects the process in its entirety and better encompasses the nature of these actions. We are also revising the remainder of the proposed regulatory text for part 460, where applicable, to reflect this change in terminology. In addition, we will use the terms ''service determination request'' and ''service determination process'' when referring to the requirements under § 460.121 in the remainder of this final rule.

Comment: All commenters that addressed the proposal at § 460.121(a) were supportive of the requirement that PACE organizations must have formal written procedures for identifying and processing service determination requests.

Response: We thank the commenters for their support of this provision and are finalizing this requirement as proposed.

Comment: The majority of commenters expressed concern with the proposal at § 460.121(b)(1)(ii) to require PACE organizations to process a request to ''otherwise change'' an existing service as a service determination request. These commenters agreed with CMS's position that PACE organizations should be responsible for processing requests to change existing services, but believed that requests to change an existing service were more comparable to a grievance that should be addressed under § 460.120, rather than a service determination request because requests of this sort suggest that a participant is dissatisfied with the characteristics of the service. The same commenters also recommended that CMS modify the proposed language at § 460.121(b)(1)(ii) by limiting requests to modify an existing service to include requests to increase, reduce, or eliminate a service.

Response: We thank the commenters for their feedback and recommendations. We disagree that requests to otherwise change an existing service under § 460.121(b)(1)(ii) are better classified as a grievance. A grievance for purposes of the PACE program, is defined in regulation at § 460.120 as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished. Requests that otherwise change an existing service would not be considered a grievance under the current definition. For example, if a participant is currently receiving two hours of home care a day in the morning, but requests to instead receive those hours in the evening because the participant is physically weaker in the evening and needs more assistance at that time, we would not consider this request a grievance and would expect the organization to process such a request as a service determination request. However, it's possible that a request to modify a service would be both a service determination request and a grievance. For example, if the participant requests their home care hours to be modified but also expresses dissatisfaction with the quality of home care being provided, we would expect the organization to process both a service determination request and a grievance. In addition, there are no regulatory timeframes for processing grievances under § 460.120, and the participant is not afforded appeal rights if a grievance is not fully resolved in their favor. As noted in the proposed rule, we believe that defining service determination requests to include requests to modify an existing service, which includes requests to increase, reduce, eliminate, or otherwise change a particular service, is an important safeguard, as participants may believe

that the services they are currently receiving are not sufficient to meet their needs (85 FR 9125). We continue to believe that this is the best way to capture and provide resolution for such requests and therefore we are finalizing this provision as proposed. As a reminder, pursuant to the requirements we are finalizing at § 460.121(e)(2), if a service determination request can be approved in full by a member of the IDT at the time the request is made, the full IDT does not need to consider it, and the PACE organization would not need to conduct a reassessment.

Comment: A commenter agreed with CMS' proposal to limit service determination requests to requests made after the development of the initial care plan. Several commenters recommended that CMS expand the scope of requests that do not constitute a service determination request under proposed § 460.121(b)(2), to include services requested during the semi-annual and change in participant status reassessment and care planning processes, services requested in the course of participants' treatment discussions with PACE IDT members, both during and outside the assessment and care planning processes, and requests for services that are not appropriate for the treatment of the participants' conditions. Another commenter agreed with expanding the scope of exclusions and suggested that requests made during a semi-annual or unscheduled assessment would necessitate pausing the reassessment and care planning process currently underway and beginning a separate service determination request process. Another commenter recommended limiting requests processed as service determination requests to those requests that occur after the completion of a required initial, semi-annual, or change in status assessment and requests that a participant or designated representative makes when they are not in agreement with the care plan at the end of any individual encounter with an IDT member.

Response: We agree that routine treatment discussions and discussions that occur during the assessment and care planning process are instrumental in determining the services necessary to meet a participant's needs. However, we also strongly believe that the recording, processing, and tracking of service determination requests is an essential beneficiary protection which ensures PACE participants' access to necessary care and services, and provides participants an avenue to appeal adverse decisions. As proposed, there is an exception at § 460.121(b)(2) for requests to initiate, modify or continue a service, made prior to the development of the initial care plan. We continue to believe that this is appropriate and are not expanding the scope of this exclusion. We do not believe that it would be in a participant's best interest to exempt requests for services made during semiannual or unscheduled reassessments required under §§ 460.104(c) and (d)(1) or during the care planning processes described in §§ 460.104(e) and 460.106(d) from the service determination process because the relevant regulations do not specify timeframes for these processes. Absent regulatory timeframes, these processes frequently take a long time to resolve and if a service determination request made as part of those processes were exempted from the proposed requirements for service determination requests, these requests could take an unacceptably long time to resolve. For the same reason, we also believe that requests for services made during treatment discussions with PACE staff, including members of the IDT and others, should be processed as service determination requests. Through CMS monitoring and oversight, we have noted cases of non-compliance with the existing requirements at § 460.104(d)(2) governing the documentation and processing of participant requests, and the provision of approved services. We believe it is important that all requests that satisfy the definition of a service determination request be processed using the process we proposed. As stated in the proposed rule (85 FR 9126), we decided that requests made during the course of treatment discussions should constitute service determination requests in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service determination requests and those that do not.

CMS would like to clarify that the exception to the definition of ''service determination request'' for requests made prior to the development of the initial care plan at § 460.121(b)(2) includes requests made during the initial care planning process under §§ 460.104(b) and 460.106(a). We recognize that the regulation text as proposed, which permits this exception ''if the request is made prior to development of the initial care plan'', may have caused confusion because this could be interpreted to mean that a participant or other requestor could make a service determination request during the development of the initial plan of care but prior to the completion of the initial plan of care. This was not our intent. As noted in the proposed rule (85 FR 9125), this exception would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased), and we continue to believe that this approach would be beneficial to the participant and the PACE organization as it is during this process that the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. In order to avoid confusion regarding when this exception would apply, we are modifying the proposed regulatory text at § 460.121(b)(2) in a manner consistent with our proposal, to emphasize our intent that this exception would apply to all requests for services made prior to completion of the development of the initial plan of care. As revised, the text of § 460.121(b)(2) will state ''Requests to initiate, modify or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care''.

Comment: Comments on CMS' proposal to allow caregivers to make service determination requests at § 460.121(c)(3) were varied. A few commenters agreed with the proposal at § 460.121(c)(3) to allow caregivers to make service determination requests, and one commenter noted that allowing caregivers to request services on behalf of a participant may increase the involvement of caregivers and distribute the burden of transmitting provider or prescriber recommendations to the IDT. However, the majority of commenters expressed concern with this proposal, which would expand the individuals who can make a service determination request to include caregivers. These commenters suggested that this may result in requests from a large number of individuals who do not have legal authority to speak on behalf of the participant, requests that are inconsistent with the wishes of the participant and designated representative, requests that may be motivated by financial or personal gain, and increased administrative burden on PACE organizations in processing these requests. These commenters suggested that the involvement of multiple caregivers could negatively impact PACE organizations' ability to respond to the wishes of the participant or their designated representative(s), for example in regard to end-of-life care decisions. These commenters noted that

it is important that the PACE organization and the IDT remain focused on the wishes of the participant, either expressed directly or through their designated representative. These commenters also stated that including caregivers, which is not a term defined in regulation text, among the individuals who are able to request service determinations on behalf of participants may have unintended, negative consequences. The commenters noted that although a caregiver or family member who has not been identified as a designated representative would not be able to make service determination requests under the existing regulatory framework, they would not be prevented from providing input related to a participant's care under § 460.102(d)(2)(ii) and § 460.106(c)(2). With regard to requests that are personally motivated, the commenters suggested that this change would permit an individual living in a participant's home who might lose housing if the participant moved to a nursing home to request home modifications or additional in-home services to permit the participant to remain at home despite the fact that those requests could be inconsistent with the wishes of the participant or their designated representative and prior determinations by the IDT that the participant cannot remain safe in the home. These commenters strongly recommended that requests for service determinations could only be made by participants or their designated representatives, stating that the term designated representative has been interpreted by PACE organizations to be either a legal representative or a representative identified according to the PACE organization's policy who is authorized to act on behalf of the participant. Additionally, all of these commenters recommended modifying the plan of care requirements in § 460.106(e) to replace the term caregiver with the term designated representative.

Response: We thank commenters who supported this provision and appreciate the feedback related to permitting caregivers to make service determination requests. While we believe the designation of a representative is important, the PACE regulations do not require or describe any specific formal process for designating a representative, nor do they require PACE organizations to develop such a process. As discussed further, in section VI.D. of this final rule related to service delivery, in response to comments, CMS confirms that the IDT may take into consideration informal support when developing the participant's plan of care. Specifically, the IDT may consider care provided by willing and able caregivers when determining what necessary services will be provided by the PACE organization, either directly or through its contractors. Given the fact that caregivers may provide some care to participants, we believe that it is equally important that caregivers are able to advocate for services on a participant's behalf. It is important that these individuals have an avenue to request services for a participant, especially when caregivers that had actively been providing care are no longer willing or able to provide care in the manner they had been. For example, if a caregiver was providing overnight supervision to a participant, but is no longer willing or able to provide that care due to the participant's increased dementia, the caregiver should be able to submit a service determination request to the PACE organization. In regard to commenters' concerns relating to the potential increase in burden on PACE organizations related to the proposal to permit caregivers to make service determination requests, we believe most PACE organizations currently allow caregivers to make these requests. According to data submitted by PACE organizations for auditing purposes from 2017 through 2019, approximately 50 percent of service determination requests were made by participants and 30 percent were made by caregivers or other family members. Because organizations are already accepting and processing requests from caregivers (as these data show), we do not anticipate that modifying the regulation in this way would result in a significant influx of requests for PACE organizations. In addition, the role of caregivers in PACE participants' lives has been recognized in CMS's policies regarding the PACE program since the first PACE interim final rule was published in 1999 (64 FR 66249), and caregivers play a vital role in the development and reevaluation of the plan of care as we noted at VI.A. of the preamble of this final rule.

We would like to state that nothing in this provision would expand which individuals may be considered a caregiver, nor is it meant to imply that any person in the participant's life may request services. As we noted in the preamble to the 2006 PACE rule (71 FR 71284), a caregiver is a person who attends to a participant's needs and has a caregiving relationship with the participant. Historically, CMS has not included employees or contractors of the PACE organization, such as providers or prescribers, as ''caregivers'' under this definition, and instead has interpreted this term to include less formal support providers such as family members. This is consistent with our discussion at 71 FR 71284 which stated that CMS uses the term ''family member'' and ''caregiver'' interchangeably. Employees and contractors of PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominantly financial incentive to provide care; we have not considered these individuals to be ''caregivers'' under the regulations. PACE organizations are already required at § 460.106(e) to involve a participant's caregiver or caregivers for purposes of care planning. We believe that those individuals, who should already have a relationship with the PACE organization, should also be able to advocate for services outside of the care planning process. We believe that permitting caregivers to make service determination requests on behalf of a participant is an important safeguard: Those participants who do not have a designated representative may rely on a caregiver to advocate for services on their behalf, and caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For the same reasons, we also do not agree with the commenters' recommendations to exclude caregivers from the care planning process at § 460.106(e). Additionally, caregivers have been involved in the care planning process under PACE since the regulations were implemented in 1999 through the interim final rule and CMS has never previously received feedback indicating that this practice might be problematic. As we gain more experience with caregiver service determination requests, we may take further action as appropriate; for example, to further refine our position on who may be considered a caregiver for purposes of making service determination requests.

With regard to requests that may be motivated by financial or personal gain, we believe that the proposed service determination process would prevent these types of personal conflicts of interest from negatively impacting participants. The IDT is responsible for deciding whether to approve or deny a service determination request, and thus functions as a gatekeeper preventing the provision of unnecessary services. Section 460.121(g) also requires the IDT to consider all relevant information when evaluating a service determination request, including the criteria specified

in § 460.92(b). Under § 460.92(b), the IDT must consider the participant's current medical, physical, emotional, and social needs, and current clinical practice guidelines and professional standards of care applicable to the particular service, when deciding to provide or deny a service. Additionally, if the IDT conducts a reassessment in response to the service determination request, the reassessment should take into consideration the participant's wishes and preferences for care, to ensure that services, if approved, are in the participant's best interest, in accordance with the participant's rights for participation in treatment decisions under § 460.112(e). If a service determination request is made and the IDT determines, after reassessing the participant, that the service is not necessary based on all relevant information, the IDT should deny the request. These requirements would apply to all requests for services, including requests for end of life care. For example, a caregiver may request palliative care for the participant, but the IDT would need to consider all relevant information prior to approving or denying the service, including the participant's and designated representative's wishes, applicable clinical guidelines, and the participant's current medical, physical, emotional, and social needs. Similarly, if a caregiver requested the participant to remain in the home for self-serving purposes, and the IDT determined that the participant was not safe to remain in the home and did not wish to remain in the home, the IDT should not approve the caregiver's request.

Therefore, we believe that the IDT plays a pivotal role in ensuring that services are provided only when necessary, and this in turn protects participants from receiving services that are not in their best interest, including those that may be motivated by financial or personal gain.

Comment: Several commenters provided feedback related to permitting prescribers or other providers to make service determination requests. One commenter was in favor of permitting prescribers or other providers to make service determination requests on behalf of a participant. Most commenters were opposed to CMS allowing other individuals to make service determination requests. These commenters noted that PACE organizations, through the participant's primary care provider, are currently required to oversee the use of specialists. In situations when another provider or prescriber's recommendation is not implemented, the IDT would be required under proposed § 460.102(d)(1)(ii) to document the reasoning behind this determination in the participant's medical record. One commenter noted that for these reasons, this contemplated proposal would be duplicative of the proposed regulatory requirements under § 460.102(d)(1)(ii), and as a result would be disruptive to the effective functioning of the IDT. Further, the commenters noted that a participant or his or her designated representative has the right to submit a service determination request if the PACE organization does not provide a recommended service.

Response: We appreciate the commenters' feedback and recognize that by finalizing our proposals at § 460.102(d)(1)(ii), we will enhance the consideration and documentation of recommendations made by specialists, and better integrate those individuals into the process of determining what care and services are necessary for participants. As discussed in section VI.C.3 of this final rule and in response to other comments received, we are finalizing the proposal at § 460.102(d)(1)(ii), largely as proposed. While we continue to believe that communication among specialists and the IDT is vital, we agree with commenters that these communications do not need to be handled through the service determination process. By requiring that the IDT document such recommendations in the medical record in accordance with § 460.210(b), including proposed §§ 460.210(b)(4) and (b)(5), if there is a subsequent service determination request made by a participant, designated representative, or a caregiver, there will be a record of the recommendation and why it was not provided. We expect that this information will provide useful perspective to the IDT and will allow the IDT to conduct a more meaningful review of the service determination request under § 460.121(g). We also agree with the commenter that a participant, designated representative, or caregiver could make a service determination request for any service that was not provided in accordance with a recommendation from an employee or contractor of a PACE organization. Because of these proposals and the integral role the IDT plays in determining what services are necessary, we do not believe that it is necessary to specifically include prescribers or other providers among the individuals who are allowed to submit service determination requests at this time. Accordingly, we are finalizing our proposals for § 460.121(c)(3) as proposed.

Comment: Commenters were supportive of CMS's proposal to allow service determination requests to be made either orally or in writing.

Response: We thank the commenters for their support of this provision.

Comment: Some commenters agreed with CMS's proposal at § 460.121(d)(2) which would allow service determination requests to be made to any employee or contractor of the PACE organization that provides direct care to a participant. The majority of these commenters responded to CMS's request for feedback on whether this requirement should be limited to a smaller subset of individuals and agreed that CMS should limit the individuals to whom a service determination request could be made to a PACE organization's employees and contractors who provide direct participant care in the participant's residence, the PACE center, and while transporting participants, which would preclude service determination requests from being made to direct care providers with whom participants would generally have less frequent contact, for example, hospital staff or other medical specialists. These commenters also suggested that requests for services made while participants are being transported should be limited to routine transportation and exclude transportation in emergency situations. Another commenter recommended limiting request submission to any employee or contractor who serve in a required interdisciplinary team member role to eliminate any confusion for participants, their designated representatives, and employees and contractors of the PACE organization on the process of submitting service determination requests.

Response: We appreciate the commenters' support for this provision. After consideration of the comments received, we will specify in the final rule that service determination requests may be made to any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants. These are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, often on a daily basis. Therefore, we believe that these are the most logical settings where service determination requests are most likely to occur. It would also be a smaller subset of employees and contractors for the PACE organization to train and oversee to

ensure those individuals were correctly identifying service determination requests when they are made. We note that a participant's residence would include a skilled-nursing facility or long-term care facility and a participant would be able to make a service determination request to staff who provide direct care to a participant in those facilities. We also recognize that if we were to finalize this requirement as proposed it could be difficult for a PACE organization to operationalize because of the varied and significant roles played by contractors in PACE. For example, PACE organizations routinely contract with hospitals and it would be difficult to train all of the employees within the hospital system to recognize and accept service determination requests.

In terms of requests made while transporting participants, we do not believe that it is necessary or appropriate to exclude transportation in emergency situations from this requirement. Under the requirements at § 460.70(a), a PACE organization is required to have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services. Because the requirement at § 460.121(d)(2) would only apply to an employee or contractor of the PACE organization, this requirement would not apply to those situations where the PACE organization does not have a contractual relationship for emergency services, including emergency transportation. Additionally, based on our oversight and monitoring experience we have never seen circumstances where a service determination request was made while a participant was being transported for emergency purposes; therefore, we do not expect that this will happen with significant frequency. More commonly, we would expect requests to be made during routine transportation services, and the PACE organization would be required to implement processes for staff and contracted employees to identify and process these requests. However, to the extent that service determination requests are made during emergency transportation, to a contractor of the PACE organization, we believe it is important for those requests to be captured and processed accordingly.

With regards to commenters' recommendation that requests only be submitted to interdisciplinary team members, we do not believe that this would be in the participant's best interest based on the nature of the care provided by a PACE organization. As discussed in the proposed rule, PACE organizations are required to provide care across all care settings and a participant may not know with whom they need to communicate in order to make a service determination request (85 FR 9127). Certain participants may also see home care aides more frequently than members of the IDT and we believe it is appropriate to permit individuals to communicate service determination requests to home health aides rather than requiring them to make such requests to a member of the IDT. Because of the vulnerability of the PACE participant population, we believe it is important to have a robust system of safeguards in place so that participants have the ability to easily request and obtain access to those services that would improve or maintain their overall health status. We believe that requiring a participant or other requestor to go to a member of the IDT would create an unnecessary hurdle and could lead to confusion, if for example, an individual is instructed by an employee or contractor of a PACE organization to make requests in a different manner.

Comment: A commenter agreed with the proposal at § 460.121(e)(1) which would require the PACE organization to bring a service determination request to the interdisciplinary team as expeditiously as the participant's health condition requires, but no later than 3 calendar days from the date the request is made. Other commenters recommended that CMS change the proposed timeframe for bringing a service determination request to the IDT from 3 calendar days to 3 business days. These commenters were fully supportive of CMS's perspective that there is an acceptable period of time between when the service determination request is made and when it is received by the IDT; however, noted that implementing a 3 calendar-day timeframe will effectively force PACE organizations to convene full IDT meetings on both Fridays and Mondays to consider requests for services initiated on Thursdays and Fridays. The commenters also noted that holidays that fall on Mondays may pose a challenge if requests must be brought to the IDT within 3 calendar days from the day the request is received. The majority of commenters also recommended CMS change the proposed timeframe for notification in paragraph (i) from 3 calendar days to 3 business days.

Response: We appreciate the commenters' concerns regarding the 3 calendar day timeframes that we proposed for processing service determination requests; however, we disagree with the commenters and consider this to be a reasonable timeframe. Section 1894(b)(1)(B) of the Act requires PACE organizations to provide necessary covered items and services 24 hours per day, every day of the year. PACE organizations must therefore be able to process requests efficiently and timely, even on weekends and holidays. Under the current requirements at § 460.104(d)(2)(iii), the IDT must generally notify a participant or designated representative of its decision to approve or deny a request within 72 hours from the date the request is received. As we stated in the preamble to the proposed rule (85 FR 9129), CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states ''72 hours from the date.'' We stated that we believe this is a reasonable timeframe for the IDT to conduct these reviews, and therefore proposed a similar timeframe in the proposed rule. We believe that requiring the IDT to notify the participant or their designated representative of its decision as expeditiously as the participant's health condition requires, but no later than 3 calendar days at § 460.121(i) provides the IDT sufficient time to meet and make a decision regarding a participant's care, taking into account weekends and holidays, and are finalizing this requirement as proposed. Additionally, we created a second timeframe at § 460.121(e) to ensure that PACE organizations bring requests to the IDT for review within a reasonable period of time. Specifically, we proposed to require that requests must be brought to the interdisciplinary team as expeditiously as the participant's condition requires but no later than 3 calendar days from the time the request is made, and we believe this timeframe is appropriate for purposes of § 460.121(e). We believe that this timeframe strikes an appropriate balance between providing sufficient time for PACE organization staff to transmit the request to the IDT, while ensuring timely resolution of participant requests. We are therefore finalizing this timeframe as proposed.

Comment: The majority of commenters requested that if CMS finalizes the proposed requirement at § 460.121(d)(2) which would allow for participants to make service determination requests to individuals other than IDT members, that CMS also

allow for service determination requests made to non-IDT members to be brought to the appropriate IDT member and that the IDT member have the opportunity to approve the request subject to the streamlined requirements set forth under § 460.121(e)(2). The commenters noted that by adopting this approach, the need for a full-IDT review as required under § 460.121(f) would not be based on who received the request but the nature of the request. The commenters stated that they would not want the additional step of allowing a non-IDT member to bring a service determination request to the appropriate IDT member to lengthen the service determination process overall and recommended that service determination requests be brought to the appropriate IDT member in time for him or her to consider the request and, if approved, notify the participant or his or her designated representative of the approval within the 3 calendar timeframe proposed at § 460.121(e)(1). The commenters stated that this approach would be consistent with CMS' objectives for § 460.121(e)(2), as noted in the proposed rule, ''the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires.'' (85 FR 9128). The commenters further suggested that consistent with CMS' observations in regard to proposed § 460.121(e)(2), the recommended approach would also reduce the current burden on PACE organizations.

Response: The exception that we proposed at § 460.121(e)(2) provided that if a member of the IDT receives a service determination request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. This provision was intended to allow for immediate approval of a service determination request during a conversation between a participant or their designated representative or caregiver and a member of the IDT. Allowing an employee or contractor of a PACE organization who is not an IDT member to communicate the request to the appropriate IDT member for approval would require the non-IDT employee or contractor to identify the appropriate member of the IDT that should receive the request, which could take several days and would take away from the immediacy of the approval. We intended to create an exception to expedite the process for approval of service determination requests, and reduce unnecessary burden on the PACE organization, given the fact that PACE organizations, as direct care providers, routinely interact with participants and these interactions often include treatment discussions that may result in a service determination request by the participant. We do not anticipate that finalizing this requirement as proposed would create a large burden on PACE organizations because, if a member of the interdisciplinary team would have been able to approve a particular service determination request in full at the time the request was made, we presume that in the event the same service determination request was brought to the full IDT, the full IDT would also have the ability to quickly approve the request at that time, without having to conduct a reassessment. Based on these considerations, we are not modifying this requirement and are finalizing this provision as proposed.

Comment: Commenters were supportive of the proposal at § 460.121(e)(2), which would allow a member of the IDT to approve a service determination request in full at the time the request is made and not be required to follow certain processing requirements. Specifically, this would exclude the requirements at proposed § 460.121(f) through (i), (j)(2), and (*l*) which include review by the full interdisciplinary team, reassessment in response to a service determination request, and notification timeframes.

Response: We thank the commenters for their support of this provision.

Comment: The majority of commenters agreed with the proposed provisions at § 460.121(g) which set forth the specific information the IDT must consider when evaluating a service determination request.

Response: We thank the commenters for their support of this provision.

Comment: Several commenters were also in favor of the proposal at § 460.121(h), which would require that if the IDT expects to deny or partially deny a service determination request, the appropriate members of the IDT, as identified by the IDT, must conduct an in-person reassessment before the IDT makes a final decision, and that the team members performing the assessment must evaluate whether the requested service is necessary to meet the participant's needs. These commenters requested clarification on whether assessments can be completed in advance of the IDT's receipt of the request, so long as the assessment is completed in response to the request.

Response: We thank the commenters for their support of this provision. With respect to assessments being completed in advance of the request being brought to the full IDT, we wish to clarify that this would be acceptable provided the regulatory requirements, including § 460.121(h), are satisfied. However, we would not expect this to occur often. As required under § 460.121(h)(1), if the IDT expects to deny or partially deny a request, the appropriate member of the IDT, as identified by the IDT, must conduct an in-person reassessment before the IDT makes a final decision. Given the 3 calendar day timeframe for a PACE organization to bring a service determination request to the IDT under § 460.121(e)(1), there may be situations when one or more members of the IDT are able to conduct a reassessment in response to a service determination request in order to gather the relevant information needed for discussion and review by the full IDT within that timeframe. However, there is a risk that the appropriate member of the IDT, as identified by the IDT, may not participate in a reassessment if the reassessment is completed prior to the IDT convening. This fact notwithstanding, if the reassessment was completed in response to a service determination request, and when the full IDT meets, the IDT determines that the assessment was conducted by the appropriate IDT members, this would be permitted.

Comment: Several commenters expressed concern that the proposed criteria that must be met for the IDT to extend the 3 calendar day timeframe for review and notification of a service determination request at § 460.121(i)(1) is overly restrictive. The commenters also recommended revising the proposed requirements under § 460.121(i)(1) to allow for extensions when a participant is not available for an assessment or when an IDT member is unexpectedly not available. The commenters explained that in addition to situations in which the requestor may request an extension of the 3-day timeframe, it is also possible that the participant may be unavailable for a reassessment that is required for the IDT to make its determination. These commenters suggested, for example that the participant may be out of town or otherwise unavailable for reasons beyond the PACE organization's control and rather than requiring the requestor to request an extension in these situations, the IDT should, on its own, be able to notify the requestor of the need for an extension beyond 3 days. The commenters also recommended that CMS not limit the extension timeframe at § 460.121(i)(1) to 5 days when the

participant or their designated representative requests an extension for a longer period of time. Further, the commenters stated that while they agree it is important that the IDT does not routinely take extensions when the participant or other requestor has not requested one or the participant is unavailable for a required reassessment, the proposed language in § 460.121(i)(2) does not take into account circumstances that necessitate such extensions. Specifically, it is possible that the IDT member identified by the IDT as needing to perform a reassessment or who is critical to the IDT's discussion of the service determination request is unexpectedly not available. In situations when the PACE organization can demonstrate the importance of this reassessment and/or the IDT member's participation in the IDT discussion and the potential for it to change the IDT's decision to deny a service, and that the circumstances surrounding the IDT member's absence could not be anticipated, the commenters argue that an extension of up to 5 business days is appropriate. They expressed their belief that extending the timeframe for notification of the service determination request would be preferable to exceeding the standard 3-day timeframe and then having to automatically process the service determination request as an appeal which would further delay the requestor's receipt of a response to his/her request.

Response: We appreciate the commenters' concerns and agree that there may be situations that arise during the course of the service determination process that would hinder a PACE organization's ability to make its decision and notify the participant or their designated representative of its decision within the required timeframes under § 460.121(i). In the proposed rule (85 FR 9129), we accounted for situations where the participant or other requestor should be able to request an extension under § 460.121(i)(1)(i) and used as an example circumstances where the participant is out of town and stated that the caregiver could request the IDT take an extension in order for the participant to be in-person for the reassessment required for the request. We would encourage the IDT to discuss service determination requests with the participant where the IDT needs to perform a reassessment and the participant would be out of town. Because decisions related to service determination requests must be made as expeditiously as the participant's condition requires, we do not believe that it would be appropriate to allow for any additional extensions beyond the proposed 5 calendar day timeframe. If the IDT is unable to conduct a reassessment within that timeframe, then we would expect that the IDT would issue a denial and subsequent appeal rights. We reiterate in this final rule that it is important that the IDT does not routinely take extensions when the participant or other requestor has not solicited it because of the frailty of the PACE population. We also note that that any extension must be documented in accordance with the recordkeeping requirements at § 460.121(m).

With respect to the recommendation that CMS allow for extensions when an IDT member is unexpectedly not available, we do not believe that it would be appropriate to view this as justifying an extension. The requirements at § 460.121(i) specify that the IDT must make its decision and provide notification of that decision as expeditiously as the participant's condition requires but no later than 3 calendar days after the date the IDT receives the request and we do not believe that it would be appropriate for an extension to be taken for a reason unrelated to the participant's availability or condition. It is the responsibility of the PACE organization to ensure that there is sufficient staff coverage to meet these requirements.

Comment: The majority of commenters agreed with the proposed provisions at § 460.121(i)(2), which would require an IDT to notify the participant or their designated representative in writing as expeditiously as the participant's condition requires but no later than 24 hours after the IDT decides to extend the timeframe under § 460.121(i)(1), and explain the reasons for the delay. However, these commenters also recommended modifying the requirement to allow PACE organizations to notify the participant or designated representative of the extension either orally or in writing. The commenters suggested that regardless of whether the notification is oral or in writing it would include an explanation of the reason(s) for the delay and would be issued no later than 24 hours after the IDT decides to extend the timeframe. They also noted that allowing oral notification would facilitate the requestor's receipt of notice of the extension, because if CMS required PACE organizations to issue written notification within 24 hours after the IDT decides to extend the timeframe, it would require at least a day or two for such written notification to reach the requestor. Additionally, regardless of whether notification was provided orally or in writing, commenters noted the PACE organization would have to maintain documentation of the notification in accordance with the recordkeeping requirements at § 460.121(m).

Response: We appreciate the commenters' suggestions to modify the proposed regulatory text at § 460.121(i)(2) to allow PACE organizations to provide notification of the decision by the IDT to extend the regulatory timeframe either orally or in writing. We believe that providing written notification of the rationale for an extension is important in order to ensure the participant receives a full explanation. Additionally, a written explanation of the extension will allow the participant to share that information with family members or caregivers if desired, for instance if the participant needs assistance with understanding the rationale. Therefore, we are not persuaded to modify the regulation at this time to allow PACE organizations to notify participants orally instead of in writing, and are finalizing the requirements under § 460.121(i)(2) as proposed. We will consider building additional flexibility into the regulation through future rulemaking. Additionally, while we are not modifying the regulation to allow for oral notification and PACE organizations will be required to provide written notification when the IDT extends the timeframe for processing a service determination request, nothing would preclude the organization from choosing to call a participant in addition to sending a written notification. This would alleviate any concerns the organization might have about providing notice to the participant in as timely a manner as possible.

Comment: The majority of commenters agreed with CMS's proposal to require PACE organizations to provide the participant or designated representative with oral or written notice of the IDT's decision to approve a service determination request under § 460.121(j)(1). However, these commenters also requested clarification regarding CMS' expectations with respect to the requirement that such notice must explain the conditions of the approval.

Response: We appreciate the commenters' support. The explanation of the conditions of an approval that the IDT is required to provide to the participant or their designated representative under § 460.121(j)(1) should include any parameters that may be applicable to the approval. We wish

to clarify that PACE organizations would only be required to explain the conditions of the approval if the request is approved in full, but there are conditions applicable to the approval. As we discussed in the proposed rule, requests are not considered approved in full unless the IDT member can approve exactly what is requested. (84 FR 9127). In these situations, if there are conditions on a particular service that are not inconsistent with a participant's request but that the IDT still needs to make the participant aware of, we would expect that they notify the participant of the conditions of the approval that apply. These conditions may include any additional information about duration or timing, or a limitation on the service that needs to be conveyed to the participant. For example, if a participant makes a general service determination request for physical therapy (and does not request a specific duration), and the PACE organization approves physical therapy, but determines that the participant only needs physical therapy 3 times a week for 6 weeks, the required notice must include the specific duration and frequency of the approved service. Another example would include circumstances where the PACE organization approves a visit to a specialist, but requires the participant to go to a particular contracted specialist, the required notice must include this information. If the request cannot be approved in full as requested, then the decision is a partial denial and the specific reason for the denial and appeal rights must be provided both orally and in writing pursuant to § 460.121(j)(2). For example, if the participant makes a service determination request for 8 hours of home care, split over 3 visits each week, but the PACE organization approves a total of 6 hours of home care, split between 2 visits each week, this would be considered a partial denial and notification would have to be provided pursuant to § 460.121(j)(2). Another example would be if a participant requested physical therapy for six weeks, but the PACE organization only approved physical therapy for four weeks. Because the PACE organization did not approve exactly what the participant requested, and only approved four weeks instead of six, that decision would be considered partially denied.

Comment: The majority of commenters agreed with CMS' proposed provisions in § 460.121(j)(2), which require PACE organizations to provide the participant or designated representative with oral and written notice of the IDT's decision to deny or partially deny a request. We proposed that this notification must include the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language, inform the participant or their designated representative of his or her right to appeal the decision under § 460.122, describe the standard and expedited appeals processes, and inform a Medicaid participant of his or her right to continue receiving disputed services during the appeals process and the conditions for continuing to receive disputed services. One commenter recommended that CMS provide PACE organizations with template language for denial notifications.

Response: We thank the commenters for their support of this provision. Historically we have not been prescriptive about PACE organizations' appeals processes, and it remains up to the PACE organization to develop a formal written appeals process with specified timeframes for response to address noncoverage or nonpayment for services under § 460.122(a), subject to the minimum requirements specified in § 460.122(c). Accordingly, we believe that each PACE organization is in the best position to create a notice that is tailored directly to its internal processes, in accordance with the requirements at § 460.122(j). We appreciate the commenters' recommendation and we may consider providing template language for denial notifications in the future, as appropriate in light of the needs of the PACE program.

Comment: In response to CMS' request for feedback on whether it would be preferable for § 460.121(j)(2)(iv) to cross-reference § 460.122(e) or § 460.122(e)(1), the majority of commenters agreed that CMS should cross-reference § 460.122(e)(1). Several commenters requested confirmation that the provisions in § 460.121(j)(2)(iv) would not prohibit a PACE organization from informing all participants, regardless of Medicaid eligibility, of their ability to continue receiving disputed services during the appeals process until issuance of the final determination.

Response: We appreciate the commenters' responses to our request for feedback and are finalizing the cross reference at § 460.121(j)(2)(iv) as proposed. At this time the requirement at § 460.121(j)(2)(iv) applies only to Medicaid eligible participants, including those participants that are dually eligible for Medicare and Medicaid, and we are not expanding this to include Medicare-only participants in this rule. PACE organizations are not required under § 460.122(e) to continue to furnish the service(s) under dispute during the appeals process for Medicare-only participants. The requirements under § 460.122(e)(1) specify that for a Medicaid participant, the PACE organization must continue to furnish the disputed services until issuance of the final determination if the PACE organization is proposing to terminate or reduce services currently being furnished or if the participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

Comment: Commenters agreed with CMS' proposal at § 460.121(k) regarding the effectuation requirements when the IDT approves a service determination request, in whole or in part. As proposed, § 460.121(k) would require PACE organizations to provide approved services as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. This provision would also require the IDT to explain when the participant may expect to receive the service in accordance with § 460.121(j)(1). Commenters also agreed with CMS's proposals under § 460.121(*l*) relating to the effect of failure by the IDT to meet the processing timeframes. CMS proposed to require the PACE organization to automatically process an appeal in accordance with § 460.122 if the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, as this failure would constitute an adverse decision.

Response: We thank the commenters for their support of these provisions and are finalizing as proposed.

Comment: Commenters were also supportive of the proposed recordkeeping requirements at § 460.121(m), which would require PACE organizations to establish and implement a process to document, track, and maintain records related to all processing requirements for service determination requests received both orally and in writing, and ensure those records would be available to the IDT to ensure that all members remain alert to pertinent participant information.

Response: We thank the commenters for their support of this provision and are finalizing as proposed.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes at §§ 460.121(e), (g), (h), (i), (j), (k), (*l*), and (m) as proposed. We are finalizing the remaining provisions at § 460.121 with several modifications. First, we have modified the terminology used at § 460.121 by changing the title to refer to ''service determination process'' and replacing the term ''service delivery request'' with ''service determination request'' throughout. We have also made corresponding changes throughout the proposed regulatory text at part 460. We are amending proposed § 460.121(a) by changing the word ''section'' to ''Part'' in order to state that PACE organizations' written procedures for identifying and processing service determination requests must be developed in accordance with the requirements in part 460 rather than § 460.121. This change will better reflect the content of our proposals under § 460.121, which specifically reference other applicable requirements in Part 460 of Title 42 and will not affect the meaning of the regulation as proposed or described in the final rule. We have made modifications to 460.121(b)(2) by changing the language from ''made prior to the development of the initial care plan'' to ''prior to completing the development of the initial plan of care'' to reflect our intent, as expressed in the preamble to the proposed rule, that this exception applies until the initial plan of care is complete. We are also amending proposed § 460.121(d)(2) to require that individuals may make service determination requests to any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants, in response to comments received about whether we should adopt an approach that permits service determination requests to be made only in those settings. In addition, at § 460.121(f) we proposed to use a question mark at the end of the paragraph title instead of a period. This was an oversight and therefore, we have modified the regulatory text to reflect this change. This change will not have a substantive impact on the effect of the regulation. Finally, we have made minor grammatical corrections to § 460.121(b)(1), (c), and (f) which will not change the intended meaning of the regulation as proposed or described in this final rule. We are finalizing the changes at § 460.104(d)(2) as proposed, except in regard to the use of the term ''service determination request.''

B. Appeals Requirements Under PACE (§§ 460.122 and 460.124)

As discussed previously, sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act require PACE organizations to have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. In the preamble to Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) interim final rule which was published in the **Federal Register** on November 24, 1999 (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule), CMS explained that we considered the appeals requirements under what is now MA when creating the appeals requirements for PACE (see 64 FR 66257 and 66258). CMS established the requirements for PACE organizations' appeals processes in §§ 460.122 (PACE organization's appeals process) and 460.124 (Additional appeal rights under Medicare or Medicaid). Over time, PACE organizations have requested that CMS explain certain aspects of the appeals processes described in §§ 460.122 and 460.124. Therefore, we proposed certain changes to §§ 460.122 and 460.124 that would provide additional detail about the appeals process and help ensure consistency in the administration of the appeals process among PACE organizations. We also proposed a few other changes to increase beneficiary awareness of and access to the appeals process, and to align with other changes in this rule. The term ''appeal'' is currently defined in § 460.122 as a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. We would add a sentence after the definition to require that PACE organizations must process all requests to initiate, modify or continue a service as a service delivery request before processing an appeal under § 460.122. As we discussed in section VI.A. of this final rule, we have seen through audits that some PACE organizations will process an appeal instead of processing a service delivery request when a participant makes a request to continue receiving a service that the PACE organization is discontinuing or reducing. We would add a sentence to this introductory paragraph in order to affirmatively require that all requests that satisfy the definition of a service delivery request under § 460.121(b) must first be processed as such before a PACE organization may process an appeal. Section 460.122(b) currently provides that upon enrollment, at least annually thereafter, and whenever the IDT denies a request for services or payment, the PACE organization must give a participant written information on the appeals process. Consistent with the changes to existing § 460.104(d)(2) and new § 460.121, which are discussed in section VI.A. of this final rule, we would modify § 460.122(b) to specify that PACE organizations must provide participants with written information on the appeals process at enrollment, at least annually thereafter, and whenever the IDT denies a service delivery request or other request for services or payment. By proposing this change, CMS was seeking to ensure that participants consistently and timely receive information about their appeal rights, including when PACE organizations deny their service delivery requests.

Section 460.122(c) provides requirements for the minimum written procedures that PACE organizations must establish for their appeals process. We have heard that these requirements have created confusion among PACE organizations, which has led to inconsistent implementation among PACE organizations and a lack of participant awareness of and participation in the appeals process. As a result, we proposed a number of changes to decrease confusion and increase beneficiary awareness of and access to the appeals process.

We proposed two modifications at paragraph (c)(2). First, we would add a participant's designated representative as someone who has the right to appeal on the participant's behalf. We believe that this is an important participant safeguard because it allows for assistance in navigating the appeals process. Additionally, in developing procedures for how a participant or a participant's designated representative files an appeal, PACE organizations would be required to include procedures for receiving oral and written appeal requests. Because of the comprehensive nature of the care PACE organizations provide, participants are likely to have more verbal interactions with staff of the PACE organization and may express their desire to appeal a decision, but may be unsure or confused as to how. We believe that by requiring PACE organizations to accept appeal requests made both orally and in writing, we would create an important safeguard for the participant population enrolled in the PACE program. By allowing both oral and written requests for appeals, this proposal would enhance participant access to the

appeals process, and to services covered under the PACE benefit.

Second, in response to questions received from PACE organizations, we would add language in paragraph (c)(4) to specify the qualifications required of an appropriate third party reviewer or members of a review committee. Specifically, we would require PACE organizations to ensure appeals are reviewed by an appropriate reviewer or committee. This includes separating the requirements that an appropriate third party reviewer and the members of a review committee must be ''independent'' and ''appropriately credentialed'' to emphasize the fact that an appropriate third party reviewer or member of a review committee must be both independent and appropriately credentialed. We discuss the use of a review committee in the preamble to the 2006 PACE final rule (see 71 FR 71302) and PACE organizations currently utilize review committees in their review processes; therefore, we would incorporate review committees in regulation at this time and require the members of review committees to satisfy the same requirements as appropriate third party reviewers. Employees or contractors of a PACE organization may participate in review committees as long as they meet the requirements set forth in § 460.122(c)(4). Consistent with the current requirements at § 460.122(c)(4), we would specify that in order to be an appropriate third party reviewer or member of a review committee, an individual must be an impartial third party who was not involved in the original action and does not have a stake in the outcome of the appeal. We also proposed to add language that more clearly defines an appropriately credentialed reviewer. As we discussed in the preamble to the 2006 final rule, the appropriate third party reviewer must be someone with expertise in the appropriate field. Thus it would not be appropriate for a social worker to review an appeal related to a physical therapy denial; nor would it be appropriate for a gynecologist to review a denial of services relating to coronary surgery (71 FR 71302). Therefore, we would modify the language in paragraph (c)(4) to specify that an appropriate third party reviewer is one who is credentialed in a field or discipline related to the appeal. We do not believe that these proposals would affect the way PACE organizations currently choose their third party reviewers since the existing regulation at § 460.122(c)(4) requires the appointment of an appropriately credentialed and impartial third party that was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal. By proposing amendments to expressly state that the same requirements also apply to the members of a review committee, we believe that as proposed this would give PACE organizations more clarity and flexibility to utilize resources within the organization as well as contracted employees.

PACE organizations have expressed confusion about the third party review process, and we are aware of inconsistent decisions made by third party reviewers, such as inconsistent decisions at different PACE organizations. In order to reduce confusion, create a more consistent application of Medicare and Medicaid coverage requirements under PACE, and increase consistency for participants, we proposed additional modifications to the requirements under § 460.122(c). Specifically, we added a new paragraph (c)(5) that would require PACE organizations to take specific steps to ensure their third party reviewers understand the PACE benefit package and the coverage requirements under the PACE program, and how to review requests in a manner consistent with both. As noted in the preamble to the 2006 PACE final rule (71 FR 71302), PACE organizations should ensure that credentialed and impartial third party reviewers are trained to make decisions in a manner similar to the determinations under section 1862(a)(1)(A) of the Act. Such determinations would be based on the participant's medical needs and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors. Therefore, we proposed, in new paragraph (c)(5), to require PACE organizations to provide written or electronic materials to an appropriate third party reviewer(s) that, at a minimum, explain that services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98, the need to make decisions in a manner consistent with determinations made under section 1862(a)(1)(A) of the Act, and the requirements in § 460.90(a) that specify that many of the limitations on the provision of services under Medicare or Medicaid do not apply in PACE.

The requirements for providing appeal notifications at § 460.122(d) currently provide that a PACE organization must give all parties involved in the appeal (1) appropriate written notification and (2) a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing. However, PACE organizations have expressed that this section of the regulation is confusing because it discusses both the notification requirements and the participant's opportunity to submit evidence during an appeal. To reduce confusion, we would separate these requirements. Accordingly, we would redesignate paragraph (g) as (h) and also change the title of paragraph (h) to ''Actions following a favorable decision.'' This redesignation allows for the addition of new paragraph (g) that sets forth notification requirements. We would modify paragraph (d) to address the existing requirement that the PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing. At new paragraph (g), we proposed to revise the notice requirements for appeals to more closely align with the notice requirements for service delivery requests at § 460.121(j) by specifying the content of the notice in order to ensure consistency and minimize confusion for PACE organizations and participants. PACE organizations would be required to give all parties involved in the appeal (for example participants or their designated representatives) appropriate written notice of all appeal decisions. In the case of appeal decisions that are favorable to the participant, the PACE organization would be required to explain any conditions on the approval in understandable language. For partially or fully adverse decisions, the PACE organization would be required to state the specific reason(s) for the denial, explain the reason(s) why the service would not improve or maintain the participant's overall health status, inform the participant of his or her right to appeal the decision, and describe the additional appeal rights under § 460.124. Conditions of approval may include, but are not limited to, the duration of the approval, limitations associated with an approval such as dosage or strength of a drug, or any coverage rules that may apply. We also proposed to revise and move the current requirements at paragraph (h) into new paragraph (g)(2)(ii). These requirements specify that for determinations that are wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify CMS, the State administering agency, and the participant. Because this paragraph includes additional notification requirements that PACE organizations

must follow after a decision is made to deny an appeal, we believe that this belongs in § 460.122(g)(2) for notice of adverse decisions. We would revise this requirement to use terminology consistent with our other amendments to § 460.122, specifically, to refer to ''partially or fully adverse'' decisions and to refer to an appeal decision rather than to a determination for consistency with § 460.122(g)(2)(i) and other sections of this regulation.

We proposed a few minor changes to align with other changes in this rule. First, we would change the reference to § 460.104(d)(2)(iv) in § 460.122(c)(1) to reference the service delivery request requirements in § 460.121(i) and (m). The current citation references the extension requirements for unscheduled reassessments; however, we believe that this reference should have been to the general timeframes for processing service delivery requests. We would redesignate the current paragraphs (c)(5) and (6) as (c)(6) and (7) in § 460.122 to allow for the addition of a new paragraph (c)(5), as discussed earlier in this section.

Lastly, we added language to § 460.124 that delineates the additional appeal rights that PACE participants are entitled to receive under Medicare or Medicaid and add processing requirements for the PACE organization. In response to comments CMS received on the 1999 PACE interim final rule, CMS discussed stakeholder concerns about the PACE appeals process in the preamble to the 2006 PACE final rule and reiterated the intended process in the preamble. (See 71 FR 71303 and 71304.) Specifically, CMS stated in the preamble to the 2006 PACE final rule that Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible participants have access to the State Fair Hearing (SFH) process (see 71 FR 71303). However, despite this clarification, CMS's audits have revealed that PACE organizations continue to misinterpret the requirements under § 460.124 relating to participants' additional appeal rights under Medicare or Medicaid. To address this issue, we proposed several changes to § 460.124. First, we would add new paragraphs (a) and (b) at § 460.124. In § 460.124(a) we would specify that Medicare participants have the right to a reconsideration by an independent review entity (IRE). We recognize that there are differences in the terminology used in PACE versus MA and therefore have to add similar language at new § 460.124(a)(1), (2), and (3) to establish in regulation the requirements for how an appeal may be made to the independent, outside entity, the timeframe in which the independent outside entity must conduct the review, and who are the parties to the appeal. In § 460.124(a) introductory text and (a)(1) we have intended to parallel the requirements at § 422.592(a) with minor differences. Under MA there is automatic escalation to the independent review entity at this level of appeal if the organization upholds its adverse decision, in whole or in part. However, in PACE, appeals are not automatically escalated because most PACE participants are dually eligible for Medicare and Medicaid benefits and these participants may choose to utilize the Medicaid or Medicare route for independent review. For these dually eligible individuals, it may be more appropriate to pursue an appeal through the Medicaid path rather than the Medicare path. The provisions relating to automatic-escalation in MA ensure that the beneficiary receives a review by an independent reviewer; however, this protection is not necessary in PACE as the PACE participant has already received an independent review on the appeal during the internal appeal processed in accordance with § 460.122. Therefore, we proposed at § 460.122(a)(1) to specify that a written request for a reconsideration must be filed with the independent review entity within 60 calendar days of the decision by the third party reviewer. We did not specify who must file the request because we discuss at § 460.124 that the PACE organization must assist the participant in choosing which appeal rights to pursue (that is, Medicaid SFH or Medicare IRE) and as such, we believe that the PACE organization is also responsible for ensuring that the request is filed with the appropriate external entity. However, a participant always maintains the right to file a request without assistance from the PACE organization. At § 460.124(a)(2) we would add a requirement that the independent review entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract. The independent review entity is currently operating under these timeframes, consistent with the requirements at § 422.592(b), and participants are currently utilizing the independent review entity to exercise their external appeal right, consistent with CMS's historical interpretation that these requirements are applicable to the PACE program. We also proposed adding language at § 460.124(a)(3) that would parallel the requirement at § 422.592(c), to specify that when the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization. We are seeking to enhance transparency and we believe it is important to make PACE organizations aware that they are considered a party to the appeal once it reaches the independent review entity. We would add a new paragraph (b) that specifies that Medicaid participants have the right to a SFH as described in part 431, subpart E. Finally, we would add a new paragraph (c) to specify that participants who are dually eligible for both Medicare and Medicaid have the right to external review by means of either the IRE or the SFH process. This provision would specify that dually eligible participants may choose to pursue an appeal through either the Medicare or Medicaid process. In accordance with the existing provisions under § 460.124, PACE organizations must assist dual eligible participants in choosing which route to pursue if both the IRE and the SFH review processes are applicable. For example, if the appeal is related to an enrollment dispute, the Medicaid SFH process would be the appropriate route for a participant to pursue. Whereas for a dispute related to a Part D medication, the IRE would be the appropriate route for a participant to pursue. By codifying these appeal rights in regulation, we are seeking to enhance transparency for PACE organizations to ensure that participants are able to access additional levels of appeal in order to receive services they believe that they are entitled to under the PACE benefit.

We summarize the comments on the proposals related to appeal requirements under PACE, and provide our responses to those comments, below.

Comment: Numerous commenters agreed with the proposed changes to the definition of ''appeal'' under § 460.122, which the commenters' noted would specifically state their understanding of CMS's longstanding policy, that a service determination request must be processed before an IDT determination regarding a request to initiate, modify, or continue a service could be appealed. Another commenter recommended revising the definition to eliminate the language ''a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions or termination of services'' and instead replace it with ''a participant or their designated representative's action taken

with respect to the PACE organization's denial of a service request to initiate, continue, increase, decrease or discontinue a service.'' The commenter suggested that this would eliminate any confusion on what constitutes an appeal.

Response: We appreciate commenter support of our changes to the definition. While we proposed adding a sentence to the introductory language of § 460.122 to require that PACE organizations process any request to initiate, modify, or continue a service as a service determination request before the PACE organization can process an appeal under § 460.122, we did not propose any changes to the current language regarding what constitutes an appeal. We have chosen not to include the designated representative in the definition because we specifically provide at § 460.122(c)(2) that a PACE organization's appeals process must include written procedures for how ''a participant or their designated representative files an appeal . . .'', we do not believe it is necessary to refer to the designated representative in the introductory text. Furthermore, we do not believe it is necessary to change the proposed definition as the commenter suggests since we are maintaining the proposed criteria for what constitutes a service determination request to include requests to initiate, modify, or continue a service. Therefore, we are finalizing our proposed changes to the introductory text of § 460.122 as proposed.

Comment: The majority of commenters recommended that CMS modify the proposed language in § 460.122(b) from, ''or other request for services or payment'' to ''or request for payment.'' These commenters expressed confusion about why CMS would include ''or other services'' in addition to a service determination request. A commenter stated that ''or other request for services or payment'' is in reality a service determination request and therefore is redundant in § 460.122(b) and should be removed.

Response: Section 460.122(b) does not address the right to appeal, but rather the responsibility of the PACE organization to provide participants with written information about their appeal rights. In addition to providing notice of these rights at enrollment and annually, we believe that it is important for the PACE organization to provide notice when it denies a service determination request, which is why we proposed to modify § 460.122(b) to include that language. We did not propose to make other changes to the text of § 460.122(b) such as removing ''or other requests for services or payment.'' We agree with commenters that all requests for services would be resolved within the service determination request process. Because all requests for services would be resolved through the service determination request process, there would be no ''other requests for services'' that might be subject to appeal, and removing this language would not substantively affect the meaning of the revised text of § 460.122(b) as proposed. However we also note that certain requests for payment may not meet the definition of a request to initiate, modify or continue a service. For example, a PACE participant may go to the hospital or emergency room without first requesting the service from the IDT, and may subsequently submit the bill to the PACE organization as a request for payment. Since the underlying service was already received, this would not be a request to initiate, modify or continue a service, but we would expect the PACE organization to provide notification of appeal rights if the payment was denied by the IDT. We can also envision scenarios where a participant receives a bill for routine care provided by a contractor of the PACE organization, such as care provided by a nursing facility or specialist, and the participant subsequently requests payment from the PACE organization. Because these services would not involve requests to initiate, modify, or continue a service, these payment decisions would be processed outside of the service determination process. For these reasons, we are persuaded to remove ''or other request for services'' but will retain ''or payment'' as this would align with our proposal to require notification of appeal rights following a denied service determination request or a decision to deny a request for payment for a service. We are therefore revising § 460.122(b) to remove the reference to ''other services'' and to require that upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment, the PACE organization must give a participant written information on the appeals process.

Comment: The majority of commenters recommended modifying the cross-reference in § 460.122(c)(1), ''Minimum requirements'', from § 460.121(g) to § 460.121(i) as it would make the appeals requirement clearer.

Response: We appreciate the commenters' recommendation and agree that this cross-reference should be revised. In section VI.B. of the proposed rule, we proposed in § 460.122(c)(1) to change the reference from § 460.104(d)(2)(iv) to §§ 460.122(i) and (m) to reference both the notification timeframes and the documentation requirements for service delivery requests. (85 FR 9133). The proposed regulation text at § 460.122(c)(1) incorrectly referenced § 460.121(g). Therefore we have modified the regulatory text in this final rule to reflect the correct reference, to §§ 460.121(i) and (m).

Comment: The majority of commenters agreed with the revisions at § 460.122(c)(2), to require that a PACE organization's appeals process must include written procedures for how a participant or their designated representative files an appeal. The commenters specifically noted their support for allowing the participant's designated representative as an individual who may submit an appeal on the participant's behalf.

Response: We thank the commenters for their support of this provision.

Comment: We received several comments on the proposed requirements for third party reviewers. The majority of commenters supported the requirements that allow for third party review by a committee at § 460.122(c)(4). The commenters also supported the requirement that a third party reviewer or committee member must be appropriately credentialed in the field or discipline related to the appeal. A commenter specifically recommended requiring that appeals of physical therapy services be reviewed by a licensed physical therapist. These commenters also supported the proposed provisions at § 460.122(c)(5), which require distribution of written or electronic materials to third party reviewers.

Response: We thank the commenters for their support of these provisions. With respect to the comment regarding review by licensed physical therapists, we expect that the PACE organization would determine what constitutes an appropriately credentialed individual in the field or discipline related to the appeal as specified at proposed § 460.122(c)(4)(i). Given the vast array of services that could be under appeal, we do not believe it would be feasible for CMS to list each discipline or set of appropriate credentials that we would expect to see in each case. Therefore, we are not adopting this suggestion. In section VI.B. of the proposed rule, we provided an example stating that it would not be appropriate for a social worker to review an appeal related to a denial of physical therapy services, and

we would expect a PACE organization to consider this guidance when making determinations about whether third party reviewers are appropriately credentialed in the field or discipline related to the appeal.

Comment: The majority of commenters recommended that CMS either clarify the meaning of, ''all parties,'' as referenced in § 460.122(d) and § 460.122(g) by adding a list of individuals that would be considered a ''party'', or modify the language to state, ''A PACE organization must give the participant or designated representative . . .'' These commenters also recommended adding designated representative as a party that must be provided information on the PACE organization's appeals process in § 460.122(b).

Response: The use of the terminology ''all parties'' is consistent with the current language used in the context of appeal notification and the opportunity to present evidence at § 460.122(d) and we proposed to retain the existing language. According to *Merriam-Webster.com*, the term ''party'' includes ''a person or group taking one side of a question, dispute, or contest.'' [75] Generally, we would interpret the term ''all parties'' to refer to all parties taking a formal position on one or the other side of the appeal, which would include the participant (and his or her designated representative, if applicable), and the PACE organization. This terminology has been in use in the PACE regulations since 1999 and based on CMS oversight activities we do not have concerns with how PACE organizations are currently interpreting this term. Under § 460.122(c)(2) a participant may file an appeal, or a participant's designated representative may file an appeal on the participant's behalf. If a designated representative has filed an appeal on behalf of a participant, that representative typically acts on the participant's behalf throughout the appeal process, and CMS considers the participant and the designated representative to be the same ''party'' for purposes of the appeal. For purposes of notification at § 460.122(g), the ''parties'' to the appeal will depend on the circumstances of the appeal. Generally, we believe the parties would include the participant or the designated representative of the participant, if applicable. For example, if a participant filed an appeal without assistance from a designated representative, the PACE organization would be required to provide notification to the participant, but if the participant designated a representative to represent him or her in the appeal, the designated representative should also receive notice. For purposes of submitting evidence during the appeal at § 460.122(d), there may be circumstances where a representative submits evidence on behalf of the participant, and there may be circumstances where both the participant and the representative submit evidence during the appeal. After consideration of the comments received, we are finalizing this provision as proposed.

With respect to the recommendation to add the designated representative as a party that must be provided information about the PACE organization's appeals process under § 460.122(b), we do not agree that this is necessary, although there may be circumstances when a designated representative should receive information about the appeals process. As we discussed earlier in this section, the PACE organization would be required to give a participant written information on the appeals process upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment. A participant could designate a representative for purposes of interacting with the PACE organization at any one of these points in time, in which case the notice to the participant could go to the designated representative who is acting on the participant's behalf. Additionally, we proposed to retain the current requirements for notification of an adverse decision in regard to a service determination request, which provide that a PACE organization must notify the participant or the designated representative orally and in writing of the adverse determination, in a notification that includes a description of both the standard and expedited appeals processes § 460.121(j)(2).

Comment: A commenter was supportive of the proposed notification requirements at § 460.122(g). The majority of commenters recommended revising the language in § 460.122(g)(2) to remove the statement, ''the PACE organization must provide the participant with written notification of the decision,'' since the requirement to notify participants is already contained in the first paragraph of § 460.122(g). These commenters also recommended removing the newly redesignated § 460.122(i). The commenters noted that the requirements to notify CMS and the State administering agency of a wholly or partially adverse decision in the newly redesignated § 460.122(i), are incorporated into § 460.122(g)(2)(ii) and are therefore duplicative.

Response: We thank the commenters for their support and for their recommendations. We recognize that the proposed language at § 460.122(g)(2) restates the requirement to provide written notification of the decision to the participant; we are persuaded to revise this section to remove the duplicative language. At § 460.122(g), we proposed that a PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal. We did not refer to ''all parties'' at § 460.122(g)(2) and we realize that this could be viewed as inconsistent. Therefore, we are removing the language at § 460.122(g)(2) that states that a PACE organization must provide the participant with written notification of the decision. By making this change we are enhancing consistency and also ensuring notification to all parties involved in the appeal. Because the designated representative is permitted to file an appeal on a participant's behalf, and therefore are parties to the appeal, we believe it is important that any notification, including one related to a partially or fully adverse decision, be communicated to all parties involved.

With regards to removing the redesignated § 460.122(i) (existing § 460.122(h)), we agree that the requirements to notify CMS and the State administering agency of a wholly or partially adverse decision in the redesignated § 460.122(i) would be duplicative of the notification requirements in proposed § 460.122(g)(2)(ii). It was not our intention to duplicate these requirements in the regulations and therefore we are revising the amendatory language to the regulation text to redesignate the current paragraph (h) as a new paragraph (g)(2)(ii), as revised.

Comment: A commenter agreed with CMS's proposal at § 460.122(g) which sets forth the requirements for providing notification of appeal decisions. The majority of commenters requested clarification regarding the proposed requirements in § 460.122(g)(2)(ii), which would require PACE organizations to provide written notification of an adverse appeal decision to the participant, CMS and the State administering agency (SAA) at the same time the decision is made. Specifically, the commenters sought to clarify the meaning of ''at the same time the decision is made'' and how long

[75] *https://www.merriam-webster.com/dictionary/party.*

organizations would have to notify CMS and the SAA.

Response: We appreciate the commenter's support of this provision. With respect to the commenters' question regarding what CMS intends by the language ''at the same time the decision is made,'' we appreciate the opportunity to share our historical interpretation of this requirement. Under the current requirements at redesignated § 460.122(c)(6), the PACE organization's appeals process must include written procedures for responses to and resolution of appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the PACE organization receives the request. Under the current requirements at §§ 460.122(f)(1) and (f)(2), a PACE organization must also have an expedited appeals process and must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal, unless the PACE organization takes an extension under § 460.122(f)(3). While both the decision and notification must be made within these regulatory timeframes, we recognize that generally the decision for an appeal will occur prior to the notification (sometimes by more than a day). Additionally, under the current requirements at § 460.122(h) (redesignated as § 460.122(g)(2)(ii)), the PACE organization must notify CMS, the State administering agency, and the participant of a determination that is wholly or partially adverse to a participant, at the same time the decision is made. We have not historically expected PACE organizations to notify CMS and the SAA of a decision at the same time as the decision is made; rather, our historical interpretation has been that notification to those entities should occur around the same time as when the PACE organization notifies the participant of the adverse decision. We would expect that organizations notify CMS and the SAA of the adverse decision at the time they notify the participant of the adverse decision, or within the regulatory timeframe for notification pursuant to §§ 460.122.

We are removing ''participant'' from the list at § 460.122(g)(2)(ii) because including that term on the list would be duplicative in light of the change to the wording of that provision. The requirement at § 460.122(g) already establishes that the PACE organization must give all parties involved in the appeal, which includes the participant (or, as applicable, his or her designated representative), appropriate written notification of the decision to approve or deny the appeal. Therefore, we believe that removing participant from the list of entities that must also receive notification of a denial or partial denial at § 460.122(g)(2)(ii) will reduce confusion without affecting the substance of our proposals.

Comment: A commenter addressed the proposals at § 460.124 and was supportive of the additional clarifications around additional appeal rights under Medicare and Medicaid.

Response: We thank the commenter for their support of this proposed provision and therefore are finalizing as proposed.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to the introductory text of § 460.122, § 460.122(c)(2), (c)(4), (c)(5), (d), (h), and § 460.124 as proposed. We are finalizing the provisions at § 460.122(b) with modifications. Specifically, we have modified the requirement at paragraph (b) by removing the language ''other requests for services''. We are finalizing the provision at paragraph (c)(1) with a minor technical correction to change the reference from § 460.121(g) to §§ 460.121(i) and (m). We are finalizing § 460.122(g) as proposed, with a few technical changes to address duplicative language. First, we removed duplicative language in paragraphs (g)(2)(i) and (g)(2)(ii) stating that the requirements in question applied to decisions that are partially or fully adverse, and added ''partially or fully'' in paragraph (g)(2) to reflect the fact that all of the requirements within (g)(2) applied to decisions that were partially or fully adverse to the participant. We also removed language from paragraph (g)(2)(i) that restated the requirement at (g) that the PACE organization must provide the participant with written notification of its decision. Similarly, at paragraph (g)(2)(ii) we have removed several references to ''the participant,'' including from the list of people who must receive notification of a partially or fully adverse decision, to reflect the fact the participant would already receive notice of any decision under § 460.122(g), as a party to the appeal. In addition, there was an oversight in the proposed amendatory language for the regulation text that would reflect the move of the current requirements at paragraph (h) into new paragraph (g)(2)(ii), as proposed at 85 FR 9133. Therefore, we are modifying the amendatory language to reflect this change.

C. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§ 460.92, 460.96, and 460.102)

1. Required Services

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act state that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[76] CMS codified these required services in § 460.92 of the regulations, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered items and services, all Medicaid covered items and services, as specified in the State's approved Medicaid plan, and other services determined necessary by the interdisciplinary team (IDT) to improve and maintain the participant's overall health status.

We proposed to modify the requirements at § 460.92 to more clearly define required services, and to specify CMS' expectations for making decisions about the services that are required under the PACE benefit package. First, we would create a new paragraph (a) and include under (a) the current requirements in § 460.92. In order to do that, we proposed to renumber existing paragraphs (a), (b), and (c) as (a)(1), (2), and (3). We would add a new paragraph (b) that provides the standards that the IDT must consider when evaluating whether to provide or deny services described under (a) for a participant.

In addition to redesignating § 460.92(a) as § 460.92(a)(1), we would modify the language to refer to all Medicare-covered services. In light of our amendments to the definition of ''services'' in § 460.6, and the current definition of that term, PACE organizations should understand that providing necessary drugs, whether they are covered under Medicare Parts A, B, or D, is an important part of the PACE benefit package. See section VI.I. of this

[76] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

final rule for a more detailed discussion of the definition of ''services.''

We would add a new paragraph (b) in order to specify the standards that the IDT must consider when evaluating whether to provide or deny services required under § 460.92(a) for a participant. Under § 460.92(b)(1) we would require the IDT to take into account all aspects of a participant's condition, including the participant's medical, physical, emotional, and social needs, when determining whether to approve or deny a request for a service. As we discussed in section VI.A. of this final rule, the determination for a service should be based on all aspects of the participant's care. For example, additional center days may not be necessary when considering the participant's physical needs, but when taking into account the participant's social needs, the IDT may find that those services become necessary in order to improve the participant's social or emotional condition. We have discovered through audits that PACE organizations sometimes only consider the medical or physical needs of a participant but do not consider their social or emotional needs when those social or emotional needs are relevant to the request.

We also proposed to add language at § 460.92(b)(2) that would require organizations to utilize current clinical practice guidelines and professional standards of care when making a decision, so long as those guidelines and standards are applicable to the particular service. PACE organizations are currently required to utilize current clinical practice guidelines and professional practice standards when developing the outcome measures for their quality improvement programs at § 460.134(b). When we discussed this requirement in the preamble to the 1999 PACE interim final rule, we stated that we expect that PACE organizations will utilize current clinical standards as a routine part of their daily operations and care management strategies. (See 64 FR 66260). However, we have discovered through our PACE audits that decisions to deny services are sometimes not based on accepted clinical guidelines or standards. We understand that current clinical practice guidelines and professional standards of care may vary based on the type of service that is being considered. For example, when determining if a participant requires a cardiac catheterization, the organization may reference clinical practice guidelines issued by the American Heart Association. On the other hand, when determining the appropriate insulin for a participant the organization may appropriately refer to guidelines published by the American Diabetic Association. We also understand that certain services may not have an applicable clinical practice guideline. For example, determining the frequency of PACE center attendance may not be based on clinical practice guidelines, but may instead be based on the medical, physical, emotional, and social needs of the participant. Therefore, we added language to (b)(2) to require the IDT to take into account current clinical practice guidelines and professional standards of care if applicable to a particular service. By adding this requirement, we do not intend to restrict a PACE organization's ability to determine what service is appropriate or necessary for a participant: The IDT would remain responsible for determining the participant's overall health status and needs, and ensuring those needs are met through the provision of necessary services.

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to utilize current clinical practice guidelines as a part of their quality improvement program, and they are required to consider the participant's physical, medical, emotional and social needs as a part of care planning discussions. We believe that by modifying this provision we will not be increasing burden on PACE organizations, as they already consider these items on a routine basis.

We summarize the comments on the proposals related to required services, and provide our responses to those comments, below.

Comment: All commenters that addressed this provision recommended that CMS modify the proposed language at § 460.92(b) to state, ''The interdisciplinary team makes determinations of whether or not to approve, deny or partially deny services for participants. These determinations must be based on an evaluation of the participant that takes into account. . .''. These commenters asserted that this modification is necessary based on the proposed removal of § 460.96(a) and they believed the revised language would clarify the IDT's authority to approve or deny services. These commenters also agreed with removal of § 460.96(a), contingent on CMS' use of the recommended language in § 460.92(b).

Response: We thank the commenters for their recommendation regarding the establishment of the IDT's authority to make decisions. As we stated in the preamble to the proposed rule, the IDT's authority and responsibilities are defined throughout the PACE regulations, and under our proposal the IDT would retain the its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Therefore, our proposal would retain the IDT's ability to make decisions to approve or deny services consistent with the proposed regulatory requirements at § 460.92(a). 85 FR 9136. As proposed, the introductory language at § 460.92(b) states ''Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section. . . .'' Paragraph (a) of section 460.92 encompasses the complete PACE benefit package including all Medicare-covered services and all Medicaid-covered services, as specified in the State's approved Medicaid plan.

We believe that commenter's proposed change to ''the interdisciplinary team makes determinations'' was suggested in order to ensure that the IDT's authority to render these decision was clear. However, we believe our proposed introductory language at § 460.92(a) appropriately articulates this authority. We would also reiterate that decisions made under 460.92(b) encompass all decisions made by the IDT and are not limited to service determination requests processed under 460.121. We do not believe that the commenters' recommendation would significantly clarify the IDT's authority to make decisions regarding what services will be approved or denied.

After consideration of the comments received, we are finalizing our changes to § 460.92 as proposed, without modification.

2. Excluded Services

As we stated earlier in this section, in the discussion regarding required services, the PACE benefit package includes all Medicare-covered items and services, all Medicaid-covered items and services, as specified in the state's approved Medicaid plan, and other services determined necessary by the IDT to improve or maintain the participant's overall health status. The regulations at § 460.96 list a number of services that are excluded from coverage under PACE. Currently, paragraph (a) states that any service that is not authorized by the IDT, even if it is a required service, is an excluded service unless it is an emergency service. In addition, paragraph (b) states that in an inpatient facility, private room and

private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental are also excluded from coverage under PACE unless specifically authorized by the IDT as part of the participant's plan of care. We proposed to remove § 460.96(a) and (b).

These proposals are consistent with our authority to amend the regulations. The exclusions in § 460.96 are not specifically listed in the PACE statute. They were included in the 1999 PACE interim final rule that implemented the PACE program in part because they were included in section A.6 of the PACE Protocol included as Addendum A to the 1999 PACE interim final rule. (See 64 FR 66247 and 66301 and subparagraphs 1894(f)(2)(A) and 1934(f)(2)(A) of the Act.) Sections 1894(f)(1) and 1934(f)(1) of the Act give the Secretary the authority to issue regulations to carry out the PACE program created under sections 1934 and 1894 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that, in issuing such regulations the Secretary shall, to the extent consistent with the provisions of sections 1894 and 1934 of the Act, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol. As we stated in the 2019 PACE final rule (84 FR 25613), we believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[77] which has now been replaced by the PACE program agreement.[78] Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements under sections 1894 or 1934 of the Act, but precludes the Secretary from modifying or waiving any of the following provisions:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive integrated acute and long-term care services.
- The IDT approach to care management and service delivery.
- Capitated, integrated financing that allows the PACE organization to pool payments received from public and private programs and individuals.
- The assumption by the PACE organization of full financial risk.

Taking this authority into account, we would remove § 460.96(a) for the following reasons. CMS has gained a significant amount of experience with the PACE program since the 1999 PACE interim final rule, and we now believe that a number of PACE organizations are interpreting the exclusion under § 460.96(a) in a manner that is not consistent with sections 1894 and 1934 of the Act. Many PACE organizations appear to be interpreting § 460.96(a) to allow an IDT to exclude from coverage any service that the IDT does not authorize for a participant, even if it is clearly covered under the Medicare or Medicaid programs and is medically necessary. For example, CMS has identified through audits that some PACE organizations have denied certain types of covered Part D drugs for participants, even when the drug is medically necessary and the participant is qualified to receive the drug under Medicare.

These denials are inconsistent with the statutory requirement under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act to provide all items and services covered by Medicare and Medicaid, as well as all additional items and services specified in regulations. As we stated in the 2006 PACE final rule (71 FR 71248), in accordance with sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. PACE organizations are required to provide all Medicare covered services and all Medicaid covered services in accordance with the State's approved Medicaid plan under current § 460.92(a) and (b). In addition, PACE organizations are required to cover other items and services that are determined necessary by the IDT to improve and maintain the participant's overall health status under current § 460.92(c). In order to ensure that IDTs continue to make decisions that are consistent with the statutory requirements, we would remove paragraph (a) from § 460.96. We believe that removing paragraph (a) is necessary in order to ensure that participants receive the services to which they are entitled under PACE.

By proposing to remove paragraph (a), we did not intend to waive or eliminate the IDT approach to care management and service delivery. The IDT's authority and responsibility are defined throughout the PACE regulations, and under this amendment, the IDT would retain its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Additionally, as discussed in our changes to § 460.92, the IDT's decision to provide or deny required services must be based on an evaluation of the participant that takes into account the participant's current medical, physical, emotional and social needs, along with any current clinical practice guidelines and professional standards of care that are applicable to the particular service. We do not believe that the current provision at § 460.96(a) affects an IDT's authority for determining what services are required under § 460.92, or changes the IDT's responsibility for coordinating 24-hour care delivery. However, we are concerned that the current language at § 460.96(a) is confusing and implies that there are some required services that are not covered under the PACE program because they are excluded. The term ''excluded'' implies that a service is outside of the benefit package or never covered. The term ''excluded'' could also suggest that services that are not authorized are not appealable, which runs counter to our historical interpretation of the PACE statutes and regulations and the policies we have promulgated to safeguard participants' right to appeal adverse decisions by the IDT. While the IDT remains responsible for determining the needs of each participant, and then implementing services that would meet those identified needs, PACE participants should always have the ability to advocate for services, through the service delivery request and appeal process, including any services the IDT determines not to be necessary (or does not authorize).

We would eliminate paragraph (b) from § 460.96 for the following reasons. Currently, this paragraph generally excludes from PACE coverage private rooms and private duty nursing services, and non-medical items for personal convenience, in an inpatient facility, but notes that a private room or private duty nursing services would be covered if medically necessary, and non-medical items for personal convenience would be covered if specifically authorized by the IDT as part of the participant's plan of care. We continue to believe that services such as a private room, private nursing services,

[77] *https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf.*

[78] *https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf.*

or non-medical personal care items would not be covered under PACE, unless they were medically necessary or authorized by the IDT as part of the participant's plan of care. However, we believe that including this provision under a section of the regulation titled ''Excluded Services'' may give a false impression that the IDT would not have to consider whether those services are medically necessary or necessary to improve and maintain the participant's overall health status. As we previously indicated, the IDT is responsible for comprehensively assessing each individual participant to determine their needs, and then providing services that would meet those needs. If the IDT determines that private nursing services or a telephone are necessary to improve and maintain the participant's health status, those services would be covered for that participant under PACE. Therefore, these are not always or by definition excluded services, and we would eliminate paragraph (b) from the excluded services provision for that reason.

In addition to eliminating paragraphs (a) and (b), we would redesignate paragraphs (c) through (e) as (a) through (c).

We did not score this provision in the Regulatory Impact Analysis section because PACE organizations are already required to cover all PACE required services under § 460.92, and by modifying the provisions relating to excluded services we are hoping to increase compliance with existing requirements.

We summarize the comments on the proposals related to excluded services, and provide our responses to those comments, below.

Comment: All commenters that addressed this proposal expressed concern with the removal of § 460.96(b). The commenters noted that although they understand CMS' rationale for removing this provision, they believe this would impede a PACE organization's ability to deny these services when they are not necessary to maintain the participant's overall health. Specifically, commenters noted that removing this provision could be interpreted to mean that inpatient facilities, private rooms and private duty nursing services could be available without approval from the IDT. The commenters also stated that they do not believe removal of this section is necessary since the services would be provided, if determined necessary by the IDT, consistent with criteria established in § 460.92(b).

Response: We appreciate the commenters' concern and wish to explain that by removing the excluded language at § 460.96(b) we would not preclude a PACE organization from denying these services if they are determined not to be necessary. Currently, § 460.96(b) provides that private rooms, private duty nursing services and nonmedical items for personal convenience are excluded from coverage under PACE unless medically necessary or specifically authorized by the IDT as part of the participant's plan of care. As such, these services are not actually excluded from coverage under PACE, and a participant is currently able to receive these services if authorized by the IDT. We do not include other services that are excluded or denied as part of the PACE benefit package in this section and we do not believe that it is necessary to specifically list out these services and therefore are finalizing this provision as proposed. As noted in the proposed rule, we do not want to give a false impression by including services that should be considered by the IDT, as appropriate, under a section of the regulation titled ''Excluded Services.''

After consideration of the comments received, we are finalizing our proposed changes under § 460.96 as proposed, without modification.

3. Responsibilities of the Interdisciplinary Team

A multidisciplinary approach to care management and service delivery is a fundamental aspect of the PACE model of care (see for example, the 1999 PACE interim final rule at 64 FR 66254). The regulations at § 460.102 require in part that the IDT must comprehensively assess and meet the needs of each participant, and that the IDT members must remain alert to pertinent input about participants from team members, participants, and caregivers. While we believe many IDTs appropriately apply the multidisciplinary approach to providing care, we have learned through our monitoring efforts that some IDTs may not consider pertinent input about participants from specialists and other clinical and non-clinical staff, whether employees, or contractors (for example, home health service providers). Because these individuals have direct contact with participants, including in the participant's home, and may have a similar level of expertise as the members of the IDT listed in § 460.102(b) or expertise in another medical field, they are likely to be in the best position to provide input that may contribute to a participant's treatment plan. An IDT could not comprehensively assess a participant and provide a multidisciplinary approach to care management if it did not consider pertinent input about a participant from any individual with direct knowledge of or contact with the participant, such as caregivers, employees, or contractors of the PACE organization, including specialists. For example, if a home care aide informed the organization that a participant seems more confused than normal, the IDT might not be able to fully meet the participant's needs if it did not take this information into consideration. While the IDT is responsible for many aspects of care provided to their participants, it might not interact with their participants on a regular basis. It is important that the IDT consider input from other individuals that have more regular or direct contact with the participant population, in order to inform its ability to appropriately meet participants' needs. Therefore, we would revise § 460.102(d)(2)(ii) by adding employees, contractors, and specialists to the individuals from whom the IDT must remain alert to pertinent input. We would include specialists because there may be circumstances in which a participant is receiving care or seeking treatment options from a provider that specializes in a particular area and we believe that input from these medical professionals is vital in order for a PACE organization to provide comprehensive care to its participants. We would add these individuals as unique sub-paragraphs under § 460.102(d)(2)(ii) in order to emphasize that these are unique groups of individuals, each of whom may provide information that is pertinent to the IDT. As part of the requirement that the IDT members remain alert to pertinent input from these individuals, we expect that the IDT members would consider all recommendations for care or services made by other team members, participants, caregivers, employees, contractors, or specialists for a participant when making treatment decisions.

We proposed a minor change to redesignate the provisions at § 460.102(d)(1) under a new (d)(1)(i), and to retain the current requirement that the IDT is responsible for the initial assessment, periodic reassessment, plan of care, and coordination of 24-hour care delivery. We would add a new § 460.102(d)(1)(ii) to require the IDT to document all recommendations for care and services and, if the service is not approved, the reasons for not approving or providing that care or service in accordance with the requirements in § 460.210(b). By requiring the IDT to document all recommendations for care

or services and, if not approved or provided, the rationale supporting the IDT's decisions, we believe our proposals under § 460.102(d) would better position the PACE organization and the IDT to remain alert to pertinent information and to share that information with participants, caregivers, and appeal entities when applicable.

We believe the burden associated with this provision is related to the documentation of the recommendations in the medical record. We discuss and account for the burden of documenting these recommendations in the medical record in the regulatory impact analysis.

We summarize the comments on the proposals related to responsibilities of the IDT, and provide our responses to those comments, below.

Comment: A commenter agreed with CMS' proposed revisions at § 460.102(d)(1)(ii) which would make the IDT responsible for documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services. However, the majority of commenters expressed concern that the requirement is not consistent with the preamble or regulatory language at proposed § 460.210(b)(4) and (5), which limits documentation to recommendations by employees and contractors of a PACE organization, including specialists, as well as the reason(s) for not approving or providing recommended services. Specifically, the commenters noted that the language as proposed at § 460.102(d)(1)(ii) could be interpreted to require the IDT to document recommendations made by the individuals other than those listed in § 460.210(b)(4).

Response: We thank the commenter who supported this provision. We do not agree, however, that the citation at § 460.102(d)(1)(ii) should be modified. We included a citation to § 460.210(b) in order to specify the IDT's responsibility for documenting all recommendations for care or services and the reasons for not approving or providing recommended care or services, if applicable, in any form encompassed under § 460.210(b). While we agree that recommendations will most often come from the individuals identified in § 460.210(b)(4), we did not propose and did not intend to limit this requirement to only those individuals. For example, redesignated § 460.210(b)(9) relates to hospital discharge summaries and, to the extent there are recommendations for care included in a summary, we would want the IDT to consider and document those recommendations. While PACE organizations contract with hospitals, it is possible that a participant would be taken to a non-contract hospital during the course of an emergency, and we would want the PACE organization to consider any recommendations for care provided by hospital staff even though the hospital was not a contract provider.

Comment: All commenters who addressed the proposals at § 460.102(d)(2)(ii), agreed with the proposal which would require the IDT to remain alert to pertinent input from any individual with knowledge of or contact with the participant. These commenters also recommended expanding the list to include the designated representative, as that individual plays a key role in the service delivery request process and appeals process.

Response: We thank the commenters for their support for this proposal and appreciate the suggestion to include the designated representative in the list of individuals that the IDT must remain alert to. We agree that designated representatives play an important role in advocating for services on behalf of the participant. We note that the change commenters suggest is consistent with our proposal; we proposed to make the individual IDT members responsible for remaining alert to pertinent input from any individual with direct knowledge of or contact with a given participant, and provided a list of examples of those individuals. The list was not all-inclusive, and we believe that designated representatives would fall within the intended class of individuals from whom IDT members must remain alert to pertinent input. Therefore, we are finalizing the regulatory text with a modification to include designated representatives among the specific list of individuals from whom the IDT must remain alert to pertinent input.

After consideration of the comments received and for the reasons outlined in our responses to comments, we are finalizing the changes to § 460.102(d)(1)(i) and § 460.102(d)(1)(ii) as proposed. We are also finalizing our proposed changes to § 460.102(d)(2)(ii) as proposed, with the exception of one modification to the regulatory text at § 460.102(d)(2)(ii)(G) to specify that the IDT must remain alert to input from designated representatives.

D. Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

As discussed at section VI.C. of this final rule, under sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act, PACE organizations provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[79] Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. These statutory provisions ensure that a PACE participant can receive all PACE covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We have implemented these requirements in several sections of the PACE regulations. For example, we require in § 460.70 that PACE organizations must have written contracts that meet specific regulatory requirements with any outside entity furnishing administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100. We also require PACE organizations to establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year at § 460.98(a). Through oversight and monitoring, we recognized that some PACE organizations are not appropriately implementing these requirements. CMS routinely sees PACE organizations deny or restrict necessary services. PACE organizations have also documented in participants' medical records that they do not provide access to care and services 24 hours a day, regardless of participant need. CMS has also learned through monitoring of PACE organizations that some organizations are not providing all care and services through employees or contractors of the organization. Instead, these organizations purport to rely on caregivers such as family members to

[79] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

provide necessary care and services to participants.

We would make several modifications to § 460.98 ''Service Delivery'' in response to failure by certain PACE organizations to fulfill their responsibilities to provide all necessary care and services, through the use of employees or contractors, as expeditiously as the participant's health condition requires, and ensure access to those services 24 hours a day, every day of the year. Currently, § 460.98(a) requires that PACE organizations establish and implement a written plan to furnish the care that meets the needs of each participant in all care settings 24 hours a day, every day of the year. We are concerned that the current version of this paragraph places more emphasis on the requirement to establish a written plan than it does on the requirement that the PACE organization actually implement such a plan by furnishing services. Therefore, we would modify paragraph (a) to more clearly emphasize that PACE organizations must not only have a plan to furnish care as described in existing § 460.98(a), but must also carry it out. We proposed to change the title of § 460.98(a) from ''Plan'' to ''Access to services'' in order to emphasize the requirement is that PACE organizations must provide access to services and not just have a plan. We also proposed to revise the language of § 460.98(a) to emphasize that PACE organizations are responsible for providing care that meets the needs of each participant, across all care settings, 24 hours a day, every day of the year, as well as establishing a written plan to ensure that care is appropriately furnished. We believe the amendments would align with the statutory requirement that PACE organizations provide access to necessary care and services at all times. We would retain the requirement that PACE organizations must establish and implement a written plan to furnish care, with one modification to specify that the plan must ensure that care is appropriately furnished. Additionally, we want to emphasize that, both under the current regulation and the amendments, the PACE organization is (and would remain, if our proposed amendments are finalized) responsible for providing this care regardless of the care setting. In other words, regardless of whether the participant receives care in the home, at the PACE center, or in an inpatient facility, the PACE organization is (and would remain) responsible for furnishing care in all care settings, 24 hours a day, every day of the year.

Currently, § 460.98(b) specifies in part that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long term care to each participant, and must furnish these services in at least the PACE center, the home, and inpatient facilities. We would make three changes to § 460.98(b) by modifying paragraph (b)(1) and adding new paragraphs (b)(4) and (5). Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, and the PACE regulations at § 460.70(a), require PACE organizations to furnish administrative and care-related services by employees or contractors of the organization. Through monitoring and oversight, we have identified instances where PACE organizations have relied on individuals other than employees or contractors to provide necessary care and services to participants. To address these concerns we added a reference to § 460.70(a) at § 460.98(b)(1) to reiterate the requirement that PACE organizations furnish all services through employees or contractors, regardless of whether the services relate to medical, health, or social services, including both acute and long term care.

We proposed to add a new paragraph at § 460.98(b)(4), to require that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs. While there is a similar requirement in § 460.104(e)(4), that services that result in a change to the care plan must be provided as expeditiously as the participant's health condition requires, we have identified through monitoring and oversight that participants routinely receive care that is determined necessary but is not formally incorporated into the care plan, and is instead handled through discipline-specific progress notes or treatment plans. For example, the primary care provider may order pain medication for a participant, but not incorporate that order into the participant's plan of care. Regardless of whether the service is in the plan of care, we believe that the PACE organization retains the responsibility of ensuring that participants receive all recommended or ordered treatment or care as expeditiously as the participant requires. We would specify at § 460.98(b)(4) that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs. We do not believe that we could implement a specific timeframe given the vast array of services that PACE organizations provide. Additionally, determining how quickly a service must be provided would depend on more than just the physical health of the participant, and PACE organizations should consider all aspects of the participant's condition, including their social, emotional, and medical needs, when determining the provision of services. For example, if the participant has a high risk of falling, the provision of a service that mitigates that risk may be necessary within a very short window of time. However, if the necessary service is a preventative trip to the dentist for routine care, the provision of that service may not be as urgent. These decisions must be made on a case by case basis and the PACE organization will be expected to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require through monitoring efforts by CMS.

Lastly, we added a new paragraph (b)(5) to § 460.98 to require PACE organizations to document, track, and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. PACE organizations would be required to document, track and monitor necessary services in order to ensure that they are actually provided in accordance with § 460.98(b)(4). CMS' audits have revealed that in practice, certain PACE organizations do not routinely track the services provided and often lack documentation that services have been rendered. In order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care. This means that not only should a PACE organization document that a service has been ordered, but that the PACE organization should also document when and how the approved service was provided. We believe that monitoring the provision of services is vital for a PACE organization in order to ensure their participants are receiving appropriate services, and that those services are achieving the desired effect. In addition, CMS regulations at § 460.134 require that PACE organizations use objective measures to demonstrate improvement across a range of areas, such as the utilization of PACE services and the effectiveness and

safety of staff-provided and contracted services, including the promptness of service delivery, among other requirements. We believe that this proposal will ensure that PACE organizations are able to more effectively meet the minimum requirements established at § 460.134.

We summarize the comments received on the proposals related to documenting and tracking the provision of services, and provide our responses to those comments, below.

Comment: While a commenter agreed with CMS' proposals at § 460.98(a) and (b)(1), the majority of commenters requested clarification on the preamble language describing the proposals. Specifically, commenters agreed that PACE organizations are responsible for providing care that meets the needs of the participant across all care settings, 24 hours a day, every day of the year, and that neither PACE organizations nor the IDTs may require caregivers to provide necessary care or services on their behalf. However, the commenters were concerned that the preamble implied that PACE organizations cannot take into consideration family or informal caregiver support when determining which services the PACE organization must furnish in order to meet these needs. In order to clarify the regulatory requirements and CMS's position, commenters requested that CMS confirm that willing and able family members or other informal caregivers may be actively involved in a participant's care and that a PACE organization would be in compliance with the proposed regulatory requirements if the IDT considers services provided to participants by willing and able caregivers when determining which services must be provided by the PACE organization. Another commenter suggested that the regulation, as proposed at § 460.98(b)(1), would not allow any individual caregivers and informal support systems to be involved in helping meet a participant's needs without contracting with the PACE organization.

Response: As noted in the proposed rule, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require the PACE organization to provide participants with all PACE-covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We believe the existing requirements are clear. Our proposed changes in § 460.98(a) and (b)(1) would not change the existing requirements; nor would they change how we have historically interpreted those requirements. Instead, our proposals would better align the regulatory language with the statutory requirements that require PACE organizations to provide access to necessary care and services at all times. The PACE organization is responsible for ensuring that the participant's needs are met 24 hours a day, every day of the year, consistent with the existing § 460.98(a).

We agree with commenters that a PACE organization cannot require or compel a caregiver to provide care that the IDT determines is necessary. However, we recognize that caregivers may be willing and able to provide some care to participants, such as cooking a meal or providing transportation to an appointment. None of our proposed changes would change CMS' expectations regarding the relationship between caregivers and PACE organizations. While we proposed to add a reference to § 460.70(a) at § 460.98(b)(1), we did not propose to change the requirement at § 460.70(a) or our interpretation of that requirement. Historically, CMS has interpreted the requirement at § 460.70(a) as not applicable in circumstances where family members or other informal support willingly provide care to PACE participants that could otherwise be provided by the PACE organization, without any compensation from or agreement with the PACE organization. Thus, we would not expect a PACE organization to have a contract with such caregivers unless the caregivers are providing services on behalf of the PACE organization and are receiving compensation from the PACE organization for doing so. We note that Merriam-Webster's dictionary defines willing as ''done, borne, or accepted by choice or without reluctance'' [80] and defines able as ''having sufficient power, skill, or resources to do something''.[81] We believe these definitions are widely understood, and provide a valuable point of reference in this context.

The IDT may take into consideration informal support that willing and able caregivers provide when determining what necessary services will be provided by the PACE organization directly or through contractors when developing the participant's plan of care. However, the existence of a caregiver does not absolve a PACE organization of its responsibilities to meet the needs of participants 24 hours a day, 7 days of the week. In determining how informal caregiver support affects the necessary services the PACE organization must provide directly or through contractors, PACE organizations must consider whether a caregiver is both willing and able to provide care, and whether it is safe for the participant to receive the care in question from the caregiver. This would include for example, when the PACE organization is evaluating participant and caregiver preferences for care during the initial assessments under § 460.104(a)(4)(iii) or when obtaining approval from the participant or their designated representative for a revised plan of care under § 460.104(e)(3). In particular, PACE organizations should not pressure a caregiver to provide any service that is necessary and that could otherwise be provided by the PACE organization, and should not rely on a willing caregiver to provide care if there is evidence that the caregiver cannot do so safely or in a way that meets the relevant needs of the participant. Additionally, PACE organizations may not deny a request to provide a service on the basis that a participant has a caregiver even if the caregiver has historically informally provided care that meets the participant's need for that service. We have seen through complaints and audits that PACE organizations sometimes inappropriately rely on caregivers, and in some instances attempt to require caregivers to provide care the IDT has determined is necessary for a participant, even when the caregiver is unable or unwilling to do so. For example, CMS has identified instances where PACE organizations attempted to require caregivers to provide 24-hour supervision or provide assistance with activities of daily living (ADLs) even after the caregivers indicated they could not do so, or were unwilling to do so. Through complaints and audits, we have also seen situations where a PACE organization inappropriately relied on a willing caregiver when it was not safe for the participant to receive care from that caregiver. For example, a caregiver may be willing to provide wound care, but without the necessary skills and knowledge to provide that care, it would be unsafe for the caregiver to attend to that need because it would increase the participant's risk of infection. We note that even when a caregiver previously had elected to provide some level of assistance to a participant, their ability or willingness to provide assistance may change during the course of a participant's enrollment in PACE, rendering the caregiver unable or unwilling to continue to provide that

[80] *https://www.merriam-webster.com/dictionary/willing.*

[81] *https://www.merriam-webster.com/dictionary/able.*

support (*e.g.,* the caregiver does not have a vehicle to accommodate a motorized wheelchair or the caregiver becomes ill). Similarly, a caregiver may express an interest in providing assistance, but may not be able to meet the needs of the participant. For example, the participant may need assistance with toileting, but the caregiver is physically unable to support this need. PACE organizations must ensure that when a caregiver is unwilling or unable to assist with the participant's care for any reason, that the needs of the participant are being met through employees or contractors of the PACE organization. In each of these situations, the PACE organization seems to be incorrectly or inappropriately determining that certain care and services are not needed because the PACE organization wants to rely upon a particular caregiver, even when it is clear from the circumstances that the participant needs the PACE organization to provide services because the caregiver is unwilling or unable to provide care, or because it is not safe for the participant to receive this care from the caregiver. For these reasons, we proposed to revise the regulations by adding a reference to § 460.70(a) at § 460.98(b) to ensure that PACE organizations understand their responsibilities, and we will continue monitoring PACE organizations for compliance with these requirements. We are finalizing these provisions as proposed.

Comment: A commenter recommended that CMS provide further clarification on how ''coordination'' and ''furnish'' are used and defined in the PACE regulations and to take steps to ensure that terms are used consistently throughout the PACE regulations. This commenter stated that under the proposed language at § 460.102(d)(1)(i), the IDT would be responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery. The commenter asserted that this has a very different meaning than the proposed requirements at § 460.98(b)(1) which states that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care, and that these services must be furnished in accordance with § 460.70(a).

Response: We agree with the commenter's observation that the proposed requirements under § 460.102(d)(1)(i) and § 460.98(b)(1) are not the same, including the fact that § 460.102(d)(1)(i) uses the term, ''coordinate'' while § 460.98(b)(1) uses the term ''furnish.'' However, we did not propose that those terms would be used interchangeably. We agree that those terms have different meanings, and we believe that those terms are used appropriately within the regulation. PACE organizations are responsible for furnishing comprehensive services to PACE participants. The IDT, which consists of a subset of PACE organizations employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization.

Comment: Multiple commenters requested clarification regarding the intent of CMS's proposal under § 460.98(b)(1) to add a reference to § 460.70(a) that would require services to be furnished through either an employee or contractor of the organization. Specifically, those commenters requested that CMS modify § 460.70(a) to address circumstances that might justify an exception to the requirement that PACE organizations must have a written contract with each entity that furnishes administrative or care related services not furnished directly by the PACE organization except for emergency services. As an example, commenters noted that there are times when a specialty provider may be in short supply and the PACE organization may be unsuccessful in obtaining a contract.

Response: We did not propose changes to § 460.70(a), and as such are not finalizing any changes to that section in this final rule. With regards to the commenter's question about out of network providers, that comment relates to the topic of network adequacy for PACE organizations and we will take the commenter's feedback into consideration in future policy development for PACE.

Comment: A commenter was supportive of the provisions at § 460.98(b)(5), while the majority of commenters expressed concern with to the use of the term ''track.'' These commenters suggested that requiring a PACE organization to track the provision of services could imply that PACE organizations would be required to establish and maintain specific logs, universes or data sets, and that such a requirement would conflict with CMS' Patients Over Paperwork initiative. These commenters stated that PACE organizations should have greater flexibility to determine how the provision of services is monitored and rather than dictating the specific manner in which PACE organizations maintain this documentation, they recommended the following regulatory text: ''The PACE organization must monitor and document the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.'' Additionally, these commenters requested that CMS explain that this provision would only require the PACE organization to monitor and track services furnished by the PACE organization's employees or contractors and not by caregivers.

Response: As noted in the proposed rule, in order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe that the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care (85 FR 9139). In order to ensure services are actually provided, we proposed that PACE organizations document, track and monitor services. We understand from commenters' concerns that the use of the word ''track'' could be interpreted to suggest that PACE organizations would be required to maintain a real time ''log'' of services which could potentially be burdensome to implement. As we stated in the proposed rule, we believe that PACE organizations should document that a service has been ordered as well as when and how the approved service was provided. It was not our intention in the proposal to dictate how an organization implements this provision, and we agree with the commenter that PACE organizations should have flexibility in how they operationalize the requirement to track, monitor and document the provision of services. We expect that PACE organizations will create their own methods for tracking and monitoring services. We reiterate that the PACE organization is responsible for furnishing all services determined necessary through its employees or contractors in accordance with existing § 460.70(a) and proposed § 460.98(b)(1), and this provision would only apply to those services furnished by the PACE organization's employees or contractors.

After consideration of the comments received, we are finalizing our proposed changes to § 460.98 without modification.

E. Access to Data and Safeguarding Records Under PACE (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires PACE organizations to collect data, maintain records, and submit reports, as required by CMS and the State Administering Agency (SAA). The current requirement at § 460.200(b) requires that PACE organizations must allow CMS and the SAA access to data and records, including but not limited to, participant health outcomes data, financial books and records, medical records, and personnel records. Some PACE organizations have requested clarification on whether access is limited to allowing CMS or the SAA to view requested information. CMS has long interpreted this provision to require that CMS and the SAA must be able to obtain, examine, or retrieve information as needed to administer and evaluate the program and fulfill their oversight obligations. Therefore, we proposed to codify CMS' interpretation of this requirement. Specifically, we would redesignate current § 460.200(b)(1) through (4) as § 460.200(b)(1)(i) through (iv), in order to add a new paragraph (b)(2) to state that CMS and the State administering agency (SAA) must be able to obtain, examine, or retrieve the information described under § 460.200(b)(1). This may include CMS or the SAA reviewing information at the PACE site or remotely. It may also include CMS requiring a PACE organization to upload or electronically transmit information, or send hard copies of required information by mail.

PACE organizations are also required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. Through our monitoring of PACE organizations, CMS has discovered that PACE organizations do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community. In fact, CMS has discovered that organizations may summarize written communications and sometimes destroy or lose original written communications. When CMS has obtained copies of original communications from an outside source (such as the family or caregiver), we have noted that organizations are not accurately summarizing information or retaining the relevant information in the communication. In light of these findings, we believe that any written communication received from a participant or their informal support (for example, a family member, caregiver, designated representative, or other member of the community) that relates to the participant's care, health or safety must be safeguarded and maintained in its original form. Therefore, we proposed to modify § 460.200(d) to require PACE organizations to maintain all written communications received from a participant or other parties in their original form when the communication relates to the participant's care, health, or safety. We would expect that this would include most, if not all, communications that an organization receives on these topics. For example, the following types of communications would need to be protected under this provision: Written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. We proposed corresponding changes to § 460.210(b)(6), to require PACE organizations to maintain original written communications in the participant's medical record, as discussed at section VI.F. of this final rule.

We believe the burden associated with this provision is related to the documentation of these original communications in the medical record. We discuss and account for the burden of documenting these communications in the medical record in the regulatory impact analysis.

We solicited comments on these proposals.

We summarize the comments on the proposals related to access to data and safeguarding records, and provide our responses to those comments, below.

Comment: All of commenters who responded to this proposal requested clarification on the provision which would require access to data described in § 460.200(b)(1) both at the PACE site and remotely. Specifically, commenters requested clarity around whether or not the provision meant that the SAA and CMS would have independent remote access to PACE organizations' medical records, without the knowledge of the PACE organizations, or if it meant that CMS would require PACE organizations to make records available, either remotely or onsite, via a web-based or comparable application with the participation of PACE organization staff. Commenters stated that participation of PACE organization staff would ensure PACE organizations could maintain a record of individuals who accessed participants' medical records and would also assist CMS and SAA reviewers in locating documentation within medical records.

Response: We appreciate commenters' feedback on this proposal. As proposed under § 460.200(b)(2), CMS and the SAA must be able to obtain, examine, or retrieve the information specified at paragraph (b)(1) of that section, which may include reviewing information at the PACE site or remotely. We wish to clarify that it is not CMS's intent that CMS or the SAA would have completely unrestricted access to a PACE organization's medical records and the provision at § 460.200(b)(2) would not permit CMS or the SAA to access a PACE organization's medical records without the PACE organization's knowledge. PACE organizations will continue to be required to grant access to medical records, which may be electronic and/or paper based, before these records are obtained, examined or retrieved by CMS or the SAA. In order to be able to obtain, examine, or access these records, CMS or the SAA may need technical assistance from PACE organization staff, but otherwise would not require staff involvement in the review process. For example, CMS or the SAA may need assistance with navigating medical record systems or locating records within medical record systems.

Comment: Commenters were split on the proposal to require original documentation to be maintained in the medical record. A commenter agreed with the proposed requirements in §§ 460.200(d)(2) and 460.210(b)(6), which would require PACE organizations to maintain all written communications received from participants or other parties, in their original form, when the communications relate to a participant's care, health or safety, including written communications from an advocacy or governmental agency. Another commenter was opposed to this provision stating that not all communication lends itself to being kept in the original form and the proposed requirement may be impracticable for mundane, routine communications such as confirming an address for a family member. This commenter recommended that CMS remove the phrase ''all written communication'' and instead provide a specific list of communications that must be kept in its original format. The

majority of commenters requested clarification and expressed some concerns regarding the proposed requirements. This included concerns that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored. These commenters also stated that requiring direct care providers to download or otherwise transfer all such communications to the medical record would be burdensome and take them away from providing care to participants. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste communications received via email or text into electronic medical records. The same commenters expressed concerns that the requirements were overly broad and recommended that CMS revise its proposals to both allow PACE organization staff to use their discretion when determining the types of communication that must be included in a participant's medical record and exclude communications related to processing of service requests, appeals and grievances as those communications are often kept in separate systems. Another commenter indicated that the practice of summarizing verbal conversations and documenting in the EMR should apply to written communications. This commenter also recommended that CMS clarify its expectations with regard to communications from advocacy or governmental agencies and suggested that faxes and emails requesting documents should not be placed in the medical record.

Response: We appreciate commenters' feedback and suggestions on §§ 460.200(d) and 460.210(b)(6). We address comments related to § 460.210(b)(6) in more detail at section VI.F of this final rule. PACE organizations are required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. As we stated in the proposed rule (85 FR 9134), through our monitoring and oversight efforts, CMS has discovered that PACE organizations do not always maintain and safeguard important records, and may often summarize written communications in their records and destroy or lose the original written communications. In addition, we have discovered that in some cases, PACE organizations are not always retaining or accurately summarizing all of the relevant information in those communications. Because our oversight efforts have revealed that all relevant information in written communications has not always been retained or accurately summarized by PACE organizations, we are not persuaded by commenters to allow PACE organizations to summarize written communications that relate to a participant's care, health or safety instead of maintaining the communication in its original form. In order for the IDT to remain alert to pertinent input from the participant and their caregivers, and for PACE organizations to provide care that meets the needs of each participant in all care settings 24 hours a day, every day of the year, we believe that communications from individuals who provide information pertinent to a participant's care, health or safety, must be safeguarded and maintained in their original form. Furthermore, we are not persuaded by one commenter's suggestion that the practice of summarizing verbal communication in the medical record should also apply to written communication. We believe that summarizing verbal communication is a reasonable and necessary practice because it would be unnecessarily burdensome to require PACE organization staff to record verbal communication verbatim. In contrast, it is not necessary to summarize written communications because entire written communications can be stored in the medical record. We also believe that, in many cases, the amount of time spent summarizing the contents of written communications would exceed the amount of time necessary to enter the original documentation into the medical record, which would negate any benefits associated with summarizing the written communication.

With respect to excluding certain communications from this requirement or providing a specific list of communications that must be kept in their original format, we note that we have already limited this requirement by only requiring PACE organizations to maintain all written communications that relate to a participant's care, health, or safety. As we stated in the proposed rule (85 FR 9135), the types of communication that would be protected under this provision include, but are not limited to: Written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. For example, if the participant sent the PACE organization a letter requesting long-term nursing facility placement or Adult Protective Services emailed the PACE organization to express concern about the participant's ability to live on their own, we would expect these communications to be maintained. Given the nature of the PACE program, we recognize that there is frequent communication between a PACE organization and various individuals regarding each participant and that many of these communications would not be appropriate to maintain. For example, if a caregiver texted the PACE organization stating that they were going to be 15 minutes late in dropping off a participant at the PACE center or a participant emailed the PACE organization because they wanted to know what type of food would be served at the PACE center on a particular day, we would not expect this communication to be maintained.

After consideration of the comments received, we are finalizing § 460.200 as proposed with a minor grammatical change in the introductory paragraph of § 460.200(d), to add ''a'' before ''PACE organization.'' This grammatical correction will not change the intended meaning of the regulation as proposed and described in this final rule.

F. Documentation in Medical Records Under PACE (§ 460.210)

In accordance with § 460.210(a), a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, that is accurately documented and available to all staff, among other requirements. We have previously discussed the importance of maintaining a complete record for each participant. In the preamble to the 2006 PACE final rule (71 FR 71326), we stated that, because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. CMS currently specifies at § 460.210(b) the minimum required contents of a medical record. Based on audit and oversight experience, we identified

additional requirements that we believe should be added under § 460.210(b) to ensure that participant medical records are fully comprehensive.

We proposed to redesignate § 460.210(b)(4) through (12) as (7) through (15), and to add three new paragraphs under § 460.210(b) to address how recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a participant's care, health or safety should be documented in the medical record. Specifically, we proposed to add a new paragraph (b)(4) that would require the PACE organization to document all recommendations for services made by employees and contractors of the PACE organization, including by all specialists such as dentists, neurologists, cardiologists, and others, in the participant's medical record. We believe that all recommendations for services from these sources must be documented in order for the IDT to remain alert to all pertinent information, even if the IDT decides not to pursue the recommendations, for example based on a determination that the service is not necessary. Recommendations are made based on the employee or contractor's determination that a participant might benefit from a particular service given the participant's health status or condition. Even if the IDT ultimately decides that the recommended service would not be necessary to improve and maintain the participant's health status, the IDT should document that recommendation in order to remain alert to why a particular contractor or employee believed that service was necessary as required by § 460.102(d)(2)(ii).

Additionally, we proposed adding a new paragraph (b)(5) that would require the IDT to document in the medical record the reason(s) for not approving or providing a service recommended by one of these sources. When an employee, contractor, or specialist recommends a service within the scope of their authority to practice, we believe that it is necessary for the IDT to consider this information and document any decision against providing the recommended service in the medical record. For example, if a gastroenterologist recommends that a participant receive drug therapy for Hepatitis C, and after reviewing the recommendation the IDT determines that treatment is not medically necessary or is contraindicated, we would require the IDT to document in the participant's medical record the rationale for not providing the recommended drug therapy, including the clinical criteria used as the basis for that determination. This not only ensures that the IDT can review the information used to make the decision, but also that the participant has access to information about the basis of the decision not to provide a recommended service. This would also align with the requirement we finalized in the 2019 PACE final rule (84 FR 25643) that requires the IDT to document the rationale for determining certain services are not necessary in the participant's plan of care following the initial comprehensive assessment. While the 2019 PACE final rule required the IDT to follow this process during the development of the initial care plan, we are expanding the requirement to account for situations that arise after the initial plan of care is developed. For example, a participant may be diagnosed with diabetes after the development of the initial care plan, and should the PACE organization determine that treatment is not necessary, we would expect that it document that decision and the reasons for that decision in the participant's medical record.

We also proposed to require PACE organizations to maintain certain written communications received by the PACE organization in the participant's medical record, in new paragraph § 460.210(b)(6). The PACE program presents unique challenges in terms of providing care to participants. PACE participants require a nursing facility level of care and often have complex medical needs. When a Medicare or Medicaid beneficiary is in a nursing home, they have daily interactions with staff, and their needs, including changes in condition, are noted by the staff and acted upon. PACE participants, on the other hand, largely remain in their own homes and might not be seen on a daily basis by PACE organization staff. PACE participants do, however, often have regular interactions with caregivers, family members, neighbors, and other members of their communities, as well as with social service organizations like local Area Agencies on Aging (AAA) or Adult Protective Services (APS) agencies. We believe that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health, and safety and to provide appropriate and timely care to the participant. We also believe information about a participant's care, health, or safety provided to a PACE organization by any of these sources could play a critical role in providing comprehensive care to the participant. Therefore, we proposed to add a new paragraph (b)(6) to § 460.210, to require PACE organizations to maintain, in a participant's medical record, original documentation of any written communication relating to the care, health, or safety of a participant that the PACE organization receives from certain sources in any format (for example, emails, faxes, letters, etc.). At a minimum, PACE organizations would be required to maintain communications from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health, or safety, as well as communications from advocacy or governmental agencies like an AAA or APS. We also proposed at § 460.200(d)(2) a reference to § 460.210(b)(6) which would require that the PACE organization maintain this information in its original written form rather than summarizing the information in the participant's record. See 85 FR 9134–9135 and 9259).

We summarize the comments we received on the proposals related to the requirements for the contents of participant medical records under § 460.210(b), and provide our responses to those comments, below.

Comment: A commenter agreed with the proposals under §§ 460.210(b)(4) and (b)(5) which would require PACE organizations to document all recommendations for services made by employees or contractors of the PACE organization, including specialists, and the reason(s) for not approving or providing services recommended by these sources in the participant's medical record.

Response: We thank the commenter for their support of this provision.

Comment: Commenters were split on the proposal to require original documentation to be maintained in the medical record. A commenter agreed with the proposed requirements in §§ 460.200(d)(2) and 460.210(b)(6), which would require PACE organizations to maintain all written communications received from participants or other parties, in their original form, when the communications relate to a participant's care, health or safety, including written communications from an advocacy or governmental agency. Another commenter was opposed to this provision stating that not all communication lends itself to being kept in the original form and the proposed requirement may be impracticable for mundane, routine communications such as confirming an

address for a family member. This commenter recommended that CMS remove the phrase ''all written communication'' and instead provide a specific list of communications that must be kept in its original format. The majority of commenters recommended that the provisions at § 460.210(b)(6) be modified consistent with their comments on the proposal at § 460.200(d)(2). Specifically, commenters were concerned that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored. These commenters also stated that requiring direct care providers to download or otherwise transfer all such communications to the medical record would be burdensome and take them away from providing care to participants. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste communications received via email or text into electronic medical records. The same commenters expressed concerns that the requirements were overly broad and recommended that CMS revise its proposals to both allow PACE organization staff to use their discretion when determining the types of communication that must be included in a participant's medical record and exclude communications related to processing of service requests, appeals and grievances as those communications are often kept in separate systems. Another commenter indicated that the practice of summarizing verbal conversations and documenting in the EMR should apply to written communications. This commenter also recommended that CMS clarify its expectations with regard to communications from advocacy or governmental agencies and suggested that faxes and emails requesting documents should not be placed in the medical record.

Response: We appreciate commenters' feedback and suggestions on §§ 460.200(d)(2) and 460.210(b)(6). As we indicated in the discussion regarding § 460.200 at section VI.E. of this final rule, we made corresponding changes to § 460.210(b)(6) to require that the PACE organization maintain written communications in their original written form in the participant's medical record. (85 FR 9135). We made these corresponding changes at § 460.210(b)(6) in order to establish requirements that would govern how PACE organizations must maintain written communications under § 460.200(d)(2). Currently, § 460.210(b)(7) (redesignated at 460.210(b)(10) in this rule) requires PACE organizations to document reports of contact with informal support, for example, caregivers, legal guardians, or next of kin in the participant's medical record. Since these reports of contact are already maintained in the medical record, we believe that PACE organizations should also maintain original written communication from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health or safety, as well as communications from advocacy or governmental agencies like an AAA or APS within the medical record. We believe that documenting this written communication is necessary to maintain a comprehensive medical record for each participant that is complete and accurately documented, and in order to ensure that the IDT is remaining alert to pertinent information. We do, however, agree with the commenters' recommendation that PACE organizations should be permitted to include an unaltered electronic copy, such as a scanned pdf, of the original written communication in a participant's medical record, which aligns with the intent of this proposal. As discussed in the proposed rule related to § 460.200(d)(2), we were motivated in making this proposal by a concern that PACE organizations are not accurately summarizing written communication or retaining relevant information in written communications they receive. (85 FR 9134). The original basis for the proposal at § 460.200(d)(2) also led us to establish the corresponding changes to § 460.210(b)(6) which would require PACE organizations to maintain these communications in the medical record. (85 FR 9135). We continue to believe that this proposal will ensure that PACE organizations retain relevant information received in written communications relating to the care, health and safety of a participant. We also believe that commenters' suggestion to permit PACE organizations to retain an unaltered electronic copy would be consistent with this proposal, while also reducing the burden associated with storing the documentation in its original format. This change means that PACE organizations would be required to maintain all covered written communications described in § 460.210(b)(6)(i) and (ii), but that they can be maintained in either their original form or as an unaltered electronic copy. We believe this change to § 460.210(b)(6) will ensure that written communications are complete, accurately documented, readily accessible, and available to all staff, while allowing additional administrative flexibility for PACE organizations in operationalizing this requirement. We are not establishing specific requirements governing where affected communications must be stored within a participant's medical record. PACE organizations may operationalize these requirements in accordance with the capabilities of their medical records systems. PACE organizations may also identify which staff will be responsible for entering these communications in the medical record. Section 460.210(b)(6) does not require that covered communications be entered by direct care staff. Although direct care staff must remain alert to the pertinent information contained within these covered communications, PACE organizations may assign the responsibility for entering these covered communications to any staff, including those that does not provide direct care to participants.

After consideration of the comments received and for the reasons outlined in our responses to comments, we are finalizing § 460.210(b)(4) and (5) as proposed. We are also finalizing § 460.210(b)(6) with one modification in the regulation text, which will require PACE organizations to include original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in the participant's medical record.

G. PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to receive accurate, easily understood information and to receive assistance in making informed health care decisions under § 460.112(b); and the participant's right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality

health care under § 460.112(c). CMS proposed to add three new participant rights in § 460.112 to increase beneficiary protections: The right to contact 1–800–MEDICARE for information or to make a complaint; the right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines; and the right to receive necessary care across all care settings, up to and including placement in a long term care facility when the PACE organization can no longer maintain the participant safely in the community through the support of PACE services.

Section 1804(b) of the Act requires CMS to provide information on Medicare programs through 1–800–MEDICARE, as a means by which individuals may seek information and assistance for Medicare programs. This number may be utilized by Medicare beneficiaries to address coverage questions, find plan information, or make complaints related to the Medicare program. While PACE organizations are responsible for providing to all participants all services covered under Medicare and Medicaid, including prescription drugs, and other services determined necessary by the IDT to improve and maintain the participant's overall health status, PACE organizations are not required to provide this toll-free number to participants in any current communication. In the MA program, MA organizations must provide this information to beneficiaries in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) under § 422.111 as well as longstanding guidance under the Medicare Communications and Marketing Guidelines.[82] We have discovered through oversight and monitoring efforts that PACE participants and/or their caregivers are often not aware that, in addition to the internal grievance process under § 460.120, participants also have the right to contact 1–800–MEDICARE; for example, to file quality of care complaints, including filing a complaint regarding the delivery of a necessary service. For example, if the IDT approved treatment for a specific condition, but the participant never received that treatment, the participant or caregiver could call 1–800-Medicare to lodge a complaint. Given the frailty of the PACE population, we believe it is important that these participants be explicitly notified of their right to have their complaints heard and resolved by calling 1–800–MEDICARE. When a participant files a complaint with 1–800–MEDICARE, the complaint gets logged and routed to a CMS account manager or case worker in order to ensure it is appropriately responded to and resolved. To ensure PACE participants are notified about 1–800–MEDICARE, we proposed to amend § 460.112 by adding a new paragraph (b)(4) which would specify that participants have the right to contact 1–800–MEDICARE for information and assistance, including to make a complaint related to quality of care or delivery of a service. PACE organizations are required under § 460.116(c)(2) to display the PACE participant rights in a prominent location in the PACE center, and to include the participant bill of rights in the enrollment agreement under § 460.154(m). Thus, by adding (b)(4) would ensure each PACE organization makes the 1–800–MEDICARE number available to participants by posting it in an accessible location at the PACE center and including it in the enrollment agreement.

We also proposed to include a participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines at new § 460.112(c)(3). PACE organizations are responsible for ensuring participants receive all necessary care from specialists, which is coordinated through the primary care provider and IDT in accordance with § 460.102(c)(2)(ii) and (d)(1). In addition, as noted in the preamble to the 1999 PACE interim final rule that implemented the PACE program (see 64 FR 66260) and the preamble to the 2006 PACE final rule that implemented § 460.92 of the regulations (see 71 FR 71305), PACE organizations must utilize clinical practice guidelines to ensure the quality of care for PACE participants. CMS has also historically required the use of clinical practice guidelines and professional standards in determining outcome measures applicable to the care of PACE participants as part of the PACE organizations quality improvement program (see § 460.134(b)). The 1999 PACE interim final rule also established the expectation that PACE organizations will utilize current clinical standards as a routine part of their daily operations. (64 FR 66260). Because part of the purpose of the quality improvement program is to identify areas to improve or maintain the delivery of services and patient care, CMS believes that these same guidelines and standards should be used as part of care planning and in making determinations about services as discussed in section VI.C. of this final rule. However, CMS' audits of PACE organizations have shown that some PACE participants have not received timely access to appropriate specialists as necessary to improve and maintain the participant's overall health status and in accordance with current clinical practice guidelines. Instead, the IDTs at some PACE organizations seem to be making their decisions based on factors not related to the participant's health condition. In some instances, participants have experienced negative outcomes because they have not received access to a specialist. Therefore, we proposed to redesignate paragraph (c)(3) as (c)(5) and add a new paragraph (c)(3), which expressly states each participant has the right to reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

Lastly, we added a new paragraph at § 460.112(c)(4) to address a participant's right to receive care across all care settings. A PACE organization is expected to provide for the care that is necessary for each participant and determine the appropriate setting in which to provide that care, up to and including placement in a long term care facility when a participant's condition requires it (see § 460.98(a) and (b)). However, CMS' monitoring and audit activity show that some PACE organizations are not providing long-term care services, even when their IDTs determine a participant can no longer live safely in their home and requires a higher level of care. We have learned that in some cases, affected participants disenroll from PACE in order to receive the long-term care that is needed. One of the purposes of the PACE program is to enable frail, older adults to live in the community as long as medically and socially feasible (see § 460.4(b)(3)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care, and providing services that are accessible and adequate to meet the needs of its participants. (See § 460.98(b) and (d)(2) respectively). Lastly, enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls, or is involuntarily disenrolled. (See § 460.160(a)). A PACE organization cannot deny placement in

[82] *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html.*

a long-term care facility if the IDT determines the participant requires 24-hour care but the PACE organization does not have a method for providing that care in the home through either its employees or contractors. See the relevant discussion under section VI.D. of this final rule regarding providing participants access to services 24 hours a day, every day of the year, across all care settings. In order to provide more specific detail about what this fundamental program requirement entails, we added § 460.112(c)(4) which would state that a participant has the right to receive necessary care in all care settings up to and including placement in a long term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

We summarize the comments on the proposals related to PACE participant rights, and provide our responses to those comments, below.

Comment: All commenters that addressed this proposal agreed with CMS's proposal to add a participant right at § 460.112(b)(4) to inform participants of their right to contact 1–800–MEDICARE for information or assistance, including making a complaint related to the quality of care or the delivery of a service. These commenters also requested that CMS ensure that call center representatives are trained on PACE requirements and are able to handle inquiries from PACE participants.

Response: We thank the commenters for expressing support for including the 1–800–MEDICARE number in the participant rights. We are committed to ensuring that participants concerns are addressed appropriately. Call center operatives are currently educated and trained on all Medicare programs, including PACE, and should be able to fully address PACE participant inquiries. PACE participants currently have the ability to contact 1–800–MEDICARE for concerns; however, participants are not utilizing this resource frequently, potentially because of a lack of knowledge about 1–800–MEDICARE, and we expect that by requiring this telephone number to be displayed in the PACE center and included in the participant's bill of rights, participants will more frequently utilize this resource if needed.

Comment: All commenters that addressed this proposal were fully supportive of the addition of § 460.112(c)(3) and (c)(4). These commenters noted that while they agree with the addition of (c)(4), there may be situations when placement in a long-term nursing facility may not be compatible with a participant's wishes.

Response: We appreciate the commenters' support for these proposals. As noted in section VI.G. of the proposed rule, a PACE organization cannot deny placement in a long-term care facility if the IDT determines that the participant requires 24-hour care, but the PACE organization is unable to provide 24-hour care in the home through either its employees or contractors. Based on our experience overseeing PACE organizations, we have observed situations in which participants and caregivers were encouraged to disenroll from the PACE organization when long-term care placement was necessary to meet the participants needs. As required by § 460.162(c), ''a PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.'' However, we understand that placement in a long-term care facility may not always be in line with a participant's wishes, and it is not our intent to require PACE organizations to place participants into long-term care facilities against their wishes.

After consideration of the comments received, we are finalizing this provision without modification.

H. Enforcement Action Appeal Rights Under PACE (§ 460.56)

Sections 1894(e)(7) and 1934(e)(7) of the Act specify that, under regulations, the provisions at section 1857(h) of the Act, governing the procedures for termination of a contract with an MA organization, apply to the termination and sanctions of a PACE program agreement and PACE organization in the same manner as they apply to an MA organization under Medicare Advantage. The current enforcement provisions at 42 CFR part 460, subpart D, do not specify a process for appeals related to civil money penalties or intermediate sanctions. However, at § 460.54, the regulations include appeal rights for termination procedures. In the preamble to the 1999 PACE interim final rule (64 FR 66236), we discuss the requirement in the BBA of 1997 that we take into account some of the requirements established for MA as we develop regulations for PACE organizations in certain areas common to both programs, such as beneficiary protections, payment rates, and sanctions. CMS has interpreted this legal framework as granting the agency the authority to utilize the appeals processes that apply to MA organizations under § 422.756 when imposing a suspension of enrollment or payment, or imposing civil money penalties on PACE organizations. Although it has not been codified in regulation, CMS currently provides PACE organizations with these appeal rights when imposing enforcement actions under §§ 460.42, 460.46, and 460.48(b).

Therefore, in an effort to enhance transparency and ensure that PACE organizations are aware of their right to appeal an enforcement action, we added a new § 460.56 in subpart D of the PACE regulations to affirmatively state that a PACE organization may request a hearing according to the procedures at § 422.756 when CMS imposes a sanction or civil money penalty under §§ 460.42, 460.46, or 460.48(b) on PACE organizations.

For suspensions of enrollment or payment listed under §§ 460.42 and 460.48(b), CMS will follow the hearing procedures for imposing intermediate sanctions at § 422.756(b), which includes the right to a hearing before a CMS designated hearing officer under subpart N of part 422. Under the process specified at § 422.756(b), CMS provides organizations with a notice of intent to impose sanctions and their right to a hearing before a CMS hearing officer. Organizations are given 15 days from the date of the notice to request a hearing.

For civil money penalties listed under § 460.46, CMS will follow the procedures for imposition of civil money penalties at § 422.756(e)(2)(v), which includes the right to a hearing before an Administrative Law Judge (ALJ) under subpart T of part 422. In addition, CMS must send a written notice of the agency's decision to impose a civil money penalty, the amount of the penalty, the date the penalty is due, information about the organization's right to a hearing and where to file the request for hearing.

We believe this will ensure PACE organizations understand the process CMS utilizes for imposing these enforcement actions, as well as the PACE organization's right to appeal those actions.

We did not include § 460.48(a) or (c) in the proposed rule because those provisions refer to the termination of a PACE program agreement, for which procedures are already set forth at § 460.54. However, § 460.48(b) authorizes us to withhold payment under the PACE program agreement, which is similar to the suspension of payment provided at § 460.42(b)(1).

Therefore, the procedures at § 422.756 would apply, as specified at § 460.56(a).

We received no comments on our proposed new § 460.56 to address enforcement action appeal rights and therefore are finalizing this provision without modification.

I. PACE Definitions (§ 460.6)

As discussed briefly at section VI.A. of this final rule, we proposed to modify our existing definition of ''services.'' Currently, the term ''services'' is defined as including items and services. We proposed a change to use the term ''service'' in § 460.6 to be consistent with the use of the singular in the terms defined under § 460.6. The definition of the singular ''service'' would also apply to the plural ''services.'' In addition, we proposed to modify our definition of ''service'' to better reflect the full scope of the PACE benefit package by stating that the term ''service'', as used in part 460, means all services that could be required under § 460.92, including items and drugs. In the 1999 PACE interim final rule, we stated that required services included all current Medicare services, all Medicaid-covered services as specified by the state's approved Medicaid plan, and specifically included ''drugs and biologicals'' as a part of a list of minimum benefits PACE organizations were required to provide. (64 FR 66246 and 66301). In the 2006 PACE final rule, we removed the specific listing of all required services because we determined that it was not possible to provide a complete list of all services that must be furnished to participants if ordered by the IDT. (71 FR 71281). Instead, we adopted the language that is currently used in § 460.92 to identify the services required as a part of the PACE benefit package. Since that time, through CMS' monitoring and oversight, we have found that some PACE organizations do not realize that they are responsible for providing the full Medicare benefit, including the provision of Part D drugs. Therefore, we proposed to make changes by adding ''drugs'' to the definition of services for PACE purposes which is consistent with how we have historically defined the types of services that are required in PACE. We believe this change is necessary to remove potential ambiguity about the meaning of the terms ''service'' or ''services'' when used in the PACE regulations.

We received no comments on the proposed definition of ''service'' in § 460.6 and therefore are finalizing this provision without modification.

VII. Technical Changes

A. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

We proposed two substantive changes to § 422.220 regarding the limits on when an MA organization may or may not pay an opt-out provider. In our proposal to amend § 422.220, we sought first to align the regulatory definition of ''physician'' in regard to private contracts with the definition found in corresponding statute. Currently, section 1802(b)(6)(B) of the Act defines ''physician,'' in regard to private contracts, as a term that is defined by paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act; however, § 422.220 currently defines ''physician,'' in respect to private contracts, using only paragraph (1) of section 1861(r) of the Act—narrowing the regulatory definition to exclude physicians who are not doctors of medicine or osteopathy. To avoid confusion about what kinds of providers the opt-out and private contracting rules apply to, we proposed to extend the regulatory definition of ''physician'' to match the statutory definition when the term is used in regard to private contracts. We designed our proposal to achieve this by adding references to paragraphs (2), (3) and (4) of section 1861(r) of the Act to the definition of ''physician'' at § 422.220 to make the regulatory provision consistent with the statute.

Second, we proposed to clarify the prohibition at § 422.220 in regard to the types of items and services for which an opt-out provider may and may not receive payment from an MA organization. In the proposed rule, we discussed our interpretation of the Medicare statute that payments for supplemental benefits are outside the scope of the statutory restriction on payments to opt-out providers. Section 1802(b)(1)(B) of the Act states that an opt-out physician or practitioner must receive no reimbursement under the Medicare statute directly or on a capitated basis and ''no amount for such item or service from an organization which receives reimbursement for such item or service under [Title XVIII] directly or on a capitated basis.'' We explained that because MA organizations only receive *reimbursement* for Part A and Part B items and services under Title XVIII of the Act, supplemental benefits are not among the items and services for which an MA organization is prohibited from making payments to an opted-out provider. In our proposal, we recommended amending the regulations at § 422.220 to make this distinction so that paragraph (a) states the prohibition on payment while paragraphs (b) and (c) direct when an MA organization must or may nonetheless pay an opt-out provider. We use the terms ''basic benefits'' and ''supplemental benefits'' consistent with how those terms are used in §§ 422.100(c) and 422.102 and in section VI.F. of this final rule.

We received the comments noted on this proposal and our responses follow.

Comment: CMS received comments from an MA organization and a provider association in regard to our proposals. The comments CMS received were fully supportive of CMS's proposal to amend CMS's regulatory definition of ''physician'' at § 422.220, which pertains to private contracts between providers and Medicare Advantage enrollees, to align with the corresponding statutory definition of ''physician'' under section 1802(b)(6)(B) of the Act. CMS also received full support from these commenters in regard to CMS's proposal to amend § 422.220 to clarify that the restrictions on payments to opt-out providers apply only to payments for basic benefits (that is, items and services covered under Parts A and B).

Response: We thank the commenters for their remarks, and believe that in finalizing these proposals we better align our regulations with the statutes from which they originated.

We received no additional comments on this proposal. After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing these proposed changes to § 422.220 without modification.

B. Disclosure Requirements for Explanation of Benefits (§ 422.111)

In a final rule titled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes; Final Rule'' (73 FR 21504) (hereinafter referred to as the April 2011 final rule), we finalized a regulation at § 422.111(b)(12) that requires an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part. Following the finalization of this regulation, CMS tested model Explanation of Benefits (EOB) templates, and, based on public comments solicited via HPMS memo and in 77 FR 70445, November 26, 2012, made final revisions to the EOB templates and issued guidance about the Part C EOBs. Subsequently, the

requirement for MA organizations to furnish Part C EOBs to their enrollees applied beginning April 1, 2014.

In the February 2020 proposed rule, we sought to clarify and codify existing requirements for the Part C EOB. First, we sought to change where this requirement appears in § 422.111(b) because paragraph (b) specifies general information about the MA plan that must be disclosed to each enrollee at the time of enrollment and annually, which is not when the EOB should be sent. We also proposed to clarify that the requirement to send the Part C EOB is permanently in effect. To achieve this, we proposed to move the substance of the regulation from (b)(12) to a new paragraph (k), with a minor change to delete the phrase ''CMS may require'' and to add the word ''must'' after ''MA organizations.'' We received no comments in regard to these two proposed changes.

We also proposed to codify the existing content requirements of the Part C EOB in new § 422.111(k)(1), (k)(2) and (k)(3). For each Part A and Part B covered item and service, mandatory supplemental benefit, and optional supplemental benefit furnished during the reporting period, we proposed that an MA organization must include a corresponding descriptor, billing code, and amount billed; total cost approved for reimbursement, share of the total cost paid by the plan; and the share of the total cost for which the enrollee is liable. We also proposed that MA organizations must include the most current year-to-date totals in the EOB: the cumulative amount billed by all providers, the cumulative total costs approved by the plan, the cumulative share of total cost paid for by the plan, the cumulative share of total cost for which the enrollee is liable, the amount an enrollee has incurred toward the MOOP limit (as applicable), and the amount an enrollee has incurred toward the deductible (as applicable). We also proposed that MA organizations must provide clear contact information for enrollee customer service, instructions on how to report fraud, and for any EOB that includes one or more denied claims, the EOB must include a clear identification of the claim(s) denied as well as information about the denial and the enrollee's appeal rights. Our proposed regulation directed that this information about denied claims in the EOB would not replace the notice for adverse coverage decisions required by §§ 422.568 and 422.570.

We also proposed to codify the time frame choices available for MA organizations in sending the EOB. Proposed § 422.111(k)(4) would require an MA organization to choose to either send EOBs on a monthly basis or quarterly basis with per-claim notification. Consistent with our current policy, we proposed that MA organizations that send EOBs monthly must send them before the end of each month that follows the month a claim was filed and that a per-claim notice must be sent on the same cycle as a monthly EOB, which is before the end of each month that follows the month a claim was filed; MA organizations that choose to send per-claim notices must also send quarterly summary EOBs. Consistent with our current policy, we also proposed that MA organizations that choose to send EOBs on a quarterly basis must send an EOB no later than the end of each month following the quarter a claim was filed.

We summarize the comments received on our proposal and our responses follow.

Comment: A commenter asked CMS to clarify the term ''filed'' as it is used in paragraph (k)(4) to require the monthly EOB to be sent before the end of the month after the month in which a claim is filed and the quarterly EOB to be sent before the end of each month that follows the quarter in which a claim was filed.

Response: We clarify that we consider a claim to be filed when it has been received by an MA organization. This is consistent with our current policy.

Comment: Although CMS did not specifically discuss the existing policy that exempts MA organizations from sending EOBs to dual-eligible enrollees, one commenter asked CMS whether or not D–SNPs must send EOBs to their enrollees as a result of this rule.

Response: Currently, MA organizations are not required to send EOBs to dual-eligible enrollees, which would necessarily include any enrollee of a D–SNP, because dual-eligible enrollees generally do not pay any out-of-pocket costs. In the April 2011 final rule, we discussed the comments we solicited on this matter, and determined we would study the issue of applicability to dual-eligible enrollees (including those enrolled in D–SNPs) further under our pilot program. (76 FR 21507). At the conclusion of our pilot program, and after reviewing additional public comments solicited via a Health Plan Management System (HPMS) memo release with a 30-day comment period, as well as a November 26, 2012 **Federal Register** notice (77 FR 70445), the policy that exempts MA organizations from sending EOBs to dual-eligible enrollees was finalized. As we did not intend to make changes to Part C EOB policy in our proposal during this current round of rulemaking, we are finalizing this exception at § 422.111(k)(5).

Comment: A commenter, an MA organization, suggested that CMS no longer require MA plans and Part D sponsors to send Part C and Part D EOBs on a monthly basis. The MA organization stated that their enrollees experience confusion in regard to their EOBs which unnecessarily leads to complaints to their customer service department and to CMS. The MAO stated that their consumer research found that enrollees often did not read or did not know how to interpret their EOBs because the documents are lengthy and complex. They also found that their enrollees had a tendency to be interested in seeing how their cost sharing applied toward their deductible and maximum-out-of-pocket costs, and less interested in information that involves complex claims details or medical terminology. The MAO also stated that enrollees often complain about receiving EOBs on a monthly basis. The MAO recommended that CMS modify existing EOB guidance to permit MA plans and Part D sponsors to send quarterly statements to enrollees that include EOB totals related to cost sharing only, rather than the full EOB.

Response: The current Part C EOB was designed to ensure that MA enrollees have all of the information necessary to make important decisions about their health care, and its content was informed by input from MA organizations, patient advocacy groups, and other stakeholders. After publication of the April 2011 final rule, we engaged MA organizations, industry and advocacy groups, and enrollees in listening sessions to gather their feedback; using the feedback we collected, we then designed and tested models through a small pilot program with a volunteer MA organization in CY 2012. After the conclusion of this process, we sought additional public comments on the models through a Health Plan Management System (HPMS) memo release with a 30-day comment period. Based on public comment we received on the HPMS memo and a November 26, 2012 **Federal Register** notice, we finalized the current models for the Part C EOB. While an enrollee may not always need the entirety of the information stated in their EOB, some circumstances (for example, appeals) may arise when the enrollee needs more information than just their updated cost-sharing totals. At this time, CMS will not be changing the content requirements of the EOB; however, we acknowledge the importance of providing easily

understandable information to enrollees and may consider limiting the content requirements in future rulemaking. We are finalizing the proposed option for MA organizations to use a quarterly cycle for furnishing the EOBs. We note that the regulation text does not require that the MA organization use the same cycle for every enrollee, so an MA organization may elect to provide an option for enrollees to select the monthly or quarterly cycle, provided that the applicable content and timing requirements are met. Finally, the Part D EOB notice is outside the scope of this rulemaking.

Comment: Some commenters asked that CMS reconsider the requirement to send enrollees hard copies of their EOBs. An MA organization suggested that rather that mail paper EOBs, plans should be permitted to instead send enrollees a paper disclosure notice instructing them to contact customer service to obtain a hardcopy, or go online to view an electronic copy. The same MA organization stated that plans should continue to mail hard copies of the Integrated Denial Notice (IDN). Another commenter suggested that CMS consider changing the default requirement to electronic EOBs with paper opt-in, and stated that savings on paper, printing, and mailing could be used toward enhanced care and benefits.

Response: While CMS continues to drive innovation with respect to electronic health data access, we also recognize that a default electronic format could create disparity for enrollees who do not have the skills or equipment to obtain their claims data digitally. In order to help ensure that all enrollees are able to access their EOBs, CMS does not support a change in policy that would permit MA organizations to send EOBs electronically by default at this time. With respect to paper and electronic EOBs, CMS is not changing the requirement (finalized in section V.E of this rule) that MA organizations mail required materials in hard copy or provide them electronically following the requirements set forth in § 422.2267(d). CMS notes that in order to send an EOB to an enrollee electronically, the MA organization must obtain prior consent from the enrollee, provide instructions on how and when the enrollee can access the EOB, have a process in place through which an enrollee can request hard copies be mailed, and have a process for automatic mailing of hard copies when electronic versions are undeliverable, consistent with the requirements outlined at § 422.2267(d)(2)(ii).

Comment: An MA organization recommended that CMS provide more flexibility with regard to the frequency that an EOB can be sent to enrollees. Specifically, the MA organization suggested that CMS allow health plans to send the EOB every two weeks.

Response: Under our current policy and the regulation being finalized here at § 422.111(k), an MA organization must deliver the EOB at least on a monthly or quarterly basis, complying with the applicable content requirements. While CMS currently permits these two different frequency cycles, plans may still communicate information to their enrollees on a more frequent basis as long as the requirements of either the monthly or quarterly cycle continue to be met. At this time, CMS will not be making changes to the EOB frequency cycles or their respective requirements.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal for § 422.111(k), with one substantive modification to provide that MA organizations are not required to send the explanation of benefits to dual-eligible enrollees.

C. Special Requirements During a Disaster or Emergency (§ 422.100)

Section 422.100(m)(5)(iii) currently requires an MA organization to provide the information described in paragraphs (m)(1), (2), (3), and (4)(i) on its website, but § 422.100(m) does not have a paragraph (m)(4)(i) and paragraph (m)(4) requires a notice to CMS regarding the MA organization's ability to resume normal operations; rather, paragraph (m)(5)(i) describes the terms and conditions of payment during a public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, which is the information we intended to be posted by the MA organization. As noted in the proposed rule, the final rule that adopted § 422.100(m), titled ''Medicare Program Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (80 FR 7912), was clear that the requirement at 422.100(m)(5)(iii) was to post the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable, which would enable enrollees and providers to know the payment policies for out-of-network services provided during disasters.

We proposed to amend § 422.100(m)(5)(iii) to correct the text, replacing the reference to paragraph (m)(4)(i) to paragraph (m)(5)(i). We also proposed to update the regulation text to use ''website'' rather than ''Web site'' since the non-hyphenated non-capitalized term ''website'' is now commonly used and more consistent with other regulations in part 422.

We received no comments on this proposal and are finalizing the proposed technical amendments to § 422.100(m)(5) for the reasons outlined in the proposed rule.

D. Effective Date for Exclusion of Coverage for Kidney Acquisitions From Basic Benefits (§ 422.100)

Section 1852(a)(1)(B)(i) of the Act defines the term ''benefits under the original Medicare Fee-for-Service program option'' for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide these benefits to MA enrollees. Section 17006(c)(1) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act by inserting ''or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)'' after ''hospice care.'' Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans will no longer cover organ acquisitions for kidney transplants.

In the April 2019 final rule, we amended the definition of ''basic benefits'' at § 422.100(c)(1) to include ''additional telehealth benefits,'' and in doing so, we also amended § 422.100(c)(1) to note the new exclusion of coverage for organ acquisitions for kidney transplants (in addition to the existing exclusion for hospice care). However, we inadvertently omitted the identification of the 2021 effective date for this change set forth in the Cures Act.

In the proposed rule, we proposed a technical correction that would add the 2021 effective date to § 422.100(c)(1) for the exclusion of original Medicare coverage for organ acquisitions for kidney transplants. Specifically, we proposed to correct the phrase ''(other than hospice care or coverage for organ acquisitions for kidney transplants)'' to read: ''(other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants).'' This provision is technical and, as stated in the proposed rule, is therefore not expected to have economic impact beyond current operating expenses.

We received no comments on this proposal and are finalizing the proposed amendments to § 422.100(c)(1) without

modification for the reasons outlined in the proposed rule.

E. Add Back Cost Plan Related Sections From Previous Final Regulation (§ 422.503)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Final Rule (hereinafter referred to as the May 2014 final rule), we finalized regulations affecting the cost plan non-renewal-related requirements (79 FR 29850 through 29851, 29959). The final regulation inadvertently identified the non-renewal section as § 422.503(b)(4)(vi)(G)(*5*)(*i*) and (*ii*) when instead the revisions should have been specified as revising § 422.503(b)(5)(i) and (ii). Although the regulatory text for the provision was published in the May 2014 final rule, it was not correctly codified in the CFR. In the February 2020 proposed rule, we proposed to designate the provision in the correct paragraph of § 422.503.

The rule we adopted in 2014 provides that an entity seeking to offer an MA organization may not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. In the February 2020 proposed rule, we proposed to codify a policy adopted in the May 2014 final rule that prohibits an organization from offering and accepting enrollment in both an MA plan and a cost plan in the same service area; that policy applied to when the MA organization and the cost plan organization were the same legal entity or corporate affiliates. The proposed rule explained the redesignation:

- In new § 422.503(b)(5)(i), we specify that an entity seeking to contract as an MA organization must not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.
- In new § 422.503(b)(5)(ii), we specify that an entity seeking to offer an MA organization must not accept, or be either the parent organization owning a controlling interest of or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

We also proposed minor technical corrections to the regulation text described in the May 2014 final rule to improve the flow of the regulation text.

CMS received comments from two healthcare organizations and a trade association.

Comment: The commenters requested that the provision not be finalized, stating that it was not necessary. They commented that should CMS finalize the proposal, that it not be applied to entities that have both a cost plan and dual eligible special needs plan (D–SNP) or EGWPs, as the likelihood of an organization moving enrollees from one of these plans to another was especially low. In addition, the commenters requested that we revise our current understanding of the service area affected by the provision to determine whether there is an overlap between a cost plan and an MA plan on a county-by-county basis.

Response: The proposal in this rule is to restore, with minor technical and grammatical changes, language from a rule published in the **Federal Register** on May 23, 2014, that was not included in the Code of Federal Regulations. As such, we are proposing a technical change and the comments are outside the scope of this rule. Similar comments regarding the scope of the policy and whether it should apply to D–SNPs were submitted and addressed in that earlier rulemaking. For public comments and CMS responses to policy questions on the provision, as well as additional discussion of this provision, see the May 23, 2014 final rule (79 FR 29850–29851; 29944; 29959).

After considering the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendment to § 422.503(b)(5) as proposed with minor grammatical changes.

F. Definition of ''Institutionalized'' (§ 422.2)

Section 1859(b)(6)(B)(i) of the Act permitted the Secretary to define the term *institutionalized* for the purposes of establishing eligibility criteria for Medicare Advantage (MA) special needs plans for individuals who are institutionalized (I–SNPs). In addition, section 1851(e)(2)(D) of the Act permitted the Secretary to define the term for purposes of eligibility for a continuous open enrollment period to enroll or change enrollment in an MA plan, except for MA MSA plans. CMS codified the current definition of *institutionalized* at § 422.2 in the January 2005 final rule (70 FR 4588) as an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for individuals with intellectual disabilities (ICF/IID); or an inpatient psychiatric facility. This definition is used in the MA regulations (42 CFR part 422) to establish eligibility for I–SNPs and eligibility for continuous open enrollment.

We proposed to revise the definition of *institutionalized* in § 422.2 to expand the list of facilities and to add a standard to use to identify additional facilities where an institutionalized individual may reside in order to provide necessary flexibility to the regulation. Under our proposal, an institutionalized individual would be an individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare);

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid);

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act;

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act;

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act;

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act;

(7) Hospital which has an agreement under section 1883 of the Act (a swing bed hospital); and,

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) but meets both of the following: (i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7).

We explained in the proposed rule our concern that the current definition is too limited in scope given the array of institution and facility types in place today. We noted how our current subregulatory guidance identifies additional facilities and that the proposed changes to the definition would align the regulatory text with existing operational practice and current guidance, clarify our policy for MA organizations, and promote the expansion of I–SNP offerings under the MA program. Our guidance (Chapter 16b of the Medicare Managed Care Manual (MMCM) and the MA Enrollment and Disenrollment

Guidance [83]) taken together list the five types of institutions in the current definition and other institutions that are identified in some way in Titles XVIII or XIX of the Act in connection with the Medicare and Medicaid programs. We also explained the need for a standard that we could use to identify additional facility types, without having to go through future rulemaking, that we believed would be appropriate to use for defining when an individual is *institutionalized.* We explained how, under our proposal and using this new standard, CMS could permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I–SNPs. We explained how our proposed new definition, as a whole, could lead to additional types of I–SNPs and provide more options to Medicare beneficiaries for special needs plans targeted to the needs of individuals who are *institutionalized.*

In the proposed rule, we acknowledged that the proposed definition would not fully align with § 423.772, which defines ''institutionalized individual'' as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act. We explained that we did not believe alignment was necessary because the definition in § 423.772 serves a different purpose than the definition we proposed for § 422.2 and that differences between the two definitions had been in place since 2005, reflecting these different purposes. (85 FR 9145)

Finally, we discussed why we did not propose to change the definition of ''institutionalized-equivalent'' even though that term is also used to establish I–SNPs and eligibility for I–SNPs.

We received the following comments related to our proposals, and our responses follow:

Comment: A commenter stated that the proposed rule disqualifies Medicare Advantage enrollees with advanced cancer disease residing in a neoplastic disease care hospital by implementing a time requirement of 90 days, and that current subregulatory guidance in section 30.3 of Chapter 2 to the Managed Care Manual and regulations at 42 CFR 422.62(a)(4) do not require the 90-day time requirement for an institutionalized stay.

Response: As proposed and finalized, the revised definition of the term *institutionalized* aligns with current CMS guidance and expands the definition of *institutionalized* in § 422.2 to reflect the evolution of institutions over time and the current landscape of institutional health care today. The current definition of *institutionalized* in § 422.2 includes, and has included since the definition was adopted in 2005 (70 FR 4596, 4714), the criterion that the MA eligible individual continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility. Our guidance in Chapter 2 of the Medicare Managed Care Manual, regarding enrollment and disenrollment, might not specifically address the requirement in the definition in § 422.2 that an individual reside or be expected to reside in a long term care facility of the type listed but that does not change the regulation. Because the definition includes individuals who are expected to reside in facility for a 90-day or longer continuous period, enrollment into an I–SNP may precede the 90-day point based on an appropriate assessment that the regulatory standards are met, as CMS explained in the preamble to the 2005 final rule. (70 FR 4596). The new definition of *institutionalized* maintains this criterion and identifies seven specific types of long-term care facilities rather than the original five institution types listed in the definition.

In addition, the definition in the final rule specifies that CMS may approve additional facilities that are not listed previously, but: (i) Furnish similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid; and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. In implementing this final rule, CMS will establish a review process to determine whether a particular different institution type meets these standards for designation under this definition and therefore permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in (or are expected to continuously reside for 90 days or longer in) such designated facilities, provided the plan meets the remaining qualifying criteria for I–SNPs. This new authority to identify non-listed facilities for purposes of determining if an individual is *institutionalized* is applicable for the contract and coverage year beginning January 1, 2022 and we intend to review requests from MA organizations and others to meet that timeframe for identifying facilities that meet this standard. In addition, individuals residing in institutions that qualify under this part of the definition will also be eligible for the continuous open enrollment under § 422.62(a)(4).

Comment: Another comment stated that the proposed rule would expand use of the definition by making it also applicable to the open enrollment period for *institutionalized* individuals. They note that this would have the effect of expanding a 90-day length of stay requirement to individuals for purposes of their qualification for the open enrollment period for *institutionalized* individuals (OEPI).

Response: The existing requirements establishing qualifications for the open enrollment period for *institutionalized* individuals (OEPI) are established in 42 CFR 422.62(a)(4), which provides that an individual who is eligible to elect an MA plan and who is *institutionalized,* as defined in § 422.2, is not limited (except with regard to MA MSA plans) in the number of elections or changes he or she may make. The use of the definition in § 422.2 to identify individuals who are eligible for this OEPI was adopted in a revision of § 422.62(a)(4) in the April 2018 final rule (83 FR 16616 through 16618, 16723). This final rule does not amend § 422.62(a)(4), so the revised definition of *institutionalized* at § 422.2 will apply to identify who is eligible for the OEPI. The revised definition expands the list of qualifying institutions and provides an opportunity for similar institutions to qualify. We disagree with the commenter, however, that the definition of *institutionalized,* as finalized under this rule, changes the previous requirement that an MA eligible individual must continuously reside or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility to meet the definition or to be eligible for the OEPI. Because the definition includes individuals who are expected to reside in facility for a 90 day or longer continuous period, enrollment into an I–SNP may precede the 90 day point based on an appropriate assessment.

Comment: Another commenter supported the proposed rule but had concerns that the change may hinder state Medicaid agency efforts to integrate Medicare and Medicaid programs on behalf of dual eligible beneficiaries through FIDE SNPs. First, the commenter believes that expanding the list of facilities and adding a

[83] Chapter 16b of the MMCM can be found here: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf;* and the MA Enrollment and Disenrollment Guidance document can be found here: *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2019_MA_Enrollment_and_Disenrollment_Guidance.pdf.*

standard to use to identify additional facilities where an institutionalized individual may reside could result in a managed care plan's ability to offer I–SNPs that do not meet the requirements to be D–SNPs to a largely dual eligible beneficiary population, and thus, the MA plan would be able operate outside of the State Medicaid Agency Contract (SMAC) requirement in section 1859 of the Act (added by the MIPPA). The commenter noted that the change in the definition of *institutionalized* creates concerns similar to the recent growth of D–SNP lookalike MA plans that CMS has sought to regulate. Second, the commenter stated that definitional change of institutionalized could potentially confuse dual eligible beneficiaries when selecting the best SNP for the beneficiary's specific needs. The commenter advised CMS and state Medicaid agencies to coordinate implementation if CMS adopted the proposed changes.

Response: We thank the commenter for their remarks, but do not share the same concerns that aligning the definition of *institutionalized* in § 422.2 with current CMS guidance and adding a standard to recognize facilities that are not listed in the definition, but serve the same function for individuals with similar needs, would adversely impact integration of Medicare and Medicaid services for dually eligible beneficiaries. First, with regard to the specifically listed facilities in the definition, this final rule is consolidating current CMS guidance regarding I–SNP and OEPI enrollment policies and is not a significant break from them. The final rule will also provide additional flexibility to account for changes in the types of institutions that could potentially be used for I–SNPs that are not covered by the current definition of *institutionalized.* As we stated in the proposed rule, we are creating criteria that would accommodate changes in forms of institutional care within American healthcare without fundamentally changing or conflicting with other regulatory and statutory provisions surrounding I–SNPs. Under the finalized rule, the definition of *institutionalized* could include, subject to CMS approval, an additional facility that is not listed previously but (i) furnishes similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. Therefore, CMS could permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I–SNPs. In addition, any I–SNP application containing newly authorized institutions will still need to meet the remaining review standards to gain approval.

Second, we recognize that a portion of I–SNP enrollees are dually eligible for Medicare and Medicaid, and that is also true for many Medicare beneficiaries requiring a nursing level of care; however, this overlap of eligible populations is not complete. This change in the definition of *institutionalized* does not change the current requirements that establish the process for I–SNP application approval such as meeting the care management requirements for all SNPs, required by section 1859(f)(5) of the Act. Given that an MA organization would need to meet a separate set of standards, we believe there is limited incentive for an MA organization to establish an I–SNP as opposed to a D–SNP as a means to circumvent the requirement for a contract between a state and MA organization, which is limited to D–SNPs under section 1859(f)(3)(D) of the Act and § 422.107. Finally, while we appreciate that having several plan options available for a beneficiary requires the beneficiary to think through his or her needs carefully and compare those to the specific benefits and costs of each plan, we do not believe that permitting I–SNPs to enroll individuals who continuously reside in (or are expected to continuously reside) for 90 days or longer in a facility that meets the new standard we are adopting creates unnecessary confusion or burden for beneficiaries. Having a number of plan choices will allow beneficiaries to choose among plans with potentially different plan networks, levels of out-of-pocket costs, and extra benefits like vision, hearing, and dental. We believe this ultimately increases the likelihood that beneficiaries will be able to find a satisfactory MA plan that fits their healthcare needs.

Comment: Another commenter supported the proposal, but recommended a clarification that a ''facility that furnishes similar long term healthcare services that are covered under Part A or Part B or Medicaid . . . .'' includes facilities/settings where the services may be furnished by external healthcare entities that are overseen by the facility.

Response: We do not believe the proposed rule will prohibit services from being furnished by external healthcare entities as long as all other requirements are met by the I–SNP and contracted facility under the plan. Therefore, we are not making the recommended revision.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revised definition of *institutionalized* at § 422.2 as proposed. In reviewing our proposal to amend the definition of *institutionalized,* we realized that the definition of ''special needs individual'' in § 422.2 refers to an individual who is institutionalized but not to an individual who is institutionalized-equivalent. In the final rule published in the **Federal Register** on January 12, 2009 (74 FR 1495 through 1496), we first clarified that that I–SNPs can enroll individuals who are institutionalized-equivalent. In that rule, we noted that section 164 of MIPPA amended section 1859(f) of the Act, allowing institutional SNPs to enroll a special needs individual who is living in the community but requires an institutional level of care (LOC) (that is, an ''institutional-equivalent individual''). In connection with that statutory amendment, we added the definition for the term ''institutionalized equivalent'' to § 422.2 but failed to amend the definition of ''special needs individual'' to include individuals who meet the standard of being institutionalized-equivalent. In order to address this oversight, we are finalizing here a technical change in the definition of ''special needs individual'' to add that an individual who is institutionalized-equivalent is also a special needs individual, which is consistent with that prior final rule and our current practice.

G. Medicare Electronic Complaint Form (§§ 422.504 and 423.505)

On April 15, 2011, CMS amended §§ 422.504 and 423.505 to add a new §§ 422.504(a)(15) and 423.505(b)(22) requiring MA and Part D plans to address and resolve complaints received through CMS' complaint tracking system and to provide a direct link on their main web page to the Medicare.gov electronic complaint form. We are finalizing our proposal to modify §§ 422.504(a)(15) and 423.505(b)(22) by removing §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii) and recodifying the substance (requiring plans to display a link to the electronic complaint form on the Medicare.gov internet website on the plan's main web page) to subpart V, Communication requirements. Sections 422.111(h)(2) and 423.128(d)(2) require MA and Part D plans to maintain a

website. In section VI.H. of this final rule, we are adding new §§ 422.2265 and 423.2265, which provide requirements for MA and Part D plan websites. Specifically, in §§ 422.2265(b) and 423.2265(b), we identify the required content for websites, including a link to the Medicare.gov electronic complaint form. We believe the requirement for a direct link is more appropriately addressed in CMS' website requirements rather than in §§ 422.504(a)(15) and 423.505(b)(22).

We are not making any substantive changes to §§ 422.504(a)(15) and 423.505(b)(22) other than minor changes in the text to make it clear that plans must use the CMS complaint tracking system to address and resolve complaints received by CMS against the plan. In connection with removing §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii), we are redesignating the substance of §§ 422.504(a)(15)(i) and 423.505(b)(22)(i) as §§ 422.504(a)(15) and 423.505(b)(22).

We received no comments on this proposal and are finalizing the proposed technical amendments to §§ 422.504(a)(15) and 423.505(b)(22) without modification for the reasons outlined in the proposed rule.

H. General Requirements for Applicable Integrated Plans and Continuation of Benefits (§§ 422.629 and 422.632)

We proposed technical changes to § 422.629(k)(4)(ii) to correct four technical errors from the April 2019 final rule. Paragraph (k)(4)(ii) references Medicare coverage criteria, however Medicaid coverage criteria are also applicable during the unified appeals process described in this section. Therefore, we proposed to add the phrase ''and Medicaid'' following ''knowledge of Medicare'' in § 422.629(k)(4)(ii).

Also in paragraph (k)(4)(ii) of this section, there is an incorrect reference to the MA organization. We proposed to replace ''MA organization'' with the correct term, ''applicable integrated plan''. Also, we proposed to add the word ''integrated'' before ''organization determination decision'' to conform to the terminology used elsewhere in § 422.629(k). Lastly, we proposed to remove the comma between the words ''expertise'' and ''in'' in the regulation text to clarify that the required expertise is in the topics identified in the text.

In § 422.632(b)(1), we proposed to change the citation from § 422.633(e) to (d). Section 422.632(b)(1) reflects the requirement that the enrollee file a request for an integrated appeal in a timely manner, with a cross reference to the regulation that sets the timeframe for such appeals. Paragraph (d) of § 422.633 sets that timeframe while paragraph (e) addresses the requirements for expedited integrated reconsiderations. We therefore proposed to amend § 422.632(b)(1) to use the correct cross-reference.

We received no comments on this proposal and are finalizing the proposed technical amendments to §§ 422.629(k)(4)(ii) and 422.632(b)(1) without modification for the reasons outlined in the proposed rule.

I. Representatives in Part D Appeals (§§ 423.560, 423.566, 423.578, 423.2014, and 423.2036)

The regulations for Medicare fee-for-service (Part A and Part B) claims and entitlement appeals at part 405, subpart I, reference two types of representatives—authorized and appointed. Section 405.902 defines an authorized representative as an individual authorized under state or other applicable law to act on behalf of a beneficiary or other party involved in an appeal, and separately defines an appointed representative as an individual appointed by a party to represent the party in a Medicare claim or claim appeal. Similarly, for appeals of Medicare Part C organization determinations, § 422.561 defines ''representative'' as an individual appointed by an enrollee or other party, or authorized under state or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. For appeals of Medicare Part D coverage determinations, however, § 423.560 defines ''appointed representative'' as meaning either an individual appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee.

For consistency in the use of these terms across Medicare programs, we proposed to replace the definition of ''appointed representative'' in § 423.560 with a definition of ''representative.'' We also proposed to replace references to appointed representatives in §§ 423.566(c)(2), 423.578(b)(4), 423.2014(a)(1)(ii), and 423.2036(c) and (d) with references to representatives.

We summarize the comment we received on this proposal and respond as follows.

Comment: We received one comment in support of the proposal to replace the definition of ''appointed representative'' in § 423.560 with a definition of ''representative.'' The commenter requested that sufficient time be built in for the implementation of this provision to allow affected enrollee communications documents to be modified to reflect this change.

Response: We appreciate the commenter's support for this proposal. Given that we are enhancing consistency in the use of the term ''representative'' across the Medicare program and not substantively altering the concept of who may be a representative in the grievance and appeals processes, we believe the effective date of this rule affords plans ample opportunity to make any necessary changes to enrollee communications.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, without modification, the proposed amendments to §§ 423.560, 423.566, 423.578, 423.2014, and 423.2036 to clarify and streamline references to ''representatives'' in the Part D appeal regulations.

J. Copayments and Coinsurance in Amount in Controversy Calculations (§§ 422.600 and 423.2006)

We proposed amendments to §§ 422.600 and 423.2006 to clarify how the amount in controversy (AIC) is calculated for appeals for MA plans, section 1876 cost plans, section 1833 health care prepayment plans and Part D plans. The regulations applicable to cost plans and healthcare prepayment plans, §§ 417.600 and 417.840 respectively, require those plans to also use the MA appeal regulations.[84]

We explained in the proposed rule the statutory background for using the same rules for calculating the AIC as used for the Medicare FFS program for MA appeals. The regulations at part 405, subpart I, specifically § 405.1006(d), provide the methodology for calculating the amount in controversy (AIC) in Medicare fee-for-service (Part A and Part B) claims and entitlement appeals. In general, and subject to the exceptions listed in §§ 405.1006(d)(2) through (6), § 405.1006(d)(1) provides that the AIC is computed as the amount that the provider or supplier bills (''the actual amount charged the individual'') for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services, and further reduced by ''any deductible and/or coinsurance amounts that may be collected for the items or services.''

For Medicare Part C appeals under part 422, subpart M, § 422.600(b) provides that the AIC is computed in

[84] We cited § 405.840 in the proposed rule but provide the correct citations here.

accordance with the part 405 rules (concerning appeals of initial determinations under original (fee-for-service) Medicare). However, we stated in the proposed rule that while original Medicare uses deductibles and coinsurance (where the beneficiary pays a percentage of the cost for an item or service) as forms of cost sharing, MA plans may also use copayments (where the enrollee pays a flat fee for an item or service) as a form of cost sharing. We stated in the proposed rule that because § 405.1006(d)(1) provides that the AIC excludes ''any deductibles and/or coinsurance amounts that may be collected for the items or services,'' questions have arisen regarding whether it is also appropriate to exclude any copayment amounts that may be collected for the items or services when applying the part 405 rules to appeals of Part C organization determinations made under part 422, subpart M. To resolve ambiguity on the proper calculation of the AIC and to help ensure that the AIC in Part C appeals is reflective of the actual amount at issue for the enrollee, we proposed to revise § 422.600(b) to clarify that the AIC, which can include any combination of Part A and Part B services, is computed in accordance with part 405, and that any references to coinsurance in the part 405 regulations, for purposes of computing the AIC under § 422.600, should be read to include both coinsurance and copayment amounts.

We also proposed a revision to the regulations for appeals of Part D plan sponsor coverage determinations and at-risk determinations made under part 423, subpart M. The AIC for these appeals is addressed in § 423.2006, which does not reference cost-sharing amounts. To clarify the AIC calculation for Part D appeals and help ensure that the AIC in Part D appeals is reflective of the actual amount at issue for the enrollee, we proposed to redesignate paragraphs § 423.2006(c)(1) and (2) to (2) and (3), and to amend (c)(1) to provide general AIC calculation provisions for Part D appeals, specifying that the AIC calculation would be reduced by any cost-sharing amounts, including deductible, coinsurance, or copayment amounts, that may be collected from the enrollee for the Part D drug(s).

We received no comments on these proposals and are finalizing amendments to §§ 422.600 and 423.2006 without modification to clarify application of the AIC rules to Part C and Part D appeals, for the reasons outlined in the proposed rule.

K. Stipulated Decisions in Part C (§ 422.562)

The regulations for Medicare fee-for-service (FFS) (Part A and Part B) claims and entitlement appeals at part 405, subpart I provide for stipulated decisions at § 405.1038(c). This provision permits Office of Medicare Hearings and Appeals (OMHA) adjudicators to issue abbreviated, stipulated decisions if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made.[85] In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the written or oral statement and without making findings of fact, conclusions of law, or further explaining the reasons for the decision. The MA appeal regulations at § 422.562(d) provide that the FFS appeals procedures in part 405, subpart I apply to appeals of Part C organization determinations to the extent they are appropriate and identifies specific part 405 regulations that are not appropriate to apply to MA appeals. We explained in the proposed rule that because MA organizations are not generally included within the definition of ''contractors'' in § 405.902, it was not readily apparent that the rules for stipulated decisions at § 405.1038(c) apply to MA appeals. For consistency with the Part D regulations (which allow stipulations to be made by Part D plan sponsors under § 423.2038(c)), and to afford OMHA adjudicators the same flexibilities in Part C cases where the MA organization that issued the organization determination and plan reconsideration no longer disputes that an item or service should be covered or that payment should be made, we proposed to revise § 422.562 by adding new paragraph (d)(3) to clarify that, for the sole purpose of applying the regulations at § 405.1038(c) to Part C appeals under part 422, subpart M, an MA organization is included in the § 405.902 definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators. As we stated in the proposed rule, we believe this revision will permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, which would ultimately benefit MA enrollees because these decisions could potentially be issued, and effectuated by the MA organization, sooner.

We received no comments on this proposal and therefore are finalizing the proposed changes to § 422.562 without modification for the reasons provided in the proposed rule.

L. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Section 1860D–4(c)(5)(C)(ii) of the Act contains exemptions from DMPs for certain beneficiaries, and provides the Secretary with the authority to elect to treat other beneficiaries as an exempted individual. As currently codified at § 423.100, exempted beneficiaries include those receiving hospice or end-of-life care, residents of a long-term care facility, or those being treated for active cancer-related pain.

Consistent with the statutory authority and current clinical literature detailed in the preamble of the proposed rule, CMS proposed to add beneficiaries with SCD to the categories of exempted beneficiaries in § 423.100.

Comment: CMS received a number of comments on this proposal, which were unanimously supportive of adding beneficiaries with SCD to the list of individuals exempted from DMPs.

Response: CMS thanks the commenters for their support.

Comment: Several commenters suggested that individuals with other disease states also should be exempt from DMPs, including: Chronic pain in cancer survivors, any chronic pain, complex regional pain syndrome, fibromyalgia, rare chronic pain diseases, Ehlers Danlos syndrome, degenerative disc disease, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, common variable immunodeficiency, and non-pain syndromes for which opioids are utilized, such as dyskinesias and autoimmune conditions affecting the excretory system.

Response: CMS appreciates these suggestions but disagrees that additional exemptions from DMPs are warranted at this time. In the April 2018 final rule establishing DMPs (83 FR 16454), CMS stated that if exemptions are crafted too broadly or are too numerous, they would risk undermining the purpose of DMPs, which serve as a patient safety tool for beneficiaries who use opioids. CMS believes it is appropriate to narrowly tailor exemptions, distinguish between different clinical scenarios, and account for differences in coordinating care in distinct patient populations. The clinical presentation of SCD is such that individuals with this condition regularly require access to opioid pain medications when experiencing acute

[85] For appeals in which the amount of payment is an issue before the ALJ or attorney adjudicator, § 405.1038(c) further provides that the written or oral statement must agree to the amount of payment the parties believe should be made.

crises in addition to treatment for chronic pain and are more likely to have additional prescribers due to frequent visits to emergency rooms.[86] These factors lead to beneficiaries with SCD being identified as PARBs by OMS criteria while case management, care coordination, and DMP coverage limitations are less practicable for them. Thus, while CMS appreciates commenters' feedback on additional disease states to be considered for exemption from DMPs, at this time CMS does not have sufficient data to demonstrate that the clinical presentation and factors affecting care coordination for the other disease states mentioned in comments make DMP activities of similarly limited value. However, CMS will continue to evaluate OMS response data, other available data sources, and medical literature for consideration in future policy development. In addition, CMS monitors DMPs to ensure they are functioning in the positive ways CMS anticipates will support appropriate pain management.

Comment: A commenter stated that disease-specific exemptions are discriminatory against beneficiaries with other diseases that involve pain and may require opioid therapy, such as inherited autoimmune disorders like ankylosing spondylitis and rheumatoid arthritis and generalized osteoarthritis.

Response: CMS disagrees that the sickle cell disease exemption we proposed is discriminatory. As background, section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who (I) receives hospice care, (II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or (III) the Secretary elects to treat as an exempted individual. While the first two exemptions are required under CARA, CMS previously exercised the authority in section 1860D–4(c)(5)(C)(ii)(III) of the Act to establish the exemption for a beneficiary who is being treated for active cancer-related pain and is exercising that authority in this rule to exempt beneficiaries with SCD. These discretionary exemptions are not discriminatory toward beneficiaries with other diseases that may require opioid therapy because inclusion in a DMP is not a punitive step. Inclusion means that a beneficiary's opioid use will be reviewed during case management for medical necessity and safety, and DMPs do not dictate the amount or length of opioid use for a beneficiary that is deemed medically necessary. Additionally, CMS adopts discretionary exemptions as part of our ongoing efforts to minimize identification of ''false positives,'' that is, beneficiaries are exempted who may meet OMS criteria but are unlikely to need case management for their safety and medical necessity review.

Comment: A few commenters requested additional flexibilities to include SCD patients in DMPs if case management suggested intervention would benefit them or if they were previously identified as an ARB and a coverage limitation was applied.

Response: Plan sponsors are not permitted to include exempted individuals in their DMPs. Based on the statutory language at section 1860D–4(c)(5)(C) of the Act, current CMS guidance[87] states that: (1) Exempted beneficiaries cannot be placed in a Part D sponsor's DMP, (2) a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report, and (3) a beneficiary's identification as an ARB terminates as soon as a sponsor discovers that the beneficiary is exempted. Other than adding individuals with SCD to the existing exemptions starting January 1, 2022, this final rule does not change existing policy with respect to exempted individuals.

Comment: A few commenters requested that CMS update OMS technical elements (for example, response codes) consistent with the final provision.

Response: CMS appreciates this comment and intends to update OMS response forms and technical guidance accordingly.

After consideration of the comments received and for the reasons provided in the proposed rule and preceding responses to comments, CMS is finalizing the exemption for beneficiaries with SCD as proposed with one modification to clarify that this definition is applicable starting in plan year 2022 instead of plan year 2021.

M. Drug Management Programs (DMPs): Additional Requirements (§§ 423.100 and 423.153)

In order to improve the clarity of the DMP regulations, CMS proposed a number of technical wording and reference changes. CMS received no comments on these proposed revisions and are finalizing them without modification for the reasons given in the proposed rule. In response to a comment received on the provision to include beneficiaries with a history of opioid-related overdose in DMPs in section III.B., CMS is making an additional technical change to add ''who is not an exempted beneficiary'' to the PARB definition at § 423.100. This change makes the definitions for PARB and ARB consistent and codifies existing guidance that once a PARB is determined to be an exempt beneficiary, they are no longer to be included in DMPs. CMS also noticed a grammatical error at § 423.153(f)(15)(ii)(D). In order to improve the clarity of the statement at this citation, CMS is changing the two occurrences of ''no later than 7 days of the date'' to ''no later than 7 days from the date'' in this statement.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our February 2020 proposed rule solicited public comment on our proposed information collection requirements, burden, and assumptions. Summaries of the public comments on the proposed information collection requirements, burden, and assumptions for the policies being implemented in this final rule are included in this

[86] James, CV and Wilson-Frederick, SM. The Invisible Crisis: Understanding Pain Management in Medicare Beneficiaries with Sickle Cell Disease. CMS Office of Minority Health Data Highlight, No. 12. Baltimore, MD. 2018. Available from: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CMS-OMH-September2018-Sickle-Cell-Data-Highlight.pdf.*

[87] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

section with our responses under: (1) ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111), (2) ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153), (3) ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128), (3) ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514), and (4) ICRs Regarding PACE.

We did not receive PRA-related comments pertaining to: (1) ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101), (2) ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153), (3) ICRs Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153), (4) ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111), (5) ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2), (6) ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128), and (7) ICRs Regarding Stipulated Decisions in Part C (§ 422.562).

The following provisions of the February 2020 proposed rule were finalized in our June 2020 final rule (85 FR 33796) and are thereby excluded from this final rule: (1) ICRs Regarding Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102), (2) ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514), (3) ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110), (4) ICRs Regarding Medical Loss Ratio (MLR) (§ 422.2440), and (5) ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38).

A. Wage Data

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), which, at the time of publication of this rule, provides May 2019 wages. In this regard, Table H1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE H1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Compliance Officer	13–1041	35.03	35.03	70.06
Computer Programmers	15–1251	44.53	44.53	89.06
Computer Systems Analysts	15–1211	46.23	46.23	92.46
Dietician	29–1031	29.97	29.97	59.94
General Operations Manager	11–1021	59.15	59.15	118.30
Health Technician, All Other	29–9098	28.17	28.17	56.34
Healthcare Social Workers	21–1022	28.51	28.51	57.02
Management Analyst	13–1111	45.94	45.94	91.88
Occupational Therapist	29–1122	41.45	41.45	82.90
Office and Administrative Support	43–9199	18.41	18.41	36.82
Medical and Health Services Managers (PACE Center Manager)	11–9111	55.37	55.37	110.74
Passenger Vehicle Driver	53–3058	15.97	15.97	31.94
Personal Care Aides	31–1120	12.71	12.71	25.42
Pharmacist	29–1051	60.34	60.34	120.68
Physical Therapist	29–1123	43.35	43.35	86.70
Physician	29–1216	96.85	96.85	193.70
Recreational Therapist	29–1125	24.58	24.58	49.16
Registered Nurse	29–1141	37.24	37.24	74.48

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2018 wage estimates, this final rule uses BLS's more recent May 2019 wage estimates. Changes to the wage estimates represent shifts in average wages of occupations between 2018 and 2019 and are presented in Table H2. The table also reflects occupation titles used in both the proposed rule and this final rule with corresponding changes in wages and changes in occupation codes.

TABLE H2—COMPARISON OF PROPOSED AND FINAL RULE WAGE DATA

Occupation title	CMS–4190–P: Occupation code (BLS: May 2018)	CMS–4190–F2 Occupation code (BLS: May 2019)	CMS–4190–P: (BLS: May 2018 ($/hr))	CMS–4190–F2: (BLS: May 2019 ($/hr))	Difference ($/hr)
Compliance Officer	13–1041	No change	69.72	70.06	+0.34
Computer Programmers	15–1131	15–1251	86.14	89.06	+2.92
Computer Systems Analysts	15–1121	15–1211	90.02	92.46	+2.44
Dietician	29–1031	No change	58.86	59.94	+1.08

TABLE H2—COMPARISON OF PROPOSED AND FINAL RULE WAGE DATA—Continued

Occupation title	CMS–4190–P: Occupation code (BLS: May 2018)	CMS–4190–F2 Occupation code (BLS: May 2019)	CMS–4190–P: (BLS: May 2018 ($/hr))	CMS–4190–F2: (BLS: May 2019 ($/hr))	Difference ($/hr)
General Operations Manager	11–1021	No change	119.12	118.30	−0.82
Healthcare Social Workers	21–1022	No change	56.22	57.02	+0.80
Management Analyst	13–1111	No change	90.76	91.88	+1.12
Occupational Therapist	29–1122	No change	82.08	82.90	+0.82
Office and Administrative Support	43–9199	No change	36.04	36.82	+0.78
Medical and Health Services Managers (PACE Center Manager)	11–9111	No change	109.36	110.74	+1.38
Personal Care Aides	31–1011	31–1120	24.36	25.42	+1.06
Pharmacist	29–1051	No change	118.90	120.68	+1.78
Physical Therapist	29–1123	No change	85.46	86.70	+1.24
Physician	29–1069	29–1216	196.04	193.70	−2.34
Recreational Therapist	29–1125	No change	48.68	49.16	+0.48
Registered Nurse	29–1141	No change	72.60	74.48	+1.88

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VII) of this final rule.

1. ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

The following changes will be submitted to OMB for approval under control number 0938–1296 (CMS–10565). Subject to renewal, the control number is currently set to expire on June 30, 2022. It was last approved on June 30, 2019 and remains active.

This rule amends § 422.101(f) to implement the new requirements legislated by the BBA of 2018 to section 1859(f) of the Act for C–SNPs and to extend them to all SNP types. Specifically, we are adding the following new regulations to account for new requirements governing SNP enrollee care management and SNP MOC submissions. The new regulations impacting MA SNP MOCs consist of the following:

• We are amending the end of § 422.101(f)(1)(i) by adding the following language: ''. . . and ensure that results from the initial and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.'' To comply with this provision, MA SNPs will have to provide the necessary guidance to SNP plan staff and develop related internal processes for employees of the SNP that are responsible for incorporating this requirement into their MOC.

• New § 422.101(f)(3)(ii)(A) through (C) will implement the requirement that: As part of the evaluation and approval of the SNP MOC, NCQA must evaluate whether goals were fulfilled from the previous MOC; plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals; plans submitting an initial MOC must provide relevant information pertaining to the MOC's goals for review and approval; and if the SNP MOC did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. Under this change, each plan's MOC must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals. Note, all SNPs are currently required to identify and clearly define measurable goals and health outcomes as part of their MOC under MOC 4, Element B: Measurable Goals and Health Outcomes for the MOC.

• Lastly, new § 422.101(f)(3)(iii) will implement the requirements that each SNP MOC submitted to CMS will be evaluated by NCQA based on a minimum benchmark (of 50 percent) for each of the existing four elements.

At the time SNP applications are due, MA organizations wishing to offer a new SNP will submit a MOC with their SNP application in the Application module in HPMS for NCQA review and approval. MA organizations wishing to renew their current SNP will submit a MOC in the MOC module in HPMS for NCQA review and approval. Based on their MOC scores, I–SNPs and D–SNPs receive an approval for a period of 1, 2, or 3 years. C–SNPs must renew their MOCs annually per section 1859(b)(6)(B)(iii) of the Act. For calendar year 2020, CMS received 273 SNP MOCs during the annual submission process and received 11 off-cycle submissions during the following time period. We believe these figures are representative of future SNP MOC submission totals going forward.

The burden related to these new requirements for SNP MOCs reflect the time and effort needed to adhere to the new requirements under the amendments to § 422.101(f), and as listed in the bullets in this section, and collect the information as previously described, as well as all other MOC data, and report this information to CMS. To derive average costs, we selected the position of registered nurse because the SNP nurse usually develops and submits the MOC to CMS and typically interacts with the health plan quality registered nurse in matters related to the MOC after it is submitted to CMS.

As is current practice, the MA organization/SNP will click on the Application or MOC module in HPMS and download the SNP MOC Matrix document. The SNP will complete the document, and then upload its MOC matrix document with the MOC narrative. The SNP MOC Matrix upload document outlines the CMS SNP MOC standards and elements that must be addressed in the MOC narrative. The document also serves as a table of contents for the MOC narrative.

Training to use the MOC module will be minimal at 3 hours annually, and training materials and non-mandatory webinar sessions are provided by CMS at no cost to the SNPs except for the time (and cost) to participate. While the training is not mandatory, SNP personnel (we believe this is a SNP compliance officer at $70.06/hr) normally attend the full 3-hour session. In aggregate, we estimate an ongoing annual burden of 819 hours (273 SNPs

* 3 hr) at a cost of $57,379 (819 hr * $70.06/hr).

Using HPMS contract year 2020 submission data, for annual submissions under 42 CFR 422.101(f)(3) we estimate that each year 273 SNPs will submit MOCs. Note, this calculation is based on estimates that include annual MOC submissions for C–SNPs and semi-annual submissions for I–SNPs and D–SNPs. I–SNPs and D–SNPs submitting a MOC can receive MOC approval for one, two, or three year terms. For each SNP, we assume an additional 6 hours at $74.48/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 1,638 hours (273 SNPs × 6 hr) at a cost of $121,998 (1,638 hr × $74.48/hr).

For plans seeking to revise their MOC based on qualifying events during the off-cycle season, we estimate that approximately 11 SNPs (D–SNPs/I–SNPs) will submit off-cycle MOC changes based on historical submission rates. For each SNP submitting off-cycle MOC changes, we assume an additional 4 hours at $74.48/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 44 hours (11 SNPs × 4 hr) at a cost of $3,277 (44 hr × $74.48/hr).

Since § 422.101(f)(3)(iii) sets a minimum benchmark for each MOC element, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at data for contract year 2020, our element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. For contract year 2020, 7 plans required submitting their MOCs for revision based on the current scoring system and an additional 7 plans decided to withdraw their MOCs before the revision process for a total of 14 MOCs. The 14 SNPs must resubmit, taking 3 hours, or half the full 6-hour estimate. In aggregate, we estimate an added ongoing annual burden of 42 hours (14 SNPs * 3 hr) at a cost of $3,128 (42 hr * $74.48/hr).

For the aforementioned MOC requirements under the amended 42 CFR 422.101(f)(3), we estimate an added annual burden of 2,543 hours (819 hr for training to use the MOC module + 1,638 hr for MOC submissions + 44 hr for MOC revisions + 42 hr for MOC resubmissions) at a cost of $185,782 ($57,379 + $121,998 + $3,277 + $3,128, respectively).

Separate from the MOC process, newly added § 422.101(f)(1)(iv) will implement a new requirement that plans provide face-to-face encounters with consenting individuals enrolled in the plan not less frequently than on an annual basis. The new regulation requires an annual face-to-face visit, that is, in-person or by visual, real-time, interactive telehealth technology, to occur starting within the first 12 months of enrollment within the plan. CMS will consider a visit to or by employed and/or contracted staff that perform clinical functions, such as direct enrollee care, as a qualifying encounter. Such activities may include, but are not limited to, annual wellness visits and/or physicals, HRA completion, meeting with the interdisciplinary team (IDT), care plan review, health-related education, and care coordination activities. It is also the expectation that any concerns related to physical, mental/behavioral health, and overall health status, including functional status, are addressed and any appropriate referrals, follow-up, and care coordination activities are provided or scheduled as necessary.

We believe that most, if not all, SNP enrollees will have a qualifying face-to-face encounter under § 422.101(f)(1)(iv) through an initial or annual HRA, a qualifying encounter with an IDT member, or an annual wellness visit. We estimate that approximately 734 SNPs that have at least 11 members will need to track face-to-face encounters for their enrollees annually. For each SNP tracking face-to-face encounters, we assume 4 hours of work by SNP personnel, typically a registered nurse. In aggregate, we estimate 2,936 hours (734 SNPs × 4 hr) at a cost of $ 218,673 (2,936 hr × $74.48/hr).

Section 422.101(f)(1)(iii) will also require that MA organizations offering a SNP must provide each enrollee with an IDT in the management of care that includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan. Plans must develop and implement this requirement into their MOC components to assure an effective management structure. We believe this requirement is consistent with currently approved information tracking practices for all existing SNPs, and thus, does not impose any new or revised requirements and/or burden beyond what is currently approved by OMB under the aforementioned control number.

The remaining changes under § 422.101(f)(2) and (3), will codify current guidance governing SNP MOC submission practices, which is captured under our active information collection request.

We received no comments on our proposed burden estimates. Consequently, we are finalizing them without modification.

2. ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

As discussed in section III.A. of this final rule, we are codifying the requirement under section 2004 of the SUPPORT Act that Part D plan sponsors establish DMPs by 2022 at § 423.153(a).

For context, in general, the required elements of a DMP are codified at § 423.153(f). The provisions require Part D sponsors to conduct case management of PARBs identified by OMS through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines.[88] After case management is completed, if a plan sponsor intends to limit a beneficiary's access to coverage of opioids and benzodiazepines, the sponsor must provide an initial written notice to the beneficiary. After the beneficiary has a 30-day time period to respond, the plan sponsor sends a second notice to the beneficiary, if the sponsor determines the beneficiary is an at-risk beneficiary (ARB), that the sponsor is implementing a coverage limitation on opioids and/or benzodiazepines, or an alternative second notice if the plan sponsor determines that the beneficiary is not an ARB. Thus, every beneficiary who receives an initial notice receives a second or alternate second notice.

In 2019, a CMS internal analysis found that a majority of Part D contracts (669 of 779, or 85.9 percent) voluntarily included a DMP. Our requirement that sponsors adopt DMPs would only affect the remaining minority of sponsors currently not offering such programs. There are 111 contracts (plan sponsors) run by 79 parent organizations that would be involved. Furthermore, we estimate that only 158 additional PARBs will be identified by these 111 contracts due to meeting the minimum OMS criteria. We estimate burden at the parent organization level because we believe that is a closer reflection of the

[88] CMS currently designates both opioids and benzodiazepines as ''Frequently Abused Drugs'' for purposes of DMPs. See ''Part D Drug Management Program Policy Guidance'', November 20, 2018, p. 6; *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

number of systems that will need to be updated versus the contract level.

The estimated reporting burden to these sponsors has four aspects. Under § 423.153(f), sponsors must: (1) Design a DMP; (2) conduct case management, which includes sending written information about PARBs to prescribers; (3) program and issue written notices to PARBs and ARBs; and (4) report data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

For one-time initial development, we estimate it would take each parent organization without a DMP 80 hours for a team of four clinical and non-clinical staff to design its DMP. Thus the burden for one parent organization is 320 hours (80 hr × 4 staff). Therefore, the aggregate burden for the 79 remaining parent organizations to develop DMPs consistent with the requirements of § 423.153(f) is 25,280 hours (79 parent organizations × 320 hr).

With regard to costs, we estimate that development, as just indicated, will require a development team consisting of four staff, two pharmacists (working at $120.68/hr) and two general operation managers (working at $118.30/hr) per organization. Thus, the average hourly wage for the organization's development team is $119.49/hr ($477.96/hr/4 staff). The rates for the development team are summarized in Table H3. Consequently, the aggregate cost to develop the DMPs is $3,020,707 ($119.49/hr * 25,280 hr) or $38,237 per parent organization ($3,020,707/79 organizations).

TABLE H3—LABOR RATES FOR THE DEVELOPMENT TEAM

Occupation	Hourly wage ($/hr)	Number of staff	Total wages ($/hr)
General operations manager	118.30	2	236.60
Pharmacist	120.68	2	241.36
Total (for hourly wage and total wages)	* 119.49	4	477.96

* Note: 119.49 is the average wage per hour (477.96/4) and equals total wages for four staff (477.96) divided by total staff (4). The 119.49 is a weighted average representing the hourly wage of the team; that is a team of four working on average at $119.49/hr. incur a total cost of $477.96. The reason an average is taken is because not all four members are working all the time. This number is important since it enters the summary table and is the only number that when multiplied by number of hours (4 staff * 1 hr) will give the correct total wage. Since this number is not a total, the ''Totals'' row header has been clarified to indicate that totals only apply ''hourly wage'' and ''total wages''. This is a standard practice.

The 79 Part D parent organizations affected by this requirement also will have to upload beneficiary notices into their internal claims systems before they can issue them. We estimate that it will take each organization, on average, 5 hours at $89.06/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimated a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $35,179 (395 hr * $89.06/hr).

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 parent organizations that did not voluntarily establish a DMP are generally smaller plans that in some cases offered alternative means of managing comprehensive beneficiary care, such as through PACE. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on internal analysis of the first 3 quarters (January–March, April–June, and July–September of 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate of 0.7 percent of beneficiaries extrapolated over the entire year, CMS can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

Once required DMP policies are developed and operational, sponsors would have to case-manage their PARBs (as outlined in § 423.153(f)(2)). The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. The burden for sending this information, which may be accomplished by any of several means (such as mail or fax), is already included in the case management burden estimates provided earlier in this section and does not need to be separately accounted for.

The case management team would consist of a pharmacist (such as initial review of medication profiles, utilization, etc.) working 2 hours at $120.68/hr; one health technician working 2 hours at $56.34/hr; and one physician working 1 hour at $193.70/hr to work directly with providers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $547.74 per PARB case managed ([2 hr × $120.68/hr] + [2 hr * $56.34/hr] + [1 hr * $193.70/hr]). Therefore, the case management team's wage is $109.55/hr ($547.74/5 hr). This is summarized in Table H4. In aggregate, we estimate an annual burden of 790 hours (5 hr × 158 beneficiaries at a cost of $86,545 per year (790 hr × $109.55/hr).

TABLE H4—HOURLY WAGE OF CASE MANAGEMENT TEAM

Occupation	Time (hours)	Wages ($/hr)	Labor cost ($)
Health Technician	2	56.34	112.68
Pharmacist	2	120.68	241.36
Physician	1	193.70	193.70

TABLE H4—HOURLY WAGE OF CASE MANAGEMENT TEAM—Continued

Occupation	Time (hours)	Wages ($/hr)	Labor cost ($)
Totals (For hours and labor cost)	5	* 109.55	547.74

* Note: 109.55 is the average wage per hour (547.74/5) and equals total wages for five staff (547.74) divided by total staff (5). The 109.55 is a weighted average representing the hourly wage of the team; that is a team of five working on average at $109.55/hr. incur a total cost of $547.74. The reason a weighted average is being used is because not all team members are working at each instant. This number is important since it enters the summary table and is the only number that when multiplied by number of hours (5 staff * 1 hr) will give the correct total wage. Since this number is not a total, the ''Totals'' row header has been clarified to indicate that totals only apply ''hours'' and ''labor cost''. This is a standard practice.

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimated that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). At most, 8 sponsors would be responsible for sending the notices to these 8 beneficiaries. CMS estimates it will take 10 minutes (0.1667 hr) at $56.34/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden for sending notices to beneficiaries of 1.3336 hours (8 beneficiaries × 0.1667 hr) at a cost of $75 (1.3336 hr × $56.34/hr).

Under § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy will be required to report to CMS the outcome of case management via OMS and any associated coverage limitation information into MARx. CMS estimates that it will take sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually × 0.0167 hr) at a cost of $149 (2.6386 hr × $56.34/hr).

Table H5 summarizes the burden associated with the mandatory DMP provision.

TABLE H5—SUMMARY FOR MANDATORY DMPS

Regulatory citation	Subject	Number of respondents	Number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost in 1st year ($)	Total cost in subsequent years ($)
§ 423.153	Creating DMP	79	79	320	25,280	119.49	3,020,707	0
§ 423.153	Upload Model Notices	79	79	5	395	89.06	35,179	0
§ 423.153	Conduct Case Management	79	158	5	790	109.55	86,545	86,545
§ 423.153	Send Model Notices	8	8	0.1667	1.3336	56.34	75	75
§ 423.153	Report to CMS	79	158	0.0167	2.6386	56.34	149	149
Total		79	482	varies	26,469	varies	3,142,655	86,769

CMS received no comments on the proposed burden estimates and assumptions. In the proposed rule, CMS had estimated the cost associated with case management of PARBs by combining the wage for all of the case management team members into one unit of case management time with the associated wage being the total of wages for the entire case management team to carry out case management ($547.74). This was reflected as 1 hour of burden in the proposed rule. While this intermediate presentation did not ultimately affect the estimate of cost associated with case management, CMS realized that this was not an accurate representation of the true time associated with case management. Case management of each of the 158 PARBs requires 5 hours of work (2 from a pharmacist, 2 from a health technician and 1 from a physician). Therefore, CMS is revising the burden calculations for case management to reflect 5 hours of burden and calculated the case management team's hourly wage, prorated according to the number of hours contributed by each team member ($109.55). CMS is revising the number of hours from 158 to 790 (158 PARBs × 5 hr) as this is more accurate. It should be noted, however, that the total cost estimates associated with case management does not change between the proposed rule and this final rule. CMS is finalizing everything else without modification.

3. ICRs Regarding Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

In this rule, CMS is finalizing the proposed changes to § 423.153(f)(16) to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors as required by section 2006 of the SUPPORT Act. As a result of this requirement, additional beneficiaries will be reported by OMS as PARBs meeting CMS' proposed criteria for having a history of opioid-related overdose. In producing the estimates below, the burden per affected enrollee for case management (5 hr/response), notification of enrollees (10 min/response), and report to CMS (1 min/response) are identical with those estimated in section VIII.B.2. (ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)) of this final rule. That is, the overall burden associated with management of each PARB is the same whether the PARB is identified based on the current clinical guidelines or the updated clinical guidelines which include the criteria for identifying PARBs with a history of opioid-related overdose. The updated clinical guideline criteria to incorporate history of opioid-related overdose increase the total number of beneficiaries identified and included in DMPs. The estimates that follow outline the burden associated with these additional PARBs.

Model beneficiary notices [89] provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, will need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal. CMS estimates it will take no more than 1 hour at $56.34/hr for a health technician to draft and implement such changes. In aggregate, CMS estimates a one-time burden of 288 hours (288 parent organizations × 1 hr/response) at a cost of $16,226 (288 hr × $56.34/hr).

Based on July 2017 through June 2018 opioid-related overdose data, CMS's internal analysis estimates that about 18,268 enrollees meet the criteria of an opioid-related overdose and would be PARBs. All of these PARBs will require case management. Using the wage and cost data outlined for the case management team in Table H4, in aggregate, CMS estimates an annual burden of 91,340 hours (5 hr × 18,268 PARBs) at a cost of $10,006,297 (91,340 hr × $109.55/hr).

In order to estimate the number of beneficiary notices needed to be sent, CMS compared two populations: (1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS estimates as 22,516 PARBs, based on internal data); and (2) beneficiaries with a history of opioid-related overdose (which CMS estimates as 18,268 PARBs, based on internal data). CMS believes the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors, due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event.[90] CMS estimates that about 47.5 percent or 8,677 beneficiaries (18,268 beneficiaries × 0.475) of this population will receive an initial notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Thus, the beneficiary will also receive a second or alternate second notice informing them whether the limitation was in fact implemented. CMS estimates it will take 10 minutes (0.1667 hr) at $56.34/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden of 1,446 hours (8,677 enrollees × 0.1667 hr) at a cost of $81,468 (1,446 hr × $56.34/hr). Evaluation of the use of point-of-sale (POS) claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, CMS does not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, CMS recognizes that this change is projected to approximately double the number of beneficiaries CMS identifies to sponsors as PARBs.

With respect to the reporting of DMP data to CMS for PARBs identified based on history of opioid-related overdose, CMS estimates it will take sponsors (on average) 1 minute (0.0167 hr) at $56.34/hr for a health technician to report in OMS and/or MARx the outcome of case management and any applicable coverage limitations. In aggregate, CMS estimates an annual burden of 305 hours (18,268 PARBs × 0.0167 hr) at a cost of $17,184 (305 hr × $56.34/hr).

Table H6 summarizes the burden associated with the inclusion of PARBs with a history of opioid-related overdose in DMPs.

TABLE H6—SUMMARY FOR IDENTIFICATION OF ADDITIONAL PARBS BASED ON HISTORY OF OPIOID-RELATED OVERDOSE

Regulatory citation	Subject	Number of respondents	Number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Total cost in 1st year ($)	Total cost in subsequent years ($)
§ 423.153(f)(16)	Revise Model Notices	288	288	1	288	56.34	16,226	0
§ 423.153(f)(16)	Conduct Case Management	288	18,268	5	91,340	109.55	10,006,297	10,006,297
§ 423.153(f)(16)	Send Model Notices	288	8,677	0.1667	1,446	56.34	81,468	81,468
§ 423.153(f)(16)	Reporting to CMS	288	18,268	0.0167	305	56.34	17,184	17,184
Total		288	45,501	*Varies*	93,379	*Varies*	10,121,175	10,104,949

We received no comments on our proposed burden estimates and assumptions. In the proposed rule, CMS had estimated the cost associated with case management of PARBs by combining the wage for all of the case management team members into one unit of case management time with the associated wage being the total of wages for the entire case management team to carry out case management ($547.74). This was reflected as 1 hour of burden in the proposed rule. While this intermediate presentation did not ultimately affect the estimate of cost associated with case management, CMS realized that this was not an accurate representation of the true time associated with case management. Case management of each of the 18,268 PARBs identified based on the definition of opioid-related overdose requires 5 hours of work (2 from a pharmacist, 2 from a health technician and 1 from a physician). Therefore, CMS is revising the burden calculations for case management to reflect 5 hours of burden and calculated the case management team's hourly wage, prorated according to the number of

[89] Notice documents available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip.*

[90] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193–1201. doi: 10.1111/add.13774.

hours contributed by each team member ($109.55). CMS is revising the number of hours from 18,268 to 91,340 (18,268 PARBs × 5 hr) as this is more accurate. It should be noted, however, that the total cost estimates associated with case management does not change between the proposed rule and this final rule. We are finalizing everything else without modification.

4. ICRs Regarding Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amended section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs when furnishing an in-home health risk assessment. Section 1852(n)(2) requires CMS to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances. In order to implement the requirements of section 1852(n)(1) for MA plans, CMS revised the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2022, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with section 1852(n)(1), we proposed that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we proposed that MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We proposed that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we did not propose to require MA plans to provide more specific instructions with respect to drug disposal, we did propose that the communication to enrollees would provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also proposed that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html.* We noted in our proposed rule that the safe disposal of drugs guidance at this website can be used for all medications not just medications that are controlled substances. We stated in our proposed rule that we believed that plan communications consistent with the standard on this website would furnish enrollees with sufficient information for proper disposal of controlled substances in their community.

The statute specifically limited this educational requirement to those situations when MA plans elect to perform in-home health risk assessments (HRAs) of MA enrollees. We note that while SNP plans are required to perform enrollee health risk assessments all other MA plan types are not required to perform health risk assessments. In addition, SNPs may conduct HRAs over the phone. Since the performance of in-home heath risk assessment is not a specific requirement for MA plans we do not track or have data on the number of in-home HRAs that MA plans elect to perform. As we will further discuss while there is a burden imposed by the law and our regulation MA plans can almost entirely avoid this burden by choosing to not perform an in-home HRA. As previously discussed the burden for an MA plan when electing to conduct an in-home HRA is that consistent with CMS guidelines as previously described it must develop written guidance for the enrollee and also furnish when possible a verbal summary of the main options for the safe disposal of unused controlled medications.

5. ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

The following changes will be submitted to OMB for approval as a reinstatement under control number 0938–10396 (CMS–1154). We received one comment in response to our proposed changes. A summary of this comment, along with our response, is provided below.

In developing the burden estimates for this final rule, we removed the exclusion of beneficiaries enrolled in the Part D Enhanced MTM model because it will end before 2022, and the deadline for plans to come into compliance with the new Part D MTM program requirements finalized in this rule is January 1, 2022.

Since the inception of the Medicare Part D benefit, the Act has required that all Part D plans offer a MTM program to eligible beneficiaries. The Act also established criteria for targeting beneficiaries for MTM program enrollment and a minimum set of services that must be included in MTM.

Under § 423.153(d), all MTM enrollees must be offered a Comprehensive Medication Review (CMR) at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM, and added a requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees. This final rule modifies our Part D regulations to incorporate those changes to the MTM requirements. The new requirements will affect the number of beneficiaries enrolled in MTM programs and potentially some of the content for the Standardized Format for the CMR and, therefore, the burden. In this regard, we are estimating burden for:

a. The expanded population of beneficiaries that must be targeted for enrollment in MTM programs;

b. Mailing safe disposal information as part of the CMR summary; and

c. Mailing safe disposal information once a year as part of a TMR or other MTM correspondence or service.

a. The Expanded Population of Beneficiaries That Must Be Targeted for Enrollment in MTM Programs

We estimate that in 2022 there will be 50,684,424 beneficiaries enrolled in Part D plans with MTM programs (line 1 of Table H7). According to internal data, we estimate that section 6064 of the SUPPORT Act requires targeting 10,366 ARBs for MTM in 2022 (line 2). Based on our experience with the MTM program, we estimate that 71.8 percent of beneficiaries targeted for MTM under the existing requirements will accept the offer of a CMR (line 3). This number has been updated based on more recent data which became available after the proposed rule was published. We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 7,443 ARBs (line 4) (10,366 targeted ARBs × 0.718) are expected to accept a CMR under the new provision.

To estimate the burden on Part D plans of furnishing CMRs to the 7,443 ARBs who would be expected to accept the offer of a CMR under the final policy, we separately calculate the labor cost of preparing the CMR and packaging it, and the non-labor cost of mailing.

To estimate the labor cost of preparing the CMR, we note that the CMR is a clinical consultation service and therefore must be administered by a pharmacist, physician, nurse practitioner, or other qualified provider. Currently, 100 percent of MTM programs employ pharmacists to conduct CMRs, which is the basis of the hourly rate estimate. Stakeholder comments that were received outside of this rulemaking effort and responded to in a previous collection of information request indicate that an average CMR requires 40 minutes or 0.6667 hours (line 5) at $120.68/hr (line 7) for a pharmacist to complete. This results in an annual labor burden of 4,962 hours (line 6) (7,443 ARBs × 0.6667 hr) at a cost of $598,814 (line 8) (4,962 hr × $120.68/hr).

To estimate the cost of mailing, we note that paper costs $2.50 per ream (500 sheets) of paper (at $0.005 per sheet) and toner costs $50.00 per cartridge and lasts for 10,000 sheets (at $0.005 per sheet). We estimate that the average CMR summary will be 6 pages in length based on revisions which would streamline the Standardized Format; therefore, the paper and printing costs for each CMR summary will be $0.06. Since CMR summaries contain private health information, they must be mailed first class, for which postage costs $0.70 per mailing. Based on industry standards, we assume envelopes cost $0.08 each, while folding and stuffing costs about $0.08 per document. We therefore estimate the non-labor cost to print and mail a CMR summary in CMS's Standardized Format will be $0.92 per mailing (line 9). This results in a cost of $6,848 (line 10) ($0.92 cost per mailing × 7,443 ARBs).

Therefore, we estimate that the total annual cost of providing CMRs to 7,443 ARBs is $605,662 (line 11) ($598,814 labor costs + $6,848 non-labor mailing costs). These figures and calculations are summarized in Table H7. The Line ID column contains identifiers for each row following the flow of logic and calculations. Where applicable, the calculations are described in the ''Source'' column.

TABLE H7—ESTIMATED BURDEN OF TARGETING ARBS FOR MTM

Line ID	Item	Number	Source
(1)	Part D enrollees in 2022	50,684,424	Internal CMS Data.
(2)	Part D enrollees expected to meet the ARB criteria	10,366	Internal CMS data.
(3)	Percent of enrollees under the existing program targeted for a CMR who accept the offer.	71.8%	Internal CMS data.
(4)	ARBs targeted for MTM expected to accept CMR offer	7,443	(2) * (3).
(5)	40 minutes is the industry standard for conducting a CMR	0.6667	Industry data.
(6)	Number of hours needed to fulfill the preparation of CMRs under the new provision including stuffing and mailing.	4,962	(4) * (5).
(7)	Wage for a pharmacist to prepare a CMR	$120.68	BLS Wage data.
(8)	Cost to send CMRs to ARBs under the new provision	$598,814	(6) * (7).
(9)	Non-labor cost of mailing one CMR: 6 pages * ($2.50 * 500 cost per page + $50/10000 cost of toner) + $0.08 stuffing + $0.08 envelope + $0.70 for postage.	$0.92	See narrative.
(10)	Non-labor cost of mailing	$6,848	(8) * (9).
(11)	Total cost for preparing and mailing the CMR to ARBs	$605,662	(8) + (10).

b. Mailing Safe-Disposal Information as Part of the CMR Summary

Under the revisions to § 423.153(d)(1) adopted in this final rule, Part D plans will be required to provide all MTM enrollees with information about safe disposal of prescription medications that are controlled substances. The provision will allow plans to mail the newly required safe disposal information either as part of the CMR summary, a TMR, or other MTM correspondence or service. We estimate the safe disposal information will take one page, may include personal information, and can be mailed out as a standalone correspondence if not included in the annual CMR.

However, for those enrollees receiving a CMR, we believe it will be most economical to include the one page with the already existing CMR summary. We solicited comments regarding this assumption, but did not receive any feedback. Therefore, we are estimating that the cost of mailing one extra page per enrollee is $0.01 (line 21 ([1 page × $2.50/ream of 500 sheets] + [1 page × $50 toner/10,000 sheets]). We note that the envelope to mail the CMR is already being paid for under current regulations (although folding and stuffing of 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost estimate and we did not receive any comments on this assumption); the $0.70 first class postage for 2 ounces is sufficient for 7 pages (there would be no increase in postage).

To estimate total mailing cost, we add the estimates of (i) total number of Part D enrollees who are not ARBs who will receive a CMR under the existing criteria and (ii) total number of ARBs who will receive a CMR under the new criteria we are adopting in this final rule.

As shown in Table H7, lines (1) and (2), we estimate that in 2022 there will be 50,684,424 Part D enrollees and, as previously determined, 10,366 of those

will meet the new MTM targeting criteria, leaving 50,674,058 Part D enrollees (Table H8, line 14) (50,684,424 Part D enrollees minus 10,366 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the existing criteria. Our internal data shows that 6.54 percent (line 15) of Part D enrollees will be targeted for MTM programs under the existing criteria. Hence, this leaves 3,314,083 Part D enrollees (0.0654 * 50,674,058) who will be targeted for MTM under the existing criteria (line 16). Of the 3,314,083 targeted enrollees, as stated previously, based on internal CMS data, we estimate 71.8 percent will accept the annual CMR offer (line 17). Therefore 2,379,512 beneficiaries (3,314,083 * 0.718) will receive a CMR under the existing criteria (line 18).

Hence, in 2022 a total of 2,386,955 enrollees will receive a CMR under the existing and new criteria (7,443 ARBs under the new criteria + 2,379,512 under the existing criteria) (line 20), at a total non-labor mailing cost of $23,870 (2,386,955 enrollees × $0.01 mailing cost per enrollee) to add an additional page containing safe disposal information to all CMRs (line 22).

The figures and calculations are summarized in Table H8.

TABLE H8—ESTIMATED BURDEN FOR MAILING SAFE DISPOSAL INFORMATION AS PART OF THE CMR

Line ID	Item	Number	Source
(12)	Part D enrollees in 2022	50,684,424	(1).
(13)	Enrollees estimated to meet ARB criteria under the new provision	10,366	(2).
(14)	Part D enrollees who do not meet ARB criteria	50,674,058	(12) – (13).
(15)	Percentage of Part D enrollees who meet the existing criteria for MTM	6.54%	Internal CMS data.
(16)	Estimated number of Part D enrollees not meeting ARB criteria who are targeted for MTM under the existing criteria.	3,314,083	(14) * (15).
(17)	Percent of enrollees under the current program targeted for an MTM who accept the offer.	71.8%	Internal CMS data.
(18)	Estimated number of Part D enrollees under the existing criteria who will receive a CMR.	2,379,512	(16) * (17).
(19)	Estimated number of Part D enrollees under the new provision meeting ARB criteria who will elect to receive a CMR.	7,443	(4).
(20)	Total number of Part D enrollees (under the existing and new criteria) who will receive a CMR.	2,386,955	(18) + (19).
(21)	Non-labor costs of one extra page (2.50/500) and toner for one page ($50/10000)	$0.01	See narrative.
(22)	Estimated cost of mailing safe disposal information with a CMR	$23,870	(20) * (21)

c. Mailing Safe Disposal Information Once a Year as Part of a TMR or Other MTM Correspondence or Service

All targeted beneficiaries who have not opted out of the MTM program must receive TMRs at least quarterly, and we are allowing Part D sponsors the flexibility of choosing whether to include safe disposal information in the CMR, through a TMR or other MTM correspondence or service at least once annually. Since we assume that 71.8 percent of targeted enrollees accept an offer of a CMR (Table H7, line 3), it follows that 28.2 percent (100 percent–71.8 percent) (Table H9, line 26) of Part D enrollees who are targeted for enrollment in an MTM program refuse the CMR offer but do not opt out of the MTM program completely. As discussed previously, 10,366 ARBs (Table H7, line (2)) under the new criteria and 3,314,083 enrollees (Table H8, line (16)) under the existing criteria, for a total of 3,324,449 enrollees (3,314,083 + 10,366) (line 25) will be targeted to receive a CMR. Therefore 937,495 enrollees (3,324,449 total enrollees × 0.282 who refuse a CMR) would need to be mailed the safe disposal information as part of a TMR or other MTM correspondence or service (line 27). For purposes of calculating the burden, we are assuming that any safe disposal information that is not included in a CMR is either (i) being mailed in a TMR, which may be as short as one page and may contain private health information or (ii) is mailed as a stand-alone document which does not contain any private health information. For purposes of impact, (i) if one additional page is included in the TMR, then there is no additional postage; (ii) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data in regard to what percentage of safe disposal information will be mailed as a CMR, TMR, or other MTM correspondence or service, we are assuming the maximum amount, which is that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage. The cost to mail one page of safe disposal information is $0.01095 per enrollee if the letter does not contain private health information and thus bulk mailing is used (line 28) [1 page × $2.50 per ream of paper/500 sheets] + [1 page × $50 per toner/10,000 pages] + [$0.19/200 items]). Therefore, we estimate that the cost of mailing safe disposal information to those MTM enrollees who do not receive it in a CMR summary is $10,266 (line 29) (937,495 enrollees × $0.01095 mailing cost per page).

These calculations are summarized in Table H9.

TABLE H9—BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO ENROLLEES NOT RECEIVING A CMR

Line ID	Item	Number	Source
(23)	The number of Part D enrollees who meet the existing criteria for MTM	3,314,083	(16).
(24)	The number of Part D enrollees who meet the criteria for ARB under the new provision.	10,366	(2).
(25)	The number of Part D enrollees meeting existing or new criteria for being targeted for a CMR.	3,324,449	(23) + (24).
(26)	The percentage of enrollees estimated to refuse the offer of a CMR (100–87%)	28.2%	100% – (17).

TABLE H9—BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO ENROLLEES NOT RECEIVING A CMR—Continued

Line ID	Item	Number	Source
(27)	Number of enrollees to whom safe disposal information must be mailed even though they don't receive a CMR.	937,495	(25) * (26).
(28)	Non-labor cost of mailing a one page correspondence (at $2.50/500 cost per page + $50/10,000 cost of toner for one page + $0.19/200 cost of bulk mailing).	$0.01095	See narrative.
(29)	Cost of mailing safe disposal information to those who do not receive a CMR	$10,266	(27) * (28).

d. Summary for Eligibility for MTMPs and Information on the Safe Disposal of Prescription Drugs

As discussed in section (b) (Table H8, line (22)), we estimate a cost of $23,870 for mailing safe disposal information to those beneficiaries receiving a CMR (under the assumption that the plan will bundle the safe disposal and CMR). In section (c) (Table H9, line 29), we estimate a total cost of $10,266 for mailing safe disposal information to those beneficiaries who do not receive a CMR. Thus, the total cost of mailing safe disposal information to all Part D beneficiaries enrolled in MTM programs is estimated to be $34,136. This is summarized in Table H10.

TABLE H10—BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO BENEFICIARIES ENROLLED IN MTM PROGRAMS

Line ID	Item	Number	Source
(30)	Estimated cost of mailing safe disposal items to those receiving a CMR (under assumption that the plan will bundle the safe disposal and CMR).	$23,870	(22).
(31)	Cost of mailing safe disposal to those who do not receive a CMR	10,266	(29).
(32)	Total cost of mailing safe disposal information	$34,136	(30) + (31).

The total additional annual cost for 288 parent organizations to provide CMRs to ARBs and to send information on safe disposal of prescription medications that are controlled substances to all MTM program enrollees is $663,668. Table H11 provides a compact summary of the bottom lines of impact by activity.

TABLE H11—SUMMARY FOR ELIGIBILITY FOR MTMPS (§ 423.153) AND INFORMATION ON THE SAFE DISPOSAL OF PRESCRIPTION DRUGS

Regulatory citation	Subject	Number of respondents	Number of responses	Time per response (hr)	Total annual time (hr)	Non labor cost for mailing ($)	Labor cost ($/hr)	Total annual cost ($)
§ 423.153	Targeting ARBs for CMR	288	7,443	0.6667	4,962	N/A	120.68	598,814
§ 423.153	Mailing ARBs CMR	288	7,443	N/A	N/A	6,848	N/A	6,848
§ 423.153	Safe Disposal Page in CMR	288	2,386,995	N/A	N/A	23,870	N/A	23,870
§ 423.153	Safe Disposal Page as part of TMR or other MTM correspondence or service.	288	937,495	N/A	N/A	10,266	N/A	10,266
Total		288	3,339,376	Varies	4,962	40,984	Varies	639,798

As indicated above, one PRA-related comment was received. The following summarizes the comment and sets out our response.

Comment: CMS received a comment stating that the percent of Part D enrollees who accept the offer of a CMR (87 percent) was overestimated.

Response: We appreciate the comment and have updated our estimate based on more recent data. We are now estimating the acceptance rate of a CMR to be closer to 71.8 percent in 2022.

As previously stated, we updated our estimates to no longer exclude beneficiaries enrolled in the Part D Enhanced MTM model because the model will end before 2022, and the deadline for plans to come into compliance with the new Part D MTM program requirements finalized in this rule is January 1, 2022. We also updated the estimates for enrollment and CMR rates based on more current data. We did not receive any comments in response to our estimates regarding the cost of mailing a CMR with information on safe disposal of prescription drugs, nor did stakeholders object to our assumption that the distribution of information on safe disposal of prescription drugs would be most economically distributed as part of the CMR summary.

6. ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

With regard to our proposed changes, comments were received and are responded to below.

In this rule, § 423.128 will require Part D sponsors to disclose, beginning in 2022, information about the risks of prolonged opioid use to enrollees. In addition to this information, Part D sponsors of MA–PDs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Part C. Part D sponsors of PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Before Part D sponsors can send this information, they would have to create

and upload materials into their internal systems. Based on 2019 CMS data, there are 608 Part D legal entities (sponsors) with which CMS contracts, associated with 288 parent organizations that these contracts identified in their initial applications, which is confirmed annually. Based on our knowledge of the way parent organizations and their Part D legal entities are structured, we believe it is appropriate to estimate burden at the parent organization level, as it is a closer reflection of the number of systems that will need to be updated versus at the contract level.

We estimate that 288 Part D sponsors would be subject to this requirement, based on 2019 data. We estimate a one-time burden of 2 hours at $120.68/hr for a pharmacist to develop the materials(s) to be sent to the beneficiaries. In aggregate, we estimate a one-time burden of 576 hours (288 parent organizations × 2 hr) at a cost of $69,512 (576 hr × $120.68/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), we believe the burden to making such updates to existing materials will be negligible as the changes will be minor and may only occur in some future years. Hence, the more accurate approach adopted here is to estimate this as a one-time update.

We also estimate that it will take on average 2 hours at $89.06/hr for a computer programmer to upload the information into the systems. This would result in a one-time burden of 576 hours (2 hr × 288 parent organizations) at a cost of $51,299 (576 hr × $89.06/hr). Once the information is uploaded into the parent organization's database, we anticipate no further burden associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The automation will include the sending of information to those enrollees who wish to receive an electronic copy. The automation will also cover updates in future years as the plan enrollment changes.

We proposed that Part D sponsors be permitted to disclose the opioid and coverage information in electronic form. Some enrollees preferred electronic notification and some preferred paper mailing. We had no way of estimating the proportions for each preference, but our experience suggests that most enrollees expect a paper mailing. Therefore, we assumed 75 percent (the average of 50 percent and 100 percent) would prefer a paper mailing, while the remaining 25 percent would prefer electronic notification.

There are several Part D enrollee groups presented in section III.D. of this final rule that we suggested could be sent the required information and thus, several approaches to estimate the burden. These enrollee group estimates ranged from sending the information to 2,698,064 to 46,759,911 enrollees.

In making estimates on the burden of sending out notices, we assumed that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs are paper, toner, and postage. We also assumed one page per notice. We therefore estimate:

- *Cost of paper:* Typical wholesale costs of paper are approximately $2.50 for a ream of 500 sheets. The cost for one page is $0.005 ($2.50/500).
- *Cost of toner:* Toner costs can range from $50 to $200 and each toner cartridge can last from 4,000 to 10,000 sheets of paper. In this rule, we assume a cost of $50 for 10,000 pages. In that regard, the cost per page is $0.005 ($50/10,000 pages).
- *Cost of postage:* Currently, the bulk postage rates are $0.19 per 200 pages. The cost per page is $0.00095 ($0.19/200 pages).

Thus, the aggregate cost per page is $0.01095 ($0.005 for paper + $0.005 for toner + $0.00095 for postage). Note that mailing costs are annual while the programming updates and the development of materials are first-year costs with minimal or no costs in future years. The product of the cost per page (at $0.01095) times the number of enrollees (35,069,933) plus the one time first year costs $120,811 ($51,299 + $69,512) equals $504,827 ([$0.01095 × 35,069,933 enrollees] + $120,811) as shown in Table H12.

TABLE H12: IMPACTS FOR PROVIDING INFORMATION TO OPIOID USERS

Item Description	Number of respondents	Number of Responses	Time per response (hr)	Total time (hr)	Non Labor Costs for mailing ($)	Labor cost ($/hr))	First year cost ($)	Cost in subsequent years ($)
Programming	288	288	2	576	NA	89.06	51,299 (Labor)	N/A
Pharmacist development of the materials	288	288	2	576	NA	120.68	69,512 (Labor)	N/A
75% of All Part D enrollees who are estimated to want paper	288	35,069,933	N/A	N/A	384,016	N/A	384,016 (Non Labor)	384,016 (Non Labor)
Total	288	35,070,509	varies	1,152	384,016	Varies	504,827	384,016

The following summarizes the PRA-related public comments that we received and sets out our response to those comments. We are finalizing our proposed provisions, burden estimates, and assumptions without change.

Comment: We received two comments that suggested a specific subset to send this information to. The commenters also recommended focusing on any beneficiary who received an opioid fill in the last 7 days, but also appreciated the flexibility provided in this rule.

Response: We thank the commenters for their feedback. Although some commenters offered their opinion on the subset that might be the best group to receive the information, there was no consensus to inform sponsors' ultimate decisions on a specific enrollee population. Because there was no consensus, CMS will continue to maintain flexibility for plans and therefore are not committing to any specific approach.

7. ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

The following changes will be submitted to OMB for approval under control number 0938–1383 (CMS–10724) for Medicare Advantage Plans and 0938–1262 (CMS–10517) for Part D Plans.

Sections 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) will require the MA organization or Part D plan sponsor, respectively, to have procedures to identify and report to CMS or its designee: (1) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and (2) any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

CMS initiated a reporting pilot program in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste, and abuse. The pilot collected all external or internal Medicare complaints and referrals submitted to the plan's Special Investigations Unit (SIU). The data collected as part of the pilot program was time limited, but broader than the scope of reporting required by sections 2008 and 6063 of the SUPPORT Act. The scope of that pilot tested the reporting of all types of health care fraud, waste, and abuse that the plan sponsors could encounter in their operations and, therefore, could be utilized as a reasonable estimate of burden involved with the quarterly plan reporting to CMS that CMS will use to implement sections 2008 and 6063 of the SUPPORT Act. The pilot program analyzed information that was reported from five of six plan participants on time spent collecting three quarterly data submissions. Based on the results of the pilot study, if every Part C plan reported, we estimate it will take 605 MA plans 149,435 hours (605 plans * 247 hr/plan) at a cost of $13,730,088 (149,435 hr * $91.88/hr for a management analyst using 2019 BLS wage estimates) to fulfill the reporting and procedure preparation in the first year as shown in Table H13. In subsequent years, we estimate an annual burden of 94,380 hours (605 plans *156 hr/plan) at a cost of $8,671,634 (94,380 hr * $91.88/hr) as shown in Table H13.

Based on the results of the pilot study, if every Part D plan reported, we estimate it will take 63 Part D plans 15,561 hours (63 plans * 247 hr/plan) at a cost of $1,429,745 (15,561 hr * $91.88/hr) to fulfill the reporting and procedure preparation in the first year as shown in Table H14. In subsequent years, we estimate an annual burden of 9,828 hours (63 plans * 156 hr/plan) at cost of $902,997 (9,828 hr * $91.88/hr) as shown in Table H14.

The first-year burden consist of the time and effort needed to prepare the procedures and report the inappropriate prescribing information. Subsequent effort consists solely of the ongoing time and cost to report the inappropriate prescribing information to CMS. We could not anticipate how many plans will need to report any payment suspension to pharmacies in the plans' network or information on inappropriate opioid prescribing to CMS.

TABLE H13: MA ORGANIZATION BURDEN ESTIMATES

Regulatory Citation	OMB Control Number	Response Summary	Total Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
§ 422.503(b)(4)(vi)(G)(*4*)	0938-1383	Report fraud and abuse	605	605	247	149,435	91.88	13,730,088	0
§ 422.503(b)(4)(vi)(G)(*4*)	0938-1383	Report fraud and abuse	605	605	156	94,380	91.88	0	8,671,634
TOTAL*			605	1,210	varies	243,815	91.88	13,730,088	8,671,634

TABLE H14: PART D PLAN SPONSOR BURDEN ESTIMATES

Regulatory Citation	OMB Control Number	Response Summary	Total Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
§ 423.504(b)(4)(vi)(G)(*4*)	0938-1262	Report fraud and abuse	63	63	247	15,561	91.88	1,429,745	0
§423.504(b)(4)(vi)(G)(*4*)	0938-1262	Report fraud and abuse	63	63	156	9,828	91.88	0	902,997
TOTAL			63	126	varies	25,389	91.88	1,429,745	902,997

We received no comments on our proposed provisions, burden estimates, and assumptions. Consequently, we are finalizing without change.

8. ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

The following changes will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262). Subject to renewal, the control number is currently set to expire on April 30, 2022.

As described in section IV.G. of this final rule, the new paragraphs at § 423.128(d)(4) and (5) require each Part D plan to implement a beneficiary RTBT no later than January 1, 2023. This tool will allow enrollees to view the information included in the prescriber RTBT system which includes complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). Plans will be able to use existing secure patient portals to fulfill this requirement, to develop a new portal, or to use a computer application.

In estimating the cost impact of this provision it is important to bear in mind that the rewards and incentives are optional for each Part D sponsor. Additionally, based on our conversations with the industry, participation on industry workgroups, and research, we understand that most Part D plans have already created beneficiary portals that satisfy existing privacy and security requirements. We believe that the few plans that have yet to create a portal or web application will have one in place by January 1, 2023. Finally, some Part D Sponsors who wish to use such a portal may find it cheaper to rent an existing portal from a third party vendor. Consequently, the impacts below are maximum impacts; they overestimate the impact of the provision by assuming that all Part D sponsors must create a completely new RTBT.

We estimate it will take 104 hours at $89.06/hr for a computer programmer to program this information into the beneficiary portal and an additional 52 hours to put this information into a user interface that is easily understood by enrollees. The time estimates are based on consultation with the healthcare industry and their IT staff to determine the time that it takes for minor changes in programming. Thus, the burden for implementing RTBT is 44,928 hours (288 organizations * 156 hr) at a cost of $4,001,288 (44,928 hr * $89.06/hr).

This is a maximum one-time first year cost. We are not estimating ongoing maintenance costs because: (1) Many plan sponsors already have a beneficiary portal and (2) the total maintenance costs per plan sponsor tend to be stable from year because although there is variation in what software needs maintenance, some software needs more usage, some needs less, and some needs routine. The average absorbs and stabilizes this variability. Adding one more software cost that is not excessively above the average would not change that average beyond rounding or uncertainty error.

We next estimated the cost of implementing the rewards and incentives program for use of RTBT. We estimated three items: (A) Development of policies for the new program, (B) updating of systems, and (C) maintaining the program. We solicited stakeholder feedback on all of our proposed assumptions. We informally questioned stakeholders who believe that only 10 percent of parent part D sponsors would create such a program. Since there are 288 Part D sponsors we expect 29 (288 * 0.10) organizations to develop and use a reward and incentive program.

(A) *Development of policy:* We estimate that for each parent organization an operations manager and compliance officer working together at a combined hourly wage of $188.36/hr ($118.30/hr + $70.06/hr) would take 40 hours. Therefore, the impact is 1,160 hours (40 hr * 29 parent organizations) at a cost of $218,498 (1,160 hr * $188.36/hr).

(B) Since systems already exist to collect enrollee data, they will only have to be updated to collect data on use of RTBT and most of this work will be done when creating the RTBT. We therefore estimate, per parent organization, an extra 40 hours for a computer programmer. Therefore, the impact is 1,160 hours (40 hr * 29 organizations) at a cost of $103,310 (1,160 hr * $89.06/hr).

(C) We estimate that 2 administrative support workers each working at $36.82/hr will take 15 hours every month to maintain the program. The impact is 10,440 hours (15 hr/month * 12 months * 2 workers * 29 organizations) at a cost of $384,401 (10,440 hr * $36.82/hr).

The aggregate impact for implementing the rewards and incentives for RTBT among those Part D sponsors who wish to do so is 57,688 hours (44,928 hr + 1,160 hr + 1,160 hr

+ 10,440 hr) at a cost of $4,707,497 ($4,001,288 + $218,498 + $103,310 + $384,401).

Since plans are in the best position to estimate their implementation costs, we solicited comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility for enrollees. In addition, because plans are in the best position to estimate any information collection implications, since they will be the stakeholders implementing this provision, we solicited comment on any other potential information collection implications. We received no comments on our proposed provisions and burden estimates. Consequently, we are finalizing them without change.

9. ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

The following changes will be submitted to OMB for approval under control number 0938–0992 (CMS–10185). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 7, 2018, and remains active.

This rule amends § 423.514(a) by giving CMS the authority to collect Part D sponsors' pharmacy performance measures data that is used to evaluate pharmacy performance, as established in their network pharmacy agreement. Given the growing practice of Part D sponsors measuring the performance of pharmacies that service Part D beneficiaries to determine the final cost of a drug under Part D, this reporting requirement will enable CMS to monitor the impact of these recoupment practices. We estimate a collection of less than 15 data elements. As noted in section IV.G of this final rule, the Part D reporting requirements data elements, consistent with our standard, will be specified through the standard non-rule PRA process after publication of this final rule. The standard non-rule process includes the publication of 60- and 30-day **Federal Register** notices. At that time, the data elements, timeline, and method of submission will be made available for public review and comment.

Although the data elements will be made available for public review through the standard PRA process, we are providing the interested parties with an initial projection of the potential burden estimates. In this regard there are currently 627 contracts that would be required to report their pharmacy performance measures' data. Part D sponsors currently report 6 sections of data to CMS in accordance with the Part D reporting requirements. Therefore, CMS does not expect compliance to these reporting requirements will result in additional start-up costs. Anticipated staff time spent performing these data collection activities would be 30 minutes for a data analyst and/or IT analyst at a rate of $92.46/hr. We will require this information to be reported at the plan level once annually. Reporting at the plan level would generate 5,234 responses since there are currently 5,234 plans. In aggregate, we estimate an annual plan sponsor burden of 2,617 hours (5,234 plans × 1 report/year × 0.5 hr/report) at a cost of $241,968 (2,617 hr × $92.46/hr). We solicited input from stakeholders on the accuracy of these estimates and on any measures that CMS could take to decrease the burden of this provision. The following comment was received.

Comment: We received one comment stating that we had underestimated the financial burden of Part D plans reporting their pharmacy collection measures.

Response: We appreciate the comment. However, we believe that based on current wages from the Bureau of Labor Statistics, and from our long current history of collecting other Part D plan reporting requirements, that our burden estimate is fair and reasonable.

We did not receive any other comments related to the projected burden for this provision. As a result, we are finalizing our proposed provisions and burden without change.

10. ICRs Regarding PACE

Subsequent to the publication of the proposed rule, we revised the burden estimates in this final rule by: (1) Incorporating service determination request (formerly ''service delivery request'') data from 2019 PACE audits which was not available at the time the estimates were published in the proposed rule, (2) updating enrollment data from 40,040 participants to 42,800 participants based on 2017–2019 enrollment data from the CMS Office of the Actuary (OACT), (3) updating PACE organization contract data from 131 PACE organizations to 133 PACE organizations based on data from the Health Plans Management System (HPMS), and (4) updating wage figures based on May 2019 BLS data.

The following changes in subsections 10a through 10e will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

a. ICRs Regarding Service Determination Request Processes Under PACE (§§ 460.104 and 460.121)

Section 460.121(i)(2) will require that PACE organizations provide written notification to participants when the interdisciplinary team extends the timeframe for processing service determination requests. Based on our experience with PACE audits during 2017, 2018, and 2019, during which time we reviewed all operating PACE organizations at least once, we found a total of 30,173 service determination requests. The average total PACE enrollment during that same period was 42,800. Thus the average number of service determination requests per 1,000 enrollees was 705 (30,173/42,800). This service determination request ratio or intensity (705 service determination requests per 1,000 enrollees) is used to estimate the number of service determination requests PACE organizations will receive from 2022–2024. The service determination request ratio is an intuitive way of capturing the rate of service determination requests per thousand enrollees and is used to estimate the burden associated with service determination requests for 2022–2024.

Based on the same audit experience and data collected, we further estimate that:

- Approximately 10.16 percent of all service determination requests currently received are extended, and
- Of those 705 service determination requests currently received per 1,000 enrollees, 77.53 percent are approved (546.6 requests per 1,000 enrollees), while 22.47 percent are denied (158.4 requests per 1,000 enrollees).

With respect to the final service determination request requirements in the new § 460.121, we estimate that half of all approved service determination requests (that is, 50 percent of the 546.6 approved requests per 1,000 enrollees or 273.3 requests per 1,000 enrollees) could be approved in full by an IDT member at the time the request is made. Because those approval decisions could be made immediately, extension notifications would not be needed for those service determination requests.

Therefore, the requirement to provide written notification when a service determination request is extended will apply to:

- The 2.28 percent of service determination requests which are extended and subsequently denied (22.47 percent of service determination requests that are denied * 10.16 percent of service determination requests that are extended); and

• The 3.94 percent of service determination requests that are approved and not routine (that is, a member of the IDT cannot approve the service determination request in full at the time the request is made) and are extended (77.53 percent of service determination requests that are approved * 50 percent of requests that are not routine * 10.16 percent of requests that are extended).

Thus the requirement will apply to 6.22 percent (2.28 percent of denied service determination requests and 3.94 percent of approved service determination requests) of all service determination requests. Based on OACT estimates, the average projected PACE enrollment for 2022–2024 is 53,549 per year or an increase of 10,749 enrollments from 2017–2019 (53,549 − 42,800). The multiplication of the estimated 2022–2024 PACE enrollment (53,549 enrollees) by the current service determination request intensity of 705 per 1,000 enrollees gives a reasonable estimate of the number of service determination requests PACE organizations will receive for 2022–2024. Based on our audit experience, we estimate that it would take the IDT approximately 1 hour to prepare and issue notification of the extension to a participant or the designated representative.

Consequently, the total annual burden for providing written notification to participants when the interdisciplinary team extends the timeframe for processing service determination requests in accordance with § 460.121(i)(2) is 2,350 hours (705 requests per 1,000 enrollees × 53,549 projected enrollment for 2022–2024 × 6.22 percent of requests that require extensions × 1 hour to process each service determination request extension) at a cost of $133,997 (2,350 hr × $57.02/hr for a Master's-level Social Worker (MSW) (BLS: Healthcare social worker) to process them).

To meet the notification requirements finalized in § 460.121(i)(2), we expect most PACE organizations will develop a template letter to notify the appropriate parties of an extension. We estimate a burden of 1 hour at a cost of $70.06/hr for a compliance officer (quality improvement coordinator) to create an extension letter template.

In addition to the one-time burden associated with creating an extension letter template, we also anticipate a one-time burden associated with the requirements we are finalizing in § 460.121(j)(2), which clarify the required content of denial notifications. As a result of these requirements, we expect that PACE organizations will need to revise their denial notification letter templates. We estimate a burden of 1 hour at a cost of $70.06/hr for a compliance officer (quality improvement coordinator) to revise any existing denial letter templates.

In aggregate, for the development and revision of both the extension notification and denial notification, we estimate it will take of 2 hours at $70.06/hr for a compliance officer (quality improvement coordinator) to create and revise the materials. We estimate a one-time burden of 266 hours (133 PACE organizations × 2 hr) at a cost of $18,636 (266 hr × $70.06/hr).

We received no comments on our proposed burden estimates in §§ 460.121 and 460.104. In this final rule, we revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) Service determination request data from 2019 PACE audits, (2) 2017–2019 enrollment data, (3) PACE organization contract data, and (4) wage data. Based on this updated data, we have revised the burden estimate for service determination request extension notification in new § 460.121(j)(2), which resulted in a decrease of 578 hours (from 2,928 hr to 2,350 hr) and $30,615 (from $164,612 to $133,997) from the proposed rule. We have also revised the burden estimate for service determination request denial notification requirements in new § 460.121(i)(2), which resulted in an increase of 4 hours (from 262 hr to 266 hr) and $369 (from $18,267 to $18,636) from the proposed rule.

b. ICRs Regarding Appeals Requirements Under PACE (§§ 460.122 and 460.124)

Section 460.122 currently states the requirements for implementing an appeals process in PACE. In this rule we are finalizing requirements for PACE organizations to develop and distribute written materials that will explain the PACE requirements to the third party reviewers that are responsible for making appeal determinations. Additionally, we are finalizing requirements for appeal decision notifications, which we expect will require PACE organizations to revise their current appeal notification materials.

For the development and distribution of materials to the third party reviewer, we estimate it will take 4 hours at $70.06/hr for a compliance officer (quality improvement coordinator) at each PACE organization to create and distribute these materials (3 hr to create and 1 hr to distribute). For the revision of the written appeal notices, we estimate it will take 1 hour at $70.06/hr for a compliance officer (quality improvement coordinator) at each PACE organization to revise the current notices.

In aggregate, we estimate a one-time burden of 665 hours [133 PACE organizations * (4 hr + 1 hr)] at a cost of $46,590 (665 hr * $70.06/hr).

We received no comments on our proposed burden estimates for this provision. In this final rule, we revised the burden estimate for developing and distributing written materials to third party reviewers using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimate includes: (1) 2017–2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated service determination request data was not utilized to revise this burden estimate since the data does not impact appeals notifications. Based on the updated data, we have revised the burden estimate for this provision which resulted in an increase of 10 hours (from 655 hr to 665 hr) and $923 (from $45,667 to $46,590) from the proposed rule.

c. ICRs Regarding Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

As discussed in section VI.D. of this final rule, we are amending § 460.98(b)(5) in part to require PACE organizations to document, track and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care.

We estimate a one-time burden of 50 hours at $56.34/hr for technical staff at each PACE organization to develop the necessary procedures and written materials. We estimate a one-time burden of 6,650 hours (133 PACE organizations * 50 hr) at a cost of $374,661 (6,650 hr * $56.34/hr) for the first year. Since PACE organizations are currently required to document all services furnished in the medical record in accordance with § 460.210(b)(2), we believe the one-time burden of 50 hours is a reasonable estimate for developing the necessary procedures and written materials to document, track, and monitor the provision of services.

We also estimate this provision will result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about the documentation, tracking and monitoring of services,

based on our experience monitoring and auditing PACE organizations.

As discussed above, PACE organizations are already required to document services furnished in the participant's medical record; however, PACE organizations will need to devote time to monitoring and tracking the provision of services. We therefore estimate a burden of 50 hours at $56.34/hr for technical staff to complete these activities, including, when warranted, revision of the aforementioned program procedures and monitoring measures. We estimate an annual burden of 6,650 hours (133 PACE organizations * 50 hr) at a cost of $374,661 (6,650 hr * $56.34/hr).

In aggregate, we estimate a burden of 13,300 hours (6,650 hr + 6,650 hr) at a cost of $749,322 ($374,661 + $374,661) for the first year of implementation. In subsequent years, we estimate a burden of 6,650 hours at a cost of $374,661 for the ongoing documentation, monitoring and tracking of services.

We received the following comments on the estimated burden for this provision.

Comment: The majority of commenters expressed concern with to the use of the term ''track.'' These commenters suggested that requiring a PACE organization to track the provision of services could imply that PACE organizations would be required to establish and maintain specific logs, universes or data sets, and that such a requirement would potentially increase burden and conflict with CMS' Patients Over Paperwork initiative.

Response: As we discussed in greater detail in section VI.D. of this final rule, we understand from commenters' concerns that the use of the word ''track'' could be interpreted to suggest that PACE organizations would be required to maintain a real time ''log'' of services which could potentially be burdensome to implement. As we stated in the proposed rule, we believe that PACE organizations should document that a service has been ordered as well as when and how the approved service was provided. It was not our intention in the proposal to dictate how an organization implements this provision, and we agree with the commenter that PACE organizations should have flexibility in how they operationalize the requirement to track, monitor and document the provision of services. We expect that PACE organizations will create their own methods for tracking and monitoring services. We note that while commenters expressed concerns regarding the potential burden, no one commented on our estimates related to the burden. We believe this indicates that we were accurate in predicting the potential burden associated with this provision.

Therefore, in this final rule, we did not revise the estimates based on comments received, but revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) 2017–2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated service determination request data was not utilized to revise this burden estimate since the data does not impact documenting and tracking the provision of services. Based on the updated data, we have revised the first year burden estimate for this provision which resulted in an increase of 200 hours (from 13,100 hr to 13,300 hr) and $82,532 (from $666,790 to $749,322) from the proposed rule. We have also revised the ongoing burden estimate for this provision which resulted in an increase of 100 hours (from 6,550 hr to 6,650 hr) and $41,266 (from $333,395 to $374,661) from the proposed rule.

d. ICRs Regarding Documentation in Medical Records Under PACE (§ 460.210)

Subsequent to the publication of our proposed rule and based on public comment, this final rule revises the proposed requirements in § 460.210(b)(6) to require PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following: (i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both and (ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

Section 460.210 currently sets out the requirements relating to medical records for PACE participants. This includes the minimum content of participant medical records. Under § 460.210(b) of this final rule, CMS requires PACE organizations to maintain additional information and documentation in the medical record, including documentation of all recommendations for services made by employees or contractors of the PACE organization, the reasons for not approving or providing any service recommended by an employee or contractor of the PACE organization, and original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant.

We expect that PACE organizations will have to revise their policies and procedures and re-train staff on the new requirements. We believe that a compliance officer (quality improvement coordinator) will be responsible for ensuring the necessary materials are updated and that staff are trained. For revising materials and training staff, we estimate a one-time burden of 10 hours at $70.06/hr for a compliance office (quality improvement coordinator) to revise materials and lead training. Therefore, the one-time burden to implement this provision is 1,330 hours (133 PACE organizations * 10 hr) at a cost of $93,180 (1,330 hr * $70.06/hr).

We also estimate this provision will result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about medical record documentation. These assumptions are based on our monitoring and oversight experience.

Each of the new requirements discussed above may require the involvement of any IDT occupation. Therefore, to determine the cost associated with this provision, we took the wages for the full IDT ($846.48/hr) and divided it by the 11 occupations included in the IDT (see Table H15) to determine an average wage of $76.95/hr ($846.48/hr/11 occupations). We believe this is the most accurate estimate as it will be unlikely all occupations will be working on the medical record at the same time, and we are unable to estimate how much any one occupation will work in comparison to the other occupations.

In the proposed rule, we estimated that the proposed requirement to maintain original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, would not create a significant burden, as organizations would only be required to store existing documentation within a medical record. Therefore, we estimated that the burden for this part of the provision would be 5 hours per PACE organization or 665 total hours (5 hr * 133 organizations) at a cost of $51,172 (665 hr * $76.95/hr).

Following publication of the proposed rule, while we did not receive any comments specific to our burden

estimates for this requirement, we did receive general comments that expressed concern regarding the potential burden associated with storing written communications in a participant's medical record. Based on these comments, we believe we underestimated the burden for this provision. In response to comments received we revised the requirements at § 460.210(b)(6) to permit PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant. This change means that PACE organizations would be required to maintain all covered written communications in § 460.210(b)(6)(i) and (ii), but that they can be maintained in either their original form or as an unaltered electronic copy. In addition to revising the regulatory text to permit PACE organizations to maintain unaltered electronic copies of affected written communications, we are also revising our burden estimates for § 460.210(b)(6). In this final rule, we estimate that the burden for maintaining original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant will be 10 hours per PACE organization or 1,330 total hours (10 hr * 133 organizations) at a cost of $102,344 (1,330 hr * $76.95/hr). This burden is an ongoing burden in all years.

This final rule at § 460.210 also requires a PACE organization to document all recommendations for services from employees or contractors of the PACE organization, including specialists, and require PACE organizations to document the reasons a service recommended by an employee or contractor of the PACE organization is not approved or provided .We considered several factors when determining the burden associated with these provisions. First, PACE organizations are already required under § 460.104(b)(1) to document the rationale for not providing services in developing the plan of care; therefore, this provision will only apply to services recommended following the initial development of the plan of care. Second, PACE organizations will only have to document the rationale under § 460.210(b)(5) when the PACE organization does not approve or provide a recommended service, so there will be no additional burden in situations where the PACE organization approves or provides a recommended service. Considering these two factors, we determined that each PACE organization will have to spend approximately 52 hours (approximately 1 hr per week) to implement this part of the regulation. Therefore, we estimate a total of 52 hours per organization per year, or a total of 6,916 hours (52 hr * 133 organizations) at a cost of $532,186 (6,916 hr * $76.95/hr).

We therefore estimate the total ongoing burden of all aspects of this provision at § 460.210 to be 8,246 hours (1,330 hr + 6,916 hr) at a cost of $634,530 ($102,344 + $532,186).

TABLE H15—WAGES FOR IDT STAFF MEMBERS

Occupation title	Occupation code	Adjusted wage * ($/hr)
Dietician	29–1031	59.94
Driver (Passenger Vehicle Driver)	53–3058	31.94
Home Care Coordinator (often a RN)	29–1141	74.48
Masters of Social Work	21–1022	57.02
Occupational Therapist	29–1122	82.90
PACE Center Manager (Medical and Health Services Manager)	11–9111	110.74
Personal Care Attendant	31–1120	25.42
Physical Therapist	29–1123	86.70
Primary Care Provider	29–1216	193.70
Recreational Therapist	29–1125	49.16
Registered Nurse	29–1141	74.48
Total		846.48
Average IDT Cost Per Hour (846.48/11 occupations)		76.95

* See section VIII.A. of this final rule for additional wage information.

We received the following comments on the estimated burden resulting from this provision in the proposed rule.

Comment: Commenters expressed concerns that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format in the medical record would increase burden for PACE organizations as well as increase burden on providers that may be responsible for transferring these communications to the medical record. As a solution, these commenters recommended permitting PACE organizations to scan written documentation and copy and paste communications received via email or text into electronic medical records.

Response: In response to commenters' concerns, we reviewed our initial burden estimate and determined that we had underestimated the burden for maintaining this documentation in its original format within the medical record. We increased the burden estimate in the final rule accordingly. In determining what an appropriate estimate for this provision would be, we considered both that we may have underestimated the original burden in the proposed rule, as well as the additional operational flexibility that we are allowing for in the final rule, as discussed in greater detail in section VI.F. of this final rule. Given these two factors, we estimate that the burden for maintaining original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant will be 10 hours per PACE organization instead of the 5 hours we initially proposed.

In this final rule, we revised the burden estimate for these provisions using updated data previously discussed in the introductory paragraph to section VIII.B.10. of this final rule. The updated data used to revise the burden estimates includes: (1) 2017–2019 enrollment data, (2) PACE organization contract data, and (3) wage data. Updated service determination request data was not utilized to revise this burden estimate since the data does

not impact medical record documentation. The estimates were also revised to account for additional burden for the requirements in § 460.210(b)(6). Based on this updated data, we have revised the burden estimate for revising materials and training related to the changes in this provision which resulted in an increase of 20 hours (from 1,310 hr to 1,330 hr) and $1,847 (from $91,333 to $93,180) from the proposed rule. We have also revised the burden estimate for the ongoing implementation of this provision which resulted in an increase of 910 hours (from 7,336 hr to 8,246 hr) and $75,453 (from $559,077 to $634,530) from the proposed rule.

e. ICRs Regarding PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed above in section VI.G., this final rule amends the participant rights to identify three additional rights, specifically, the participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines, the right to call 1–800–MEDICARE for information and assistance, and the right to receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community. PACE organizations are currently required to provide a copy of the participant rights to participants at the time of enrollment and to post a copy of the rights in the center. Under this rule, PACE organizations will be required to revise the current participant rights to account for the three new requirements and post a copy of the revised document.

We estimate it will take 2 hours at $70.06/hr for a compliance officer (quality improvement coordinator) to update the participant rights information included in the enrollment information and post the new participant rights in the center. In aggregate, we estimate a one-time burden of 266 hr (133 PACE organizations * 2 hr) at a cost of $18,636 (266 hr * $70.06/hr).

We did not receive any comments related to our projected burden estimates for this provision. With the exception of the adjusted number of organizations, we are finalizing the proposed burden without change.

11. ICRs Regarding Stipulated Decisions in Part C (§ 422.562)

In order to permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, we are providing in § 422.562(d) that, for the sole purpose of applying § 405.1038(c), MA organizations are included in the definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators under § 405.1038. We are scoring this impact as negligible for several reasons. The total number of favorable decisions in MA for contract year 2018, the most recent year for which we have complete appeals data, was 578. The number of these overturned denials that were stipulated decisions is not currently quantifiable as it is not data that existing appeals systems are equipped to track, and ALJs do not track this data on their own.

We consulted with OMHA for its opinion on stipulated decisions. OMHA estimated that the number of contractors submitting oral or written statements in an ALJ hearing or attorney adjudicator review was in the single digits as plans typically prefer an alternate, informal approach that removes the claim from the appeals process altogether: Requesting that the beneficiary withdraw their appeal and resubmit their claim for payment.

CMS estimates that while this change would positively impact beneficiaries both in receipt of their items or services, and afford beneficiaries due process protections in a formalized stipulated decisions process, the number of beneficiaries that would be affected is minimal. Despite this estimation of negligible impact, we included this change to promote regulatory uniformity in OMHA's approach to stipulated decisions as far as Medicare contractors are concerned. The submission of a written or oral statement seeking a stipulated decision is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the burden for preparing and filing the oral or written statement for use in the appeal is exempt from the requirements of the PRA.

We received no comments on the assumptions related to our proposed provisions. We are finalizing the burden assessment on these provisions without modification.

C. Summary of Information Collection Requirements and Associated Burden Estimates

TABLE H16: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN [1]

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
SNPS (see ICR #1, above)	422.101(f)(3)	Training	0938-1296	273	273	3	819	NA	70.06	57,379	57,379
SNPS (see ICR #1, above)	422.101(f)(3)	MOC submission	0938-1296	273	273	6	1,638	NA	74.48	121,998	121,998
SNPS (see ICR #1, above)	422.101(f)(3)	MOC off cycle revision	0938-1296	11	11	4	44	NA	74.48	3,277	3,277
SNPS (see ICR #1, above)	422.101(f)(3)	MOC resubmission	0938-1296	14	14	3	42	NA	74.48	3,128	3,128
SNPS (see ICR #1, above)	422.101(f)(1)(iv)	Face to Face	0938-1296	734	734	4	2,936	NA	74.48	218,673	218,673
DMP (see ICR #2, above)	423.153	Creating DMP (for those without DMPs)	0938-0964	79	79	320	25,280	NA	119.49	3,020,707	0
DMP (see ICR #2, above)	423.153	Upload Templates (Those without DMP)	0938-0964	79	79	5	395	NA	89.06	35,179	0
DMP (see ICR #2, above)	423.153	Case Management (those without DMPs	0938-0964	79	158	5	790	NA	109.55	86,545	86,545
DMP (see ICR #2, above)	423.153	Sending notices (those without DMPs)	0938-0964	8	8	0.1667	1.3336	NA	56.34	75	75
DMP (see ICR #2, above)	423.153	Report to CMS (Those without DMPs)	0938-0964	79	158	0.0167	2.6386	NA	56.34	149	149
DMP (see ICR #3, above)	423.153(f)(16)	Revise templates (newly identified PARBs)	0938-0964	288	288	1	288	NA	56.34	16,226	0
DMP (see ICR #3, above)	423.153(f)(16)	Case Management (newly identified PARBs)	0938-0964	288	18,268	5	91,340	NA	109.55	10,006,297	10,006,297
DMP (see ICR #3, above)	423.153(f)(16)	Send notices (newly identified PARBs)	0938-0964	288	8,677	0.1667	1,446	NA	56.34	81,468	81,468

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
DMP (see ICR #3, above)	423.153(f)(16)	Report to CMS (newly identified PARB)	0938-0964	288	18,268	0.0167	305	NA	56.34	17,184	17,184
MTMP (see ICR #5, above)	423.153	Targeting ARBs For MTM	0938-1154	288	7,443	0.6667	4,962	NA	120.68	598,814	598,814
MTMP (see ICR #5, above)	423.153	Mailing ARBs CMR	0938-1154	288	7,443	NA	NA	6,848	N/A	6,848	6,848
MTMP (see ICR #5, above)	423.153	Safe Disposal Page in CMR	0938-1154	288	2,386,955	NA	NA	23,870	N/A	23,870	23,870
MTMP (see ICR #5, above)	423.153	Safe Disposal page in TMR	0938-1154	288	937,495	NA	NA	10,266	N/A	10,266	10,266
Education on addiction (see ICR #6, above)	423.128	Create materials	0938-0964	288	288	2	576	NA	120.68	69,512	0
Education on addiction (see ICR #6, above)	423.128	Update systems	0938-0964	288	288	2	576	NA	89.06	51,299	0
Education on addiction (see ICR #6, above)	423.128	Sending notices	0938-0964	288	35,069,933	NA	NA	384,016		384,016	384,016
Fraud & Abuse Pt C (see ICR #7, above)	422.503(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1383	605	605	247	149,435	NA	91.88	13,730,088	0
Fraud & Abuse Pt C (see ICR #7, above)	422.503(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1383	605	605	156	94,380	NA	91.88	NA	8,671,634
Fraud & Abuse Pt D (see ICR #7, above)	423.504(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1262	63	63	247	15,561	NA	91.88	1,429,745	0
Fraud & Abuse Pt D (see ICR #7, above)	423.504(b)(4)(vi)(G)(*4*)	Report Fraud and abuse	0938-1262	63	63	156	9,828	NA	91.88	NA	902,997
RTBT (see ICR #8, above)	423.128	Implementing RTBT	0938-0763	288	288	156	44,928	NA	89.06	4,001,288	0
RTBT (see ICR #8, above)	423.128	Policy Development	0938-0763	29	29	40	1,160	NA	188.36	218,498	0
RTBT (see ICR #8, above)	423.128	Update Systems	0938-0763	29	29	40	1,160	NA	89.06	103,310	0
RTBT (see ICR #8, above)	423.128	Program Maintenance	0938-0763	29	348	30	10,440	NA	36.82	384,401	384,401

Provision	Regulation under Title 42 of the CFR	Response Summary	OMB Control Number	Total Number of respondents	Total Number of Responses	Time per response (hr)	Total Annual Time (hr)	Non-labor cost ($)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
Pharmacy performance (see ICR #9, above)*	423.514	Pharmacy performance	0938-0992	5,234	5,234	0.5	2,617	NA	92.46	241,968	241,968
PACE (see ICR #10a, above)	460.104(d)(2) and 460.121	Extension notification	0938-0790	133	2,350	1	2,350	NA	57.02	133,997	133,997
PACE (see ICR #10a, above)	460.104(d)(2) and 460.121	Update for extension notification	0938-0790	133	133	2	266	NA	70.06	18,636	0
PACE (see ICR #10b, above)	422.122	Update appeal notices	0938-0790	133	133	5	665	NA	70.06	46,590	0
PACE (see ICR #10c, above)	460.98	Develop written materials for tracking	0938-0790	133	133	50	6,650	NA	56.34	374,661	0
PACE (see ICR #10c, above)	460.98	Tracking services	0938-0790	133	133	50	6,650	NA	56.34	374,661	374,661
PACE (see ICR #10d, above)	460.210	Medical record documentation training	0938-0790	133	133	10	1,330	NA	70.06	93,180	0
PACE (see ICR #10d, above)	460.210	Documentation of written communication about care of PACE enrollees	0938-0790	133	133	62	8,246	NA	76.95	634,530	634,530
PACE (see ICR #10e, above)	460.112	Update for patients' rights	0938-0790	133	133	2	266	NA	70.06	18,636	0
Total				6236	38,467,492	Varies	487,373	424,997	Varies	36,617,099	22,964,175

*The reporting requirements data elements, consistent with our standard, will be specified through the standard non-rule PRA process after publication of this final rule.

IX. Regulatory Impact Analysis

A. Statement of Need

The provisions in this final rule implement specific provisions of the BBA of 2018 and the SUPPORT Act. The statutory need for these policies is clear. However, this rule also contains discretionary policies, including enhancements to the Programs of All-Inclusive Care for the Elderly (PACE) requirements, hence we provide economic justification for some of these noteworthy provisions in the following paragraphs.

Based on industry feedback over the course of several years, and our experiences auditing PACE organizations, we proposed to modify certain PACE requirements to enhance stakeholders' understanding of our requirements and reduce administrative burden. Stakeholders have suggested that the existing processes for addressing service determination requests is burdensome for PACE organizations, and can delay participants' access to services. We are finalizing several changes to the PACE regulations to streamline these processes while ensuring that important participant protections remain intact. We estimate these changes will save PACE organizations, as a whole, approximately $16.8 million in the first year, increasing (due to expected increased PACE enrollment), to $21.3 million in ten years.

Summaries of the public comments that are within the scope of the provisions' proposed regulatory impact analyses implemented in this final rule are included in this section with our responses under the appropriate headings.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 801–808), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This rule is economically significant under Executive Order 12866, as it may result in over $100 million in costs, benefits, or transfers annually. The Office of Information and Regulatory Affairs has designated this rule as a major rule pursuant to the Congressional Review Act, 5 U.S.C. 804(2).

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This final rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $156 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA–PD, and PDP contracts), 55 state Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $110.74 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 19 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore $2,100 (19 hours × $110.74). Therefore, we estimate that the maximum total cost of reviewing this final rule is $4.2 million ($2,104 × 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $0.4 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule has several dozen provisions. Although several provisions are technical or codify existing guidance, and therefore are not expected to have economic impact beyond current operating expenses, there are other provisions with paperwork or other costs. These provisions are analyzed in both this section and in section VIII of this final rule. A compact summary of burdens by year and provision are summarized in Tables H16 and I14 of this final rule. Also, where appropriate the cost burdens and cost savings of groups of provisions that are related are summarized in this section. For example, Table H16 of section VIII of this final rule lists eight paperwork burdens related to PACE organizations which are summarized in Table I7 of this section. Table I7 is then used in Table I9 to give total savings related to PACE organizations, the total savings reflecting all costs and savings of the various provisions whether paperwork or not.

This rule has several affected stakeholders. They include (1) insurance companies, including the five types of Medicare health plans, MA organizations, PDPs, cost plans, PACE organizations, and demonstration projects, (2) providers, including institutional providers, outpatient providers, clinical laboratories, and

pharmacies, and (3) enrollees. Some descriptive data on these stakeholders are as follows:

• Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for ''small size'' with 88 percent of pharmacies, those with under 20 employees, considered small.

• Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business.

• Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.

• Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20–500 employees) considered small.

• Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this final rule does not have a significant economic impact on a substantial number of small entities. To defend our position, we first describe at a high level the cash flows related to the Medicare program. We then provide more specific details.

The high-level underlying idea in creating the MA, Medicare cost plan, and MA–PD Medicare health insurance programs, is to allow private insurers to coordinate care, resulting in efficiencies of cost. The high-level underlying idea in creating the non-government-managed Prescription Drug program (PDPs and drug portion of MA–PDs) is to allow beneficiaries to obtain prescription drugs in a competitive market to reduce costs. For MA, MA–PD, and cost plans, enrollees obtain the same original Medicare Part A and B services they would otherwise obtain in the original Medicare program, generally at reduced cost (however, for the small percentage of plans bidding above the benchmark, enrollees pay more, but this percentage of plans is not ''significant'' as defined by the RFA and as justified below).

The savings achieved by the MA and the MA–PD plans, the amount of reduced cost, can then be used by the private insurers in a variety of ways, including providing supplemental benefits to the required original Part A and Part B Medicare services. Some examples of these supplemental benefits include vision, dental, and hearing; in addition, MA plans may provide supplemental benefits in the form of reductions in cost sharing compared to the Medicare FFS program. The cost for furnishing these supplemental benefits comes from a combination of the Medicare Trust Fund and enrollee premiums.

Part D plans submit bids and are paid by the Medicare Trust Fund for their projected costs in the form of direct premium subsidy and reinsurance. For any enrolled low-income beneficiaries, plans receive and additional low-income premium subsidy and low-income cost sharing subsidy. The national average monthly bid amount, or NAMBA, determines the base premium. A plan's premium is the sum of the base premium and the difference between its bid amount and the NAMBA.

Thus the cost of providing services by these insurers is met by a variety of government funding and in some cases by enrollee premiums.

In order to achieve these goals, the government pays the MA health plans a portion of the funds that would have been paid had plan enrollees remained in original Medicare. These funds are then used to provide additional benefits on behalf of the health plans' enrollees. This unique insurance relationship has several consequences beneficial to all parties: First, the various insurance programs are not expected to suffer burden or losses since the government subsidizes them; second, the government often incurs savings because health plans, by virtue of coordinating care, are furnishing the same services, albeit often at a reduced cost. This lack of expected burden applies to both large and small health plans. As a consequence of this design, the unique MA regulations, such as those in this final rule, are defined so that small entities are not expected to incur additional burden since the cost of complying with any final rule is passed on to the government.

We next examine in detail each of the stakeholders and explain how they can bear cost. (1) For Pharmacies and Drug Stores, NAICS 446110; (2) for Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) for Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) for SNFs, NAICS 623110: Each of these are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs, PFFS, and MSA, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the coming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA. There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs

for the coming year are fully paid by the government. However, the government also pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost sharing, lower Part B or Part D premiums, or supplemental benefits. (Supplemental benefits may also partially be paid by enrollee premiums if the plan chooses to use premiums or offers optional supplemental benefits that enrollees may elect to purchase.) It would follow that if the provisions of this final rule cause the bid to increase and if the benchmark remains unchanged or increases by less than the bid does, then the result would be a reduced rebate and possibly fewer supplemental benefits for the health plans' enrollees.

CMS has observed that from year to year MA organizations prefer to reduce their profit margins, rather than substantially change their benefit package. This is due to marketing forces; a plan lowering supplemental benefits even for one year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it is advantageous for the MA Organization to temporarily reduce margins, rather than reduce benefits.

We note that we do not have definitive data on this. That is, we can at most note the way profit margins and supplemental benefits vary from year to year. The thought processes behind the plan are not reported. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.

A second indirect impact arises from effects on the MLR. More specifically, several provisions of this final rule have non-benefit, administrative classification. For example, the RTBT provision is a requirement for plans to utilize or create certain software; the cost of this creation is classified as administrative and hence is entered in the bid as a non-benefit expense. Similarly, the cost of rewards and incentives is being codified at § 422.134(g)(3) as a non-benefit expense in the plan bid. Several other provisions, including those related to models of care, call centers, and marketing standards, represent non-benefit administrative cost. A non-benefit expense contributes to the denominator of the MLR but not the numerator.

If the costs of complying with a particular provision are excessive, then the MLR could be adversely impacted and MLR requirements could possibly not be met. For contract year 2014 and subsequent contract years, MA organizations, Part D sponsors, and cost plans are required to report their MLRs and are subject to financial and other penalties for failure to meet the statutory requirement that they have an MLR of at least 85 percent (§§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination.

There are two ways of showing that this burden is not substantial for at least one provision. As noted in section VIII.B.7. of this final rule, the estimated cost of creating and maintaining an RTBT is $4.7 million. We explicitly requested stakeholder impact on this specific estimate and received none. The experience of OACT is that for almost all plans, an extra burden of $0.7 million is unlikely to affect the MLR.

Additionally, the RTBT provision addresses multiple possibilities of implementation, some of them significantly less costly than others. Plans, in implementing the RTBT have the following options: (1) Whether they want to develop a new portal, or use an existing computer application, (2) whether they want to offer rewards and incentives to their enrollees who log onto the beneficiary RTBT, (3) whether they want to exclude certain clinically appropriate formulary alternatives from the RTBT, and (4) whether they want to include the negotiated price.

By both allowing exclusions from the RTBT and also by not requiring that plans build their own portals, the RTBT cost may be significantly less than $4.7 million.

Based on the previous discussion, we certify that this final rule does not have a significant economic impact on a substantial number of small entities.

D. Anticipated Effects

Some provisions of this final rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section VIII of this final rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section VIII of this final rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table I13 and the discussion afterwards.

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

This provision requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under the Part D sponsor's drug management program. We projected a list of approximately 18,000 beneficiaries that met the criteria for this provision between July 2017 and June 2018, but did not meet other criteria for classification as a potential at-risk beneficiary. Under this provision, this population is projected to (1) increase the population of enrollees requiring case management by plan sponsors (see section IX.B.3. of this final rule), and (2) reduce Part D drug cost.

We evaluated their Prescription Drug Event (PDE) data for the same July 2017 and June 2018 period to determine the effects of this provision. After examining the PDE data, we found that these beneficiaries had an average gross drug cost per beneficiary per year of $9,675. Because this amount is high relative to the typical Part D spending and because they do not meet other at-risk criteria, it is likely that many of these beneficiaries have conditions that require expensive specialty medications. These drugs have complex clinical criteria that are difficult to alter through utilization management. Accordingly, and because there is no directly pertinent information available on the potential savings for increased prescription drug management on this segment of the population, we have, based on the actuarial judgment of staff with pharmaceutical experience as well as based on discussions with pharmacists, assumed that 5 percent of their Part D drug cost would be reduced

through additional plan management. We note that the we received no comments on this estimate as a result of its publication in the proposed rule and therefore believe it reasonable. Our estimated fiscal year federal savings rounded to the nearest million are shown in Table I1. Since these drugs would not be purchased as a result of efficient case management, they represent reduction in goods consumed and are true savings to the Medicare Trust Fund.

TABLE I1: ESTIMATED BENEFITS TO THE MEDICARE TRUST FUND OF THE INCLUSION OF ADDITIONAL AT-RISK BENEFICIARIES

	Fiscal Year ($ in millions)										Total 2023-2032 Impact ($ in millions)
Fiscal Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2032
Estimated Impact	5.8	7.7	7.7	7.7	7.7	7.7	7.7	7.7	7.7	7.7	75.4

Table I2 summarizes the aggregate impact of the changes to DMPs. It reflects all the estimates related to DMPs in section IX of this final rule (which incur costs) and the savings due to reduction in drug costs discussed in this Regulatory Impact Analysis.

TABLE I2: SUMMARY OF DMP IMPACTS BY PROVISION (MILLIONS $) *

	1st Year Savings	1st Year Cost	Annual Savings 2nd – 10th Year	Annual Cost 2nd – 10th Year	Total 10-Year Savings	Total 10-Year Cost
Creation of DMPs for those parent organizations without DMPs		3.0				3.0
Case management of PARBs for those parent organizations without DMPs		0.1		0.1		0.9
Case Management of PARBs with history of opioid overdose		10.0		10.0		100.1
Other paperwork		0.2		0.1		1.0
DMP drug savings	5.8		7.7		75.4	
Total					75.4	105.0
Net Impact (Cost) Over 10 Years						29.6

*Minor discrepancies in the above table are due to rounding. Further detail for DMP paperwork costs may be found in Table H16; the DMP drug savings may be obtained from Table I1.

2. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

The SUPPORT Act requires automatic escalation of drug management program appeals to the independent outside entity contracted with the Secretary for review and resolution. We are finalizing our proposal to codify that provision, with a modification to permit plan sponsors up to 24 hours after the expiration of the applicable adjudication timeframe to assemble and forward the administrative case file to the IRE. We do not believe the modification reflected in this final rule impacts our previous estimate. To estimate the impact, we first determined how many Part D sponsors had implemented drug management plans. As of July 9, 2019, we found that 60 Part D sponsors had implemented drug management plans. Next, we estimated of the number of CARA-appeals per 1,000 enrollees and the percentage of plan denials related to CARA. To do this, we contacted nine Part D sponsors and asked how many CARA related appeals they had received from January 1, 2019 through July 31, 2019.

Of those nine, eight plans responded they had have not received any CARA appeals. One Part D sponsor responded to say they had received CARA related appeals. That plan reported a rate of 0.014 CARA related appeals per 1000 enrollees. This accounted for 0.08 percent of plan denials. Since there are about 28,600 appeals per year, therefore there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46 and typically an IRE will take at most 1 hour to review most cases, the total burden is about $4,656.58 (23 cases

* $202.46 * 1 hour) which is entered as $0.0 million in the summary table since regulatory accounting standards impose a rounding to the nearest tenth of a million.

3. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

We were unable to determine the overall impact of implementing sections 2008 and 6063 of the SUPPORT Act because we do not have adequate data to support an estimate of the potential costs and savings. While we do have access to estimates of overall Medicare Part D opioid spending, sections 2008 and 6063 of the SUPPORT ACT are not expected to impact all Part D opioid prescriptions, nor do we expect that they would impact all pharmacies that dispense those medications. For example, section 2008 of the SUPPORT Act requires Part D plan sponsors to report to CMS any payment suspension pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o) of the Act. In addition, section 6063 of the SUPPORT Act requires MA organizations and Part D plan sponsors to report information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by the plan related to inappropriate prescribing of opioids. In both cases, these provisions would directly impact a percentage of all opioid prescriptions written by prescribers and dispensed by pharmacies. While we believe there may be savings generated through actions taken by Part D plan sponsors that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans), as well as additional law enforcement actions, we cannot estimate the impact at this time. We welcomed comment and suggestions for data that could be relied upon for this purpose.

We received no comments on the proposed regulatory impact and consequently we are finalizing them without modification.

4. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We are finalizing measure updates, clarifying and codifying policies in this final rule. These changes are routine and are not expected to have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These types of routine changes have historically had very little or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

We are also clarifying some of the current rules around assigning Quality Bonus Payment (QBP) ratings and codifying the rules around assigning QBP ratings for new contracts under existing parent organizations. We are not finalizing any changes to our current QBP policies, so there will be no impact on the Medicare Trust Fund from these provisions.

5. Permitting a Second, ''Preferred,'' Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

The option for Part D sponsors to offer a second, ''preferred'' specialty tier has the potential to impact Part D drug costs in at least two ways. First, a Part D sponsor may have additional negotiating power with brand drug manufacturers by offering a preferential tier position relative to the current single specialty tier. Second, Part D sponsors may promote lower-cost biosimilar biological products on a preferred specialty tier. We consider each of these possibilities in the following discussion.

For a Part D sponsor to be able to negotiate better formulary position and lower beneficiary cost sharing for a particular specialty-tier drug, there must be a substantial difference between the cost sharing on the preferred specialty tier and the higher cost-sharing, specialty tier. Because the regulation limits the maximum allowable cost sharing to the range of 25 to 33 percent, Part D sponsors must achieve this difference by lowering the cost sharing on the preferred specialty tier. For example, because of the high cost for specialty-tier drugs and the structure of the Part D benefit, Part D enrollees and prescribers might not significantly alter their behavior in response to a five percent change in coinsurance. A substantial reduction in the cost sharing for preferred specialty tier would necessitate a substantial increase in cost sharing for other tiers to maintain an actuarially equivalent benefit, which may unfavorably change the competitive position of the Part D sponsor's plan offering. In particular, a plan that offers lower cost sharing on high-cost specialty-tier drugs and higher cost sharing on conventional drugs would risk adverse selection from Part D enrollees.

In addition, allowing tiering exceptions between the preferred specialty tier and the higher cost-sharing, specialty tier creates a risk for the Part D sponsor that may exceed the benefit of being better able to negotiate with respect to brand drugs. A portion of the higher cost-sharing, specialty-tier drugs may be granted exceptions as the clinical criteria for such Part D drugs is complex and can lead to different prescriptions for beneficiaries with similar conditions. These Part D drugs are often more complicated chemically and apply to complex conditions, such as Rheumatoid Arthritis or Multiple Sclerosis. This added complexity requires greater specialized knowledge than a traditional small molecule drug would for denying an exception. This will be known to manufacturers, who will be less inclined to provide additional incentives for the preferred placement given that a significant amount of non-preferred use will limit any market share gains from their enhanced formulary position. Part D sponsors would also face additional liability from the difference in cost sharing between the preferred and the higher cost-sharing, specialty tiers on prescriptions that are granted tiering exceptions. This dynamic serves as a disincentive for Part D sponsors to place specialty-tier-eligible drugs on a non-specialty, non-preferred drug tier under current regulation.

Regarding savings from biosimilar biological products that could be promoted through a preferred specialty tier, some of the same previously discussed issues still apply. For example, Part D sponsors may expect a portion of a non-preferred reference biological product's utilization to be given an exception to the preferred tier for a biosimilar biological product if such biosimilar biological product is not licensed for all of the same indications as the reference biological product. Furthermore, the selection of these products is often largely determined by the behavior of the prescriber rather than the formulary status of the Part D sponsor. If the prescriber prefers the reference biological product, they are more likely to prescribe it rather than the biosimilar biological product, regardless of the formulary position.

This is particularly true for specialty-tier drugs, where the differences in total drug cost and the cost-sharing requirements of the plan are not as extreme as the differences between conventional brand and generic drugs. Finally, it is worth noting that several large Part D sponsors do not currently promote biosimilar biological products. For example, Zarxio®, a biosimilar biological product to Neupogen®, is not included on the formulary for several large Part D plans.

Our conclusion is that the provisions of the final rule to allow Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier are unlikely to have a material impact on Part D costs. While it is possible that a small savings to the Part D program could result from the enhanced flexibility, particularly for MA–PD plans with greater prescriber integration, broad adoption of a second specialty tier is unlikely. Nevertheless, we believe there are reasons for a second specialty tier. As discussed in more detail in section IV.E. of this final rule, stakeholders requesting this change have posited that it might lead to better rebates on certain Part D drugs and reduced costs for Part D enrollees and CMS. Most importantly, we are currently not aware of any major adverse effects that could result to Part D enrollees by allowing Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier. For example, concern for undue financial burden on some Part D enrollees has prompted us to retain the current maximum allowable cost sharing (that is, 25/33 percent, as discussed in more detail in section IV.E. of this final rule). Additionally, we solicited comment regarding whether negative consequences to Part D enrollees could result from this proposal. If there were no foreseeable notable harms to Part D enrollees, it would seem reasonable to provide the requested flexibility to Part D sponsors and see if additional benefits do result, while monitoring implementation for adverse effects and responding as necessary.

As discussed in section IV.E. of this final rule, improving Part D enrollee access to needed drugs, including lowering drug costs, are central goals for CMS. While this regulatory impact analysis assesses the potential impact this policy will have on Part D drug costs, we also believe this policy has the potential to impact patient access and lower drug costs more broadly, by providing further incentives for manufacturers to develop generic drugs and biosimilar and interchangeable biological products. Even if notable savings for the Part D program were not to materialize, individual Part D enrollees might save a great deal on rebated Part D drugs. Or, the policy might result in the benefit of (1) more formulary choices, or (2) more choices at a lower cost than might have otherwise been the case. These, in turn, might lead to positive health outcomes with associated indirect savings to Part D enrollees or the government. We solicited comment on any other unforeseen benefits that might result. And, again, in finalizing this proposal, we will closely monitor for any adverse effects and take any necessary action including warranted changes for future rulemaking.

Comment: Some commenters suggested that CMS should conduct additional research on the impact of specialty tiers on Part D enrollees, generally, before enacting this policy.

Response: In finalizing our proposals to permit Part D sponsors to maintain up to two specialty tiers, we intend to monitor the uptake of the use of a second specialty tier. We are unclear about, generally, what the commenters believe we should research, given the Part D enrollee protections we are finalizing as part of this final rule.

Comment: Some commenters suggested that the specialty tier(s) serve as perverse ''reverse insurance,'' reasoning that the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit.

Some commenters stated that CMS's proposals exacerbate an existing lack of transparency and the impact of misaligned rebate incentives in the Part D program because CMS's proposal provides no incentive or imposes no requirement that the rebates on these high-cost drugs be passed on to Part D enrollees at the point of sale. They suggested that these misaligned incentives lead to inappropriate tier placements as Part D sponsors choose higher negotiated prices in exchange for higher rebates, and may prefer a drug with a higher net cost over a less expensive alternative. These commenters suggested that CMS's proposals, due to this inappropriate tier placement, could increase costs to Part D enrollees and the government in two ways: First, as Part D enrollees enter catastrophic coverage more quickly; and second, because Part D enrollees could pay more for preferred products, despite a lower coinsurance percentage, because the coinsurance percent is calculated from a higher list price. These commenters also suggested that misaligned rebate incentives in the Part D program will discourage plan use of newer market alternatives.

Response: We disagree with the sentiment that the specialty tier(s) serve as a perverse, ''reverse insurance'' whereby the sickest patients who need specialty-tier eligible drugs subsidize the benefit to keep premiums and cost sharing on non-specialty tiers lower for the rest of the benefit. We believe this reasoning is flawed because the specialty tier is aligned with the Defined Standard benefit, and the Part D plan bid requirements also necessitate that the benefit structure below the specialty tier also be actuarially equivalent to the Defined Standard benefit. Therefore, the use of specialty-tier eligible drugs has no differential impact on lowering the premiums and cost sharing on non-specialty tiers for the rest of the benefit. Finally, our proposals would not change the role of rebates in the Part D program.

Comment: Relative to the Part D enrollee and governmental impacts of CMS's proposals, some commenters urged CMS to ensure premiums do not go up, and others expressed concern that cost sharing on other (in other words, non-specialty) tiers would increase as Part D sponsors are required to maintain actuarial equivalence. Some commenters suggested that plans will utilize a second specialty tier to shift more risk of financial exposure to Part D enrollees, leading to higher coinsurance for enrollees who use specialty-tier drugs.

Relative to the Part D sponsor impacts of our proposals, some suggested that CMS's proposals would increase costs to Part D sponsors due to increases in administrative burden from tiering exceptions requests. Others disagreed with CMS's assertion that without any specialty tiers, plan costs would increase, and stated that CMS provided no data to suggest that specialty tier drugs at lower cost sharing could cause increases to premiums or cost sharing for non-specialty tiers.

Some commenters were concerned that CMS's proposals would increase costs to Part D enrollees, the government, and Part D sponsors. These commenters suggested that if the higher cost-sharing, specialty tier were kept at the current specialty tier cost threshold (in other words, 25/33 percent) with no changes (in other words, permitting the higher cost-sharing, specialty tier to have cost sharing greater than 25/33 percent), the Part D sponsor's costs for specialty drugs would increase, leading, in turn, to higher bids, and higher premiums and cost sharing for Part D enrollees.

Response: Substantial reductions in cost sharing below the 25/33 percent

maximum for the preferred specialty tier necessitate substantial increases in cost sharing for non-specialty tiers in order to meet actuarial equivalence requirements. Therefore, we recognize that, in order for Part D sponsors to offer competitive plan benefit designs, Part D sponsors may not offer plan benefit designs with cost sharing for the preferred specialty tier far below the 25/33 percent maximum for the higher cost-sharing, specialty tier, and consequently, Part D enrollee savings for drugs on the preferred specialty tier may be limited. However, because § 423.104(d)(2)(iv)(D) maintains the existing 25/33 percent maximum allowable cost sharing for the specialty tiers, Part D enrollees will not pay more for specialty-tier drugs under our proposals than they do now. Therefore, we disagree that our proposals will increase Part D enrollees' cost sharing for specialty-tier drugs.

We do not understand the commenter's assertion that plans will utilize a second specialty tier to shift more risk of financial exposure to Part D enrollees, leading to higher coinsurance for enrollees who use specialty-tier drugs. While this may be the case in the commercial market, which does not, as a matter of policy, establish or maintain either a specialty-tier cost threshold or a maximum allowable cost sharing, and thus, may have incentives to place more drugs on the specialty tier(s), the methodologies to establish an increase the specialty-tier cost threshold that we are finalizing in this rule will serve to limit the specialty tier(s) to only the highest-cost Part D drugs. We welcome further input on this matter.

Because specialty-tier drugs are playing an increasing role in the prescription drug marketplace, and we have concern about the impact this will have on the Part D program, we believe that the increase in volume of specialty-tier drugs, but not our proposals, could increase costs to the government.

Regarding administrative burden, tiering exceptions are requested at a much lower volume than formulary exception requests and coverage determinations in general. Based on 2019 Part D plan reported data, tiering exceptions accounted for only 10.8 percent of all exception requests received at the coverage determination level, and 5.6 percent of all coverage determination requests. We do not anticipate that our proposals to permit Part D sponsors to maintain up to two specialty tiers will significantly impact this volume.

Although implementation will be delayed until coverage year 2022, we are finalizing as proposed our proposals to permit a second specialty tier, except that we are not finalizing our proposal to specify a specialty tier threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*) which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products,'' and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

6. Service Determination Request Processes Under PACE (§§ 460.104 and 460.121)

We have revised the estimated impact from that presented in the proposed rule in the following ways: (1) We adjusted our estimates to account for an increase in wages according to the May 2019 BLS, (2) we included 2019 PACE audit data which was not available at the time these estimates were published in the proposed rule, (3) we updated enrollment data based on 2017–2019 data from the CMS Office of the Actuary (OACT) and (4) we updated PACE organization contract data based on data from the Health Plans Management System (HPMS). Based on these revisions, we continue to estimate that the finalized provisions will result in savings to PACE organizations.

To estimate the savings from the revisions we are finalizing to the service determination request provisions, we rely upon the assumptions described in the next section. These assumptions are based on our experience monitoring PACE organizations' compliance with current service determination request requirements and on data collected during those monitoring efforts.

We estimate that under the current regulation, the aggregate total annual cost to all PACE organizations for processing service determination requests is approximately $33.2 million.

We estimated that cost by using the following assumptions. First, we estimate the wages for each of the 11 Interdisciplinary team (IDT) members in order to better estimate a total cost. The eleven disciplines shown are the minimum disciplines required to compose the IDT under § 460.102(b). The occupation codes and wages used come from the BLS's website. The wage for each discipline includes the mean hourly wage plus 100 percent of the mean hourly wage for overhead and fringe benefits. Table I3 allows us to estimate the mean hourly wage of the IDT as a whole.

TABLE I3—WAGES FOR IDT STAFF MEMBERS

Occupation title	Occupation code	Mean hourly wage with overhead and fringe benefits ($)
Dietician	29–1031	59.94
Driver	53–3058	31.94
Home Care Coordinator (often an RN)	29–1141	74.48
Masters of Social Work	21–1022	57.02
Occupational Therapist	29–1122	82.90
PACE Center Manager	11–9111	110.74

TABLE I3—WAGES FOR IDT STAFF MEMBERS—Continued

Occupation title	Occupation code	Mean hourly wage with overhead and fringe benefits ($)
Personal Care Attendant	31–1120	25.42
Physical Therapist	29–1123	86.70
Primary Care Provider	29–1216	193.70
Recreational Therapist	29–1125	49.16
Registered Nurse	29–1141	74.48
Total		846.48
Wages/hr (Total/11)		76.95

Currently, when processing a service determination request, the IDT must determine the appropriate discipline(s) to conduct a reassessment under § 460.104(d)(2) and is responsible for notifying the participant or designated representative of its decision to approve or deny a request under § 460.104(d)(2)(iii). Based on our experiences monitoring PACE organizations, we estimate that the IDT takes approximately 1 hour to handle these responsibilities for each service determination request (1 × $846.48 = $846.48).

Reassessments performed in response to service determination requests are varied and may be done by multiple disciplines. For purposes of this estimate, we assume a registered nurse (RN) and Master's-level social worker (MSW) conduct reassessments, and that the total hours for reassessments equals 1.5 hours per discipline. Therefore, we estimate that reassessments would cost (1.5 × $74.48 = $111.72) and (1.5 × $57.02 = $85.53). This is summarized in Table I4.

TABLE I4—COST PER SERVICE DETERMINATION REQUEST FOR A PACE ORGANIZATION ASSESSMENT

Occupation title	Occupation code	Wage/hr ($)	Time (hr)	Total cost ($)
Masters of Social Work	21–1022	57.02	1.5	85.53
Registered Nurse	29–1141	74.48	1.5	111.72
Total Cost				197.25

Additionally, once a decision has been rendered, one discipline (usually the MSW) notifies the applicable parties which we believe takes about 1 hour (1 × $57.02 = $57.02). This is summarized in Table I5.

TABLE I5—COST PER SERVICE DETERMINATION REQUEST FOR A PACE ORGANIZATION NOTIFICATION

Occupation title	Occupation code	Wage/hr ($)	Time (hr)	Total cost ($)
Masters of Social Work	21–1022	57.02	1	57.02

Therefore, the processing of a service determination request under current regulations is $1,100.75 ($57.02 + $846.48 + $197.25) per request.

Additionally, based on combined audit data collected from all PACE organizations in 2017, 2018, and 2019 we estimate there are 705.0 service determination requests per 1,000 enrollees (30,173 total service determination requests for 2017, 2018, and 2019 divided by 42,800, the average enrollment for that time period). Consequently, the total cost of processing service determination requests for 2017–2019 under the current regulations was approximately $33.2 million (705.0 service determination requests/1,000 enrollees × 42,800 enrollees × $1,100.75 per service determination request) per year.

We anticipate the changes in § 460.121 of this final rule will reduce burden on PACE organizations in the following ways. First, the final rule establishes a streamlined approval process for service determination requests when an IDT member can approve the request in full at the time the request is made, under new § 460.121(e)(2). These approved requests will not need to be brought to the full IDT for review and will not require the IDT to conduct a reassessment. We also do not anticipate notification of the approval adding an additional burden because the IDT member would approve the request immediately and presumably satisfy the notification requirements under § 460.121(j)(1) at the time the request is made. As discussed in section VIII.B.10. of this final rule, we estimate:

- 22.47 percent of all service determination requests are denied, while 77.53 percent are approved; and
- Of the 77.53 percent of service determination requests that are approved, 50 percent of those are routine (that is, can be approved in full by an IDT member), while 50 percent are not routine.

Consequently,

• 273 service determination requests/1,000 enrollees are routine and approved (50 percent routine × 77.5 percent approved × 705.0 service determination requests/1,000 enrollees);

• 158 service determination requests/1,000 enrollees are denied (22.5 percent × 705.0 service determination requests/1,000 enrollees); and

• 273 service determination requests/1,000 enrollees are approved but not routine (77.5 percent approved × 50 percent not routine × 705.0 service determination requests/1,000 enrollees).

These estimates are summarized in Table I6.

TABLE I6—BREAKOUT OF SERVICE DETERMINATION REQUESTS BY TYPE

Row ID	Formula	Item	Number or percentage
(1)		Average enrollment PACE, 2017, 2018, 2019	42,800
(2)		Total unduplicated service determination requests (SDR) 2017–2019	30,173
(3)	(2)/(1) * 1000	Number of SDR per 1000 enrollees	705.0
(4)		Percentage of SDR Approved	77.53
(5)	100% − (4)	Percentage of SDR with denial	22.47
(6)		Percentage of approved SDR, easily approved	50
(7)	(3) * (4)	Total approved SDR per 1000 enrollees	547
(8)	(3) * (5)	Total SR with denial per 1000 enrollees	158
(9)	(7) * (6)	Total easily approved SDR per 1000 enrollees	273
(10)	(7) − (9)	Total not-easily approved SDR per 1000 enrollees	273
(11)	(8) + (9) + (10)	Aggregate SDR per 1000 enrollees per year	705.0

We are finalizing the relevant PACE service determination request proposals without substantive modification, and our burden estimates for the final provisions are based on the following assumptions:

• Service determination requests that an IDT member is able to approve in full at the time the request is made under § 460.121(e)(2) will not require full IDT review, assessment, or a separate notification. Although some work is involved in such approvals, we are estimating the cost as $0 since: (i) No reassessment is needed consistent with § 460.121(e)(2)(ii), (ii) no separate notification will generally be needed under § 460.121(j)(1), (iii) review by the full IDT is not required under § 460.121(e)(2)(ii) and (iv) the estimated time for an IDT member to approve an easily approved service determination request in full is small and hence the total cost is negligible and can be done as a part of the PACE organization's routine day to day activities.

• Denied service determination requests require review by the full IDT under § 460.121(f), an in-person assessment pursuant to 460.121(h)(1), and notification.

• Service determination requests that are approved, but cannot be approved in full at the time the request is made, will require review by the full IDT under § 460.121(f) and notification pursuant to § 460.121(j)(1) but would not require an assessment.

In section VIII.B. of this final rule, we identified eight requirements across five provisions anticipated to increase burden for PACE organizations. These eight requirements, their projected first year costs, and their projected annual costs after the first year are summarized in Table I7.

TABLE I7—PAPERWORK COSTS ASSOCIATED WITH THIS FINAL RULE

Item	1st year cost *	Cost for years 2–10 if applicable
Extension notification	133,997	133,997
Update for extension notification	18,636	
Update Appeal Notices	46,590	
Develop written materials for tracking	374,661	
Tracking services	374,661	374,661
Medical record documentation training	93,180	
Medical record documentation	634,530	634,530
Update for patients' rights	18,636	
Totals (in Millions $)	1.7	1.1

To estimate the total savings over 10 years we proceed as follows:

• We estimate the total savings without additional paperwork for 2017–2019 by subtracting the projected cost under the proposed provisions from the actual cost under the current provisions. Table I8 presents these calculations, showing a $15.2 million savings, without considering paperwork, for 2017–2019.

• For any year between 2022 and 2031, we divide the projected enrollment for that year by the actual enrollment for 2017–2019. Since costs are per 1000 enrollees, this quotient when multiplied by 15.2 million will give the savings for that year without considering paperwork requests.

• Finally, since paperwork requests are an additional burden, we subtract paperwork costs from the savings to ascertain the projected savings for that year. In subtracting paperwork costs, we must subtract an annual cost in all years and a special one-time first year cost in 2022. Table I9 presents this 10-year projection.

We illustrate these calculations by deriving the $15.2 million savings estimated based upon the data 2017 through 2019, and presented in Table I9. That is, if the provisions of this rule had

been adopted between 2017 and 2019, there would have been a savings of $15.2 million. This can be shown as follows:

- *Actual Cost (without paperwork) for 2017–2019:* 33.2 million.
- *Cost (without paperwork) if these provisions were adopted:* 18.0 million.
- *Total savings (Difference of the last two rows):* 15.2 million.

As we explained previously, in order to arrive at the 33.2 million and the 18.0 million, we considered the following:

- $33.2 = 42,800 enrollees * 705.0 service determination requests/1,000 enrollees * $1,100.75 (IDT + assessment + notification)
- $18.0 = $10.6 (10.56) + $7.5 (7.44) + $0
- $10.6 = 42,800 enrollees * 273 service determination requests/1,000 enrollees × ($1,100.75 − $197.25)
- $7.4 = 42,800 enrollees * 158 service determination requests/1,000 enrollees × ($1,100.75)
- $0 = 42,800 enrollees * 273 service determination requests/1,000 enrollees × $0

As can be seen, the savings comes from the fact that whereas current regulations require that all 705.0 service determination requests/1,000 enrollees be processed by the IDT (at a cost of $1,100.75), the draft final regulations only require that 431 service determination requests (158 service determination requests/1,000 enrollees that are denied and 273 service determination requests/1,000 enrollees that are approved but not routine) would go to the full IDT for processing, but another 273 service determination requests would be approved and routine and therefore would not impose any administrative cost on the PACE organization. Additionally, the 273 approved but not routine requests that would go to the IDT would be a reduced cost of $1,100.75 − $197.25 since assessments would not be done for all of those approvals. We anticipate this final rule will reduce administrative burden on the PACE organization, and allow IDT members to focus more time on providing participant care.

TABLE I8: ITEMIZED AND TOTAL COST PER YEAR FOR CURRENT OPERATIONS AND PROPOSED FOR BASE PERIOD (2017-2019)

Item	Current	Proposed	Proposed	Proposed	Proposed
	Aggregate SR	Total SR Easily Approved	Total SR Not Easily Approved	Total SR with Denial	Total Cost (millions $) Proposed
Aggregate SR per 1000 per Year	705.0	273	273	158	
Full IDT Review	$846.48		$846.48	$846.48	
Assessment	$197.25			$197.25	
Notification	$57.02		$57.02	$57.02	
Total Cost/SR without Paperwork	$1,100.75	$0.00	$903.50	$1,100.75	
Average Enrollment 2017-2019	42,800	40,151	42,800	42,800	
Total Cost (millions) (2017-2019)	$33.2	$0.0	$10.6	$7.5	18.0
Total Savings (2017-2019) without Paperwork					15.2

TABLE I9: 10-YEAR AGGREGATE PROJECTED SAVINGS FROM PROPOSED PACE PROVISIONS

Year	Enrollment	Base Year Enrollment	Annual Savings 2017 - 2019 without Paperwork	Annual Paperwork Cost	Special 1st Year Paperwork Cost	Adjusted Savings Current Year
(1)	(2)	(3)	(4)	(5)	(6)	(2)/(3)*(4)-((5)+(6))
2022	52,181	42,800	$15.2	1.1	0.6	16.8
2023	53,558	42,800	$15.2	1.1	0	17.9
2024	54,909	42,800	$15.2	1.1	0	18.3
2025	56,259	42,800	$15.2	1.1	0	18.8
2026	57,581	42,800	$15.2	1.1	0	19.3
2027	58,854	42,800	$15.2	1.1	0	19.7
2028	60,069	42,800	$15.2	1.1	0	20.2
2029	61,207	42,800	$15.2	1.1	0	20.6
2030	62,239	42,800	$15.2	1.1	0	20.9
2031	63,195	42,800	$15.2	1.1	0	21.3
Total						193.8

To clarify Table I9, consider the following:

- As noted previously, the actual non-paper savings for the base year, had this provision been implemented between 2017 and 2019, would have been $15.2 million for the 42,800 enrollees.
- The OACT projects 52,181 PACE enrollees for 2022.
- Since enrollment is projected to increase by a factor of 1.2191 (52,181/42,800), and we are estimating service determination requests per 1,000 enrollees, we project the non-paper savings for 2022 to be 1.2191 × $15.2 = $18.5 million. In other words, the 2017–2019 costs under the current regulation and proposed regulation would involve a product of 2017–2019 enrollment (about 42,800) times the number of service requests per 1,000. The 2022 costs use the same formula, however the 42,800 is replaced by 52,181. It follows that multiplying the 2017–2019 savings by 52,181/42,800 gives us the correct 2022 savings. Since the difference between the current cost and the proposed cost is savings, it follows that multiplying this difference by the ratio of 52,181/42,800 gives the updated savings).
- However, these are savings without paperwork costs. Table I7 indicates an ongoing $1.1 million cost in all years. The extra cost in the first year $0.6 million (in addition to the $1.1 ongoing cost) is derived from Table I7 as the total first year cost of $1.7 million minus the ongoing cost in subsequent years of $1.1 million.
- Therefore, the total savings for 2022 would be $18.5 − (1.1 + 0.6) = $16.8 million.
- The other rows are calculated similarly.

Accordingly, the finalized provisions streamline the processes for addressing service determination requests in PACE are projected to save PACE organizations $16.8 million in 2022 with a gradual increase in savings to $21.5 million by 2031. The aggregate savings from 2022–2031 is $193.8 million. These savings are to industry (PACE organizations) because administrative burden is being reduced. Additionally, each blank cell in Table I8 corresponds to a proposal to eliminate an unnecessary burden.

We received no comments regarding the impact related to the proposed PACE provisions however we have revised our estimate in the following ways: (1) We updated our projected costs for §§ 460.121, 460.122, 460.124, 460.98, 460.210, and 460.112, (2) we adjusted estimates to account for an increase in wages according to the May 2019 BLS, (3) we included 2019 PACE audit data which was not available at the time these estimates were published in the proposed rule, (4) we updated enrollment data based on data from OACT and (5) we updated PACE organization contract data based on data from HPMS.

Specifically, the projected costs for documenting and tracking the provision of services under PACE (§ 460.98), appeals requirements under PACE (§ 460.122), and participant rights (§ 460.112) provisions were updated to account for: (1) An increase in wages according to the May 2019 BLS, (2) updated enrollment data from OACT, and (3) updated PACE organization

contract data based on data from HPMS. Projected costs and savings associated with service determination request (§ 460.121) were updated to account for: (1) An increase in wages according to the May 2019 BLS, (2) updated enrollment data based on data from OACT, (3) updated PACE organization contract data based data from HPMS, and (4) updated service determination request data from PACE audits conducted from 2017 through 2019. As a result of comments, we also revised costs for documentation in medical records under PACE (§ 460.210), which accounts for: (1) An increase in wages according to the May 2019 BLS, (2) updated enrollment data based on data from OACT, (3) updated PACE organization contract data based on data from HPMS, and (4) revisions to the proposed requirements for maintaining all written communications received from a participant or other parties in their original form, as discussed in section VIII.B.10. of this final rule.

7. Beneficiaries With Sickle Cell Disease (§ 423.100)

Based on analysis of 2018 data, we found that about 683 beneficiaries (1.3 percent) who met the minimum OMS criteria or who had a history of an opioid-related overdose had sickle cell disease and would be affected by the finalized exemption. Since we estimate that less than 10 percent of these 683 beneficiaries would have been targeted for case management, the resulting savings is $0.0 million (10 percent × 683 enrollees × $542.46 for each case management).

E. Alternatives Considered

CMS did not develop Alternatives Considered sections for most of the provisions in this final rule as they generally are direct implementations of federal laws or codifications of existing policy for the Part C and D programs. In this section, CMS includes discussions of Alternatives Considered for the provisions to which they are applicable.

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

As the Medicare Part D program is a prescription drug benefit and opioid-related overdoses can be due to both prescription opioids, which may be covered under Part D, and illicit opioids, this raises a question of how CMS should define history of opioid-related overdose. CMS considered two options for defining history of an opioid-related overdose plus two alternatives.

Opioid overdose codes (ICD–10) were identified using Medicare FFS Claims data and Part C Encounter data. When considering overdose, we noted that prescription opioids can also be obtained through illegal or illicit means. The available overdose diagnosis codes describe the type of drug involved in the poisoning but do not specify how the drugs were obtained. There is also an unspecified opioid overdose code. Therefore, assumptions were made to classify an overdose code as prescription or illicit. For example, code 40.4 (other synthetic opioids) was classified as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. Conversely, code 40.2 (other opioids) may include poisoning due to oxycodone which was classified as prescription opioid overdose but may have been obtained illegally.

Option 1: Include beneficiaries with either prescription or illicit opioid-related overdoses. This option would allow CMS to proactively identify the most potential at-risk beneficiaries with a history of opioid-related overdoses, regardless whether the opioid is prescription or illicit, so that they can be reported to the Part D sponsor and reviewed through a DMP. This option represents the largest program size of all of the options. Based on data between July 2017 and June 2018, CMS estimates that there were about 28,891 beneficiaries with prescription or illicit opioid-related overdoses who would have been identified and reported as potential at-risk beneficiaries through the OMS.

Option 2: The program size for this option, as a subset of Option 1, decreases by 37 percent to 18,268 if we were to identify only those beneficiaries reported to have at least one opioid prescription drug claim during the 6-month OMS measurement period (approximately 63 percent had opioid Part D claim(s)), which means that they have at least one relatively current opioid prescriber.

Option 3: Identify beneficiaries with only prescription opioid-related overdoses. This approach would utilize a 12-month lookback period to identify beneficiaries with a history of prescription opioid overdoses. Based on data between July 2017 and June 2018, CMS estimates that there were about 21,037 beneficiaries with prescription opioid-related overdoses who would be identified and reported by OMS.

Option 4: Since about 72 percent of beneficiaries had at least one Part D opioid claim in the 6-month OMS measurement period, this option, as a subset of Option 3, decreases the program size to 15,217 beneficiaries if we were to require beneficiaries reported to have at least one opioid prescription drug claim, which means that they have at least one relatively current opioid prescriber.

As noted, the primary impact will result from needing to case manage the additional beneficiaries identified as meeting the proposed definition. At the proposed hour and skill levels defined, this introduces a projected cost of $547.74 per additional beneficiary undergoing case management. The various economic impacts for the alternatives considered are summarized in Table I10.

TABLE I10—ECONOMIC IMPACT OF ALTERNATIVES CONSIDERED

Alternative (criteria)	Number of enrollees affected	Total cost (millions $)
Option 1	28,891	15.8
Option 2 (finalized)	18,268	10.0
Option 3	21,037	11.5
Option 4	15,217	8.3

CMS is finalizing the proposal to define history of opioid-related overdose as defined in Option 2. This option incorporates the risk factor most predictive for another overdose or suicide-related event and is commensurate with the Administration's commitment to vigorously address the opioid epidemic. However, this approach keeps a clear tie between opioid-related overdoses and the Part D program by requiring a recent

prescription opioid prescriber, which simultaneously increases the likelihood for successful provider outreach through case management by the sponsor. We received no comments on this proposal and therefore are finalizing this provision without modification.

2. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We initially contemplated requiring that each plan as part of its MTM program develop educational materials regarding the safe disposal of prescription drugs that are controlled substances for its beneficiaries. Though each plan would have had a greater cost to develop such materials, the information might have included more local resources specific to individual plans. However, for the sake of consistency, and to reduce burden on MTM programs, we proposed that Part D plans would be required to furnish materials in their MTM programs that meet criteria specified in § 422.111(j) as part of a CMR, TMR, or other MTM correspondence or service.

We also considered whether we should extend MTM eligibility to potential at-risk beneficiaries (PARBs) instead of to just those determined to be at risk. We believe that providing MTM to PARBs might have been beneficial for this population. However, the SUPPORT Act is clear that the extended MTM eligibility criteria should apply only to at-risk beneficiaries.

After careful consideration of all comments received, and for the reasons set forth in section III.E. of this final rule, we are finalizing our proposal to add a requirement that Part D sponsors target ARBs for enrollment in their MTM programs. Part D plan sponsors will be required to comply with this new requirement by January 1, 2022. We are also finalizing the requirement that plans furnish information on safe disposal of prescription drugs that are controlled substances to MTM program enrollees at § 423.153(d)(1)(vii)(E), with a modification to clarify that plans may do so through use of a CMR, TMR or other MTM correspondence or service. We did not receive any comments on our impact analysis.

3. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The provision regarding educating MA and Part D beneficiaries on opioid risks and alternative treatments is discussed in section III.D. of this final rule. In section IX.B.6. of this final rule, we estimated a maximum impact assuming that all plans would want to send all Part D enrollees information and that 75 percent of enrollees would request paper versus electronic communication.

However, we emphasize that the SUPPORT Act does not require CMS to set a standard as to which enrollees receive the required information. As indicated in section III.D. of this final rule, the SUPPORT Act gives plans flexibility to choose which enrollees to send the information. To facilitate plan choice, we have provided a wide range of alternatives in Table I11. The alternatives are based on the number of days the enrollee has been on opioids, the possible gaps in opioid treatment, as well as the cause of the opioid treatment; we, for example, think it very reasonable that sponsors would not want to send notices to opioid users in hospice or with cancer as this could unduly alarm them; therefore, one alternative is to carve these populations out. Although not a policy alternative, we also consider two alternatives for paper estimates; a conservative approach is that only half (50 percent) of enrollees would request paper while the more aggressive approach assumes 75 percent so request. As can be seen, despite the wide range of differences, costs vary only between $0.1 and $0.5 million.

TABLE I11: IMPACTS OF SEVERAL ALTERNATIVES FOR PROVIDING INFORMATION TO OPIOID USERS

(A) Issue	(B) Number of Opioid Users in this Category	(C) Number of Part D Sponsors	(D) Percentage of Enrollees Wanting Paper Delivery	(E) Cost per Plan or Enrollee for Paper Copies	(F) Aggregate Cost (B)* (D)*(E)	(G) Total Cost for this Scenario	Total Cost Rounded (millions)
2 hours of programming	N/A	288	N/A	178.12	51,299	N/A	N/A
2 hours for a pharmacist to develop the materials	N/A	288	N/A	241.36	69,512	N/A	N/A
Total first year programming and development cost	N/A	N/A	N/A	N/A	120,811	N/A	N/A
75% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	75%	0.01095	22,158	142,969	0.1
50% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	50%	0.01095	14,772	135,533	0.1
75% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	75%	0.01095	31,345	152,156	0.2
50% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	50%	0.01095	20,897	141,708	0.1
75% want paper; 7-day usage	7,163,615	N/A	75%	0.01095	58,831	179,642	0.2
50% want paper; 7-day usage	7,163,615	N/A	50%	0.01095	39,221	160,032	0.2
75% want paper; All opioid users (1 year)	11,027,271	N/A	75%	0.01095	90,561	211,372	0.2
50% want paper; All opioid users (1 year)	11,027,271	N/A	50%	0.01095	60,374	181,185	0.2
75% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	75%	0.01095	132,501	253,312	0.3
50% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	50%	0.01095	88,334	209,145	0.2
75% want paper; All Part D enrollees	46,759,911	N/A	75%	0.01095	384,016	504,827	0.5
50% want paper; All Part D enrollees	46,759,911	N/A	50%	0.01095	256,011	376,822	0.4

Comment: A few commenters suggested that sponsors send information on opioid alternatives to *all* Part D beneficiaries.

Response: As noted earlier in this rule, the SUPPORT Act gives plan sponsors flexibility to choose which enrollees to send the information and sponsors have the most accurate beneficiary information and may wish to select a specific subset to send this information to.

We are finalizing this provision with modification. As explained in section A of this final rule, while the statutory requirement begins with coverage year 2021, this regulation will be applicable beginning January 1, 2022 rather than January 1, 2021 as initially proposed. Although implementation will be delayed until coverage year 2022, we are finalizing without modification for our proposal to permit Part D sponsors to send information on opioid alternatives to all beneficiaries, or to a specific subset as determined by the sponsor.

4. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We would allow Part D sponsors to have two specialty tiers, under the existing policy at § 423.578(c)(3)(ii), Part D sponsors would be required to permit tiering exceptions between the two specialty tiers. We also considered permitting Part D sponsors to exempt tiering exceptions between the two specialty tiers, but we are concerned that removing the Part D enrollee protection requiring exceptions between the two specialty tiers could negate benefits that might otherwise have accrued to Part D enrollees under a two specialty-tier policy when there is a therapeutic alternative on the preferred specialty tier that a Part D enrollee is unable to take.

Additionally, although we proposed to codify at § 423.104(d)(2)(iv)(E) the maximum allowable cost sharing under current policy, because we note that the deductible applies to all tiers and it is unclear that we should continue to differentiate the specialty tier from other tiers on the basis of the deductible, we also considered decreasing the maximum permissible cost sharing to the 25 percent Defined Standard coinsurance for Part D plans with decreased or no deductibles. As a result, we would anticipate that Part D sponsors would need to raise cost sharing on non-specialty-tier drugs to maintain actuarial equivalence. If this applies to all plans, then there should be no budget impact, as they must still return to a basic benefit design that is actuarially equivalent to the Defined Standard benefit, and there will be no adverse selection. Additionally, we do not expect impacts from this proposal to the private sector, as additional specialty tiers already exist in that market. Plans with a high proportion of dual-eligible enrollees are less likely to offer a second specialty tier, because the lower cost sharing would be less impactful for those beneficiaries. As a result, we don't expect material impacts to Medicaid costs.

Finally, although we proposed at § 423.104(d)(2)(iv)(B) to increase the specialty-tier cost threshold for all plan years in which CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding ''to'' the nearest $10 increment, in order to reestablish the 1 percent outlier threshold, CMS is also considering a change in this methodology such that CMS would always round ''up'' to the nearest $10 increment. This rounding up methodology would: (a) Ensure that the new specialty-tier cost threshold actually meets the 1 percent outlier threshold, and (b) provide more stability to the specialty-tier cost threshold. Although the $780 30-day equivalent ingredient cost we determined to be the specialty-tier cost threshold for this final rule did not require rounding, had we arrived at a 30-day equivalent ingredient cost of, for example, $772, rounding up to $780 30-day equivalent ingredient cost would have an insignificant impact on the number of drugs meeting the specialty-tier cost threshold.

As noted above, because of conflicting forces, we have not estimated a quantitative cost to this provision and acknowledged at most a possible qualitative savings. Similarly, these alternatives would not change costs.

Comment: We did not receive any comments regarding the alternative on which we solicited comment to always round ''up'' to the nearest $10 increment.

Response: Due to the balance of other comments, we are not finalizing this alternative.

Comment: Some commenters preferred that CMS permit Part D sponsors to impose cost sharing on the higher-cost sharing, specialty tier higher than the current maximum allowable cost sharing of 25/33 percent.

Response: As discussed in section IV.E. of this final rule, we continue to have concerns that permitting Part D sponsors to impose cost sharing on the higher-cost sharing, specialty tier higher than the current maximum allowable cost sharing of 25/33 percent is discriminatory.

Comment: Some commenters preferred CMS's option to permit Part D sponsors to exempt both specialty tiers from tiering exceptions, even between the two tiers.

Response: As discussed in section IV.E. of this final rule, although we believe reasonable arguments can be made with regard to our statutory authority relative to both our proposal and the alternative, we are concerned that the alternative could make the preferred specialty tier vulnerable to tiering exceptions to the non-specialty tiers, which could impede the ability of Part D sponsors to offer actuarially equivalent benefit designs.

Although implementation will be delayed until coverage year 2022, we are finalizing as proposed our proposals to permit a second specialty tier, except we are not finalizing our proposal to specify a specialty tier threshold of $780. Additionally, in response to comments, we are finalizing new paragraph § 423.104(d)(2)(iv)(A)(*6*) which describes the eligibility for placement on the specialty tier of newly-FDA-approved Part D drugs.

To retain the policies in effect before coverage year 2022, we are amending the definition of specialty tier at § 423.560 by adding paragraph (i) to clarify that the existing definition will apply before coverage year 2022, and paragraph (ii) to cross reference the definition which appears in § 423.104(d)(2)(iv), which will apply beginning coverage year 2022. Additionally, as discussed in section IV.E.2. of this final rule, we are amending § 423.578(a)(6)(iii) by adding paragraph (A) to cross reference the definition of specialty tier which will apply before coverage year 2022, and paragraph (B) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv) which will apply beginning coverage year 2022. Additionally, paragraph (A) will remove the phrase ''and biological products,'' and paragraph (B) will (1) reflect the possibility of a second specialty tier, and (2) clarify that Part D sponsors may design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.

5. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

We are requiring that each Part D plan adopt a beneficiary RTBT by January 1, 2023. We had considered requiring that this regulatory action occur by January 1, 2021 to coincide with the requirement of a prescriber RTBT and the other regulatory actions in this rule. However, we wanted to ensure that plans had adequate time to focus on implementing the prescriber RTBT by the currently mandated January 1, 2021 deadline.

This option would probably not change the cost impact which, in section H8 of this final rule, was estimated as $4 million for implementation and $0.4 million for policy development and ongoing maintenance. The major driver of change in cost would be changes in

wages. We have already updated the 2018 wages in the NPRM to the current 2019 wages. The wages for general operations manager have decreased while the wages for compliance officer have increased. If we assume this continues for next year there would be no change in the $0.4 million estimate. Computer programmer wages are increased by about 3 percent per year which would increase the $4 million implementation cost by about $0.1 million.

We also considered requiring that plans display this information via a third party website or web application. However, since we discovered that plans already have patient portals that provide some of the mandated information, we believe it would be less confusing for beneficiaries to keep this information on the plan portal. In addition, it would be less of a burden on plans for them to put the information on the portals, rather than supply the information to a third party.

Another variation that we considered was to require that Part D sponsors clarify to enrollees that medications listed in the beneficiary RTBT are based on the formulary and that options may exist outside of the formulary. However, we ultimately decided that this requirement was not necessary, since Part D formularies already provide a robust array of options for Part D enrollees and we believe that Part D sponsors are in the best positon to judge whether such a statement is necessary. As a result, we declined to adopt this requirement.

We received no comments on our estimated impacts and are therefore finalizing it as proposed.

6. Service Determination Request Processes Under PACE (§ 460.121)

As we drafted this provision we considered several alternatives.

Alternative 1: First, we considered requiring that requests that can be immediately approved by a member of the IDT would still require a reassessment. We rejected this approach because the IDT member, based on their knowledge of the participant, would know quickly that the services were appropriate and would therefore not need to conduct a reassessment to make that determination.

Alternative 2: Second, we considered continuing to require that all requests that go to the full IDT would require a reassessment even if the service can be approved. We also rejected this approach because we do not believe it would be necessary to require a reassessment if the IDT can approve a service based on their knowledge of the participant.

The alternatives, the finalized approach, as well as the current approach are listed in Table I12 with total 10-year impact over 10 years.

TABLE I12: CURRENT, FINALIZED, AND ALTERNATIVE SAVINGS

Alternative Description	10-Year Savings (millions $)	SDR Type	Require IDT Review?	Require Reassessment?	Require Separate Notification?
Current	0	Easy approval	Yes	Yes	Yes
		Non-easy approval	Yes	Yes	Yes
		Denied	Yes	Yes	Yes
Finalized	193.8	Easy approval			
		Non-easy approval	Yes		Yes
		Denied	Yes	Yes	Yes
Alternative I	162.5	Easy approval		Yes	
IDT member can easily approve but requires a reassessment		Non-easy approval	Yes		Yes
		Denied	Yes	Yes	Yes
Alternative II	162.5	Easy approval			
IDT member cannot easily approve, require a reassessment for all requests that go to the full IDT		Non-easy approval	Yes	Yes	Yes
		Denied	Yes	Yes	Yes

F. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table I13, we have prepared an accounting statement showing the savings and costs associated with the provisions of this final rule for calendar years 2022 through 2031. Table I13 is based on Tables I14A, I14B, and I14C which lists savings and costs by provision. Table I13 is expressed in millions of dollars with both costs and savings listed as positive numbers; aggregate impact is expressed as a positive number since the aggregate impact is savings. As can be seen, the net annualized savings of this rule is about $2.9 to $3.4 million per year. The net raw savings over 10 years is $36.9 million. Minor seeming discrepancies in totals in Tables I14A, I14B, and I14C reflects use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these savings from various perspectives may be found in Table I14.

TABLE I13: ACCOUNTING TABLE (MILLIONS $)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Savings in 2021 dollars	3.0	3.5	2022-2031	Federal government, MA organizations, and Part D sponsors
Annualized Monetized Savings in 2021 dollars	26.6	26.8	2022-2031	Federal government, MA organizations, and Part D sponsors
Annualized Monetized Cost in 2021 dollars	23.6	23.3	2022-2031	Federal government, MA organizations, and Part D sponsors

* Both savings and costs are expressed as positive numbers. For example, at 7 percent there is an annualized savings of $26.6 million and an annualized cost of $23.6 million, resulting in an annualized net savings of $3.0 million.

The following Table I14 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table I14 is broken into Table I14A (2022 through 2025), Table I14B (2026 through 2029), and Table I14C (2030 through 2031, as well as raw totals). In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs. All numbers are in millions. Tables I14A, I14B, and I14C form the basis for Table I13. The savings in these tables are true savings reflecting reduced consumption of services and goods.

TABLE I14A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2022 THROUGH 2025*

	2022 Savings	2022 Cost	2023 Savings	2023 Cost	2024 Savings	2024 cost	2025 Savings	2025 Cost
Total Savings	22.6		25.6		26.1		26.5	
Total Costs		34.9		21.8		21.8		21.8
Aggregate Total	(12.3)		3.8		4.2		4.7	
MTMP		0.6		0.6		0.6		0.6
SNP MOCS		0.4		0.4		0.4		0.4
PACE Service Determination requests	16.8		17.9		18.3		18.8	
Fraud & Abuse Pt C,D		15.2		9.6		9.6		9.6
Educating at risk enrollees		0.5		0.4		0.4		0.4
RTBT		4.7		0.4		0.4		0.4
Pharmacy Performance Measures		0.2		0.2		0.2		0.2
Creating DMPs for those without them		3.0				0.0		0.0
Other DMP Paperwork		0.2		0.1		0.1		0.1
DMP Case management for PARBs with opioid overdose history		10.0		10.0		10.0		10.0
Case Management for those parent organizations without DMPs		0.1		0.1		0.1		0.1
DMP Drug savings	5.8		7.7		7.7		7.7	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

TABLE I14B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2026 THROUGH 2029*

	2026 Savings	2026 Cost	2027 Savings	2027 Cost	2028 Savings	2028 Cost	2029 Savings	2029 Cost
Total Savings	27.0		27.5		27.9		28.3	
Total Costs		21.8		21.8		21.8		21.8
Aggregate Total	5.2		5.6		6.1		6.5	
MTMP		0.6		0.6		0.6		0.6
SNP MOCS		0.4		0.4		0.4		0.4
PACE Service Determination requests	19.3		19.7		20.2		20.6	
Fraud & Abuse Pt C,D		9.6		9.6		9.6		9.6
Educating at risk enrollees		0.4		0.4		0.4		0.4
RTBT		0.4		0.4		0.4		0.4
Pharmacy Performance Measures		0.2		0.2		0.2		0.2
Creating DMPs for those without them		-		-		-		-
Other DMP Paperwork		0.1		0.1		0.1		0.1
DMP Case management for PARBs with opioid overdose history		10.0		10.0		10.0		10.0
Case Management for those parent organizations without DMPs		0.1		0.1		0.1		0.1
DMP Drug savings	7.7		7.7		7.7		7.7	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

TABLE I14C: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2030 THROUGH 2031 AND RAW TOTALS*

	2030 Savings	2030 Cost	2031 Savings	2031 Costs	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)
Total Savings	28.7		29.0		269.2	
Total Costs		21.8		21.8		231.3
Aggregate Total	6.8		7.2		37.9	
MTMP		0.6		0.6		6.4
SNP MOCS		0.4		0.4		4.0
PACE Service Determination requests	20.9		21.3		193.8	
Fraud & Abuse Pt C,D		9.6		9.6		101.3
Educating at risk enrollees		0.4		0.4		4.0
RTBT		0.4		0.4		8.2
Pharmacy Performance Measures		0.2		0.2		2.4
Creating DMPs for those without them		-		-		3.0
Other DMP Paperwork		0.1		0.1		1.0
DMP Case management for PARBs with opioid overdose history		10.0		10.0		100.1
Case Management for those parent organizations without DMPs		0.1		0.1		0.9
DMP Drug savings	7.7		7.7		75.4	

*Both savings and costs are indicated with positive numbers. Net impact when positive indicates savings and when negative indicates a cost. Calculations use spreadsheet accuracy and actual numbers; consequently, totals may have minor rounding errors.

The following information supplements Table I14 and also identifies how impacts calculated in section VIII of this final rule affect the calculations of this section and the tables.

- For two provisions, DMP and PACE, this Regulatory Impact Analysis provides tables summarizing a variety of impacts with line items for the paperwork burdens of section VIII of this final rule. Thus the section VIII impacts are reflected both in Table I14 (summary table) and Table I13 (monetized table) as well as in special tables in this section.
- For six provisions (MTMP, RTBT, SNP MOCs, pharmacy performance measures, educating at risk enrollees, and Fraud and Abuse), the only impacts are calculated in section VIII of this final rule. These six provisions have those section VIII impacts listed in Table I14.

We received comments on impacts in certain individual provisions. These comments as well as our responses, including changes to impacts, have been addressed in the appropriate provision sections, with many of these discussions presented in section VIII.D. of this final rule. Additionally, we did not receive any comments on the summary or monetized table per se and are therefore finalizing these numbers as proposed with appropriate adjustments for provisions not included in this first final rule, the updated impacts, and updated wage estimates.

G. Conclusion

As indicated in Table I13, we estimate that this final rule generates annualized cost savings of approximately $3 to $3.5 million (depending on the discount factor used) per year over 2022 through 2031.

As indicated in Table I14, the primary drivers of savings are (1) revisions to the PACE program resulting in greater efficiencies and (2) increased vigilance for at-risk beneficiaries with a consequent reduction in drug costs. These savings are offset by costs from fraud and abuse efforts and a variety of outreach efforts to at-risk beneficiaries.

The net savings are true savings since they reflect reductions in consumption of goods and services. These savings by plans arising from reduction of services and consumptions of goods are ultimately passed back to the Medicare Trust Fund which reduce the dollar spending needed for plans.

The savings for the federal government are $75.4 million over 10 years, arising exclusively from DMP savings on reduced prescription drug spending. Administrative savings such as those from the PACE provisions may not accrue directly to the Medicare Trust Fund.

H. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is a deregulatory action under Executive Order 13771. At a 7 percent rate, this rule is estimated to save $3.7 million a year in 2016 dollars over an infinite time horizon.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to reads as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.370(a) is amended by—

■ a. Revising paragraph (1) of the definition of ''Credible allegation of fraud''; and

■ b. Adding the definition for ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 4. Section 417.496 is added to read as follows:

§ 417.496 Cost plan crosswalk.

(a) *General rules*—(1) *Definition.* Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition.* (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules.* The cost plan must comply with renewal and nonrenewal rules in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal.* A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception.* (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and may permit a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 5. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

Section 422.2 is amended by—

■ a. Revising the definition of ''Institutionalized'';

■ b. Adding the definition of ''Parent organization'' in alphabetical order to read; and

■ c. Revising the definition of ''Special needs individual''.

The revisions and addition read as follows:

§ 422.2 Definitions.

* * * * *

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Special needs individual means an MA eligible individual who is institutionalized or institutionalized-equivalent, as those terms are defined in this section, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

* * * * *

■ 6. Section 422.100 is amended by—

■ a. Revising paragraphs (c)(1) and (2);

■ b. Redesignating paragraph (d)(2) as paragraph (d)(2)(i);

■ c. Adding paragraph (d)(2)(ii);

■ d. Revising paragraph (m)(5)(iii).

The revisions and additions read as follows:

§ 422.100 General requirements.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing.

(B) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare (This specifically includes Medicare Parts A, B, and D).

(d) * * *

(2) * * *

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

* * * * *

(m) * * *

(5) * * *

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

■ 7. Section 422.101 by—

■ a. Revising paragraphs (f)(1) introductory text and (f)(1)(i) and (iii); and

■ b. Adding paragraph (f)(1)(iv);

■ c. Revising paragraph (f)(2) introductory text; and

■ d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's

individualized care plan as required under paragraph (f)(1)(ii) of this section.

* * * * *

(iii) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(iv) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

* * * * *

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark.

■ 8. Section 422.102 is amended—

■ a. In paragraph (a)(4) by removing the phrase ''only as a mandatory'' and adding in its place the phrase ''for Part A and B benefits only as a mandatory''; and

■ b. Adding paragraphs (a)(5) and (6).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit (reductions or payment of cost sharing for Part D drugs is not permissible as a Part C supplemental benefit).

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

* * * * *

■ 9. Section 422.111 is amended by—

■ a. Removing paragraph (b)(12);

■ b. Redesignating paragraph (h)(1)(i) as paragraph (h)(1)(i)(A);

■ c. Adding paragraph (h)(1)(i)(B);

■ d. Adding paragraphs (h)(1)(ii)(A) through (C);

■ e. Redesignating paragraph (h)(1)(iii) as (h)(1)(iii)(A);

■ f. Adding paragraph (h)(1)(iii)(B);

■ g. Adding paragraphs (h)(1)(iv), (j), and (k).

The revisions and additions read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(h) * * *

(1) * * *

(i)(A) * * *

(B) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan, with the following exceptions:

(1) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(2) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(ii) * * *

(A) For coverage beginning on and after January 1, 2022, limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii) (A) * * *

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

* * * * *

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under an MA plan who is furnished an in-home health risk assessment on or after January 1, 2022. For purposes of this paragraph (j), a health risk assessment furnished to an individual who is residing in an institutional setting, such as a nursing facility, that has the primary

responsibility for the disposal of unused medications, is not considered an in-home health risk assessment. As part of the in-home health risk assessment, the enrollee must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary of the written information as described at paragraphs (j)(1) through (6) of this section when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(1) Unused medications should be disposed of as soon as possible.

(2) The U.S. Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or other authorized sites. Include a web link to the information available on the DEA website at *www.deatakeback.com* and the web link to the DEA search engine which enables beneficiaries to identify drug take back sites in their community at the following web address: *https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1.*

(3) Community take back sites are the preferred method of disposing of unused controlled substances.

(4) The location of two or more drug take back sites that are available in the community where the enrollee resides.

(5) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers. If applicable, the instructions may also include information on the availability of in-home drug deactivation kits in the enrollee's community.

(6) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(1) *Information requirements for the reporting period.* Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals.* Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements.* (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification before the end of each month that follows the month in which a claim was filed.

(5) *Exceptions.* MA organizations are not required to send the explanation of benefits to dual-eligible enrollees.

■ 10. Section 422.134 is revised to read as follows:

§ 422.134 Reward and incentive programs.

(a) *Definitions.* As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s) program, reward(s) program, and *R&I program* mean the same thing as rewards and incentives program.

Incentive(s), R&I, and *rewards and incentives* mean the same things as reward(s).

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities.* (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(iv) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(v) Be provided with accommodations consistent with the goal of the target activity to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To ensure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (g)(1) of this section and must not design a program based on the achievement of a health status measurement.

(d) *Reward items.* (1) The reward item for a target activity must meet all of the following:

(i) Be offered identically to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, to the enrollee, such as through transfer of ownership or delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements.* An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure.* MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous.* (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally, all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

■ 11. Section 422.162 is amended—

■ a. By revising paragraphs (b)(3)(iv)(A) and (B); and

■ b. By adding paragraph (b)(4).

The additions and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

(4) *Quality bonus payment ratings.* (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

* * * * *

■ 12. Section 422.164 is amended by revising paragraph (g)(1)(iii)(A) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2022, if there is a contract consolidation as described at § 422.162(b)(3), the TMP or audit data are combined for the consumed and surviving contracts

before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

* * * * *

■ 13. Section 422.166 is amended—

■ a. By adding paragraph (d)(2)(vi); and

■ b. By adding a sentence to the end of paragraph (i)(8).

The additions read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(d) * * *

(2) * * *

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under § 422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on *www.medicare.gov.* The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous 3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on *www.medicare.gov.*

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

* * * * *

(i) * * *

(8) * * * Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

* * * * *

■ 14. Section 422.220 is revised to read as follows:

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

■ 15. Section 422.252 is amended by revising the definition of ''New MA plan'' to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a plan that meets the following:

(1) Offered under a new MA contract.

(2) Offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

* * * * *

■ 16. Section 422.500 is amended in paragraph (b) by adding the definitions of ''Fraud hotline tip'', ''Inappropriate prescribing'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and

includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

■ 17. Section 422.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, with the exception of a sanction imposed under § 422.752(d) or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 422.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent organization completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

* * * * *

■ 18. Section 422.503 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) and (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5) * * *

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

* * * * *

■ 19. Section 422.504 is amended by revising paragraph (a)(15) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) Through the CMS complaint tracking system, to address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 20. Section 422.530 is added to subpart K to read as follows:

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/nonrenewal rules.* The MA organization

must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* An MA organization may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer those affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year, consistent with 42 CFR 422.2263 and 423.2263.

(2) *Special needs plans (SNPs).* In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C–SNPs).* (A) Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(C) Non-renewing C–SNP with a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior C–SNP contained.

(ii) *Institutional SNP.* (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions.* In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and may permit a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) plan changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries, considering whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. Crosswalks from a network based PFFS plan to a non-network or partial network PFFS plan will not be permitted.

(2) When MA contracts offered by two different MA organizations that share the same parent organization are consolidated such that the separate contracts are consolidated under one surviving contract, the enrollees from the consolidating contracts may be crosswalked to an MA plan under the surviving contract.

(3) When a renewing D–SNP with a multi-state service area reduces its service area or, in the case of a D–SNP in an MA regional plan contract, nonrenews and creates state-specific local preferred provider organization plans in its place to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D–SNPs, offered under the same parent organization (even if the D–SNPs are offered by two different MA organizations), and for which the enrollees are eligible, as CMS determines is necessary to accommodate changes to the contracts between the state and D–SNP under § 422.107. For this crosswalk exception, CMS will permit enrollees to be moved between different contracts.

(4) When a renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it

is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For this crosswalk exception, CMS will not permit enrollees to be moved between different contracts.

(5) Renewing C–SNP with a grouping of multiple conditions that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(d) *Procedures.* (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An MA organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies requesting MA organizations of the approval or denial after the crosswalk exception request deadline.

■ 21. Section 422.550 is amended by adding paragraph (f) to read as follows:

§ 422.550 General provisions.

* * * * *

(f) *Sale of beneficiaries not permitted.* (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

■ 22. Section 422.562 is amended by adding paragraph (d)(3) to read as follows:

§ 422.562 General provisions.

* * * * *

(d) * * *

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of ''contractors'' as it relates to stipulated decisions.

■ 23. Section 422.568 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization dismisses an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a request with the MA organization.

■ 24. Section 422.570 is amended by adding paragraph (g) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization dismisses an expedited organization request in accordance with § 422.568.

■ 25. Section 422.582 is amended—

■ a. In paragraph (e) by removing the word ''written''; and

■ b. By adding paragraphs (f) through (i).

The additions to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(f) *Dismissing a request.* The MA organization dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

■ 26. Section 422.584 is amended by adding paragraph (g) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(g) *Dismissing a request.* The MA organization dismisses an expedited reconsideration request in accordance with § 422.582(f) through (i).

■ 27. Section 422.590 is amended by adding paragraph (i) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(i) *Requests for review of a dismissal by the independent entity.* If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other proper party under § 422.578 has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

■ 28. Section 422.592 is amended—

■ a. In paragraph (a) by adding a sentence at the end of the paragraph; and

■ b. By adding paragraphs (d) through (i).

The additions to read as follows:

§ 422.592 Reconsideration by an independent entity.

(a) * * * In accordance with § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

* * * * *

(d) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a request for withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 29. Section 422.600 is amended in paragraph (b) by adding a new sentence at the end of the paragraph to read as follows:

§ 422.600 Right to a hearing.

* * * * *

(b) * * * For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

* * * * *

■ 30. Section 422.629 is amended by revising paragraph (k)(4)(ii) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(4) * * *

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision.

* * * * *

■ 31. Section 422.631 is amended by adding paragraphs (e) through (i) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(e) *Dismissing a request.* The applicable integrated plan dismisses a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a request with the applicable integrated plan.

■ 32. Section 422.632 is amended in paragraph (b)(1) by removing the reference ''§ 422.633(e)'' and adding in its place the reference ''§ 422.633(d)''.

§ 422.632 [Amended]

■ 33. Section 422.633 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan dismisses an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(*l*) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the dismissal is vacated under paragraph (j) of this section.

■ 34. Section 422.760 is amended by redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively, and adding a new paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by The Office of Management and Budget (OMB) annually.

(ii) *Calculation of minimum penalty amounts.* (A) Per determination and per enrollee minimum penalty amounts increases by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts is updated no more often than every 3 years.

(C) CMS does the following:

(*1*) Tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts.

(*2*) Announces the penalties and amounts described in paragraph (b) of this section on an annual basis.

* * * * *

■ 35. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

■ 36. Section 422.2261 is added to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization.

(3) Unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* MA organizations may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

■ 37. Section 422.2262 is revised to read as follows:

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, except when used in logos or taglines.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Advantage (HMO).'' MA organizations are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment, except for factually accurate descriptions of the MA organization's policies adopted in accordance with § 422.74(b)(1) and (d)(1) of this chapter.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(iii) Use the term ''free'' in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the MA organization must prominently include, at least once, the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, ''H'' for MA or Section 1876 Cost Plans, ''R'' for Regional PPO plans (RPPOs), or ''Y'' for MCE, a means of identification available for Plans/Part D sponsors that have multiple MA contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communications materials or an uppercase ''M'' for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 38. Section 422.2263 is added to read as follows:

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other providers are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the MA organization's website about the existence of OEP.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how MA organizations must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA–PDs and the summary rating for MA-only plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable, unless using Star Ratings to convey overall MA organization performance (for example, ''Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the MA organization must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5-star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5-star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 39. Section 422.2264 is revised to read as follows:

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business.* MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) When reaching out to a beneficiary regarding plan business, as outlined in this section, MA organizations must offer the beneficiary the ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries.* MA organizations and their agents or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) MA organizations may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) If a marketing event directly follows an educational event, the beneficiary must be made aware of the change and given the opportunity to leave prior to the marketing event beginning.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products, such as annuities.

■ 40. Section 422.2265 is added to read as follows:

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements.* (1) MA organization websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content.* MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A searchable provider directory.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the Medicare.gov electronic complaint form.

(9) Disaster and emergency policy consistent with § 422.100(m)(5)(iii).

(10) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(11) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(12) For MSA plans, the following statements:

(i) ''You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.''

(ii) ''Tax publications are available on the IRS website at *http://www.irs.gov* or from 1–800–TAX–FORM (1–800–829–3676).''

(c) *Required posted materials.* MA organization's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website

by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 41. Section 422.2266 is added to read as follows:

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities performed on behalf of the MA organization.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting.* MA organization activities in the health care setting are those activities, including marketing activities that are conducted by MA organization staff or on behalf of the MA organization, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

(f) *Activities of Institutional Special Needs Plans (I–SNPs) Serving Long-Term Care Facility Residents* (1) Depending on the context of a given situation, I–SNP contracted with a long-term care facility can be viewed as both a provider and a plan.

(2) I–SNPs may use staff operating in a social worker capacity to provide information, including marketing materials (excluding enrollment forms), to residents of a long term care facility.

(3) Social workers of the I–SNP (whether employees, agents, or contracted providers) may not accept or collect a scope of appointment or enrollment form on behalf of the I–SNP.

(4) Unless the beneficiary or the beneficiary's authorized representative initiates additional contact with or by the plan, all other marketing and outreach activities in the beneficiary's room must follow the requirements for beneficiary contact under § 422.2264

(5) All other activities with healthcare providers or in the healthcare setting must comply with §§ 422.2266(a), (b), (c), (d), and (e).

■ 42. Section 422.2267 is added to read as follows:

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) The MA organization may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and MA organizations may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard-copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to § 422.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 422.111(b)) must be provided annually and must be provided:

(i) To current enrollees of the plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB).* MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on medical benefits, including:

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Information on prescription drug expenses, including:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30-or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) A statement that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D–SNP)s, the SB must identify or describe the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document identifying the Medicaid benefits that accompanies the SB.

(E) For D–SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D–SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form.* This is a model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare health plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 422.506(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's' region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy, and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy,

options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory.* This is a model communications material through which plans must provide the information under § 422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B)*(1)* Updates to hardcopy provider directories must be completed within 30 days.

(2) Hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice.* This is a model communications material through which plans must provide the information required under § 422.111(e). The provider termination notice must be both of the following:

(i) Provided in hard copy.

(ii) Sent via U.S. mail (first class postage is recommended, but not required).

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organizations that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice.* This is a model communications material through which plans must notify enrollees when a provider they visit or consult has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN)).* This is a standardized communications material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC).* This is a standardized communications material used to convey beneficiary appeal rights when a plan is terminating previously-approved coverage in a Skilled Nursing Facility (SNF), Comprehensive Outpatient Rehabilitation Facility (CORF), or Home Health setting (HHA).

(18) *Detailed Explanation of Non-Coverage (DENC).* This is a standardized communications material used to convey to a beneficiary why their current Medicare covered SNF, CORF or HHA services should end.

(19) *Appointment of Representative (AOR).* This is a standardized communications material used to authorize or appoint an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM).* This is a standardized communications material used to convey a beneficiary's rights as a hospital inpatient and appeal rights when their covered inpatient hospital stay is ending.

(21) *Detailed Notice of Discharge Form (DND).* This is a standardized communications material, as required under § 422.622(e), used to convey to a beneficiary why their current Medicare covered inpatient hospital stay should end.

(22) *Medicare Outpatient Observation Notice (MOON).* This is a standardized communications material used to inform a beneficiary that he or she is an outpatient receiving observation services.

(23) *Appeal and Grievance Data Form.* This is a standardized communications material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing.* This is a standardized communications material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing.* This is a standardized communications material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement.* This is a model communications material used by non-contracted providers to waive beneficiary liability for payment for denied services while utilizing the enrollee appeals process under subpart M of part 422.

(28) *Notice of Appeal Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal.* This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(31) *Star Ratings Disclaimer.* This is model content through which plans must:

(i) Convey that MA organizations are evaluated yearly by Medicare.

(ii) Convey that the ratings are based on a 5-star rating system.

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(32) *SSBCI Disclaimer.* This is model content through which MA organizations must:

(i) Convey the benefits mentioned are a part of special supplemental benefits.

(ii) Convey that not all members will qualify.

(iii) Include the model content in the material copy which mentions SSBCI benefits.

(33) *Accommodations Disclaimer.* This is model content through which MA organizations must:

(i) Convey that accommodations for persons with special needs are available.

(ii) Provide a telephone number and TTY number.

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events described under § 422.2264(c).

(34) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) MA organizations must include the following statement when mailing health and wellness information: ''Health and wellness or prevention information.''

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(35) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(36) *Provider Co-branded Material Disclaimer.* This is model content through which MA organizations must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned, unless the co-branding is with a provider network or health system that represents 90 percent or more of the network as a whole.

(37) *Out of Network Non-Contracted Provider Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Out-of-network/non-contracted providers are under no obligation to treat Plan members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost-sharing that applies to out-of-network services,'' and must be included whenever materials reference out-of-network/non-contracted providers.

(38) *NCQA SNP Approval Statement.* This is model content and must be used by SNPs who have received NCQA approval. MA organizations must:

(i) Convey that MA organization has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP).

(ii) Include the last contract year of NCQA approval.

(iii) Convey that the approval is based on a review of [insert Plan Name's] Model of Care.

(iv) Not include numeric SNP approval scores.

§ 422.2268 [Removed]

■ 43. Section 422.2268 is removed.

■ 44. Section 422.2274 is revised to read as follows:

§ 422.2274 Agent, broker, and other third party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent MA

organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight.* MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell, including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in MA plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules.* (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay pro-rated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at an amount up to 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA–PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA–PD), the MA organization may only pay compensation at the renewal rate for the MA–PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation

for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments).* (1) Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Administrative payments can be based on enrollment provided payments are at or below the value of those services in the marketplace.

(f) *Payments for referrals.* Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries) to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 45. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 46. Section 423.4 is amended by adding definitions for ''Credible allegation of fraud'', ''Fraud hotline tip'', ''Inappropriate prescribing'', ''Parent organization'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

* * * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

* * * * *

■ 47. Section 423.100 is amended—
■ a. In the definition of ''Applicable drug'' by revising paragraph (1)(ii);
■ b. In the definition of ''Exempted beneficiary'' by:
■ i. Removing the word ''or'' at the end of paragraph (2);
■ ii. Removing the period at the end of paragraph (3) and adding ''; or'' in its place; and
■ iii. Adding paragraph (4); and
■ c. By revising the introductory text in the definition of ''Potential at-risk beneficiary''.

The revisions and addition read as follows:

§ 423.100 Definitions.

* * * * *

Applicable drug * * *

(1) * * *

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and

* * * * *

Exempted beneficiary * * *

(4) Has sickle cell disease.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual who is not an exempted beneficiary (as defined in this section) and—

* * * * *

■ 48. Section 423.104 is amended by adding paragraph (d)(2)(iv) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iv) Specialty tier means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(*2*) of this section) that are greater than the specialty tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold.* CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(*1*) *30-day equivalent ingredient cost.* Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(*2*) *30-day equivalent supply.* CMS determines the 30-day equivalent supply as follows: If the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(*3*) *Top 1 percent.* CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(*4*) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(*5*) *Claims history.* Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold.

(*6*) *No claims history.* For newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor estimates that ingredient cost portion of their negotiated prices for a 30-day equivalent supply, as defined in subparagraph (d)(2)(iv)(A)(*2*), is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to the requirements at § 423.120(b).

(B) *Limit on specialty-tier cost threshold adjustment.* (*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold.* CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing.* A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(*1*) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(*2*) For Part D plans with no deductible, 33 percent coinsurance.

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

* * * * *

■ 49. Section 423.128 is amended by—
■ a. Revising paragraph (a)(1);
■ b. Adding paragraph (b)(11);
■ c. Adding paragraphs (d)(1)(i)(A) and (B), and (ii)(A) through (C);
■ d. Redesignating paragraph (d)(1)(iii) as (d)(1)(iii)(A);
■ e. Adding paragraph (d)(1)(iii)(B); and
■ f. Adding paragraphs (d)(1)(v) and (vi) and (d)(4) and (5).

The revisions and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

(a) * * *

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part, except as provided in paragraph (b)(11)(ii) of this section;

* * * * *

(b) * * *

(11) *Opioid information.* (i) Beginning January 1, 2022, and subject to paragraph (b)(11)(ii) of this section, a Part D sponsor must disclose to each enrollee at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications—

(*1*) In the case of an MA–PD, under such plan; and

(*2*) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan, with the following exceptions:

(*1*) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(*2*) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(B) For coverage beginning on and after January 1, 2022, any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) * * *

(A) For coverage beginning on and after January 1, 2022, limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) * * *.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

* * * * *

(v) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

(vi) For coverage beginning on and after January 1, 2022, provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

* * * * *

(4) Beginning on January 1, 2023, a Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Formulary medication alternatives for a given condition.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (vi) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of reasonable value, both individually and in the aggregate.

(ii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, health status, or other prohibited basis.

(iii) Not be offered in the form of cash or other cash equivalents.

(iv) Not be used to target potential enrollees.

(v) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vi) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

* * * * *

■ 50. Section 423.153 is amended by—

■ a. Revising the section heading;

■ b. Revising paragraph (a);

■ c. By adding paragraphs (d)(1)(vii)(E) and (F);

■ d. By revising paragraph (d)(2);

■ e. By revising paragraph (f)(1) introductory text;

■ f. In paragraph (f)(3)(ii) introductory text by removing the phrase ''paragraphs (f)(10) and (11) of this section'' and adding its place the phrase ''paragraphs (f)(9) through (13) of this section'';

■ g. In paragraph (f)(4)(ii)(A) by removing the phrase ''paragraph (f)(2)(ii)(B) of this section'' and adding its place the phrase ''paragraph (f)(3)(ii)(A) of this section'';

■ h. In paragraph (f)(4)(ii)(A) by removing the phrase ''paragraph (f)(4)(i)(B) of this section'' and adding in its place the phrase ''paragraph (f)(2)(i)(B) of this section'';

■ i. Revising paragraphs (f)(5)(ii)(C)(*3*), (f)(6)(ii)(C)(*4*), and (f)(8)(i);

■ j. In paragraph (f)(15)(ii)(C) by removing the phrase ''any potential at-risk beneficiary'' and adding in its place the phrase ''any potential at-risk beneficiary or at-risk beneficiary'' and changing ''definition'' to ''definitions'';

■ k. In paragraph (f)(15)(ii)(D) by changing ''no later than 7 days of the date'' to ''no later than 7 days from the date'';

■ l. By revising paragraph (f)(16); and

■ m. By revising the heading of paragraph (g).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), drug management programs, and access to Medicare Parts A and B claims data extracts.

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in

paragraphs (b), (c), and (d) of this section. No later than January 1, 2022, a Part D plan sponsor must have established a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section.

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(E) Beginning January 1, 2022, for enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or other MTM correspondence or service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

(i)(A) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(C) Are likely to incur the following annual Part D drug costs:

(*1*) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(*2*) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv); or

(ii) Beginning January 1, 2022, are at-risk beneficiaries as defined in § 423.100.

* * * * *

(f) * * *

(1) *Written policies and procedures.* A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. In the case of a Part D sponsor, including a PACE organization, without its own or a contracted P&T committee because it does not use a formulary, the written policies and procedures described in this section must be approved by the Part D sponsor's medical director as described at § 423.562(a)(5) (or, for a PACE organization, at § 460.60(b)) and applicable clinical and other staff or contractors as determined appropriate by the medical director. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

* * * * *

(3) * * *

(ii) In accordance with paragraphs (f)(9) through (13) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are—

* * * * *

(4) * * *

(A) Except as provided in paragraph (f)(3)(ii)(A) of this section regarding a prescriber limitation, if the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(2)(i)(B) of this section for eliciting information from the prescribers.

(5) * * *

(ii) * * *

(C) * * *

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at §§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(6) * * *

(ii) * * *

(C) * * *

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(*i*) A description of both the standard and expedited redetermination processes.

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*iii*) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(8) * * *

(i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) The date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

(15) * * *

(ii) * * *

(C) Provide information to CMS about any potential at-risk beneficiary or at-risk beneficiary that meets paragraph (2) of the definitions in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

(D) Provide information to CMS as soon as possible but no later than 7 days from the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 7 days from a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

* * * * *

(16) *Clinical guidelines.* Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or a Part D sponsor using clinical guidelines that—

(i) Are developed with stakeholder consultation;

(ii) Are based on:

(1) The acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors; or

(2) Beginning January 1, 2022, a history of opioid-related overdose as determined by at least one recent claim that contains a principal diagnosis indicating opioid overdose, and at least one recent claim for an opioid medication other than an opioid used for medication assisted therapy (MAT).

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts*— * * *

* * * * *

■ 51. Section 423.182 is amended by revising paragraphs (b)(3)(ii)(A) and (B) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for CAHPS. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except CAHPS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

■ 52. Section 423.184 is amended by revising paragraph (g)(1)(ii)(A) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2022, if there is a contract consolidation as described at § 423.182(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(ii)(B) through (M) of this section is applied.

* * * * *

■ 53. Section 423.186 is amended by adding a sentence to the end of paragraph (i)(6) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(i) * * *

(6) * * * Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

* * * * *

■ 54. Section 423.265 is amended by revising paragraph (b)(2) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

* * * * *

■ 55. Section 423.286 is amended by revising paragraph (d)(4)(ii) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(d) * * *

(4) * * *

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5 percent)/ 25.5 percent).

* * * * *

■ 56. Section 423.503 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under to subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

* * * * *

■ 57. Section 423.503 is amended by revising paragraph (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

* * * * *

■ 58. Section 423.504 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the

Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The Part D plan sponsor must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the Part D plan sponsor on the referral. (*6*)(*i*) The plan sponsor is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS provides plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

* * * * *

■ 59. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 60. Section 423.514 is amended by redesignating paragraph (a)(5) as paragraph (a)(6) and adding a new paragraph (a)(5) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) * * *

(5) Pharmacy performance measures.

* * * * *

■ 61. Section 423.551 is amended by revising paragraph (g)(2) to read as follows:

§ 423.551 General provisions.

* * * * *

(g) * * *

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

* * * * *

■ 62. Section 423.560 is amended by—

■ a. Removing the definition of ''Appointed representative'';

■ b. Adding the definition of ''Representative'' in alphabetical order; and

■ c. Revising the definition of ''Specialty tier''.

The addition and revision read as follows:

§ 423.560 Definitions.

* * * * *

Representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M, of this chapter.

Specialty tier: (1) Before January 1, 2022, means a formulary cost-sharing tier dedicated to very high cost Part D drugs that exceed a cost threshold established by the Secretary; and

(2) Beginning January 1, 2022, has the meaning given the term in § 423.104.

■ 63. Section 423.566 is amended by revising paragraph (c)(2) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(c) * * *

(2) The enrollee's representative, on behalf of the enrollee; or

* * * * *

■ 64. Section 423.568 is amended by adding paragraphs (i) through (m) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(i) *Dismissing a request.* The Part D plan sponsor dismisses a coverage determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the individual making the request is not permitted to request a coverage determination under § 423.566(c).

(2) When the Part D plan sponsor determines the party failed to make out a valid request for a coverage determination that substantially complies with paragraph (a) of this section.

(3) When an enrollee or the enrollee's representative files a request for a coverage determination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(4) When a party filing the coverage determination request submits a timely request for withdrawal of the request for a coverage determination with the Part D plan sponsor.

(j) *Notice of dismissal.* The Part D plan must mail or otherwise transmit a written notice of the dismissal of the

coverage determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(k) *Vacating a dismissal.* If good cause is established, the Part D plan sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(*l*) *Effect of dismissal.* The Part D plan sponsor's dismissal is binding unless it is modified or reversed by the Part D plan sponsor or vacated under paragraph (k) of this section.

(m) *Withdrawing a request.* A party that requests a coverage determination may withdraw its request at any time before the decision is issued by filing a request with the Part D plan sponsor.

■ 65. Section 423.570 is amended by adding paragraph (f) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited coverage determination in accordance with § 423.568.

■ 66. Section 423.578 is amended—

■ a. By revising paragraph (a)(6)(iii); and

■ b. In paragraph (b)(4) by removing the phrase ''the enrollee's appointed representative'' and adding in its place the phrase ''the enrollee's representative''.

The revision reads as follows:

§ 423.578 Exceptions process.

(a) * * *

(6) * * *

(iii)(A) Before January 1, 2022, if a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier are not eligible for a tiering exception.

(B) Beginning January 1, 2022, if a Part D sponsor maintains one or two specialty tiers, as defined in § 423.104, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exception(s) to non-specialty tiers.

* * * * *

■ 67. Section 423.582 is amended—

■ a. In paragraph (d) by removing the word ''written'' and

■ b. By adding paragraphs (e) through (h).

The additions read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(e) *Dismissing a request.* A Part D plan sponsor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the decision is vacated under paragraph (g) of this section.

■ 68. Section 423.584 is amended by adding paragraph (f) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited redetermination in accordance with § 423.582.

■ 69. Section 423.590 is amended by adding paragraphs (i) and (j) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other proper party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

■ 70. Section 423.600 is amended by—

■ a. Revising paragraph (b); and

■ b. Adding paragraphs (f) through (k).

The revision and additions read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

* * * * *

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

* * * * *

(f) The party who files a request for reconsideration may withdraw it by filing a request with the IRE.

(g) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a

proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (a) of this section.

(4) When an enrollee or the enrollee's representative files a request for reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to continue the appeal.

(5) When a party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration consistent with § 423.590. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 71. Section 423.760 is amended by—

■ a. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and

■ b. Adding a new paragraph (b)(3).

The addition reads as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessments imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by the Office of Management and Budget (OMB) annually.

(ii) *Calculation of penalty amounts.* (A) Per determination and per enrollee penalty amounts are increased by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts will be updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announce them on an annual basis.

* * * * *

■ 72. Section 423.2006 is amended by redesignating paragraphs (c)(1) and (2) as paragraphs (c)(2) and (3) and adding a new paragraph (c)(1) to read as follows:

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(c) * * *

(1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including deductible, coinsurance, or copayment amounts that may be collected from the enrollee for the Part D drug(s).

* * * * *

§ 423.2014 [Amended]

■ 73. Section 423.2014 is amended in paragraph (a)(1)(ii) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative''.

§ 423.2036 [Amended]

■ 74. Section 423.2036 is amended in paragraphs (c) and (d) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative'' each time it appears.

■ 75. Section 423.2260 is revised to read as follows:

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the Part D sponsor (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a Part D plan or plans.

(B) Influence a beneficiary's decision making process when making a Part D plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not

limited to the Part D sponsor's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

■ 76. Section 423.2261 is added to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements.* Part D sponsors must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor.

(3) Unless specified by CMS, third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* Part D sponsors may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS.

(3) The material has been accepted under File and Use, as follows:

(i) The Part D sponsor may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

■ 77. Section 423.2262 is revised to read as follows:

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements except when used in logos or taglines.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Drug Plan (PDP)''. Part D sponsors are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment except for factually accurate descriptions of the PDP sponsor's policies adopted in accordance with § 423.44(b)(1) and (d)(1) of this chapter.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor's product provided the

endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the Part D sponsor must prominently include, at least once, the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, ''S'' for PDPs, or ''Y'' for MCE, a means of identification available for Plans/Part D sponsors that have multiple PDP contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI-PLAN'' instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI-PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communication materials or an uppercase ''M'' for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 423.2267.

(iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 78. Section 423.2263 is added to read as follows.

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other pharmacies are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, a Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the Part D sponsor's website about the existence of OEP.

(ii) During the OEP, a Part D sponsors may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how Part D sponsors must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA–PDs and the summary rating for PDP plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable unless using Star Ratings to convey overall Part D sponsor performance (for example, ''Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the Part D sponsor must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star PDP contracts:

(i) May not market the 5-star special enrollment period, as defined in § 423.38(c)(20), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5- star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the Part D sponsor's contract received a summary rating of 2.5 stars or below in Part D for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 79. Section 423.2264 is revised to read as follows:

§ 423.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the Part D sponsor or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) Part D sponsors may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) Part D sponsors may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business.* Part D sponsors may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) A Part D sponsor may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in an MA or cost plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) Part D sponsors may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) When reaching out to a beneficiary regarding plan business, as outlined in this section, Part D sponsor must offer the beneficiary the ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries.* Part D sponsors and their agent or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, Part D sponsors and agents/brokers may not market specific Part D sponsors or benefits.

(ii) Part D sponsors holding or participating in educational events may do any of the following:

(A) Distribute communication materials.

(B) Answer beneficiary initiated questions pertaining to Part D plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) Part D sponsors holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) Part D sponsors may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 423.2260.

(i) If a marketing event directly follows an educational event, the beneficiary must be made aware of the change and given the opportunity to leave prior to the marketing event beginning.

(ii) Part D sponsors holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) Part D sponsors holding or participating in marketing events may not do any of the following:

(A) Require sign in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the Part D sponsor (or the agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) Part D sponsors holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) Part D sponsors holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products such as annuities.

■ 80. Section 423.2265 is added to read as follows:

§ 423.2265 Websites.

As required under § 423.128(d)(2), Part D sponsors must have a website.

(a) *General website requirements.* (1) Part D sponsor websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the Part D sponsor's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change

(v) Keep PDP content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) Part D sponsor websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the Part D sponsor is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the Part D sponsor.

(b) *Required content.* A Part D sponsor's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable pharmacy directory.

(4) A searchable pharmacy directory.

(5) A searchable formulary.

(6) Information on enrollees' and Part D sponsors' rights and responsibilities upon disenrollment. Part D sponsors may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the *Medicare.gov* electronic complaint.

(9) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(10) Prescription Drug Transition Policy.

(11) LIS Premium Summary Chart.

(12) Prescription Drug Transition Policy.

(13) A separate section or page about MTM programs providing the following:

(i) Explanation of MTM program, including eligibility requirements, the purpose and benefits of MTM, how to obtain MTM service documents including the Medication list, that the service is free, and a summary of services.

(ii) Information on how to obtain information about the MTM program, including how the member will know they are eligible and enrolled into the MTM program, the comprehensive medication review and targeted medication reviews, a description of how reviews are conducted and delivered, including time commitments and materials beneficiaries will receive.

(c) *Required posted materials.* A Part D sponsor's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Pharmacy Directory.

(v) Formulary.

(vi) Utilization Management Forms for physicians and enrollees.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for Physicians and Enrollees.

(ii) Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 81. Section 423.2266 is added to read as follows:

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.
(2) Vestibules.
(3) Waiting rooms.
(4) Hospital or nursing home cafeterias.
(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition in this paragraph (c) fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract or participate or both.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor. During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D plan or sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities performed on behalf of the Part D sponsor.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting.* Part D sponsor activities in the health care setting are those activities, including marketing activities that are conducted by Part D sponsor or on behalf of the Part D sponsor, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

■ 82. Section 423.2267 is added to read as follows:

§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing MA language for a Part D plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) When CMS issues standardized content, Part D sponsors—

(3) The Part D sponsor may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and Part D sponsor may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the sponsor's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, Part D sponsors:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use

CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* Part D sponsors must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, Part D sponsors may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to § 423.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 423.128(b)) must be provided annually and must be provided:

(i) To current enrollees of plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part D explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 423.128(e). Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

(3) *Annual Notice of Change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 423.128(g)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment Checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form so that the enrollees understand important plan benefits and rules. The PECL references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB).* Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on prescription drug expenses, including:

(1) Monthly plan premium

(*2*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*3*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(*4*) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) Plan sponsors may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form.* This is the model communications material through which plans must provide the information required under § 423.32(b).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.32(d).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(9) *Formulary.* This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(10) *Low Income Subsidy (LIS) Notice.* This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(11) *Low Income Subsidy (LIS) Rider.* This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(12) *Midyear Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a midyear change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(13) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice in this section, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare prescription drug plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 423.507(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(H) Include the Part D sponsor's call center telephone number, TTY number, and hours and days of operation.

(14) *Part D Transition Letter.* This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within three days of adjudication of temporary transition fill.

(15) *Pharmacy Directory.* This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the Part D sponsor becomes aware of changes.

(A) All updates to the online pharmacy directories must be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(16) *Prescription transfer letter.* This is a model communications material that must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(17) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsors that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(18) *Coverage Determination Notices.* This is a model communications material through which plans must provide the information under § 423.568.

(19) *Excluded Provider Notices.* This is a model communications material

through which plans must notify enrollees when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(20) *Notice of Denial of Medicare Prescription Drug Coverage.* This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(21) *Medicare Prescription Drug Coverage and Your Rights.* This is a standardized communications material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(22) *Medicare Part D Coverage Determination Request Form.* This is a model communications material used to collect additional information from a prescriber.

(23) *Request for Additional Information.* This is a standardized communications material used by the Part D sponsor to request a beneficiary obtain additional information from the prescriber regarding a beneficiary's exception request.

(24) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(25) *Notice of Inquiry.* This is a model communications material from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(26) *Notice of Case Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(27) *Request for Reconsideration of Medicare Prescription Drug Denial.* This is a model communications material used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(28) *Notice of Redetermination.* This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(29) *LEP Reconsideration Request Form.* This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal.* This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(33) *Star Ratings Disclaimer.* This is model content through which plans must:

(i) Convey that plan sponsors are evaluated yearly by Medicare

(ii) Convey that the ratings are based on a 5-star rating system

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(34) *Accommodations Disclaimer.* This is model content through which plans must:

(i) Convey that accommodations for persons with special needs is available

(ii) Provide a telephone number and TTY number

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events as described under § 423.2264(c).

(35) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) Part D sponsors must include the following statement when mailing health and wellness information ''Health and wellness or prevention information.''

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(36) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(37) *Provider Co-Branded Material Disclaimer.* This is model content through which Part D sponsors must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned.

§ 423.2268 [Removed]

■ 83. Section 423.2268 is removed.

■ 84. Section 423.2274 is revised to read as follows:

§ 423.2274 Agent, broker, and other third party requirements.

If a Part D sponsor uses agents and brokers to sell its Medicare Part D plans, the requirements in paragraphs (a) through (e) of this section are applicable. If a Part D sponsor makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent/broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. Beginning January 1, 2021, the FMV is $81. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and the Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued pursuant to § 422.312 of this chapter.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent Part D sponsors must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *Part D sponsor oversight.* Part D sponsors must oversee first tier, downstream, and related entities that represent Part D sponsor to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. Part D sponsors must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the Part D sponsor has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination if required by state law.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the Part D sponsor intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, Part D sponsor may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in Part D plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules.* (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) Part D sponsors may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) Part D sponsors may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, Part D sponsors may pay compensation at or below FMV.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors must pay pro-rated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case,

the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at an amount up to 50 percent of FMV.

(i) Part D sponsors may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in a PDP, the Part D sponsor may pay only the PDP compensation (and not compensation for MA enrollment under § 422.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP enrollment.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) Part D sponsors must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage *(*for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments).* (1) Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Administrative payments can be based on enrollment provided payments are at or below the value of those services in the marketplace.

(f) *Payments for referrals.* Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries), recommendation, provision, or other means of referring beneficiaries to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan.

■ 85. Section 423.2305 is amended by revising the definition for ''Applicable discount'' to read as follows.

§ 423.2305 Definitions.

* * * * *

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 86. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 87. Section 455.2 is amended by—

■ a. In the definition of ''Credible allegation of fraud,'' revising paragraph (1); and

■ b. Adding the definition of ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 88. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 89. Section 460.6 is amended by revising the definition of ''Services'' to read as follows:

§ 460.6 Definitions.

* * * * *

Service, as used in this part, means all services that could be required under § 460.92, including items and drugs.

* * * * *

■ 90. Section 460.56 is added to subpart D to read as follows:

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

■ 91. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(1) All Medicare-covered services.

(2) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

§ 460.96 [Amended]

■ 92. Section 460.96 is amended by—

■ a. Removing paragraphs (a) and (b); and

■ b. Redesignating paragraphs (c) through (e) as paragraphs (a) through (c).

■ 93. Section 460.98 is amended by—

■ a. Revising paragraph (a);

■ b. Adding a sentence to the end of paragraph (b)(1); and

■ c. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) * * *

(1) * * * These services must be furnished in accordance with § 460.70(a).

* * * * *

(4) Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

(5) The PACE organization must document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

* * * * *

■ 94. Section 460.102 is amended by revising paragraphs (d)(1) and (d)(2)(ii) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following:

(i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.

(ii) Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(2) * * *

(ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.

(B) Participants.

(C) Caregivers.

(D) Employees.

(E) Contractors.

(F) Specialists.

(G) Designated representatives.

* * * * *

■ 95. Section 460.104 is amended by revising paragraph (d)(2) to read as follows:

§ 460.104 Participant assessment.

* * * * *

(d) * * *

(2) *In response to a service determination request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service determination request, and may conduct reassessments as determined necessary for approved services.

* * * * *

■ 96. Section 460.112 is amended by—

■ a. Adding paragraph (b)(4);

■ b. Redesignating paragraph (c)(3) as paragraph (c)(5); and

■ c. Adding new paragraphs (c)(3) and (4).

The additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

* * * * *

(b) * * *

(4) To contact 1–800–MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(c) * * *

(3) To have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

* * * * *

■ 97. Section 460.121 is added to read as follows:

§ 460.121 Service determination process.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service determination requests in accordance with the requirements of this Part.

(b) *What is a service determination request*—(1) *Requests that constitute a service determination request.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service determination requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care.

(c) *Who can make a service determination request.* Any of the

following individuals can make a service determination request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service determination request.* An individual may make a service determination request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants.

(e) *Processing a service determination request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service determination request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service determination request in full at the time the request is made, the PACE organization—

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service determination request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service determination request in accordance with paragraphs (f) through (i), (j)(2), and (*l*) of this section.

(f) *Who must review a service determination request.* The full interdisciplinary team must review and discuss each service determination request and decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team must consider all relevant information when evaluating a service determination request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in § 460.92(b).

(h) *Reassessments in response to a service determination request.* (1) If the interdisciplinary team expects to deny or partially deny a service determination request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service determination request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service determination request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*—(1) *Notice of decisions to approve a service determination request.* If the interdisciplinary team makes a determination to approve a service determination request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service determination request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service determination request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.

(iii) Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service determination request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all

processing requirements for service determination requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

■ 98. Section 460.122 is amended by—

■ a. Revising the introductory text and paragraphs (b) and (c)(1), (2), and (4);

■ b. Redesignating paragraphs (c)(5) and (6) as paragraphs (c)(6) and (7), respectively;

■ c. Adding a new paragraph (c)(5);

■ d. Revising paragraphs (d), (g) and (h);

The revisions and additions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. A request to initiate, modify or continue a service must first be processed as a service determination request under § 460.121 before the PACE organization can process an appeal under this section.

* * * * *

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment, the PACE organization must give a participant written information on the appeals process.

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in §§ 460.121(i) and (m).

(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.

* * * * *

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

* * * * *

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

* * * * *

(g) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of partially or fully adverse decisions.* (i) Notice of any denial must—

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) At the same time the decision is made, the PACE organization must also notify the following:

(A) CMS.

(B) The State administering agency.

(h) *Actions following a favorable decision.* A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

* * * * *

■ 99. Section 460.124 is revised to read as follows:

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under § 460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

■ 100. Section 460.200 is amended by—

■ a. Redesignating paragraphs (b)(1) through (4) as paragraphs (b)(1)(i) through (iv), respectively;

■ b. Adding a new paragraph (b)(2); and

■ c. Revising paragraph (d).

The addition and revision read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(b) * * *

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

* * * * *

(d) *Safeguarding data and records.* A PACE organization must do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received from participants or other parties in their

original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).

* * * * *

■ 101. Section 460.210 is amended by—

■ a. Redesignating paragraphs (b)(4) through (12) as (b)(7) through (15); and

■ b. Adding new paragraphs (b)(4) through (6).

The additions read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(4) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

* * * * *

Dated: October 29, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 6, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00538 Filed 1–15–21; 8:45 am]

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Part X

Department of the Treasury

31 CFR Part 33

Department of Health and Human Services

45 CFR Parts 155, 156

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations; Final Rule

DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505–AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 155 and 156

[CMS–9914–F]

RIN 0938–AU18

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services (HHS), Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule sets forth provisions related to user fees for federally-facilitated Exchanges and State-based Exchanges on the Federal Platform. It includes changes related to acceptance of payments by issuers of individual market Qualified Health Plans and clarifies the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It also adds a new direct enrollment option for federally-facilitated Exchanges and State Exchanges and implements changes related to section 1332 State Innovation Waivers.

DATES: These regulations are effective on March 15, 2021.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, (301) 492–4305, Rogelyn McLean, (301) 492–4229, Usree Bandyopadhyay, (410) 786–6650, Grace Bristol, (410) 786–8437, or Kiahana Brooks, (301) 492–5229, for general information.

Aaron Franz, (410) 786–8027, for matters related to user fees.

Robert Yates, (301) 492–5151, for matters related to the direct enrollment option for federally-facilitated Exchange states, State-based Exchanges on the Federal Platform, and State Exchanges.

Erika Melman, (301) 492–4348, for matters related to network adequacy standards.

Emily Ames, (301) 492–4246, for matters related to acceptance of payments by QHP issuers.

Lina Rashid, (443) 902–2823, Michelle Koltov, (301) 492–4225, or Kimberly Koch, (202) 622–0854, for matters related to State Innovation Waivers.

SUPPLEMENTARY INFORMATION: In the December 4, 2020 **Federal Register**, HHS and the Department of the Treasury published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations'' proposed rule (85 FR 78572) (hereinafter referred to as the ''proposed 2022 Payment Notice'' or ''proposed rule'') that proposed revisions to regulations in 31 CFR part 33 and 45 CFR parts 147, 150, 153, 155, 156, 158, and 184, and policies that would reduce fiscal and regulatory burdens across related program areas and provide stakeholders with greater flexibility. This final rule addresses only a subset of the policies and proposed regulatory revisions addressed in the proposed 2022 Payment Notice, including certain policies and related proposed revisions to regulations in 31 CFR part 33 and 45 CFR parts 155 and 156. HHS continues to review comments to the proposed 2022 Payment Notice and intends to address the remaining provisions in future rulemaking.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act (PPACA) [1] through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS (hereinafter referred to as ''Secretary'') and heads of all other executive departments and agencies with authorities and responsibilities under PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In the December 4, 2020 **Federal Register**, we [2] published the proposed 2022 Payment Notice, which proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility.

In previous rulemaking, we established provisions and parameters to implement many PPACA requirements and programs. In this final rule, we are amending some of these provisions and parameters, with a focus on providing states with additional flexibilities, reducing unnecessary regulatory burdens on stakeholders, empowering consumers, and improving affordability.

[1] PPACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of PPACA, was enacted on March 30, 2010. In this rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

[2] As this rule is jointly published by HHS and the Department of the Treasury, HHS clarifies that throughout this final rule, the term 'we' refers only to HHS.

As we do every year in the HHS notice of benefit and payment parameters (Payment Notice), we are finalizing the user fee rates for issuers offering plans through the Exchanges using the federal platform. For the 2022 plan year, we are lowering the federally-facilitated Exchange (FFE) and State-based Exchange on the Federal Platform (SBE–FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and HHS contract estimates for the 2022 plan year. We are also finalizing a user fee rate for 2023 of 1.5 percent of total monthly premiums for FFE and SBE–FP states that elect in 2023 the direct enrollment option discussed later in the preamble.

We are updating the standards related to QHP issuers' acceptance of payments for premiums and cost sharing to require individual market QHP issuers to accept premium payments made by or on behalf of an enrollee in connection with an individual coverage health reimbursement arrangement (individual coverage HRA) or qualified small employer health reimbursement arrangement (QSEHRA). We are also providing a clarification to the network adequacy rules to reflect the longstanding interpretation that § 156.230 does not apply to plans seeking QHP certification that do not differentiate benefits based on whether or not enrollees receive covered services from providers that are members of the plan's provider network.

We are establishing a new direct enrollment option under which a State Exchange, SBE–FP, or an FFE state can elect to rely on direct enrollment to offer individual market consumers an enhanced QHP shopping experience. Under this option, instead of operating a centralized enrollment website, states may, with HHS approval, use direct enrollment technology to establish pathways to QHP issuers, web-brokers, and agents and brokers, to allow consumers to apply for and receive a determination or assessment of eligibility for insurance affordability programs and enroll in a QHP, or if applicable, be transferred to Medicaid or the Children's Health Insurance Program (CHIP).

The Secretaries of HHS and the Treasury (collectively, the Secretaries) are finalizing the proposal regarding State Innovation Waivers under section 1332 of PPACA, with modifications in response to comments, to codify many of the policies and interpretations outlined in the 2018 ''State Relief and Empowerment Waivers'' guidance (83 FR 53575) [3] (hereinafter referred to as the 2018 Guidance) into section 1332 regulations governing waiver application procedures, monitoring and compliance, and periodic evaluations in order to give states certainty regarding the requirements to receive and maintain approval by the HHS and the Department of the Treasury (collectively, the Departments) for State Innovation Waivers under section 1332 of PPACA.

We intend to address the other topics and proposed policies outlined in the proposed 2022 Payment Notice in future rulemaking, taking into account comments received on those proposals.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including PPACA. Subtitles A and C of title I of PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans [4] and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.

Sections 1311(b) and 1321(b) of PPACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in PPACA. Section 1321(c)(1) of PPACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of PPACA. Section 1311(d) of PPACA describes the minimum functions of an Exchange. Section 1311(e)(1) of PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c)(1) of PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state.

Section 1312(e) of PPACA directs the Secretary to establish procedures under which a state may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

Sections 1313 and 1321 of PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of PPACA. Section 1321(a)(1) of PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of PPACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of PPACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 establishes federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

Section 1321(d) of PPACA provides that nothing in title I of PPACA must be construed to preempt any state law that does not prevent the application of title I of PPACA. Section 1311(k) of PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1332 of PPACA provides the Secretaries with the discretion to approve a state's proposal to waive specific provisions of PPACA, provided the state's section 1332 waiver plan meets certain requirements. The Departments finalized implementing

[3] *https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf.*

[4] The term ''group health plan'' is used in title XXVII of the PHS Act and is distinct from the term ''health plan'' as used in other provisions of title I of PPACA. The term ''health plan'' does not include self-insured group health plans.

regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Departments' application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

The 21st Century Cures Act (Cures Act), Public Law 114–255, 130 Stat. 1033, was enacted on December 13, 2016. Section 18001 of the Cures Act amends the Internal Revenue Code (Code), the Employee Retirement Income Security Act of 1974, and the PHS Act to permit an eligible employer to provide a QSEHRA to its eligible employees. Section 9831(d) of the Code, as amended by the Cures Act, establishes requirements for providing a QSEHRA. On October 31, 2017, the Department of the Treasury and the Internal Revenue Service (IRS) issued Notice 2017–67, 2017–47 IRB 517, to provide guidance on the requirements for providing a QSEHRA.

1. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. In the July 15, 2011 **Federal Register** (76 FR 41865), we published a proposed rule with proposals to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

2. Health Reimbursement Arrangements

On October 29, 2018, the Departments of HHS, Labor, and the Treasury published proposed regulations in the **Federal Register** (83 FR 54420) on health reimbursement arrangements (HRAs) and other account-based group health plans including individual coverage HRAs. On June 20, 2019, the Departments of HHS, Labor, and the Treasury published final regulations in the **Federal Register** (84 FR 28888) on HRAs and other account-based group health plans.

3. State Innovation Waivers

Section 1332(a)(4)(B) of PPACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments published the ''Application, Review, and Reporting Process for Waivers for State Innovation'' proposed rule [5] in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of PPACA. On February 27, 2012, the Departments published the ''Application, Review, and Reporting Process for Waivers for State Innovation'' final rule [6] in the **Federal Register** (77 FR 11700) (hereinafter referred to as the ''2012 Final Rule''). On October 24, 2018, the Departments issued the 2018 Guidance, which superseded the previous guidance [7] published on December 16, 2015 in the **Federal Register** (80 FR 78131) and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. On November 6, 2020, the Departments issued an interim final rule [8] in the **Federal Register** (85 FR 71142), which revised regulations relating to public notice procedures to set forth flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of PPACA during the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges. We have held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly the direct enrollment option for FFE states and State Exchanges.

We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), and regular contact with states, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received on the proposals addressed in this final rule as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 155 and 156. In addition, the regulations outlined in this final rule governing State Innovation Waivers under section 1332 of PPACA are codified in 31 CFR part 33 and 45 CFR part 155.

We establish a new direct enrollment option for State Exchanges, SBE–FPs and FFE states to use direct enrollment technology and non-Exchange websites developed by approved web-brokers, issuers, and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange.

As we do every year in the annual HHS notice of benefit and payment parameters, we set forth the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the federal platform. We also finalize modifications to the regulations addressing network adequacy standards for non-network plans. Finally, we require individual market QHP issuers to accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA or QSEHRA.

The changes in 31 CFR part 33 and 45 CFR part 155 related to State Innovation Waivers finalize with modifications the proposals to codify many of the policies and interpretations outlined in the existing 2018 Guidance into the section 1332 waiver implementation regulations in order to give states certainty regarding the requirements to receive and maintain approval of State Innovation Waivers by the Departments.

III. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule—Department of Health and Human Services

In the December 4, 2020 **Federal Register** (86 FR 78572), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and

[5] *https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf.*

[6] *https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf.*

[7] *https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf.*

[8] *https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.*

Pharmacy Benefit Manager Standards; Updates To State Innovation Waiver (Section 1332 Waiver) Implementing Regulations'' proposed rule. We received 542 comments in response to the policies in the proposed 2022 Payment Notice. Comments were received from members of Congress, state entities, such as departments of insurance and State Exchanges, health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that are not addressed in this final rule.

In this final rule, we provide a summary of the proposed provisions we are addressing in this final rule, a summary of the public comments received that relate to those proposals, our responses to these comments, and a description of the provisions we are finalizing.

We first address comments regarding the publication of this final rule and the comment period.

Comment: Multiple commenters criticized the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments. Some commenters also expressed concern that HHS would not adequately review and consider all comments before issuing a final rule; that HHS appears to be rushing to finalize substantial changes to regulations that would hamper access to coverage through the Exchanges; and that HHS should defer any major policy decisions affecting access to Exchange coverage to the incoming Administration.

Response: We disagree that the comment period was not long enough to allow stakeholders to provide meaningful comments. Each year, we generally have set a 30-day comment period to accommodate issuer filing deadlines for the upcoming plan year and to avoid creating significant challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products. Moreover, we found commenters' submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule. We further recognize the importance of federal agencies reviewing and considering all relevant comments before issuing a final rule. For this reason, HHS determined that it was appropriate to address in this final rule only those policies in the proposed 2022 Payment Notice that were most important to advancing the policy goals of reducing fiscal and regulatory burdens across related program areas and providing stakeholders with greater flexibility. Limiting the policies addressed in this final rule allowed us to review all relevant comments and expedite the publication of this final rule.

For reasons more fully reviewed in the preamble discussions related to specific policies in this final rule, we also disagree that the rule will hamper access to Exchange coverage. The policies we finalize in this rule have the potential to increase access to Exchange coverage. For example, the Exchange DE option we finalize in this rule has the potential to increase incentives for licensed agents, brokers, and web-brokers to promote Exchange enrollment through improvements to the consumer application and enrollment experience. The policies this final rule adopts in relation to section 1332 waivers are designed to provide flexibilities that will allow states to propose and implement waiver plans to increase access to Exchange coverage by reducing premiums. In addition, the policies related to individual coverage HRAs and QSEHRAs are being finalized to remove obstacles and ensure individuals offered these types of coverage have seamless access to enroll in individual market QHP coverage.

Finally, we disagree that major policy decisions should be deferred until a new Administration is in place, as this final rule constitutes a valid exercise of the Departments' rulemaking authorities.

A. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Standards for Direct Enrollment Entities (§ 155.221)

a. FFE, SBE–FP, and State Exchange Direct Enrollment Option

Classic Direct Enrollment (Classic DE) and Enhanced Direct Enrollment (EDE) are pathways offered as part of the FFE's DE program under which third-party entities (issuers, agents and brokers, and web brokers) are approved by HHS to assist consumers with QHP plan selection and enrollment through a non-Exchange website in a manner considered to be through the Exchange.[9] The Classic DE and EDE pathways are available in FFE and SBE–FP states. In light of the success of the FFEs' DE program in improving the consumer experience, we proposed to provide additional options for states that wish to promote more flexible and lower-cost private sector approaches for assisting consumers with shopping and enrolling in individual market QHP coverage offered through Exchanges.

While we have taken a number of actions to reduce the burden on states of establishing State Exchanges, we wish to maximize flexibility for all states to oversee their own health care markets and to address unique state market dynamics. In the Exchange Final Rule,[10] we recognized that states are best equipped to adapt Exchange functions to their local markets and the unique needs of their residents.[11] In addition, we recognized that for decades, issuers, licensed agents and brokers, and web-brokers have been engaging directly with consumers in offering health insurance and assisting consumers in selecting, enrolling in, and managing their coverage. We believe that the proposal to establish a new DE option for Exchanges would allow states to continue to more effectively exercise their traditional oversight authority over health insurance markets, while enhancing the consumer experience, increasing competition, and lowering costs.

To date, Exchange eligibility application and enrollment activities have been supported through Exchange-operated websites. One of the primary advantages of this design is that consumers can access one-stop shopping for all QHPs offered through an Exchange and can access relevant details on such plans in a standardized format. Before Exchanges existed, consumers shopping for individual health insurance coverage who searched for this information would generally have to contact multiple issuers or visit

[9] Classic DE is the original version of DE, which utilizes a ''double redirect'' from a DE entity's non-Exchange website to *HealthCare.gov* where the eligibility application is submitted and an eligibility determination is made by the Exchange, and then back to the DE entity's non-Exchange website for QHP shopping and plan selection consistent with applicable requirements in §§ 155.220(c)(3)(i), 155.221, 156.265, or 156.1230(b). EDE is the version of DE which allows consumers to complete all steps in the application, eligibility and enrollment processes on the DE entity's non-Exchange website consistent with applicable requirements in §§ 155.220(c)(3)(ii), 155.221, 156.265, or 156.1230(b). EDE uses application programming interfaces (APIs) that are made available, owned, and maintained by CMS to transfer data between *HealthCare.gov* and the DE entity's non-Exchange website.

[10] 77 FR 18310 (March 27, 2012). Available at *https://www.govinfo.gov/content/pkg/FR-2012-03-27/pdf/2012-6125.pdf.*

[11] See, for example, 77 FR at 18313.

multiple websites, and the information would often be presented inconsistently, preventing true apples-to-apples comparison shopping. Exchange-run eligibility application and enrollment websites also help to manage coordination of coverage between private health insurance coverage and Medicaid and CHIP by offering full eligibility and enrollment integration between the programs or by providing connections to those public programs for individuals who may qualify for participation.

While Exchange-operated eligibility application and enrollment websites have undoubtedly helped many consumers shop for and compare plans, they also present some significant potential disadvantages given historical and current implementations of Exchange-operated websites. First, as we explained in the proposed rule, it can be costly and burdensome to create and operate Exchanges, including not only the cost of designing and maintaining a complex website, but also the burden of staffing and operating call centers that must be scaled up during each annual Open Enrollment Period (OEP), and then scaled down during lower-traffic periods.

Second, the design of Exchange-operated websites also tends to result in choke points when a large number of consumers use the same website at the same time to apply, shop for, and enroll in coverage. For example, on high traffic days near the end of the annual OEP, some consumers trying to access *HealthCare.gov* have been redirected to the FFE call center or told to come back to the website at a later time to complete their enrollment due to high volume. The ability for consumers to shop for coverage through any one of the websites operated by Classic DE and EDE entities with which HHS partners during these high traffic days provides an important, additional avenue to ensure consumers complete their plan selection and enroll in coverage. Although we recognize that without robust participation and competition among DE entities, a DE entity's website may experience similar choke points due to high consumer traffic, we believe that providing Exchanges in states that elect this option with the flexibility to partner with more than one DE entity mitigates this risk.

Third, we believe it is inherently difficult for Exchanges to keep up with the rapid pace of innovation in e-commerce and the ever-evolving preferences of online shoppers, who are accustomed to shopping for the products they buy in a manner that is not only tailored to their specific needs, but is also aesthetically appealing and constantly refreshed. Federal and state governments, for example, can be limited in their ability to frequently refresh and update the consumer experience due to the length of time it can take to award vendor contracts.[12] Finally, we have heard criticisms from some stakeholders, including agents, brokers, and web-brokers, that the Exchange-operated eligibility application and enrollment website model competes directly with and may crowd out market players such as web-brokers, licensed agents and brokers, and issuers, dampening commercial investments in outreach and marketing by these market players to reach new consumers, including those who are currently uninsured.

We believe that both the FFE's DE and EDE pathways have promoted innovation and competition in states whose consumers use *HealthCare.gov* and have ultimately led to better experiences for consumers in these states. The FFE's Classic DE pathway has been in operation since the launch of the FFE in 2013. The FFE EDE pathway has been in operation since 2018. Together, for the 2020 Plan Year, the Classic DE and EDE pathways were responsible for approximately 29 percent of FFE enrollments. The recent experience from the 2021 Open Enrollment Period shows substantial growth in the use of the EDE pathway. The number of consumers who enrolled through the EDE pathway more than doubled from the prior 2020 Open Enrollment Period—increasing from approximately 521,000 to 1,130,000 plan selections, representing 37 percent of FFE enrollments.

Currently, the *HealthCare.gov* eligibility application and enrollment website and approved private sector non-Exchange websites operate in parallel to enroll consumers in individual market QHPs offered through the FFEs and SBE–FPs. Like Exchange-operated websites, non-Exchange websites operated by Classic DE and EDE entity partners in FFE and SBE–FP states are required to provide standardized comparative information to assist consumers shopping for coverage.[13] DE entities are also able to provide assistance with a broader array of plan options, including both on- and off-Exchange plan options and ancillary products. These additional coverage options are important for many consumers who do not qualify for premium tax credits or have less incentive to enroll in Exchange coverage, including employees with an offer of an affordable individual coverage HRA who may wish to opt into that coverage, as well as employees offered both an individual coverage HRA and a cafeteria plan because section 125(f)(3) of the Code specifically prohibits using salary reduction contributions under a cafeteria plan to purchase on-Exchange coverage.[14] Finally, the FFE's EDE pathway helps to reduce costs to the federal government by enrolling many consumers without using the FFEs' eligibility application intake and enrollment resources (for example, the Marketplace call center and the *HealthCare.gov* website).

To build on the success of the FFE's Classic DE and EDE pathways in FFE and SBE–FP states that use *HealthCare.gov*, and to offer additional flexibility to all Exchanges, we proposed a new opportunity for states to adapt Exchange activities to the needs of local state markets and leverage the benefits of direct enrollment to enhance the consumer experience through a private sector-focused consumer engagement and enrollment strategy. We proposed to add § 155.221(j) to establish a process for states to elect a new Exchange Direct Enrollment option (Exchange DE option) in which a state can request to allow private sector entities (including QHP issuers, web-brokers, agents and brokers) to operate enrollment websites through which consumers can apply, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs), if otherwise eligible.

[12] For example, Federal contracting rules generally require full and open competitions under which federal agencies must seek proposals to fulfill an agency's needs for contractor services. See 10 U.S.C. 2304 and 41 U.S.C. 3301. These competitions generally last for months and may impede an agency's ability to quickly engage a vendor for the information technology services like those that may be necessary to update, improve, or otherwise address issues with the consumer shopping, eligibility, and enrollment experience. Moreover, even if a federal or state agency has a suitable contract in place that covers such services, there may not be sufficient funds allocated to the contract or otherwise available to the agency to cover the services at the time they are needed or desired. In these situations, government agencies like State Exchanges and HHS may be required to delay the services until a future funding cycle. Commercial entities like DE and EDE entities generally do not face such impediments and may more readily respond to consumer needs and preferences.

[13] See, for example, 45 CFR 155.220(c)(3)(i)(A) (for web-brokers) and 156.1230(a)(1)(ii) (for QHP issuers).

[14] As detailed in the proposed 2022 Payment Notice, there is a growing cohort of consumers who may be interested in off-Exchange coverage options. See 85 FR 78616–78619.

We proposed in § 155.221(j) that, subject to HHS approval, a state may elect for the Exchange in the state to engage one or more entities described in paragraph (a) [15] to facilitate QHP enrollments through its Exchange. Under this option, similar to the current FFE DE program, approved DE entities would enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange [16] and would also assist individuals in applying for, and receiving eligibility determinations from the Exchange, for APTCs and CSRs.

In § 155.221(j)(1), we proposed requirements that would apply to traditional State Exchanges that do not rely on the federal eligibility and enrollment platform that want to pursue the Exchange DE option and become an SBE–DE. In § 155.221(j)(2), we proposed requirements that would apply to states with an FFE or SBE–FP [17] that want to pursue the Exchange DE option and become an FFE–DE or SBE–FP–DE. We proposed that, subject to HHS approval, the Exchange DE option may be implemented in states with a State Exchange starting in plan year 2022. We proposed that, subject to HHS approval, the Exchange DE option may be implemented in states with an FFE or SBE–FP starting in plan year 2023.

Under the Exchange DE option, states would be able to request to adopt a private sector-based enrollment approach as an alternative to the consumer-facing enrollment website operated by the Exchange (for example, *HealthCare.gov* for the FFEs). This decentralized, private sector-focused approach would transition application and enrollment functions to websites operated by approved partners (DE partners) to serve as the online platform(s) through which consumers apply for and enroll in individual market QHPs offered through the Exchange in their state, as well as apply for and receive determinations of APTC and cost-sharing reduction (CSR) eligibility for QHP coverage offered through the Exchange. The Exchange in a state that elects this option would implement a direct enrollment pathway (or pathways) with secure connections between its back-end eligibility determination system and the websites (or systems) of approved issuers, web-brokers, or agents and brokers that enable consumers to complete and submit the single streamlined eligibility application as described in § 155.405, receive an eligibility determination from the Exchange, select a plan and enroll in a QHP, with or without APTC and CSRs (if otherwise eligible). Exchanges would continue to be responsible for meeting, and ensuring its approved DE partners meet, all applicable statutory and regulatory requirements governing application for and enrollment in QHPs and other applicable state health subsidy programs.[18] Under the Exchange DE option, the Exchange would also remain the entity responsible for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, assessing or determining whether an applicant is eligible for Medicaid or CHIP, and conducting required verifications of consumer eligibility against trusted data sources. The Exchange would also continue to be responsible for sharing eligibility determination and enrollment information in coordination with issuers and HHS in accordance with 45 CFR 155.400, 155.430, and 155.340. The Exchange will continue to issue the applicable APTC to carriers on behalf of qualified individuals, and continue to be responsible for sharing this information with the IRS to support reconciliation of APTC on individual tax returns.

Consistent with section 1311(d)(4)(F) of PPACA and 45 CFR 155.302, under the Exchange DE option, the Exchange would also continue to be responsible for conducting assessments or determinations of eligibility for Medicaid and CHIP, and where appropriate, for referring individuals who are assessed or determined eligible for Medicaid or CHIP to the appropriate state Medicaid agency for enrollment in those programs.[19]

In proposing the Exchange DE option, we noted that the applicable statutory provisions do not require Exchanges to operate an enrollment website. Rather, section 1311(d)(4)(C) of PPACA provides that an Exchange must maintain an internet website through which enrollees and prospective enrollees of QHPs may obtain standardized comparative information on QHPs available in the state. Within the statutory framework, these are some of the specific minimum functions an Exchange must undertake to facilitate the purchase of QHPs under section 1311(b)(1)(A) of PPACA and make available QHPs to qualified individuals and employers under section 1311(d)(2)(A) of PPACA. These minimum functions facilitate the purchase of QHPs by helping to make the purchase of QHPs easier and administering elements of the structure necessary to make QHPs available. An Exchange can continue to meet these obligations without operating a singular consumer-facing eligibility and enrollment website. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require that Exchanges provide consumers with the ability to view comparative information on QHP options, but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for eligibility and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. We further explained that Exchanges, rather than DE entities, in states that elect to pursue this new option would continue to be responsible for determining eligibility for, and granting, exemption certifications under section 1311(d)(4)(H) of PPACA, as applicable; making available an electronic calculator consistent with section 1311(d)(4)(G) of PPACA; establishing a Navigator program as required under section 1311(d)(4)(K) of PPACA; and providing for the operation of a toll-free telephone hotline under section 1311(d)(4)(B) of PPACA.

[15] Section 155.221(a) identifies QHP issuers and web-brokers as eligible direct enrollment entities.

[16] Section 1401(a) of PPACA added new section 36B to the Code, which provides for PTCs for eligible individuals, while section 1402 of PPACA provides for CSRs for eligible individuals. For individuals to be eligible to receive PTCs, among other requirements, PPACA requires that individuals be enrolled in a QHP through an Exchange. CMS has interpreted this statutory language to allow a QHP issuer to enroll an applicant who initiates enrollment directly with the QHP issuer. See § 156.1230, whereby individuals enrolling directly on the site of a QHP issuer are considered enrolled ''through an Exchange'' so long as the issuer meets applicable requirements. We adopted a similar approach to allow a web-broker to enroll an applicant who seeks to enroll through the web-broker's website. See § 155.220(a)(2) and (c), whereby individuals enrolling directly through the site of a web-broker are considered enrolled ''through an Exchange'' so long as the web-broker meets applicable requirements.

[17] As detailed further below, states with an SBE–FP can request to pursue the Exchange DE option as an SBE–FP–DE. If a state that currently operates an SBE–FP is interested in transitioning to a full State Exchange that implements this Exchange DE option, it would need to update its Blueprint accordingly, and meet statutory and regulatory requirements to become a State Exchange implementing the Exchange DE option (an SBE–DE). Such requirements include operating its own eligibility and enrollment platform rather than relying on the federal platform.

[18] See section 1413(e) of PPACA for a definition of the term ''applicable state health subsidy program.''

[19] Section 1311(d)(4)(F) of PPACA requires Exchanges to inform individuals of eligibility requirements for Medicaid, CHIP, or any applicable state or local public programs and, if through screening of the application the Exchange determines such individuals are eligible for any such program and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).

In connection with the Exchange DE option, the Exchange would also be required to make available a website listing basic QHP information for comparison, and a listing with links to approved partner websites for consumer shopping, plan selection, and enrollment activities. Consistent with section 1311(d)(4)(E) of PPACA, the comparative plan information presented on the Exchange website would need to continue to utilize a standardized format, including the use of the uniform summary of benefits and coverage established under section 2715 of the PHS Act.[20] The standardized comparative information displayed on Exchange websites must also continue to include the quality ratings assigned to each QHP offered through the Exchange.[21] Finally, the Exchange, along with its issuers and registered agents and brokers, which may also function as DE entities, would continue to be responsible for meeting federal accessibility standards under 45 CFR 155.205(c) for individuals living with disabilities and for individuals who have limited English proficiency.[22]

Through private sector partners such as web-brokers and issuers, states may pursue alternatives to *HealthCare.gov* or other centralized, publicly-operated Exchange enrollment websites to enhance the consumer experience and provide additional incentives for insurers and licensed agents and brokers to conduct marketing and outreach to enroll more consumers in coverage. While states may consider creating enhanced commission structures or providing other market-based incentives, we also recognize the inherent incentive to issuers, web-brokers, and agents and brokers that will result from removing what some stakeholders view as a dominant public-sector competitor, making them the primary channels through which individuals shop for and enroll in individual market QHPs in those states.[23] In the proposed rule we recognized that consumers who apply and enroll through a DE partner will have the benefit of assistance from a state-licensed agent or broker if they so choose. These agents and brokers will have been recognized by the relevant state as possessing the specialized expertise necessary to help consumers choose between health insurance options.

(1) Federally-Facilitated Exchange Direct Enrollment (FFE–DE) and State Exchange on the Federal Platform Direct Enrollment (SBE–FP–DE) Option

We proposed an option for any FFE or SBE–FP state to request the use of direct enrollment as the avenue through which individual market consumers and qualified individuals can shop for and purchase a QHP offered through the Exchange in the state, and apply and receive determinations of eligibility for APTC and CSRs. While SBE–FP states have the authority and responsibility for certifying QHPs and performing consumer outreach and assistance activities, because they rely on the federal eligibility and enrollment platform and consumer-facing website, in this respect they are more similar to the FFE–DE model than the SBE–DE model. In addition, the current FFE DE program and accompanying requirements also apply in SBE–FP states.[24]

Under the proposed FFE–DE and SBE–FP–DE option, *HealthCare.gov* would continue to provide the same standardized comparative information on QHP options that is available today. The FFE would post and maintain an up-to-date list on *HealthCare.gov* of approved direct enrollment partners operating in the state. As such, consumers would still be able to view comparative information on *HealthCare.gov* for all QHP options available in their area and would also be able to access information to connect with approved direct enrollment partners in that state. In the event that any approved direct enrollment partner does not have the technical capability to process a consumer eligibility application, *HealthCare.gov* would process that application. The Exchange would continue to have responsibility for operating a toll-free call center to provide eligibility and enrollment support for all consumers, pursuant to 45 CFR 155.205(a). However, under the Exchange DE option, there may be some cases where the DE partner may be best able to provide additional support to a consumer in completing their enrollment through the DE partner's website. We proposed to codify requirements at 45 CFR 155.221(j)(2)(ii), whereby a state that elects to implement the Exchange DE option must execute a federal agreement with HHS that defines the division of responsibilities between HHS and the state. This would include the Exchange's responsibilities, as well as DE partners' responsibilities for various activities, such as those pertaining to operating a toll-free call center to provide eligibility and enrollment support for consumers that enroll in coverage through an approved DE partner's website.

By leveraging private sector entities and directing consumers to approved direct enrollment partners, the vast majority of consumer traffic would flow to direct enrollment partners, leaving the *HealthCare.gov* structure in place primarily to provide the supporting functions that it does today, like the processing of data matching issues and special enrollment period verification documentation, casework, and eligibility appeals.

As noted above, the FFE would remain the entity responsible for making eligibility determinations and verifying whether an applicant is eligible for QHP enrollment, APTC and CSRs. The FFE would also continue to reconcile eligibility and enrollment information with issuers, in accordance with 45 CFR 155.340, 155.400, and 155.430, in order for HHS to issue the applicable APTC to carriers on behalf of qualified individuals, and would share similar information with the IRS to facilitate the IRS' reconciliation of APTC on individual tax returns. Under this option, given that an FFE–DE state or SBE–FP–DE state would use one or more participating, federally-approved Classic DE and EDE entities, at a minimum, the FFE privacy and security standards[25] and the FFE DE program

[20] See 45 CFR 155.205(b).

[21] See section 1311(d)(4)(D) of PPACA and 45 CFR 155.205(b). Also see sections 1311(c)(3) and (c)(4) of PPACA and 45 CFR 155.1400 and 1405.

[22] Covered entities such as States, recipients of Federal financial assistance from HHS, programs or activities administered by HHS under title I of PPACA (such as the FFE), and programs or activities administered by any entity established under Title I (such as State Exchanges), must comply with applicable federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age, and disability. These laws include Section 1557 of PPACA (42 U.S.C. 18116) (Section 1557), Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (Title VI), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (Section 504), and the Americans with Disabilities Act of 1990 (29 U.S.C. 12101 *et seq.*) (ADA).

[23] Removing this public-sector competitor may be of particular interest due to the competitive advantage Exchanges hold over web-brokers under federal user fee and medical loss ratio (MLR) regulations. Consumers pay for both Exchange user fees and web-broker commissions indirectly through higher premiums. However, Exchange user fees and web-broker commissions are accounted for differently in the MLR calculation. Exchange user fees, a portion of which are used to fund Exchange-operated eligibility and enrollment websites that could be considered to be competitive with EDE interfaces, are treated as taxes, which makes it easier to meet the MLR requirement. In contrast, web-broker commissions count toward administrative costs, which makes it harder for issuers to meet the MLR requirements. This MLR accounting disparity on that portion of the Exchange user fees arguably disadvantages EDE entities.

[24] See, for example, 45 CFR 155.220(l) and 155.221(h).

[25] See 45 CFR 155.260 through 155.285.

requirements [26] would continue to apply.

We proposed in § 155.221(j)(2) that a state with an FFE or SBE–FP may request to pursue the FFE–DE or SBE–FP–DE option starting in plan year 2023, as applicable. We proposed that, pursuant to a request from the state, HHS may partner with the requesting state to implement the direct enrollment option described in paragraph (j). The FFE or SBE–FP must meet all applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined eligibility application required under § 155.405. To obtain HHS approval to implement this option, the state must coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the state, necessary to operationalize the required changes to implement this option. We proposed to codify these new requirements at paragraph (j)(2)(i). Additionally, we proposed to codify requirements at paragraph (j)(2)(ii), whereby the state must execute a federal agreement with HHS that includes the terms and conditions for the arrangement and that defines the division of responsibilities between HHS and the state. Further, to obtain HHS approval to implement the FFE–DE or SBE–FP–DE option, we proposed at § 155.221(j)(2)(iii) that the state must agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) in support of the responsibilities undertaken by the state and HHS. Finally, we proposed at paragraph (j)(2)(iv) that the state would be required to perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of PPACA, including complying with reporting and compliance activities required by HHS and described in the Federal agreement entered into pursuant to paragraph (j)(2)(ii).

(2) State Exchange Direct Enrollment Option (SBE–DE)

We proposed that a State Exchange that does not rely on the federal eligibility and enrollment platform can also elect the Exchange DE option to engage approved private-sector entities as the pathway (or pathways) for consumers in their state to apply for, and enroll in, QHPs offered through the Exchange. Under this option, the State Exchange would remain responsible for continuing to operate an internet website to provide the same standardized comparative information on QHP options that is available today and for making eligibility determinations via its eligibility rules engine for consumers applying for APTC, CSRs, and enrollment in QHPs offered through the Exchange. However, this new option would permit multiple private entities, such as a combination of web-brokers and QHP issuers, to provide the consumer-facing resources for consumers to apply for and enroll in individual market coverage offered through the Exchange. State Exchanges that pursue this option could thereby leverage direct enrollment technology and direct consumers to approved partner non-Exchange websites to apply for APTC and CSRs, as well as select and enroll in a QHP offered through the Exchange (if otherwise eligible). In the event that direct enrollment partners in the state do not have the technical capability to process any consumer's application, the State Exchange would be required to maintain the capability to process that application through its own consumer-facing website.

We proposed in § 155.221(j)(1) that a state with a State Exchange that does not rely on the federal eligibility and enrollment platform may request approval to pursue the SBE–DE option by submitting a revised Exchange Blueprint within 90 days of their targeted launch date, in accordance with § 155.105(e) to do so.[27] We also proposed that the State Exchange must meet all other applicable federal statutory and regulatory requirements for the operation of an Exchange, including establishing and maintaining the single, streamlined eligibility application under § 155.405. Following submission of a revised Exchange Blueprint, HHS would have up to a total of 90 days [28] to review this revised submission and render a decision as to approval. We proposed to codify the new requirement at § 155.221(j)(2)(ii) that, to obtain HHS approval, the state would need to provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities. Additionally, in accordance with § 155.105(c)(2) and the new requirement proposed at § 155.221(j)(1)(ii), a State Exchange that implements the SBE–DE option would be required to demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for APTC and cost sharing for QHPs.

While we proposed that State Exchanges that elect to implement the Exchange DE option would retain the flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state, we would encourage these states to review and adopt processes and standards similar to those in the existing FFE federal direct enrollment and EDE framework, as described in 45 CFR 155.220, 155.221, 156.1230, and in sub-regulatory guidance.[29] Moreover, we proposed to codify a new requirement at § 155.221(j)(1)(iii) whereby State Exchanges that elect to implement the Exchange DE option are obligated to ensure that a minimum of one state-approved direct enrollment entity meets the minimum federal requirements applicable to DE entities that seek approval to participate in the FFE DE program, including requirements at 45 CFR 155.220 and 155.221, and is capable of enrolling all consumers in the state. In particular, we explained that we believe it is critical that State Exchanges that elect to implement the Exchange DE option ensure, at a minimum, that at least one approved web-broker DE entity meets requirements that align with the FFE standards under 45 CFR 155.220(c)(3)(i)(A) and (D) [30] to ensure

[26] See 45 CFR 155.220, 155.221, and 156.1230.

[27] This approach is consistent with the framework established in prior rulemakings that require a state to notify HHS and receive written approval from HHS before significant changes are made to the Exchange Blueprint. See, for example, 77 FR at 18316. Significant changes could include altering a key function of Exchange operations or other changes to the Exchange Blueprint that would have an impact on the operation of the Exchange. This includes, but is not limited to the process for enrollment in a QHP. See, for example, 76 FR at 41871.

[28] As detailed in § 155.105(e), HHS generally has 60 days after receipt of a completed request to complete its review of a significant change to an Exchange Blueprint and, for good cause, may extend the review period by an additional 30 days up to a total of 90 days.

[29] See generally CMS guidance for becoming a web-broker in the FFEs, available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf.*

[30] In addition to ensuring there is at least one website available in the state that satisfies all accessibility requirements under § 155.205(c), we proposed that there must also be at least one website available in the state through which consumers can view and enroll in all available QHPs in the state.

consumers have at least one option through which to view detailed QHP information for all available QHPs in the state that also meets accessibility requirements under 45 CFR 155.205(c). Therefore, we proposed that if no direct enrollment partner in an SBE–DE state meets these requirements, the state would be required to continue operation of its own Exchange website to ensure there is one enrollment pathway in the state that does. To assist states in meeting requirements to become an SBE–DE, we noted that states would have the flexibility to partner with an existing, HHS-approved web-broker direct enrollment partner as a starting point to develop their own direct enrollment programs, as these entities would have already met requirements for HHS approval to participate in the FFE's DE program.

We requested comment on all aspects of these proposals, including any comments related to timing, governance, and any other considerations needed to effectively operationalize these proposed FFE–DE, SBE–FP–DE, and SBE–DE options. The following is a summary of the comments we received and our responses.

Comment: We received several comments that expressed support for the proposed Exchange DE option because of the flexibility it provides, noting that the Exchange DE option will increase consumer choice and competition among DE entities, potentially leading to reduced costs for consumers. These comments also included caveats or recommendations. For example, one commenter recommended delaying implementation of the proposed Exchange DE option pending additional stakeholder consultation to further explore potential advantages or disadvantages of the proposed Exchange DE option, including conducting consumer focus groups, accounting for operational considerations for QHPs and stand-alone dental plans (SADP), and conducting an assessment of the potential impact of the Exchange DE option on enrollment and premiums. One commenter recommended additional consumer support options be made available, namely the adoption of controls to ensure non-QHP options are readily-identifiable. Another commenter recommended that HHS work closely with DE entities, including issuers, in advance of implementation of the proposed Exchange DE option to further develop operational requirements. This commenter also recommended that there be one primary website available to consumers to enter their information so that they do not have to complete multiple eligibility applications.

Response: We appreciate commenters' support for this option and are finalizing with some minor clarifying edits to the regulatory text. We believe the Exchange DE option will provide states and Exchanges with additional flexibility to tailor consumers' health insurance shopping experience, allowing states and their residents to reap the expected potential benefits of leveraging private sector DE partners, including increased choice in consumer experience to complete the enrollment process, access to information on additional plan options, and lower costs. We also underscore that this option is strictly permissive for states, and we welcome states that are interested in pursuing these options to undertake research, stakeholder consultation particularly with issuers and web-brokers, and data gathering at the state level to inform any operational requirements related to how the Exchange DE option is implemented to ensure it is tailored to meet the needs of their residents.

We also believe it is important for consumers to have access to tools and resources to compare their coverage options. Under the Exchange DE option, consumers will be able to view standardized information to compare QHPs using the website of their choice, and will still be able to access *HealthCare.gov* (or similar information technology infrastructure in a state with a State Exchange) should they choose to, or if necessary. Consumers will also continue to have access to other Exchange tools and resources—such as the single, streamlined eligibility application, a toll-free telephone number to request assistance, an electronic calculator to determine the actual cost of coverage after the application of any APTC and CSRs, as well as Navigators, other Assisters, and licensed agents and brokers. As detailed elsewhere in this final rule, at a minimum, the existing FFE DE program requirements will continue to apply in any state that is approved to implement an FFE–DE or SBE–FP–DE. These existing requirements include several safeguards to ensure non-QHP options are readily identifiable.[31] For SBE–DE states, we finalize in § 155.221(j)(1)(iii) the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements to participate in the FFE DE program (including the FFE's plan display requirements) and we encourage these states to more broadly adopt standards similar to the existing FFE DE program for all DE partners approved by the state.

We believe that the Exchange DE option will drive the private sector to make consumer-centric investments that will improve consumers' shopping experiences, as these private entities are incentivized to provide the best possible consumer experience to retain their consumer base year-over-year and to attract new consumers each year. While the Exchange DE option is not available today, with an expanded available customer base, issuers, web-brokers, and individual agents and brokers will have an increased incentive to invest in providing the resources necessary to serve a majority of consumers, and in focusing marketing and outreach activities to attract new consumers, including the currently uninsured population. We believe these increased incentives to invest in the consumer enrollment experience will, over time, increase consumer enrollment by persons who would not otherwise have enrolled, a potentially healthier population who may improve the health of the risk pool and lead to lower premiums.

Comment: Nearly all commenters on this rulemaking cautioned about potential harmful impacts to consumers from the introduction of the Exchange DE option. Commenters asserted that the Exchange DE option may effectively eliminate access to *HealthCare.gov* and State Exchange websites, by allowing access to apply and enroll for QHP coverage through multiple private websites operated by DE entities. Commenters believed that because existing Exchange consumers have established relationships with, and have relied on, the centralized Exchange enrollment website in their state to serve as an unbiased resource to provide eligibility determinations, enroll in QHPs, and receive APTC/CSR eligibility determinations, the Exchange DE option would result in a new, fragmented process that would likely lead to consumer confusion and mistrust. They further stated that the negative impacts of effectively eliminating the Exchange-run enrollment websites as an option would outweigh the benefits of making this new option available to consumers. One commenter, which operates as an EDE entity, noted that while DE entities account for a significant volume of

[31] See, for example, 45 CFR 155.221(b)(1)–(3). In the proposed rule, we proposed to provide additional flexibilities regarding the plan display standards currently captured at 45 CFR 155.221(b)(1) and (3) in certain circumstances. See 85 FR at 78616–78618. We intend to address these proposals in future rulemaking and, if finalized, would also consider and address the intersection with the new Exchange DE option as necessary or appropriate.

HealthCare.gov enrollment today, elimination of the centralized FFE or SBE enrollment platforms would lead to various forms of disruption for the majority of consumers who already are accustomed to relying on an Exchange-operated website for enrollment.

Response: We understand commenters' concerns about the potential impact of the Exchange DE option and acknowledge that any transition or change can be unsettling and disruptive. However, we disagree that the potential negative impacts of the Exchange DE option outweigh the benefits given the success of the Federal DE and EDE pathways, and we note that the Exchange DE option is not a requirement for states, and that states have ample flexibility to tailor operational requirements and any transition steps to the needs of their health care markets. We also note that several states have made full transitions from the FFE to become an SBE, providing models of successful transitions to new enrollment platforms with minimal disruptions. In addition, an Exchange in a state that elects this option must at a minimum continue to operate an internet website that provides the same standardized comparative QHP information that is available today, along with an up-to-date listing of approved DE entities operating in the state. We believe that the continued availability of this website will mitigate any potential consumer confusion caused by the availability of multiple enrollment pathways. We further note that in states that choose to implement the Exchange DE option, the Exchange will remain available to consumers whose eligibility applications cannot be processed by an approved DE entity. States choosing the Exchange DE option also have the flexibility to continue making available its Exchange eligibility and enrollment website despite the availability of DE partner websites, or to define other instances in which the Exchange enrollment website would be available to consumers, including instances in which a consumer makes a request to apply through an Exchange-run website. We are also requiring that Exchanges in states choosing to implement the Exchange DE option continue to meet all applicable statutory and regulatory requirements. This includes, but is not limited to, the Exchange retaining responsibility for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, conducting required verifications of consumer eligibility against trusted data sources, and conducting assessments or determinations of eligibility for Medicaid and CHIP for all applicants, and where appropriate, refer individuals assessed or determined eligible for such coverage to the appropriate state Medicaid agency for enrollment in those programs. Consumers will therefore continue to have access to an unbiased resource for comparative QHP information and eligibility determinations in states that elect this option. We also strongly encourage DE entities to undergo appropriate coordination efforts with the Exchange. In particular, additional coordination will be required to ensure consumer communications, particularly consumer eligibility notices sent by the Exchange regarding coverage obtained by enrolling through a DE entity website do not result in consumer confusion.

The FFE already has experience transitioning consumers already enrolled in Exchange coverage through *HealthCare.gov* between enrollment platforms to new State Exchange platforms as evidenced by the successful transitions of SBE–FP states to SBE states. Most recently, ahead of the plan year 2021 open enrollment period, New Jersey and Pennsylvania transitioned from SBE–FPs to SBEs. Among the most critical work streams associated with these transitions was the migration of these states' consumer eligibility and enrollment data from *HealthCare.gov* to the respective State Exchange eligibility and enrollment platforms such that existing Exchange consumers could re-enroll directly through the State Exchange. We believe that any consumer disruptions can be minimized during a transition process by incorporating safeguards during the transition, such as robust stakeholder consultation with issuers and other partners, proactive coordination with other state agencies, targeted consumer outreach and education, and contingency planning to ensure consumers can fall back on *HealthCare.gov* if needed. The implementation plans developed under § 155.221(j)(1)(ii) and (j)(2)(i) should include details on any such measures. In addition, for states pursuing the SBE–DE option, HHS intends to examine these types of issues as part of the operational readiness assessment under § 155.221(j)(1)(i). Based on the FFE's experience, we expect that given the ability of existing DE entities to meet consumer needs and reduce burden on Exchanges, introducing DE entities as the primary consumer-facing pathway to enroll in coverage in states that elect this new option will be beneficial to all stakeholders.

Comment: An overwhelming majority of commenters on this rulemaking argued that there are potential conflicts of interest, particularly financial incentives, that would put DE entities at odds with consumers seeking coverage and the policy goals of PPACA. Commenters noted that the proposed Exchange DE option will increase the incentive for DE entities, particularly agents and brokers, to compete among each other for commissions, which could lead to consumers being directed to the most profitable products, rather than those best-suited for their health care needs. Several commenters emphasized that, in many cases, the most profitable product for DE entities is non-QHP coverage. Commenters thus fear that the Exchange DE option could lead to deceptive marketing practices and an increase in fraud, as well as more consumers who are uninsured, or who enroll in coverage even if it does not adequately meet their health care needs. Commenters were also concerned that the Exchange DE option could result in consumers being steered toward less robust non-comprehensive coverage (for instance, short-term limited duration insurance (STLDI) plans) that generally bring higher commissions to agents and brokers and web-brokers, but do not meet PPACA requirements. Commenters also asserted that consumers could be required to pay higher out-of-pocket costs because they did not receive information related to, or were misinformed about, the availability of Exchange financial assistance. A few commenters raised similar concerns related to Navigators and other Exchange assisters using DE entity websites to enroll consumers since consumers could be misled by the inclusion of non-QHP products on the DE entity websites, by the omission of critical information related to coverage options, or by confusion that could result when consumers are required to visit multiple DE entity websites to review comprehensive information on all available QHPs in a state.

Several commenters also raised concerns about protecting consumer privacy and security under the Exchange DE option, under which a consumer must share personally identifiable information with a private DE entity that could be misused in the absence of a robust regulatory framework to protect against this abuse.

We also received many comments that cautioned against potential negative impacts of working with DE entities to coordinate coverage with other insurance affordability programs. In

particular, commenters noted that DE entities generally do not have the incentive or expertise to ensure consumers receive a Medicaid eligibility assessment or determination, and to subsequently transfer them to the appropriate state website to complete the enrollment process. These commenters requested additional information on how HHS would ensure that this coordination of coverage will occur in order for HHS to maintain its ''no wrong door'' policy.

Response: We acknowledge that there must be sufficient oversight of all states approved to implement the Exchange DE option, as well as oversight of the DE entities themselves, to ensure the proper alignment and management of incentives. The many comments we received that raised concerns around potential misalignment of incentives and conflicts of interest serve to highlight key areas where HHS and the states can be proactive to implement additional controls and work closely with DE entities to prevent fraud, waste, and abuse, particularly with respect to protecting against deceptive marketing and inappropriate steering. We reiterate that, at a minimum, the existing FFE DE program requirements will continue to apply in any state that is approved to implement an FFE–DE or SBE–FP–DE. These existing requirements include safeguards to protect against deceptive marketing practices and ensure consumers have the information they need to make informed decisions.[32] For SBE–DE states, we finalize in § 155.221(j)(1)(iii) the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements to participate in the FFE DE program (including the FFE's safeguards to protect against deceptive marketing practices and ensure consumers have the information needed to make informed decisions) and we encourage these states to more broadly adopt standards similar to the existing FFE DE program for all DE partners approved by the state. We note too that recent federal legislation addressing surprise billing[33] generally requires issuers of STLDI plans to disclose to potential enrollees any broker commissions for STLDI plans prior to plan selection. This transparency requirement should further mitigate risk presented by any misalignment of incentives that could result in inappropriate steering. Other controls could also be implemented by states to check misalignment of incentives and mitigate the risk that DE entities will improperly steer consumers toward non-QHP products and allow consumers to make informed choices.

We also reiterate that DE entities operating under the FFE–DE and SBE–FP–DE options would be required to meet FFE privacy and security standards while SBE–DEs have the flexibility to ensure similar standards are in place to protect consumer information. HHS intends to continue to strengthen the regulatory and operational controls that would apply to DE entities operating in FFE and SBE–FP states that elect this option to ensure that sufficient protections are in place. Generally, assuming due diligence and appropriate regulatory and operational safeguards to ensure oversight over DE entities, and taking into account that these organizations have a strong business interest in serving their customers effectively to maintain their customers, we believe that the balance of risk is acceptable. Thus, we believe that the potential benefits of the Exchange DE option outweigh the burdens of oversight and the risk of fraud, waste, and abuse.

We also agree that it is important for consumers to continue receiving Medicaid and CHIP eligibility assessments or determinations when they apply for Exchange QHP enrollment and financial assistance through DE entities. In states implementing the Exchange DE option, the Exchange would still be required to establish and maintain the single, streamlined eligibility application as required under § 155.405, and make eligibility assessments and determinations of Medicaid or CHIP eligibility as required under § 155.302. Exchanges would also remain the entity responsible for making all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs, conducting required verifications of consumer eligibility against trusted data sources, and SBE–FPs and FFEs that elect this option can choose among HHS-approved entities already operating through the FFE's DE program, and we are requiring SBE–DEs to have at least one DE entity with whom they partner that can display and allow for enrollment in all QHPs available in the state. We also intend to work closely with states electing this option to ensure that they meet these and other applicable requirements, and that there are appropriate back-end application interfaces in place between the Exchange's eligibility platform and approved DE entities to ensure that all consumers have a seamless experience completing the single, streamlined eligibility application and receiving an eligibility determination just as if they were applying for coverage directly through the Exchange website. These are examples of the areas HHS intends to focus on when assessing an SBE–DE state's operational readiness under § 155.221(j)(1)(i) and implementation plan under § 155.221(j)(1)(ii). For states interested in pursuing the FFE–DE or SBE–FP–DE option, these are areas that would need to be considered and addressed, as appropriate, as part of the implementation plan under § 155.221(j)(2)(i) and the Federal agreement under § 155.221(j)(2)(ii). While we acknowledge comments that the Exchange DE option could produce a disjointed enrollment process to a certain degree for some consumers, we believe that the benefits of providing consumers with more options outweigh the drawbacks, especially since they will still be completing the single, streamlined eligibility application on an approved DE partner's website in order to access APTCs and CSRs, or access Medicaid and CHIP coverage, if eligible. We also believe our focus on coordinating closely with states as part of the rollout process and transition to the Exchange DE option will help mitigate any risk of a reduction in Exchange or Medicaid and CHIP enrollment, as well as any potential increase in the uninsured.

Finally, the availability of the Exchange DE option does not directly affect the existence or operation of Navigator and other assister programs created by PPACA. As indicated above and detailed in the proposed rule, states that implement the Exchange DE option (DE states) will still be required to establish a Navigator program as required under section 1311(d)(4)(K) of PPACA. In all states that are approved to implement the DE option, the Exchange in the state must continue to make available an internet website that provides the same standardized comparative information on QHP options that is available on Exchange websites today. Therefore, Navigators and certified application counselors (collectively assisters), as well as agents and brokers, in DE states will still be able to view on State Exchange websites or *HealthCare.gov,* as applicable, comparative information for all QHP options available in the state, and will also be able to access information to connect with approved DE entities in their states. Moreover, each DE state

[32] See, for example, 45 CFR 155.220(j)(2)(i) and 156.1230(b)(2). Also see supra note 30.

[33] See Sec. 202 of Division BB of Public Law: 116–260, the Consolidated Appropriations Act, 2021, signed into law on 12/27/2020. *https://www.congress.gov/bill/116th-congress/house-bill/133.*

must ensure that at least one DE entity website is capable of processing all eligibility applications, including those that present complex enrollment scenarios, or else the state must continue to make available its own website that possesses such capability.

Finally, we note that the DE option requirements we finalize in this rule will provide Navigators and certified application counselors greater flexibility to effectively assist consumers than currently exists under the FFE's assister programs. For instance, in 2015 the FFE issued guidance (the 2015 guidance) instructing that FFE assisters should not use non-Exchange websites when providing enrollment assistance except as reference tools to supplement information on *HealthCare.gov.* But given the consumer protections that will apply in DE option states to ensure ready access to information on all QHPs available in a state (which include consumer-protective requirements that were not in place at the time we published the 2015 guidance),[34] there is no need to similarly limit assisters' ability to use DE entity websites to assist consumers.[35] We appreciate that actual implementation of the DE option will require states and HHS to closely monitor the program to ensure that consumers are receiving complete and accurate information and effective assistance. In the event HHS becomes aware of the need for additional or different DE option requirements, or greater clarity regarding DE option requirements, HHS may issue future guidance or pursue future rulemaking.

Comment: Many commenters argued that HHS does not have the legal authority under sections 1103,1302, 1311, or 1312 of PPACA to permit states and Exchanges to implement the Exchange DE option. Some commenters also argued that the Exchange DE option violates the spirit and intent of PPACA and represents an attempt to replace congressional legislation in violation of the Administrative Procedure Act (APA). Other commenters argued that the Exchange DE option is not based on a reasonable interpretation of specific aspects of PPACA and implementing regulations. In particular, some commenters argued that the Exchange DE option violates Section 1311(d)(1) of PPACA that requires that Exchanges be operated by a ''governmental agency or nonprofit entity that is established by a State.'' Some commenters also argued that HHS does not have the authority to delegate essential government functions currently performed by Exchanges to private entities.

Response: We disagree. The Exchange DE option requires that participating states and HHS continue to meet all applicable requirements of PPACA, including applicable requirements under section 1311 of PPACA. This is captured in the regulatory text at § 155.221(j)(1) and (2), which states that Exchanges must meet all federal statutory and regulatory requirements for the operation of an Exchange. As detailed above and in the proposed rule, Exchanges in states that elect this option must continue to provide the required minimum functions established in PPACA and comply with applicable requirements. This includes the responsibility to make all determinations of whether an applicant is eligible for QHP enrollment, APTC, and CSRs; conducting required verifications of consumer eligibility against trusted data sources; conducting assessments or determinations of eligibility for Medicaid and CHIP, and where appropriate, referring individuals who are assessed or determined eligible for Medicaid or CHIP to the appropriate state agency for enrollment in those programs; certifying plans as QHPs, making QHPs available to consumers, and facilitating the purchase of QHPs; granting exemption certifications, as applicable; making an electronic calculator available; establishing a Navigator program; and providing for the operation of a toll-free telephone hotline. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require that Exchanges provide consumers with the ability to view comparative information on QHP options, but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for eligibility and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. An Exchange can continue to meet these obligations without operating a consumer-facing enrollment website and Exchanges in states that elect this option must continue to operate a website that provides the same standardized comparative information about QHPs that is available today.[36] In addition, we maintain that states choosing to transition to the SBE–DE or SBE–FP–DE option must still meet the requirements of Section 1311(d)(1) of PPACA.[37] The arrangements that states would make with the DE entities approved to provide a consumer shopping and enrollment portal would be no different than the current contracting arrangements that HHS enters into today with approved partners who participate in the FFE DE program. It is also similar to the arrangements Exchanges may enter into today to provide other services, such as a call center, to their consumers.[38] Finally, we note how the Exchange DE option aligns with the general structure of how PPACA assigns states substantial authority to administer provisions of the law—including giving states the primary responsibility to create Exchanges and relying on states as the primary enforcers of PPACA's insurance regulations and Exchange requirements.[39] Accordingly, HHS is of the view that the Exchange DE option is consistent with the language, spirit, and intent of PPACA and its implementing regulations and there is sufficient authority to permit states to pursue this option. Moreover, consumers would still have available to them a centralized website, operated by the Exchange, to obtain standardized comparative information about available QHPs, as

[34] See 85 FR 78613.

[35] As detailed in the proposed rule, we are also revisiting our policy regarding the ability of FFE assisters' use of web-broker non-Exchange websites. See 85 FR at 78611–78614. If finalized as proposed, this policy change would permit assisters in FFEs and SBE–FPs to also use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided certain conditions are met.

[36] We further note that HHS met its obligations under section 1103 of PPACA when it established the internet Portal and developed the standardized format to be used for the presentation of information on coverage option by July 1, 2010. See, for example, Health Care Reform Insurance Web Portal Requirements; Interim Final Rule with Comment Period, 75 FR 24470 (May 5, 2010). We also disagree with commenters who suggested that sections 1302 or 1312 of PPACA are legal obstacles to the adoption of the Exchange DE option. Section 1302 relates to the development of the essential health benefits package and accompanying benefit requirements (for example, requirements related to cost-sharing and actuarial value levels of coverage). Section 1312 establishes requirements related to consumer choice and the establishment of single risk pools by issuers. As such, section 1302 and section 1312's single risk pool provisions generally outline benefits, plan design, and rating requirements applicable to issuers of non-grandfathered health insurance coverage, and issuers must continue to comply with these requirements in any state that elects to adopt the Exchange DE option. The other provisions in section 1312, such as those related to consumers' choice of whether to enroll in coverage through an Exchange, the continued operation of the market outside the Exchanges, the option for states to allow agents or brokers to assist with Exchange enrollments, and the enrollment of members of Congress in plans offered through an Exchange also would continue to apply in states that elect to adopt the Exchange DE option and do not preclude our finalizing the Exchange DE option.

[37] For FFE states that elect and are approved to transition to the FFE–DE option, CMS, on behalf of HHS will continue to be responsible for operation of the Exchange consistent with section 1321(c)(1).

[38] See, for example, section 1311(f)(3).

[39] See section 2723(a)(1) of the PHS Act and section 1321(c)(2).

well as information about and links to approved partners' enrollment websites. Finally, they would still have access to the Exchange itself to apply for, and enroll in, coverage should that be necessary. Given that states electing the Exchange DE option remain subject to the requirements of PPACA and its implementing regulations, we further disagree that the flexibility we are providing to meet those requirements constitutes an attempt to replace congressional legislation in violation of the APA.

Comment: Many commenters argued that the Exchange DE option is not legally permissible in the absence of a section 1332 waiver, and should only be approved through the section 1332 waiver process. Some commenters highlighted in particular the benefits of the section 1332 waiver public notice and comment process as an additional safeguard that they asserted would be beneficial to any state interested in pursuing the Exchange DE option. Some commenters further argued that Georgia's recent section 1332 waiver proposal to implement activities similar to those proposed under the Exchange DE option was wrongfully approved and that even if another state were to apply for a section 1332 waiver to implement the Exchange DE option, such a waiver plan would violate section 1332's coverage guardrail because they believe enrollment would generally be reduced.

Response: The merits of the Departments' decision to approve Georgia's section 1332 waiver is not in the scope of this rulemaking. However, we clarify that a section 1332 waiver is not required for a state to be approved for and to implement the Exchange DE option. Georgia's section 1332 waiver is distinguishable from the Exchange DE option we finalize here because states that elect and implement the Exchange DE option would still be required to meet all Exchange requirements under PPACA, while under its section 1332 waiver plan Georgia waived certain Exchange requirements under section 1311.[40] Moreover, under Georgia's section 1332 waiver, consumers in Georgia will no longer be able to access and utilize *HealthCare.gov,* and a state statute expressly prohibits the state from implementing a State Exchange and from establishing a Navigator program or its equivalent.[41]

In contrast, in states that elect the FFE–DE or SBE–FP–DE option, consumers will continue to have the *HealthCare.gov* website available to them to view standardized comparative information about QHPs and the Exchange will be required to continue to operate its respective Navigator program. States that elect to become or transition to an SBE–DE would similarly be required to maintain and make available the State Exchange website for standardized comparative information, the state's respective Navigator program to assist consumers, and the state's associated eligibility rules engine to make eligibility determinations, as well as the state's enrollment platform, in the event that there is not a DE entity capable of processing a consumer's application. We also recognize the importance of a meaningful public notice and comment process, and note that states that elect to pursue the Exchange DE option have the discretion to provide for a state public notice and comment process should they deem it to be beneficial.

Comment: Many commenters noted that programmatic guardrails or operational parameters are not adequately defined and incorporated into the rule to allow for effective implementation of the Exchange DE option, particularly with respect to ensuring oversight over DE entities. In particular, commenters noted a lack of clarity about the responsibilities of DE entities regarding administering consumer education and assistance to ensure consumers are not confused or misled about their coverage options. In particular, commenters noted that it is not clear how HHS would ensure DE entities operate in an unbiased, transparent manner such that consumers can effectively compare and make an informed choice among all available QHP options, know when they are viewing non-QHP options, and receive information on public coverage options they may be determined eligible for, such as Medicaid and CHIP. Several commenters noted that we should be more definitive about the responsibilities of the DE entities regarding display of QHPs and choice of QHPs, including how DE entities and Exchanges should handle the scenario where a consumer wishes to enroll in an issuer's QHP when a particular DE entity is not appointed to sell products by that issuer.

Response: In proposing the Exchange DE option, we wanted to strike an appropriate balance to provide states with appropriate flexibility to implement the Exchange DE option in a manner that is tailored to the needs of their unique health care markets while still meeting the applicable federal requirements. We have included a broad framework of baseline federal requirements governing the Exchange DE option in this final rule and welcome states interested in pursuing this option to adopt any additional state-specific requirements they deem necessary to effectively oversee DE entities and protect consumers. It is important to note that the framework of programmatic parameters and federal requirements governing the Exchange DE option included in this final rule is meant to serve as a floor and not a ceiling. We also share commenters' concerns about ensuring effective oversight over DE entities and protecting consumers. As explained in the proposed rule, given that an FFE–DE or SBE–FP–DE state would use one or more DE entities approved to participate in the FFE DE program, at a minimum, the FFE privacy and security standards[42] and the FFE DE program requirements[43] would continue to apply. This includes the requirement for web brokers under § 155.220(c)(3)(i)(B) to provide consumers with the ability to view all QHPs offered through the Exchange and the corresponding similar requirement for issuers at § 156.1230(a)(1)(ii); the requirement for web brokers under § 155.220(c)(3)(i)(A) to display QHP information comparable to information available on the Exchange website or display a subset of QHP information and a disclaimer with a link to the Exchange and the corresponding similar requirement for issuers at § 156.1230(a)(1)(iv); as well as the requirements at §§ 156.1230(b)(2) and 155.220(j)(2)(i) applicable to all DE entities to provide consumers with correct information, without omission of material fact, and refrain from marketing or conduct that is misleading, coercive, or discriminatory.

For SBE–DE states, we codify in § 155.221(j)(1)(iii) the requirement for the state to ensure that a minimum of at least one DE entity approved by the state meets minimum federal requirements for HHS approval to participate in the FFE DE program (including the examples highlighted in the prior sentence) and we encourage these states to more broadly adopt processes and standards similar to the

[40] As detailed in Georgia's approval letter and Specific Terms and Conditions (STCs), the Exchange requirements in sections 1311(b), (c), (d), (e) and (i) are waived to the extent they conflict with the Georgia Access Model as described in the state's approved waiver. See *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-/1332-GA-Approval-Letter-STCs.pdf.*

[41] See O.C.G.A. sec. 33–1–23, available at: *https://law.justia.com/codes/georgia/2019/title-33/chapter-1/section-33-1-23.*

[42] See 45 CFR 155.260 through 155.285.

[43] See 45 CFR 155.220, 155.221 and 156.1230.

existing FFE DE program for all DE partners approved by the state. At the same time, however, SBE–DE states would retain general flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state. HHS would review and assess an SBE–DE state's process, standards and oversight approach for DE entities as part of the operational readiness assessment under § 155.221(j)(1)(i). We also intend to continue engaging stakeholders on, and develop, additional programmatic and operational requirements through future rulemaking and sub-regulatory guidance, as necessary or appropriate. Furthermore, additional technical assistance and operational details related to implementation of the FFE–DE and SBE–FP–DE options may be best defined and addressed during the development of the implementation plan under § 155.221(j)(2)(i) and the federal agreement that states electing to implement the FFE–DE or SBE–FP–DE option must execute with HHS under § 155.221(j)(2)(ii). This approach allows HHS to be responsive to programmatic and operational concerns in real time, as well as tailor the implementation to meet a state's unique market conditions or needs of its residents.

Comment: Several supportive commenters recommended that CMS delay implementation of the Exchange DE option pending further research, evidence gathering, stakeholder consultation, and a more robust public comment process to quantify potential impacts and adequately inform programmatic and operational parameters. Many opposing commenters requested that we strike it from this rulemaking entirely for the same reasons. In particular, commenters noted interest in potential impacts on premiums, as well as how enrollment in various insurance affordability programs and the uninsured could impact the risk pool. Other commenters noted that it is not clear that the Exchange DE option represents a better value proposition than the current centralized Exchange enrollment model and requested that HHS gather additional data to quantify the value of this new option. Commenters questioned the premise that a centralized consumer-facing website is less efficient than fracturing the consumer-facing pathway and consumer experience among multiple platforms, potentially leading to increased cost and burden on consumers. Many commenters also contend that a centralized consumer-facing website is the more efficient and effective model for states and Exchanges, as well, rather than the state or an Exchange having to manage multiple DE entity relationships and their associated technical infrastructure, including multiple DE entity websites and their interfaces to the back-end Exchange eligibility and enrollment platform that must be managed under the Exchange DE option.

Response: We proposed and are finalizing this new Exchange DE option in response to our experience operating the *HealthCare.gov* platform and stakeholder feedback, including the comments about challenges related to Exchanges becoming a dominant public-sector competitor that can crowd out other market players. We also emphasize this option is strictly permissive for states. Whether the Exchange DE option or a centralized Exchange website is more efficient, or provides better value, for a given state is contingent on the unique circumstances of that state's health care market and the needs of its residents. Therefore, we do not believe that one or the other can be characterized as generally more efficient, or a better value, across all states. As states consider and elect the Exchange DE option, we will coordinate and engage in information sharing with these states as appropriate to assess the efficacy and value of this option from the federal perspective. This will help inform our continued consideration and development of programmatic and operational parameters and any additional regulatory requirements related to these options. Given that the health care market of each state is unique, we also welcome states that are interested in pursuing the Exchange DE option to undertake their own research, stakeholder consultation, and data gathering to determine whether it represents a sensible value proposition for their consumers. We also welcome the sharing of any information and data on findings, best practices, and lessons learned. Finally, expected impacts to the premiums and the risk pool have been addressed in the Regulatory Impact Analysis (RIA) in this rulemaking.

Comment: A few commenters noted that the potential consequences of the Exchange DE option, including Exchanges no longer serving as the single pathway for many to get covered, present potential barriers to accessing QHP or Medicaid coverage, and risks of being underinsured or becoming uninsured would disproportionately impact various vulnerable groups, namely historically-marginalized populations, individuals with pre-existing conditions, individuals with substance-abuse disorders, rural and low-income populations, non-English-speaking populations, and others. One commenter noted that it could encourage health inequities between white communities and communities of color particularly with respect to substance abuse addiction.

Response: We share concerns about health disparities and the disproportionate impact on vulnerable population groups or the creation of inequity that exist in today's health care system, and commend commenters for identifying these issues as particular areas where HHS and states can remain proactive and diligent. States that elect to pursue the SBE–DE option should consider these issues and detail their communication and outreach strategy to target vulnerable populations as part of the implementation plan required under § 155.221(j)(1)(ii). Similarly, HHS will partner with FFE–DE and SBE–FP–DE states to consider these issues when developing the implementation plan under § 155.221(j)(2)(i). Through the various requirements and controls we are finalizing, particularly accessibility and non-discrimination requirements, the requirement that the Exchange remain available to consumers who need it, as well as the flexibility states will have to implement additional requirements and controls to protect consumers, we believe that such disproportionate impacts can be prevented or mitigated. We note that the Exchange DE option offers a platform for multiple DE entities to compete to serve consumers, which creates an opportunity for DE entities to specialize to serve specific populations, including vulnerable populations. As such, the Exchange DE option holds potential to better connect vulnerable populations to coverage than a centralized one-size-fits-all Exchange model. Again, we welcome the sharing of any information and data on findings, best practices, and lessons learned.

Following our review of the comments, we are finalizing this proposal but have amended the regulatory text to underscore our requirement that State Exchanges electing the DE option must ensure at a minimum, that at least one approved web-broker DE entity meets requirements that align with the FFE standards under §§ 155.220 and 155.221 to ensure consumers have at least one option through which to view detailed QHP information for all available QHPs in the state and enroll in a QHP. We have also incorporated minor clarifying edits throughout the regulatory text. We

will also continue to assess the need for any additional programmatic and operational parameters, as well as any additions to the regulatory requirements, to ensure necessary protections for consumers in states that implement the Exchange DE option.

B. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

a. FFE and SBE–FP User Fee Rates for the 2022 Benefit Year (§ 156.50(c))

Section 1311(d)(5)(A) of PPACA requires states to ensure that Exchanges are self-sustaining, which may include the state allowing an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specify that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. In addition, OMB Circular No. A–25 establishes federal policy regarding the assessment of user charges under other statutes and applies to the extent permitted by law. Furthermore, OMB Circular A–25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public. Activities performed by the federal government that do not provide issuers participating in an FFE with a special benefit are not covered by this user fee. As in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP.

For the 2022 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities through which FFE issuers receive a special benefit also include the Health Insurance and Oversight System (HIOS) and Multidimensional Insurance Data Analytics System (MIDAS) platforms, which are partially funded by Exchange user fees. Based on estimated costs, enrollment (accounting for anticipated establishment of state Exchanges in certain states in which FFEs are currently operating), and premiums for the 2021 plan year, we proposed a 2022 user fee rate for all participating FFE issuers at 2.25 percent of total monthly premiums. This proposed user fee rate reflects our estimates for the 2022 benefit year of costs for operating the FFEs, premiums, enrollment, and transitions in Exchange models (from the FFE and SBE–FP models to either the SBE–FP, FFE–DE or State Exchange models (state transitions)). The proposed FFE user fee rate is lower than the 3.0 percent FFE user fee rate that we established for benefit years 2020 and 2021, and the 3.5 percent FFE user fee rate that we established for benefit years 2014 through 2019. After accounting for the impact of the lower user fee rate, we estimated that we would have the necessary funding available to fully fund user-fee eligible Exchange activities in 2022. We sought comment on this proposed 2022 FFE user fee rate.

As previously discussed, OMB Circular No. A–25 establishes federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. SBE–FPs enter into a federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or state.

The benefits provided to SBE–FP issuers by the federal government include use of the federal information technology platform and call center infrastructure used to support eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs as defined at section 1413(e) of PPACA, and QHP enrollment functions under § 155.400. The user fee rate for SBE–FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. Based on this methodology, we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 1.75 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. This proposed rate is lower than the 2.5 percent user fee rate that we had established for the 2021 benefit year. The lower proposed user fee rate for SBE–FP issuers for the 2022 benefit year reflects our estimates of costs for operating the Federal Exchanges, premiums, enrollment, as well as state Exchange transitions for the 2022 benefit year, and the costs associated with performing these services that benefit SBE–FP issuers. We sought comment on the proposed 2022 SBE–FP user fee rate.

We received public comments on the proposed FFE and SBE–FP user fee rates for the 2022 benefit year (§ 156.50(c)). The following is a summary of the comments we received and our responses.

Comment: Several commenters supported lowering the FFE and SBE–FP user fee rates as proposed, with some commenters supporting the lower user fee rates so long as the reduction does not adversely impact FFE operations. Other commenters opposed the proposed user fee rates and asked that HHS raise the user fee rates to previous levels, 3.5 percent for FFE issuers and 2.5 percent for SBE–FP issuers, and use any excess user fees for education, consumer outreach, improving *HealthCare.gov,* or to otherwise increase funding levels for these activities. Some commenters asked that HHS maintain the current 2021 user fee rates of 3.0 percent for FFE issuers and 2.5 percent for SBE–FPs issuers. Other commenters recommended HHS finalize a lesser reduction to the user fee rates than the 0.75 percentage point reductions we

proposed. Several other commenters opposed the proposed user fee rates, noting that the reduction in user fee rates could negatively affect State Exchanges by limiting the funding available for national marketing and outreach, which those states rely on to encourage enrollment in all Exchange types. However, one commenter suggested further lowering the FFE and SBE–FP user fee rates to 2 percent and 1.5 percent respectively. This commenter stated that the additional reductions would better align the user fee rates with the reduced scope of operations performed by HHS.

Several commenters asked that HHS use user fees to improve Exchange services for populations facing heightened barriers to enrollment, such as those in rural areas and those with limited English proficiency. One commenter questioned whether lowering the user fee rate was sound budgeting practice.

Response: We are finalizing the 2022 benefit year user fee rates at 2.25 percent for FFE issuers and 1.75 percent for SBE–FP issuers, which is lower than the user fee rates for the 2021 benefit year. We estimate that these user fee rates will provide the necessary funding for the full functioning of the federal platform for the 2022 benefit year. Based on future projected changes in costs, enrollment, and premiums, we project that HHS can fully fund federal platform costs associated with providing special benefits to these issuers.

HHS remains committed to providing a seamless enrollment experience for consumers who enroll in coverage through an Exchange that uses the federal platform and to providing a value based approach to outreach and marketing activities. We believe that the services offered by the FFEs are sufficient to support all consumers seeking to enroll in coverage through the FFEs and SBE–FPs. The experience from the recently closed 2021 Open Enrollment Period shows *HealthCare.gov* and the call center operated well with the investments made over recent years to improve stability and the consumer experience on the federal platform. Specifically, the reduced user fee rates we adopt in this final rule will not impede federal platform services and will continue to apply resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment. We will continue to evaluate consumer outreach and education needs within the normal budget process. Additionally, we will continue to evaluate the user fee rates and the associated costs to operate the federal platform for future benefit years.

Comment: Some commenters requested more transparency and data on how user fees are calculated and allocated, and information on how funding for *HealthCare.gov* is allocated. Several commenters noted that without data transparency, it is difficult to meaningfully comment on the proposed user fee reductions. One commenter requested that HHS delay finalization of the 2022 benefit year user fee rates until more data is made publicly available.

Response: We believe that the information provided in the proposed rule in support of the user fee rate proposals was sufficient to allow commenters to meaningfully assess and comment on the appropriateness of our user fee rate proposals. As we explained in the preamble to the proposed rule, the FFE and SBE–FP user fee rates for the 2022 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE–FPs, and evaluation of expected enrollment and premiums for the 2022 benefit year. To calculate these expected costs, we make reasonable assumptions about the expected market for the upcoming benefit years and we reconsider these assumptions and re-estimate these costs on an annual basis with the most recent data available. For example, for the 2022 benefit year, we considered whether we needed to make changes to our cost, premium, and enrollment assumptions based on data from the 2020 benefit year and made updates to our projections as appropriate.

User fee-eligible costs are estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore, proprietary. We will continue to outline user fee-eligible functional areas in the annual HHS notice of benefit and payment parameters, and will evaluate contract activities related to operation of the FFE user fee-eligible functions. The categories that are considered user fee-eligible include activities that provide special benefits to issuers offering QHPs through the federal platform, and do not include activities that are provided to all QHP issuers. For example, functions related to risk adjustment program operations and operations associated with APTC calculation and payment, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2022 benefit year), are not included in the FFE or SBE–FP user fee-eligible costs. However, costs related to Exchange-related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are considered FFE user fee-eligible costs. SBE–FPs conduct their own health plan certification reviews and consumer information and outreach, and therefore, the SBE–FP user fee rate is determined based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE–FPs.

Based on our estimates and after considering comments, we continue to believe that a user fee rate of 2.25 percent for FFE issuers and 1.75 percent for SBE–FP issuers will provide the necessary funding for the full functioning of the federal platform for the 2022 benefit year, and therefore, we are finalizing the FFE and SBE–FP user fee rates as proposed.

b. FFE–DE and SBE–FP–DE User Fee Rates for the 2023 Benefit Year (§ 156.50(c)(3))

In the proposed rule, we proposed to allow states served by an FFE or SBE–FP to implement the proposed direct enrollment option under § 155.221(j) beginning with plan year 2023, under which one or more private direct enrollment entities approved by the FFE would operate non-Exchange websites through which consumers may apply for and enroll in a QHP, with or without APTC or CSR (if otherwise eligible), in a manner considered to be through the Exchange. Under the Exchange DE option, QHP issuers offering plans through an FFE–DE or SBE–FP–DE would continue to receive some of the benefits received by FFE and SBE–FP issuers; however, some consumer outreach, education, and support activities would be provided by the state or through the approved DE partners.[44] As previously discussed, OMB Circular No. A–25 establishes federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. As such, we proposed in new § 156.50(c)(3) to charge issuers offering QHPs through an FFE–DE or an SBE–FP–DE a user fee for the services and benefits provided to those issuers by HHS as the administrator of the FFE. We proposed to charge issuers offering QHPs through an FFE–DE or SBE–FP–DE a user fee rate calculated based on the proportion of FFE user fee-eligible costs incurred by HHS that are

[44] See above for more information on the direct enrollment option under § 155.221(j).

associated with implementation and operation of the FFE–DE or SBE–FP–DE. We assumed that the use of FFE services will be less for FFE–DE and SBE–FP–DE states in 2023 than for FFE and SBE–FP states during the same time period. Therefore, to provide some certainty for states that consider a transition to a proposed FFE–DE or SBE–FP–DE, we proposed a 2023 user fee rate of 1.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an FFE–DE or SBE–FP–DE in plan year 2023.

In a state that implements the Exchange DE option, the Exchange in the state would no longer provide many of the consumer-facing enrollment-related activities that are currently being performed through the federal platform, or such activities would be substantially reduced. For example, the use of the Marketplace call center and *HealthCare.gov* website will be substantially diminished. Because of the role of the state in operating SBE–FPs, the value to issuers and the associated costs of operating these functions in FFEs are typically higher. The reduction of these functions and costs is reflected by a larger proposed reduction in the user fee rate for issuers in FFE–DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE–FP–DEs from the rate applicable in SBE–FPs (from 1.75 percent to 1.5 percent), resulting in the same proposed user fee rate for FFE–DEs and SBE–FP–DEs. We sought comment on the FFE–DE or SBE–FP–DE user fee rate, including whether the rate should be state-specific or higher or lower depending on whether the Exchange is an FFE–DE or SBE–FP–DE. We also sought comment on the specific services HHS will provide consistent with the Federal agreement we proposed to require under new § 155.221(j)(2)(ii). We sought comment on the FFE–DE and SBE–FP–DE user fee rates for the 2023 benefit year.

We are finalizing the 2023 FFE–DE and SBE–FP–DE user fee rate as proposed. We also make clear that HHS intends to collect these user fees on a monthly basis as it does with the FFE and SBE–FP user fees, consistent with the netting regulations at 45 CFR 156.1210. The following is a summary of the public comments we received on the FFE–DE and SBE–FP–DE user fee rate proposal for the 2023 benefit year and our responses.

Comment: We received several comments in support of a lower user fee rate for FFE–DE and SBE–FP–DE states. Other commenters expressed a general skepticism or disapproval of this user fee rate as an extension of their disapproval of the proposed Exchange DE option. One commenter believed that increased reliance on agents and brokers calls for increased spending on their oversight, and thus a higher FFE–DE and SBE–FP–DE user fee rate than that proposed would be appropriate.

Response: We are finalizing the proposed 1.5 percent of premium user fee rate for issuers offering plans through FFE–DEs and SBE–FP–DEs for the 2023 benefit year. We proposed this user fee rate to provide clarity and predictability regarding the user fee rate HHS would assess in FFE–DE and SBE–FP–DE states in order to allow states to evaluate whether to elect the Exchange DE option beginning with the 2023 benefit year. As discussed earlier in the preamble, this user fee rate is reflective of the costs incurred by HHS to support FFE–DE and SBE–FP–DE operations. Changes to HHS's costs, such as those related to oversight of agents and brokers, changes to underlying estimates of premiums and enrollment, or changes to the models adopted by states for their Exchanges could impact the user fee rate for 2023 or future benefit years. Therefore, we will continue to evaluate our estimates and will revisit the 2023 FFE–DE and SBE–FP–DE user fee rates in the 2023 Payment Notice proposed rule in compliance with our regulations.[45]

Comment: One commenter questioned the validity of a single user fee rate for issuers in FFE–DE and SBE–FP–DE states. The commenter asserted that even where differences between the services provided to FFE–DE and SBE–FP–DE issuers were minimized, a single user fee rate may not be justified.

Response: The 1.5 percent of premium user fee rate we proposed for FFE–DE and SBE–FP–DE issuers was calculated based on the proportion of FFE user-fee eligible costs that HHS anticipates it would incur to support the operation of an FFE–DE or SBE–FP–DE. We assumed that the use of federal platform services will be less for FFE–DEs and SBE–FP–DEs in 2023 than for an FFE or SBE–FP during the same time period.

Under the Exchange DE option, an Exchange would no longer provide many of the consumer-facing enrollment-related activities that are currently being performed through the federal platform for FFEs and SBE–FPs, or such activities would be substantially reduced. For example, the use of the Marketplace call center and *HealthCare.gov* website will be substantially diminished. Because of the role of the state in operating SBE–FPs, the value to issuers and the associated costs of operating these functions in FFEs is typically higher. The reduction of these functions and costs is reflected by a larger proposed reduction in the user fee rate for issuers in FFE–DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE–FP–DEs from the rate applicable in SBE–FPs (from 1.75 percent to 1.5 percent). These reductions resulted in the same user fee rate for issuers offering QHPs through FFE–DEs and SBE–FP–DEs.

2. Network Adequacy Standards (§ 156.230)

We are finalizing the proposed revisions to 45 CFR 156.230, which implements section 1311(c)(1)(B) of PPACA and describes network adequacy standards for plans seeking certification as QHPs. As we stated in the proposed rule, we have received questions regarding whether § 156.230 requirements apply to a plan that does not vary benefits based on whether enrollees receive services from an in-network or out-of-network provider.

As we stated in the proposed rule, nothing in PPACA requires a QHP issuer to use a provider network and § 156.230 does not impose any network adequacy certification requirement for QHPs that do not use a provider network. Accordingly, an issuer might design and seek QHP certification for a plan that does not use a provider network and provides equal benefits for the same covered services without regard to whether the issuer has a network participation agreement with the provider that furnishes the covered services. To address any ambiguity in this section, we proposed to codify this longstanding interpretation at paragraph (f) to provide that a plan that does not vary benefits based on whether the issuer has a network participation agreement with a provider that furnishes covered services is not required to comply with the network adequacy standards at paragraphs (a) through (e) of § 156.230 to qualify for certification as a QHP. In the proposed rule, we explained that this proposal would simply clarify existing QHP requirements and would not add to, change, or remove any QHP certification requirements.

We received public comments on the proposed updates to the QHP network

[45] We note that even if this further consideration does not lead us to propose a change to the FFE–DE or SBE–FP–DE user fee rates applicable for the 2023 benefit year, we intend to address the 2023 FFE–DE and SBE–FP–DE user fee in the 2023 Payment Notice proposed rule in compliance with our regulations. See 45 CFR 156.50(c).

adequacy standards under § 156.230. The following is a summary of the comments we received and our responses.

Comment: Of the comments received addressing this provision, a plurality supported this clarification, asserting that it will encourage variety in the kinds of plans certified as QHPs, lower costs by fostering more competition between issuers, increase enrollee access to providers, and reduce pressure on providers to enter into network agreements with issuers.

Response: We agree with commenters and are finalizing this clarification as proposed. Since plan year 2016, § 156.230(a) has applied only to QHPs that utilize a provider network.[46] The provision finalized here only clarifies this existing policy by adding explicit regulatory text reflecting the regulation's inapplicability to plans that do not utilize a provider network and do not vary benefits for covered services based on whether or not they are provided by an in-network or out-of-network provider.

Comment: A few commenters opposed the proposed clarification, asserting that it would reduce CMS's ability to oversee QHP issuers and ensure issuer accountability. A few commenters requested clarification on whether plans that do not utilize a provider network must comply with other QHP certification and market-wide requirements, such as requirements related to maximum out-of-pocket limits, cost-sharing protections, coverage of essential health benefits (EHB), actuarial value standards, inclusion of essential community providers, and non-discrimination standards under § 156.125. Some of these commenters opposed finalization of this provision until CMS could be assured that such plans would comply with these requirements.

Response: The provision finalized here only clarifies that plans that do not utilize a provider network are not required to satisfy the network adequacy standards at § 156.230 to obtain QHP certification. This final rule does not add to, change, or remove QHP certification requirements, nor does it add to, change, or remove any requirement for these plans to comply with the market reform provisions under title I of PPACA. Plans that do not utilize a provider network must still comply with all applicable QHP certification requirements to obtain QHP certification, which ensures that any plan that does not comply with applicable QHP certification requirements will be denied QHP certification.

Comment: A few commenters cautioned about the potential proliferation of QHPs that do not utilize a provider network, which could place consumers in the middle of payment disputes between issuers and providers. One commenter asserted that, while CMS should do more to encourage issuers to develop plans that do not utilize a provider network, QHP certification should be reserved for plans that utilize adequate provider networks and meet all other QHP certification requirements.

Response: We proposed no substantive changes to QHP certification requirements and decline to disqualify plans that do not utilize provider networks from obtaining QHP certification. Since plan year 2016, the text of § 156.230(a) has stated that the section only applies to QHPs that utilize a provider network.[47] While plans that do not utilize a provider network have always been eligible to apply for QHP certification, only 12 plans that did not utilize a provider network have ever been approved as QHPs in the FFEs.[48]

Comment: One commenter requested that CMS disclose the plans that do not utilize a provider network that have sought or received certification as QHPs.

Response: CMS releases QHP certification information in Public Use Files (PUFs) at *https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.* The Plan Attributes PUF lists the plan type for each plan approved as a QHP. There were 12 plans certified as QHPs in Wisconsin for plan year 2016 that did not utilize a provider network. No such plans have been granted QHP certification in an FFE since.

We are finalizing this policy as proposed.

3. Enrollment Process for Qualified Individuals (§ 156.1240)

We are finalizing the proposed revisions to § 156.1240, with a modification in response to comments. Under § 156.1240(a), QHP issuers are required to accept a variety of payment methods so that individuals without a bank account or a credit card will have readily available options for making monthly premium payments. Specifically, paragraph (a)(1) of § 156.1240 requires QHP issuers to follow the premium payment process established by an Exchange in accordance with 45 CFR 155.240. Paragraph (a)(2) requires QHP issuers to accept for all payments in the individual market, at a minimum, paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and to present equally all payment method options to allow a consumer to select their preferred payment method. We proposed to add new paragraph (a)(3) to require individual market QHP issuers to also accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. As explained in the proposed rule, we received questions indicating that there is some confusion over whether issuers must accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. Individual coverage HRAs are a new type of health reimbursement arrangement that employers may offer to employees as of January 1, 2020.[49] QSEHRAs are another new type of HRA that qualified small employers can provide to their employees pursuant to section 9831 of the Code. In general, employers may offer individual coverage HRAs or provide QSEHRAs to their employees as a means of providing tax-advantaged reimbursements for medical care expenses, including premiums for individual health insurance coverage that they purchase for themselves and their families. Reimbursement from individual coverage HRAs and QSEHRAs may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments (individual or aggregate) by the employer, employee organization, or other plan sponsor to the health insurance issuer.[50]

We proposed to add a new § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual

[46] 80 FR at 10830 (February 27, 2015). Available at *https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.*

[47] See 80 FR at 10830, 10873 (February 27, 2015) (explaining HHS's proposal to modify § 156.230(a) ''to specify that this section only applies to QHPs that use a provider network'' and finalizing § 156.230(a) to state that ''[e]ach QHP issuer *that uses a provider network* must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets . . . standards [under § 156.230(a)] . . . .'') (italics added). Available at *https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf.*

[48] Twelve such plans were approved as QHPs in Wisconsin for plan year 2016. See plan type data for QHPs, available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.*

[49] See 84 FR 28888.

[50] See 84 FR at 28950–51 (''[E]mployer funds paid from an HRA go directly to a participant or a health insurance issuer because the economic substance of the transaction is the same—that is, the funds are being used to discharge an employee's premium payment obligations.'').

coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. We proposed that QHP issuers would be required to accept such payments when they are made using a method of payment described in § 156.1240(a)(2). We recognized some individual coverage HRAs and QSEHRAs prefer to make aggregate payments on behalf of multiple employees to a QHP issuer. We further encouraged QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate these aggregate payments, as this approach could ease administration of individual coverage HRAs and QSEHRAs. We also explained that this proposal would help ensure that individual coverage HRAs or QSEHRAs operate as intended, and would address potential stakeholder confusion regarding whether QHP issuers must accept payments made from individual coverage HRAs or QSEHRAs. However, we did not propose to require QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when made using a form of payment that is not described in § 156.1240(a)(2) or to accept aggregate payments from an individual coverage HRA or QSEHRA made on behalf of multiple enrollees.

We are finalizing this policy, but with a modification to clarify that QHP issuers not only must accept payments made on behalf of an enrollee directly from an individual coverage HRA or QSEHRA, but must also accept payments made directly by an enrollee using funds from an individual coverage HRA or QSEHRA, so long as such payments are made using a form of payment that is described in § 156.1240(a)(2).

We received public comments on the proposed updates to § 156.1240. The following is a summary of the comments we received and our responses.

Comment: Most commenters who commented on this proposal supported it. Several commenters noted that it would help overcome issuer confusion about whether they must accept payments from an individual coverage HRA or QSEHRA, which commenters stated has been an obstacle to the implementation of these options. One commenter reported that some issuers have refused to accept payments from an individual coverage HRA or QSEHRA when it was used to purchase coverage through a special enrollment period, and that this change would ensure that individuals offered an individual coverage HRA or provided a QSEHRA would be able to enroll in individual market QHP coverage. A few commenters encouraged CMS to require that QHP issuers accept aggregate payments from individual coverage HRAs or QSEHRAs made on behalf of multiple enrollees.

A smaller number of commenters opposed the proposal and stated that whether to accept premium payments made by an individual coverage HRA or QSEHRA on behalf of an enrollee should be at the option of the issuer, rather than required by HHS. A few commenters were concerned that accepting these payments, particularly aggregate payments, was not issuer standard practice and would be operationally difficult to implement. They raised concerns about the issuer burden associated with building the IT infrastructure to facilitate roster, or list, billing.

Response: We did not propose and are not finalizing a requirement for QHP issuers to accept aggregate payments from individual coverage HRAs or QSEHRAs.[51] We also did not propose and are not finalizing any requirement that QHP issuers facilitate roster, or list, billing. We instead encourage QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate acceptance of aggregate payments from these HRA vehicles. We are not inclined to require more at this time given the relative infancy of individual coverage HRAs and QSEHRAs, but we expect the proposal we are finalizing that requires QHP issuers to accept premium payments received directly from an individual coverage HRA or QSEHRA to ease administration of individual coverage HRAs and QSEHRAs. This rule will also make the individual coverage HRA and QSEHRA experience more seamless for employees by ensuring that individual coverage HRAs and QSEHRAs may pay employee premiums directly, rather than only reimbursing employees after they have paid first out of their own pockets.

We understand that some QHP issuers are working to build IT systems to accommodate aggregate payments. However, because not all QHP issuers can accept aggregate payments using their existing IT infrastructure, it could be costly and time-consuming to require all QHP issuers to accept them. As individual coverage HRAs and QSEHRAs grow in popularity, we anticipate the benefits of making such an IT investment may outweigh the costs for most QHP issuers. However, at this time, with individual coverage HRAs and QSEHRAs still in their infancy, the final rule does not require QHP issuers to accept such aggregate payments, even if such payments are made using a form of payment that is described in § 156.1240(a)(2). Additionally, we recognize that it may not previously have been standard practice for every individual market QHP issuer to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA. Although some QHP issuers may incur administrative costs for operational changes necessary to comply with the payment acceptance requirement adopted in this final rule, such costs should be minimal because QHP issuers are already required to accept the forms of payment described in § 156.1240(a)(2) for all payments in the individual market. Therefore, we believe the benefits of requiring individual market QHP issuers to accept payments from individual coverage HRAs and QSEHRAs, rather than employees having to pay premiums out-of-pocket and then seek reimbursement at a later time, outweighs these administrative costs and is in the best interests of consumers.

Comment: Several commenters stated that individual coverage HRAs and QSEHRAs constitute third party payments, which issuers are not required to accept under § 156.1250.

Response: Individual coverage HRAs and QSEHRAs are structured to reimburse an employee for eligible medical care expenses that are paid by the employee. HHS considers any payments for eligible medical care expenses that are reimbursed by an employer through an individual coverage HRA or a QSEHRA per the terms of the employee's compensation package, including payments for eligible individual market premiums, to be payments by the employee, not the employer. This remains true regardless of whether funds from an individual coverage HRA or QSEHRA are transmitted directly by an enrollee or by an employer. As such, payments from these HRA vehicles for individual market coverage do not constitute third party payments. To ensure that QHP issuers do not erroneously reject payments as third party payments when the payments are made in connection with an individual coverage HRA or QSEHRA that are transmitted directly by an enrollee or by an employer, we are finalizing revisions to § 156.1240(a)(3) that make clear that all such payments must be accepted so long as they are made using a form of payment described in § 156.1240(a)(2).

We recognize that individual coverage HRAs and QSEHRAs may differ in how

[51] 85 FR 78572, 78644.

they are administered. While some individual coverage HRAs and QSEHRAs may pay premiums directly to issuers on behalf of covered individuals, others may reimburse covered individuals for incurred or paid covered expenses. It is important that, regardless of how an individual coverage HRA or QSEHRA is administered, individuals covered by individual coverage HRAs and QSEHRAs be able to use HRA funds to enroll in QHP coverage. We can identify no compelling reason to treat payments from an individual coverage HRA and QSEHRA differently based on whether the payments are made directly to the QHP issuer or to the covered individual. In either case, the payment functions as a reimbursement to the employee for the employee's premium payment as part of the employee's compensation package.[52]

After considering comments, we are finalizing § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. To address potential confusion about the payment acceptance requirements, in response to comments, we specify in the regulation text that QHP issuers must also accept payments that are made directly by an enrollee in connection with an individual coverage HRA or QSEHRA. These requirements apply so long as such premium payments are made using a payment method described in § 156.1240(a)(2).

[52] See 84 FR at 28951 (''[U]nder the [HRA] final rules, 'reimbursement' may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments, individual or aggregate, by the employer, employee organization, or other plan sponsor to the health insurance issuer.'').

IV. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule—Department of Health and Human Services and Department of the Treasury

A. 31 CFR Part 33 and 45 CFR Part 155—State Innovation Waivers

1. Section 1332 Application Procedures (31 CFR 33.108 and 45 CFR 155.1308), Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320), and Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

Section 1332 of PPACA permits states to apply for a State Innovation Waiver (also referred to as a section 1332 waiver or State Relief and Empowerment Waiver) to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to obtain high value and affordable health coverage regardless of income, geography, age, sex, or health status, while simultaneously empowering states to develop health coverage strategies that best meet the needs of their residents. In the proposed rule, the Departments sought to provide states with consistency and predictability by proposing to codify the Departments' interpretative guidance published in the **Federal Register** in 2018, regarding how the Departments will apply section 1332 of PPACA to determine whether applications for section 1332 waivers will be approved. In this final rule, the Departments are finalizing these policies, with modifications to explicitly incorporate major policies outlined in the 2018 Guidance into the text of relevant section 1332 regulations.

Under section 1332 of PPACA, the Secretaries may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements (referred to as the statutory guardrails): (1) The proposal will provide coverage that is at least as comprehensive as coverage defined in PPACA section 1302(b) and offered through Exchanges established by title I of PPACA, as certified by the Office of the Actuary of CMS, based on sufficient data from the state and from comparable states about their experience with programs created by PPACA and the provisions of PPACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of PPACA; (3) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided under title I of PPACA; and (4) the proposal will not increase the federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrails.

The Departments are also responsible under section 1332 of PPACA for monitoring a waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the waiver. Specifically, section 1332 of PPACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers. The Secretaries must also provide for a process under which states with approved waivers must submit periodic reports concerning the implementation of the state's waiver program.

In October 2018, the Departments issued the 2018 Guidance,[53] which provides additional guidance for states that wish to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. The 2018 Guidance also includes information regarding how the Departments will apply the section 1332 statutory guardrails to evaluate whether a waiver is approvable. Section 1332 of PPACA and the 2018 Guidance empower states to address problems with their individual insurance markets and increase coverage options for their residents, and to encourage states to evaluate and adopt innovative strategies to reduce future overall health care spending. Together, the statutory guardrails and the 2018 Guidance provide states a reliable roadmap to follow in designing section 1332 waiver programs that will promote a stable health insurance market that offers more choice and affordability to state residents.

In this final rule, the Departments provide certainty to states that the requirements and expectations of the section 1332 program will not change abruptly, or without notice to states and the public, and an opportunity to comment. Specifically, the Departments proposed to incorporate by reference the 2018 Guidance in full in the regulations

[53] 83 FR 53575 (Oct. 24, 2018).

governing section 1332 waiver application procedures, monitoring and compliance, and periodic evaluation requirements. The Departments are finalizing the policies, with modifications made in response to public comments to codify many of the policies and interpretations outlined in the 2018 Guidance specifically in the text of the section 1332 implementing regulations. The Departments are of the view that this rulemaking will give states greater certainty regarding how the Departments will apply section 1332's statutory guardrails when determining whether a state's waiver proposal can receive and maintain approval by the Departments.

31 CFR 33.108 and 45 CFR 155.1308 specify the application procedures a section 1332 waiver proposal must meet to be approved by the Secretaries. Under these regulations, an application for initial approval of a section 1332 waiver will not be considered complete unless the application complies with the application procedures under 31 CFR 33.108(f) and 45 CFR 155.1308(f), including written evidence of the state's compliance with the public notice requirements set forth in 31 CFR 33.112 and 45 CFR 155.1312. Furthermore, an application must provide a comprehensive description of the enacted state legislation and program to implement a plan meeting the requirements for a waiver under section 1332; a copy of the enacted state legislation authorizing such waiver request; a list of the provisions of law that the state seeks to waive including a brief description of the reason for the specific request; and the analyses, actuarial certifications, data, assumptions, targets and other information sufficient to provide the Secretaries with the necessary data to determine that the state's proposed waiver meets the statutory guardrails. The 2018 Guidance provides supplementary information about the Departments' analysis as to whether a proposed section 1332 waiver plan meets requirements for approval, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. The 2018 Guidance also clarifies adjustments the Secretaries may make to maintain federal deficit neutrality, and explains how states may rely on existing legislative authority in certain circumstances as authorization for section 1332 waivers.

The Departments are of the view that formalizing these policies and interpretations through rulemaking will encourage more states to pursue waivers without being concerned that some of the rules may change without sufficient notice after they have submitted a waiver application. As such, the Departments are finalizing modifications to 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to codify in regulation the manner in which the Departments will apply the comprehensiveness, affordability, and coverage 'section 1332 guardrails' [54] as outlined in the 2018 Guidance. Specifically, this final rule adds regulatory language to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) explaining that the Departments will consider the comprehensive coverage guardrail to be met by a state waiver plan if the plan will provide consumers access to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. This final rule also adds language to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) providing that the Departments will consider the affordability requirement to be met by a state waiver plan that will provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These modifications also provide, consistent with the 2018 Guidance, that the Departments will consider the comprehensiveness and affordability guardrails met if a waiver plan provides access to coverage that is as comprehensive and affordable as coverage forecasted to have been available in the absence of the waiver, and is projected to be available to a comparable number of people under the waiver.

This final rule also adds regulatory language to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) providing that for purposes of the coverage guardrail, coverage refers to minimum essential coverage as defined in 26 U.S.C. 5000A(f) and 26 CFR 1.5000A–2, and health insurance coverage as defined in 45 CFR 144.103. No changes are being made to the Federal deficit neutrality guardrail under 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D), which prohibits approval of any waiver plan that is projected to increase the Federal deficit.

The Departments are also finalizing a modification to 31 CFR 33.108(f)(3)(i) and 45 CFR 155.1308(f)(3)(i) to provide that the Departments may consider existing legislation in analyzing whether the state has satisfied the requirement that the state enact a law under section 1332(b)(2)(A) of PPACA that provides statutory authority to enforce PPACA provisions or the state plan, combined with a duly-enacted state regulation or executive order. The Departments are of the view that these modifications will allow states to better plan for future section 1332 waiver applications and provide certainty to states as they invest significant state resources toward the submission of a section 1332 waiver application and the implementation of a section 1332 waiver plan, particularly waivers that require multi-year preparation.

In the proposed rule, the Departments proposed to incorporate the 2018 Guidance in full into the Departments' monitoring and compliance regulations at 31 CFR 155.1320 and 45 CFR 155.1320. Specifically, under the current regulations, the Secretaries reserve the right to suspend or terminate a waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially failed to comply with the terms and conditions of the waiver. The Departments will review and, when appropriate, investigate documented complaints that the state is failing to materially comply with requirements specified in the approved waiver and the specific terms and conditions (STCs) for the approval of the waiver signed by the Departments and the state. In addition, the Departments will promptly share with the state any complaint that they may receive and will notify the state of any applicable monitoring and compliance issues. States with approved section 1332 waivers must comply with all applicable federal laws and regulations (unless specifically waived) and must come into compliance with any changes in federal law or regulations affecting section 1332 waivers.

The Departments are finalizing a modification to 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1) to explicitly require that the Departments examine monitoring and compliance consistent with 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv)and guidance published by the Departments. The

[54] Under section 1332 of PPACA, the Departments may approve a state's section 1332 waiver application when the Departments determine the waiver plan will meet the four criteria specified in section 1332(b)(1), including the guardrails related to comprehensiveness, affordability, and coverage, as well as a fourth guardrail related to deficit neutrality.

Departments are of the view that codifying many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations will provide certainty regarding how the Departments will evaluate and review section 1332 waiver programs, as states submit information concerning the implementation of their waiver programs.

In the proposed rule, the Departments also proposed to incorporate the 2018 Guidance in full in the periodic evaluation requirements regulations at 31 CFR 33.128 and 45 CFR 155.1328. Under current regulations, the Departments are responsible for evaluating the waiver using federal data, information reported by states, and the waiver application itself to ensure that the Departments can exercise appropriate oversight of the approved waiver. Per 31 CFR 33.120(f) and 45 CFR 155.1320(f), the state must fully cooperate with the Departments or an independent evaluator selected by the Departments, to undertake an independent evaluation of any component of the section 1332 waiver. As part of this required cooperation, the state must submit all requested data and information to the Departments or the independent evaluator. The state generally must meet the statutory requirements in each year that the waiver is in effect; as such the primary focus of the periodic evaluations will be the four statutory guardrails. However, the Departments will consider the longer-term impacts of a state's waiver plan.

The Departments are finalizing a modification to 31 CFR 33.128 and 45 CFR 155.1328 to require that the Departments periodically evaluate approved waivers to ensure the program is consistent with 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. The Departments are of the view that codifying many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations will provide certainty regarding how the Departments will evaluate whether a state may maintain approval of its section 1332 waiver. The Departments also are of the view that this policy will help states to anticipate the data that will be most relevant and helpful to the Departments' analyses of a state's compliance with the specific terms and conditions approved by the Departments and other applicable requirements.

The Departments are finalizing the policies, as stated above, with modifications to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR 155.1308, 45 CFR 155.1320, and 45 CFR 155.1328 to codify many of the policies and interpretations outlined in the 2018 Guidance in the section 1332 implementing regulations. The Departments are of the view that the increased certainty that would result from incorporating these policies in the 2018 Guidance into the section 1332 implementing regulations will allow states to have greater confidence that the significant time and monetary investments necessary to plan for, submit, and implement a section 1332 waiver will not result in wasted resources and taxpayer dollars. The Departments are also of the view that these modifications finalized in this final rule will help to increase state innovation, which could lead to more affordable health coverage for individuals and families in states that implement a section 1332 waiver program.

The Departments sought comments on these proposals. The Departments received public comments on the proposed updates to the regulations detailing the section 1332 application procedures (31 CFR 33.108 and 45 CFR 155.1308), monitoring and compliance (31 CFR 33.120 and 45 CFR 155.1320), and periodic evaluation requirements (31 CFR 33.128 and 45 CFR 155.1328). In addition, the Departments previously solicited public comments on the 2018 Guidance for a 60-day period (October 22, 2018 through December 24, 2018). During that period, the Departments received approximately 2,100 public comments.

Based on the Departments' review and consideration of comments in response to the proposed rule and the 2018 Guidance, their experience with section 1332 waivers, and the positive market effects that have been attained as a result of existing section 1332 waiver programs, the Departments will not revise the 2018 Guidance or otherwise modify the policies that they are now explicitly incorporating into regulation in this final rule. However, in response to comments, the Departments will not incorporate by reference the 2018 Guidance in the section 1332 implementing regulations, but are finalizing modifications to the text of those implementing regulations to codify many of the policies and interpretations outlined in the 2018 Guidance. Later in this section of the preamble, the Departments review and respond to comments received in 2018 in response to the 2018 Guidance, as well as those received in response to the proposals to incorporate the 2018 Guidance into the section 1332 implementing regulations in the proposed rule, which were largely similar to comments submitted on the 2018 Guidance.

Comment: A few commenters stated that it is not proper to incorporate by reference the 2018 Guidance under 1 CFR 51.7(b) because it is an HHS publication or under 1 CFR 51.7(c)(1) because it has previously been published in the **Federal Register**. Another commenter stated that the 2018 Guidance is amorphous and imprecise, such that the proposed cross-references to the 2018 Guidance do not fit the definition of a rule under 5 U.S.C. 551. Other commenters asserted that it was bad policy to codify the 2018 Guidance by reference rather than by crafting concrete regulatory language.

One commenter stated that the Departments failed to comply with H.R. 3010, the Regulatory Flexibility Act of 2011, which the commenter believes to include a legal mandate that a federal agency, as part of an agency's evaluation of any proposed regulatory change, must analyze its distributional effects, which specifically refers to the impact of a regulatory action across the population and economy, divided up in various ways (for example, income groups, race, sex, industrial sector, geography).[55] The commenter further stated that the Departments failed to adequately identify and analyze the effects of codifying the 2018 Guidance. One commenter noted that the Department of the Treasury's participation was necessary for any regulation issued regarding section 1332 waivers and CMS cannot act alone.

Response: The Departments appreciate these commenters' concerns and want to ensure the requirements are clear to the public. The goal of the proposal to incorporate the 2018 Guidance into the section 1332 implementing regulations was to provide stability and certainty to states with existing waivers and to those who may be in the process of or interested in pursuing such a waiver. The Departments agree with commenters that suggested the Departments craft more specific regulatory text, rather than finalize the proposed incorporation of the 2018 Guidance by reference, to codify the Departments' interpretations in these regulations. As such, in this rule, the Departments are finalizing

[55] The Departments' research shows that H.R. 3010, the Regulatory Flexibility Act of 2011, was never signed into law. Notwithstanding, the Departments respond to the commenter's concerns here and in the RIA, section VI.C.3 of this final rule.

modifications to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR 155.1308, 45 CFR 155.1320, and 45 CFR 155.1328 to codify many of the policies and interpretations outlined in the 2018 Guidance in the section 1332 waiver program's implementing regulations. Specifically, the Departments are adding language to 31 CFR 33.108(f)(3)(i) and 45 CFR 155.1308(f)(3)(i) providing that the Departments may consider existing legislation in analyzing whether the state has satisfied the requirement that the state enact a law under section 1332(b)(2)(A) of PPACA if that legislation provides statutory authority to enforce PPACA provisions or the state plan, combined with a duly-enacted state regulation or executive order. Additionally, the Departments are finalizing changes to 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to codify many of the 2018 Guidance guardrail interpretations into regulations. The Departments are also finalizing changes to 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1) to explicitly require that the Departments examine monitoring and compliance requirements consistent with the guardrail interpretations outlined in 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. Lastly, the Departments are finalizing changes to 31 CFR 33.128 and 45 CFR 155.1328 to require that the Departments periodically evaluate approved waivers to ensure the program is consistent with the guardrail interpretations outlined in 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) and guidance published by the Departments. As described below, the policies and interpretations outlined in the 2018 Guidance remain unchanged. These regulatory modifications are being made in response to commenters' recommendations to craft concrete regulatory language and to further ensure that these finalized requirements are clear to the public.

Regarding some commenters' concerns that the Departments' did not analyze the distributional effect on the population and economy across subgroups that could result from incorporating the 2018 Guidance into regulation, the Departments are of the view that the data and information necessary to such an analysis are unavailable at this time. In particular, the Departments are unable to estimate or determine how many or which states may apply for a waiver using the regulatory modifications finalized in this final rule. As discussed in detail in the RIA under section VI.C.3 of this final rule, it would be difficult for the Departments to predict and analyze the impact of various state waiver plans that have not been submitted, including the distributional effects on various segments of the population. The Departments are of the view that meaningful analyses of the distributional effects of waiver proposals will be possible upon states' submissions to the Departments of complete section 1332 waiver applications. Pursuant to section 1332 of PPACA, the Departments must conduct reviews of section 1332 waiver applications on an individual basis. The distributional effects of each proposed waiver plan will be analyzed as part of the Departments' review, and members of the public and other stakeholders will have two distinct opportunities to comment on the distributional effects of a waiver during the state and federal public comment periods.

The Departments also agree that the Department of the Treasury's participation was necessary to the section 1332 proposals in the proposed rule. Thus, HHS did not act alone in developing or publishing the section 1332 proposals in the proposed rule. The proposed rule's section 1332 proposals were issued by both HHS and the Department of the Treasury, and in this final rule, the Departments are finalizing changes to relevant provisions in both 31 CFR part 33 (Treasury regulations) and 45 CFR part 155 (HHS regulations).

Comment: A few commenters expressed their support for the 2018 Guidance and its incorporation into the section 1332 implementing regulations. These commenters supported simplifying and streamlining the process for obtaining section 1332 waivers and affording states flexibility in meeting the guardrails for obtaining a waiver. Another commenter supported this proposal because it will provide certainty and allow states to utilize section 1332 waivers as intended, without adding unnecessary cost and time dealing with proposals that do not meet the necessary standards. The commenter further noted that such action is especially appreciated as state budgets are stretched thin due to the COVID–19 pandemic. One commenter noted that codifying the Departments' 2018 Guidance is especially important because of the significant time and taxpayer resources to develop and submit a waiver application. One commenter also noted that the process of developing a proposal and submitting it may take significant time and taxpayer resources, such that states may not want to undertake section 1332 waivers if the probability of success is low and the probability of the Departments changing requirements is high.

Furthermore, a few commenters noted that incorporating the 2018 Guidance into regulation will continue to improve the ability of states to access the flexibilities allowed by section 1332 waivers, empowering new innovation in the push to lower health costs. One commenter noted that a June 2020 CMS analysis of the effect of implemented section 1332 state-based reinsurance waivers found that premiums were an average of 17.7 percent lower during the 2020 plan year in the 12 states that had approved section 1332 waivers in place than they would have been without those waivers. The same commenter also noted that the results of 1332 waivers have been impressive thus far and that CMS should allow states to rely on existing regulatory direction across administrations, particularly when the existing framework demonstrates clear, positive results.

Response: The Departments appreciate commenters' support for these proposals. The Departments agree that codifying many of the policies and interpretations outlined in the 2018 Guidance into the implementing regulations will provide stability and certainty to states as they invest significant state resources towards submission of a section 1332 waiver application and implementation of an approved section 1332 waiver, particularly waivers that require multi-year preparation. The Departments also agree that implemented section 1332 waivers are lowering premiums for consumers, and that section 1332 waivers are an important tool to lower costs and strengthen state health insurance markets by providing a variety of coverage options. The Departments note that all states that have implemented a section 1332 reinsurance waiver plan have reduced premiums compared to a scenario without these waivers in place.[56] As described in this preamble, the Departments are finalizing these policies, with modifications, to codify many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations and are not otherwise making changes to the 2018 Guidance.

Comment: A majority of commenters did not support either the 2018

[56] See CCIIO Data Brief Series, State Relief and Empowerment Waivers: State-based Reinsurance Programs (June 2020), available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf.*

Guidance or its incorporation into the section 1332 regulations. Many of these commenters stated that the 2018 Guidance and its proposed codification would undermine the congressional intent underlying the section 1332 guardrails and effectively codify policy they believe is based on a misinterpretation of the statute. A few commenters recommended rescinding and abandoning the 2018 Guidance completely and that the Departments return to the prior interpretation of the guardrails described in now superseded guidance issued in 2015 (referred to as the 2015 Guidance).[57]

Response: The Departments acknowledge commenters' concerns, but do not agree that the 2018 Guidance suffers from the purported flaws these commenters describe. The Departments note that the 2018 Guidance has been in place for more than 2 years and states have relied upon it to better understand the submission requirements for a section 1332 waiver application and how the Departments apply and interpret these requirements. The Departments are of the view that the changes finalized in this rule provide predictability and certainty for states as they decide whether to invest resources in developing and implementing innovative wavier proposals. Further, the 2018 Guidance aims to lower barriers to innovation for states seeking to reform their health insurance markets. As described more fully below, the Departments maintain that the policies announced in the 2018 Guidance are based on a sound interpretation of section 1332 of PPACA.

Comment: A majority of commenters did not support the policies outlined in the 2018 Guidance, specifically those related to how the Departments would analyze and determine whether a waiver proposal complies with the section 1332 guardrails. All of these commenters expressed concerns regarding the legality of the coverage, affordability, and comprehensiveness guardrail interpretations included in the 2018 Guidance.

Many commenters expressed concerns with the focus on the ''availability of comprehensive and affordable coverage'' in the 2018 Guidance and its effect on how the Departments could apply the coverage, affordability, and comprehensiveness guardrails. Some commenters raised a fundamental concern that the Department's current interpretation conflicts with the plain language and Congressional intent of the statute, and stated that the Departments should revert to the previous approach (as outlined in the 2015 Guidance) requiring that only those actually covered in EHB-compliant plans be counted toward compliance with the guardrails. Some commenters asserted that the statute requires the Departments to consider the estimated number of state residents who would actually enroll in comprehensive, affordable coverage if the waiver were approved and implemented, not just the estimated number of residents who would have the opportunity to enroll in such coverage. The commenters were concerned that the focus on the interpretation of the availability of comprehensive and affordable coverage in the 2018 Guidance would result in fewer residents enrolled in comprehensive and affordable coverage, and would contradict the congressional intent behind the statutory guardrails. Other commenters asserted that the interpretation of the availability of comprehensive and affordable coverage for the coverage guardrail allows for a disjointed application of the guardrails whereby a state can meet the coverage guardrail, while its waiver plan reduces the overall comprehensiveness and affordability of coverage in a state.

Some commenters were concerned that the Departments' consideration of all forms of private coverage in addition to public coverage, including employer-based coverage, individual market coverage, and other forms of private health coverage would include forms of coverage that are not subject to the federal market reform requirements, including short-term, limited duration insurance (STLDI) plans and association health plans (AHPs). Other commenters were concerned that, because the 2018 Guidance would allow for STLDI to be included as a form of coverage under the analysis of whether a proposed waiver plan meets the section 1332 guardrails, there may be consumer confusion regarding what STLDI plans cover and do not cover in terms of benefits and out-of-pocket spending.

Commenters also expressed generalized concern that the 2018 Guidance could permit states to implement waiver programs that support consumer uptake of alternative plan options, including plans such as STLDI and AHPs that can be underwritten, or plans that do not meet EHB standards. In particular, commenters were concerned, in relation to the affordability guardrail, that measures taken under a state waiver program to facilitate coverage in such alternative plan options (for example, allowing the use of subsidies for such coverage) would result in fewer comprehensive plans in the market, and that those comprehensive plans would be less affordable. Commenters asserted that this would perpetuate a tendency for comprehensive coverage to attract higher-risk consumers, while healthier, lower-risk consumers would tend to enroll in alternative plan options, with non-comprehensive coverage. This, the commenters assert, would change the risk pool, bifurcating the market into low-risk consumers enrolled in alternative plan options and high-risk consumers enrolled in comprehensive coverage and comprehensive coverage would become less affordable and less available. Commenters thus asserted concerns related to the comprehensiveness and affordability guardrails that fewer individuals would be covered by comprehensive, affordable coverage with cost-sharing protections, and any interpretation of the section 1332 guardrails that allows approval of a waiver plan that promotes less comprehensive forms of coverage such as STLDI and AHPs is inconsistent with the statute.

Commenters also expressed concern that these alternative plan options are not subject to the same limitations as comprehensive coverage in terms of consumer protections and could also impact the affordability guardrail. For instance, these alternative plan options generally lack financial limitations like out-of-pocket maximums and are not subject to the federal prohibition on annual and lifetime limits for EHB. These commenters asserted that lower-risk consumers would tend to enroll in such alternative plan options because of these plan options' lower premiums and that these consumers would bear the financial risks associated with having coverage that places no limit on enrollee out-of-pocket expenses. Furthermore, commenters asserted that these consumers could then experience an unexpected, catastrophic health event, and could therefore be forced to pay substantially more in out-of-pocket costs than if they had enrolled in comprehensive coverage. Commenters asserted that such out-of-pocket costs would far exceed any savings consumers might achieve by rejecting comprehensive coverage and choosing a cheaper alternative.

There were a variety of other comments related to potential market impacts of the interpretation of the guardrails included in the 2018 Guidance. Some commenters noted that issuers offering comprehensive coverage might be more prone to exit a market

[57] Waivers for State Innovation, 80 FR 78131, available at *https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf.*

due to instability caused by the entry of alternative plan options. These commenters raised concerns regarding the potential degradation of the risk pool due to the increased likelihood of high health care costs with healthier consumers tending to choose alternative plan options. Other commenters raised concerns that the 2018 Guidance would lead to increased uninsured and underinsured populations, which would in turn increase emergency room utilization and health care costs. Some commenters were also concerned about the impact on the risk pool that they stated could occur as a result of the inclusion of alternative plan options as a form of coverage and allowing subsidies to be used towards purchasing these plans.

Response: The Departments acknowledge commenters' concerns and agree that section 1332 waivers should be designed to improve a state's health care market while protecting those in vulnerable populations, including consumers with pre-existing conditions. However, the Departments are of the view that the 2018 Guidance is based on a sound interpretation of section 1332 of PPACA and represents a reasonable and appropriate application of the section 1332 guardrails. The Departments also are of the view that the 2018 Guidance provides states more flexibility to address problems caused by PPACA and to give Americans more options to get health coverage that better meets their needs. Under the framework outlined in the 2018 Guidance, states can pursue waivers to improve their individual insurance markets, increase affordable coverage options for their residents, and ensure that people with pre-existing conditions are protected. For all waiver requests, the Departments retain the discretion to decide whether to approve a section 1332 waiver based on the particular circumstances of each state's application, provided that the Departments determine that all of the guardrails are satisfied, and the Departments must in all cases evaluate each application for compliance with section 1332 statutory requirements.

The Departments are of the view that the framework outlined in 2018 Guidance is based upon a sound interpretation of section 1332 and its requirements for approval of a section 1332 waiver. Under section 1332, the Departments may approve a state's section 1332 waiver application when the Departments determine the waiver plan will meet the section 1332 guardrails. For example, section 1332(b)(1)(C) of PPACA, the coverage guardrail, requires that a state's plan under a waiver will provide coverage ''to at least a comparable number of its residents'' as would occur without the waiver. However, the statutory text for the coverage guardrail is silent as to the type of coverage that is required or must be considered as part of this analysis. In addition, sections 1332(b)(1)(A) and (B) of PPACA state only that the state's waiver plan must ''provide'' coverage that is as comprehensive and affordable as would occur without a waiver, but do not require that people actually purchase and enroll in this coverage under a waiver. By its plain language, the term provide means ''to supply or make available'' and does not require or imply that people must use what is provided.[58] Prior to the publication of the 2018 Guidance, the interpretations and policies outlined in the 2015 Guidance focused on the number of individuals actually estimated to enroll in comprehensive and affordable coverage that meets all requirements under title I of PPACA, in effect reading the ''to at least a comparable number of its residents'' language from the coverage guardrail into the comprehensiveness and affordability guardrails as well.[59] However, neither the language nor structure of the statute compels that reading.

The Departments are of the view that the interpretations of the guardrails in the 2018 Guidance are reasonable and encourage states to provide, alongside coverage options that comply with PPACA market reforms, innovative coverage options that, while potentially less comprehensive than coverage established under PPACA, could be better suited to consumer needs and potentially more affordable and attractive to a broad range of a state's residents. Regarding the commenters' concerns about the focus on ''availability of comprehensive and affordable coverage'' as outlined in the 2018 Guidance (83 FR 53578) and its impact on how the Departments would analyze the guardrails when reviewing section 1332 waiver applications, the Departments are of the view that this focus loosens restrictions imposed by the interpretations outlined in the 2015 Guidance that were not required by PPACA and that previously limited state flexibility and consumer choice. While the 2015 Guidance focused on the number of individuals who would actually be provided comprehensive and affordable coverage under a proposed state waiver plan, the 2018 Guidance shifted focus to whether a waiver plan would actually make available comprehensive and affordable coverage to state residents. Under the 2018 Guidance and the regulatory changes finalized in this rule, the coverage available under the proposed waiver must be both as comprehensive and affordable as coverage available without the waiver. As noted previously, this shift comports with the plain language of the statute by establishing that ''provide coverage'' does not mean anything more than for such coverage to be supplied or available to consumers under the waiver. This shift would allow states to provide access to health insurance coverage at different price points and benefit levels. This shift ensures that state residents who wish to retain comprehensive coverage similar to that provided under PPACA can continue to do so, while permitting a state waiver plan to also provide access to other coverage options that may be better suited to consumer needs and more attractive to many other individuals. In addition, the 2018 Guidance focuses on the aggregate effects of a waiver on all state residents, rather than requiring that the guardrails be met for specific sub-populations. This interpretation provides states more flexibility to consider the effects on all categories of residents and to decide that improvements in comprehensiveness and affordability for state residents as a whole offset any small detrimental effects for particular residents. As explained in the 2018 Guidance, the state's analysis should address in the application for the section 1332 waiver how the section 1332 state waiver plan supports and empowers those with low income as well at those with high expected health care costs.

When applying the coverage guardrail, a comparable number of residents must still be covered as would have been covered absent the waiver. The 2018 Guidance also explains that the Departments conduct an assessment that takes into account whether the section 1332 state plan sufficiently prevents gaps in or discontinuations of coverage to address any decreases in coverage for specific sub-populations.

The Departments generally have discretion to interpret the statutory guardrails, including ambiguous or undefined terms, and continue to be of the view that the interpretations and policies outlined in the 2018 Guidance are consistent with the statute. As such, the Departments are finalizing amendments to 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to codify policies and interpretations outlined in

[58] Merriam Webster. Available at *https://www.merriam-webster.com/dictionary/provide.*

[59] See 80 FR 78132–33 (discussion of the affordability guardrail in the 2015 Guidance).

the 2018 Guidance into the section 1332 waiver implementing regulations.

In response to commenters' concerns regarding the Departments' consideration of ''all forms of private coverage in addition to public coverage, including employer-based coverage, individual market coverage, and other forms of private health coverage'' (85 FR 53579) for the purposes of the coverage guardrail as outlined in the 2018 Guidance, the Departments are of the view that consumers are best suited to determine what coverage best suits their individual or family's needs, whether that is a QHP, a major medical non-QHP, an STLDI plan, or another available coverage option. Section 1332 waivers should empower states to present innovative plans to provide access to coverage to every state resident, including those individuals who are not eligible for Medicaid or CHIP or who cannot afford comprehensive, major-medical coverage, but still want or need some form of coverage to protect against catastrophic expenses. In addition, regarding some commenters' concerns that fewer people may actually be covered, the Departments note that when applying the coverage guardrail, a comparable number of residents must still be covered as would have been covered absent the waiver. In response to commenters' concerns regarding the impact on the affordability guardrail due to the alternative plan options that are not subject to the same consumer protections as comprehensive coverage, the Departments previously noted that the affordability guardrail refers to state residents' ability to pay for health care expenses relative to their incomes and may generally be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to his or her income. Therefore, states are required to include such analyses in waiver applications. As such, the Departments are finalizing amendments to 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) as discussed in this section of the preamble.

We generally disagree with the commenters' suggestion that the consideration of alternative plan options, including STLDI plans, in the analysis of whether a proposed waiver meets the section 1332 guardrails, may result in consumer confusion about the benefits and coverage offered by STLDI plans. If a waiver were approved that included alternative plan options, residents in the state would continue to have access under the state's waiver plan to the same metal level plans and catastrophic plans that include EHB that are available today. Consumers would therefore have access to at least the same coverage and cost-sharing protections against excessive out-of-pocket spending as without the waiver. The availability of alternative plan options would be another option for consumers to consider as they shop for and enroll in coverage. However, recognizing the need and importance to ensure consumers are making informed choices, the Departments note that existing federal regulation requires issuers of STLDI plans to prominently display in the contract and in any application materials a consumer disclosure notice that informs consumers about the limitations of STLDI plans.[60] The Departments further note that, to the extent STLDI plans are displayed on non-Exchange direct enrollment websites approved by the FFE to assist with Exchange applications and enrollment, those websites must clearly distinguish QHPs from other available coverage options and are prohibited from displaying STLDI plans side-by-side on the same website page with QHPs.[61] These display requirements ensure that consumers can easily discern which plans are QHPs eligible for APTC and which are not. In addition, many states have adopted state-specific marketing and other consumer protection laws intended to help consumers understand the differences between the different available coverage options.

The Departments are of the view that concerns related to the potential increase in the cost of comprehensive coverage are not warranted because the application of the guardrails would prevent the approval of a waiver that would reduce access to comprehensive health coverage. Under the guardrails, a waiver clearly cannot be approved if it raises the cost of the comprehensive coverage that is available to consumers. The Departments are confident that the review process applicable to section 1332 waiver applications and the Departments' discretion to reject waiver applications that would result in unreasonable harm to a state's risk pool are sufficient to mitigate commenters' concerns that the cost of comprehensive coverage will increase, in terms of premiums and out of pocket spending. Specifically, the Departments are required to evaluate each state's proposal to determine that it meets the section 1332 requirements. The Departments undertake extensive analysis and reviews of research and program information as part of these determinations. As provided in 31 CFR part 33 and 45 CFR part 155, subpart N, the waiver application must include analysis and supporting data that demonstrates that the waiver satisfies the guardrails. As such, a state is required to include an actuarial analysis and actuarial certification, economic analysis, data and assumptions and other necessary information to support the state's estimates that the proposed waiver will meet the requirements of section 1332. The actuarial and economic analysis must appropriately model the impact of the waiver plan, including impacts on enrollment and affordability for individual market single risk pool coverage, relative to a without-waiver baseline. Any net increase in premiums in the individual market risk pool in a with waiver scenario, compared to a without-waiver scenario, would likely not meet the guardrails and would not be an approvable waiver application. In addition the Departments maintain the discretion to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrail requirements. As such, the Departments can deny a proposed waiver plan that meets the guardrails, if the Departments determine the waiver would cause more harm than good to the state's residents or to a state's risk pool.

Comment: Some commenters raised concerns regarding how the interpretation of the guardrails, including the focus on the ''availability of comprehensive and affordable coverage'', in the 2018 Guidance would impact maintaining protections for vulnerable populations and consumers with pre-existing conditions. In particular, commenters raised concerns that alternative plan options can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Commenters asserted that coupled with the diminished affordability of comprehensive coverage, this possibility puts high-risk individuals at great risk of going without effective coverage for their health care needs. Commenters also raised concerns that the guidance

[60] See 45 CFR 144.103 (defining STLDI and providing the language of the required consumer disclosure notice).

[61] See 45 CFR 155.221(b)(1) (direct enrollment entities must ''[d]isplay and market QHPs and non-QHPs on separate website pages on its non-Exchange website. . . .''); 45 CFR 155.221(b)(3) (direct enrollment entities must ''[l]imit marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. . . .'').

provides the flexibility to craft hypothetical EHB-benchmarks that could further diminish the quality and affordability even of comprehensive coverage under a waiver program.

Some commenters also expressed concern that the potential market effects would generally have a disparate impact on vulnerable populations, especially low-income consumers and those with pre-existing conditions. Additionally, these commenters expressed concern that a disparate impact on any particular group would not necessarily cause the Departments to deny a waiver application, even though the impact on vulnerable population groups would be taken into account. Many vulnerable population groups were represented in the comments, including the elderly and those with pre-existing conditions like cystic fibrosis, ostomy/continent diversion, heart disease, arthritis, epilepsy, muscular dystrophy, leukemia/lymphoma, hemophilia, and others. Commenters raised the importance of ensuring compliance with specific PPACA market reforms including coverage of preventive services without cost sharing, the prohibition of pre-existing condition exclusions, the rating rules, and EHB coverage requirements, including prescription drugs and mental health and substance use disorder services. Commenters also stated concern for young adults who heavily rely on comprehensive coverage and key benefits like mental health care.

Response: The Departments understand commenters' concerns regarding potential impacts on vulnerable populations. The Departments are of the view that it is important that vulnerable populations have the support they need to obtain affordable and comprehensive coverage that meets their individual or family needs. As outlined in the 2018 Guidance, the Departments are committed to supporting and empowering those in need.[62] Furthermore, as discussed in the 2018 Guidance, the state should address in the application for the section 1332 waiver how the section 1332 state plan addresses the principles outlined in the 2018 Guidance to support and empower those with low incomes as well at those with high expected health care costs as it relates to the coverage, comprehensiveness, and affordability guardrails. The Departments also note that state section 1332 waiver applications are reviewed by the Departments on an individual basis, and in the 2018 Guidance, the Departments explained that state waiver applications should also identify any types of individuals for whom affordability of coverage would be reduced by the waiver and any types of individuals for whom affordability of coverage would be improved under the waiver. In addition, the Departments have encouraged and continue to encourage states to develop waiver proposals that support and empower those with low incomes as well at those with high expected health care costs. The Departments further note and emphasize that section 1332 waiver authority cannot be used to waive many of PPACA's consumer protections, including coverage of preventive services without cost sharing, the prohibition against pre-existing conditions exclusions, guaranteed issue, or the rating rules. As such, consumers will continue to have access to comprehensive coverage options that are subject to and must comply with PPACA market reforms identified by commenters.

Comment: A few commenters recommended that the Departments provide more flexibility for states to meet the requirement that a waivers will not increase the federal deficit. They recommended that instead of mandating that all waiver applications meet the deficit neutrality guardrail for each and every year of the waiver, they should instead be required to meet the deficit neutrality guardrail over a 10-year period. These commenters noted that this approach would be consistent with how CBO scores are generally analyzed for budget neutrality over a 10-year period, and would be consistent with the current requirement for states to include a 10-year budget projection in a state section 1332 waiver application.

Response: The Departments appreciate these commenters' recommendation, but the Departments are not making any changes to the Departments' interpretation or application of the federal deficit guardrail. Therefore, the Departments continue to require that a waiver must not increase the federal deficit over the period of the waiver (which may not exceed 5 years unless renewed) or in total over the 10-year budget plan submitted by the state as part of the application.

Comment: A few commenters expressed concern that allowing states to rely on existing general authority to enforce PPACA, in conjunction with a duly enacted regulation or Executive Order, delays stakeholder notification of a state's proposal and does not provide stakeholders adequate time to prepare comments or work with state legislatures to address concerns with proposed legislation.

Response: The Departments acknowledge these commenters' concerns, but note that the section 1332 implementing regulations include requirements for public notice at the state and federal level for new waiver applications.[63] In addition, states are not precluded from providing additional notice of an intent to submit a section 1332 waiver application under the section 1332 implementing regulations. The Departments therefore are not making any changes to this policy and will continue to apply the interpretation that permits states to rely on existing general authority to enforce PPACA, in conjunction with a duly enacted regulation or Executive Order.

Comment: A few commenters stated that the revisions in the 2018 Guidance constituted a significant change to prior section 1332 waiver policy and should have been proposed through rulemaking. Several commenters requested the Departments consider the comments submitted and publish a revised version of the guidance. Additional commenters stated that the 30-day comment period for the proposed 2022 Payment Notice was too short and did not provide sufficient opportunity for commenters to address the impact of these requirements to date and the potential prospective impact, including the potential negative consequences for consumers seeking affordable coverage to meet their health needs. Other commenters recommended that this rule is not an appropriate place to propose moving the 2018 Guidance into regulation and if the Departments want to pursue these policies, then the Departments must retract these provisions from this rule and repost the entire 2018 Guidance through the full APA rulemaking process with a separate notice-and-comment period.

Response: The Departments appreciate commenters' interest in policies affecting section 1332 waivers. The Departments are of the view that a

[62] From 2018 Guidance principles: ''Support and empower those in need. Americans should have access to affordable, high value health insurance. Some Americans, particularly those with low incomes or high expected health care costs, may require financial assistance. Policies in section 1332 waiver applications should support state residents in need in the purchase of private coverage with financial assistance that meets their specific health care situations.'' (83 FR 53577).

[63] *See* 31 CFR 33.112 and 45 CFR 155.1312; 31 CFR 33.116 and 45 CFR 155.1316. Also note that there is flexibility under 31 CFR 33.118 and 45 CFR 155.1318 for states to request, subject to approval by the Departments, modification from the normal public notice requirements during the COVID–19 PHE when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interest of consumers.

longer comment period would have delayed the publication of this final rule and created significant challenges in providing certainty for states developing section 1332 waiver proposals or those with existing approved waivers. Furthermore, while the Departments generally disagree that the 2018 Guidance should have been formalized in rulemaking initially or that there is a need to codify amendments to the section 1332 regulations through a separate rulemaking, stakeholders and the general public have now had two opportunities to provide feedback on the policies and interpretations outlined. The Departments have considered comments received in response to the 2018 Guidance, as well as those received in response to the section 1332 policies in the proposed rule. After consideration of these comments, for the reasons outlined earlier in this section of the preamble, the Departments are finalizing amendments to the section 1332 implementing regulations to codify many of the policies and interpretations outlined in the 2018 Guidance. The Departments, however, are not changing any of the substantive policies or interpretations in the 2018 Guidance, as the goal of this effort is to provide stability and certainty to states with existing approved waiver plans and those who may be interested in pursuing a section 1332 waiver.

Comment: Commenters requested that the Departments closely monitor waiver proposals to ensure fair and adequate access to affordable and comprehensive coverage, particularly in light of the COVID–19 PHE. A few commenters highlighted that the timing of this proposal could be particularly harmful given the current COVID–19 PHE. These commenters were concerned that this policy will have a disproportionate impact on certain populations, that have also been disproportionally impacted by COVID–19, such as certain racial and ethnic populations.

Several commenters requested that CMS closely monitor waiver proposals to ensure fair and adequate access and payment for Federally Qualified Health Centers (FQHC) services.[64] Commenters also encouraged CMS to prioritize section 1332 waiver proposals that maintain the statutory requirement for qualified health plans to include essential community providers, like FQHCs, that serve predominately low-income individuals, and that CMS encourage states to explore section 1332 waivers that expand the vital enabling services, including outreach and enrollment assistance.

Response: The Departments note that the purpose of section 1332 waivers is for states to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. For instance, to date, reinsurance waivers have delivered measurable premium reductions. These benefits may be particularly important to address COVID–19, and the Departments have already issued regulations to provide states with flexibility to take advantage of section 1332 waivers to address the immediate issues COVID–19 presents.[65] The Departments are of the view that this rule further supports state efforts to take advantage of section 1332 waivers to address the COVID–19 PHE.

The Departments are of the view there are many areas, including those identified by commenters, in which compliance monitoring will be particularly important to ensure that approved waivers continue to meet the statutory criteria for approval, especially during the current COVID–19 PHE. Given that all policy changes can have a range of impacts due to the specifics of the state, such as the time the policy was implemented, the specific operational choices, and other market factors, the Departments may include strict safeguards and monitoring protocols in the approval letter and waiver terms and conditions to ensure that the waiver continues to meet the guardrails, including the impact on certain populations, for the duration of the waiver period. The federal government is committed to an all of government approach to providing COVID–19 relief.[66] In addition, throughout the COVID–19 PHE, CMS has worked to ensure the safety of the American public and has offered states, providers, suppliers, and group health plans and health insurance issuers flexibilities in furnishing and providing services to combat COVID–19. To the extent possible, the Departments intend to align this monitoring with each state's waiver design to effectively evaluate waiver program performance, while keeping administrative burdens to a minimum.

[64] Specifically, the FQHC protections in section 1311(c)(1)(C)) of PPACA and section 10104(b)(2) of PPACA (adding (g) to section 1311 of PPACA)) should not be compromised in any waiver granted to a state under section 1332.

[65] See 85 FR 71142 (Nov. 6, 2020) (adopting flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during the COVID–19 PHE).

[66] See *https://www.usa.gov/coronavirus.*

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

A. ICRs Regarding State Innovation Waivers (31 CFR 33.108, 45 CFR 155.1308, 31 CFR 33.120, 45 CFR 155.1320, 31 CFR 33.128 and 45 CFR 155.1328)

The Departments are finalizing regulatory revisions codifying into section 1332 regulations policies initially announced in the 2018 Guidance governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. The Departments are not altering any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans. The Departments anticipate that implementing these provisions will not significantly change the associated burden. The burden related to this information collection (Review and Approval Process for Waivers for State Innovation (CMS–10383)) is currently under review by OMB. CMS did not receive comments on these ICRs.

B. ICRs Regarding Exchange Direct Enrollment (DE) Option (§ 155.221)

Current SBEs that elect to implement the Exchange DE option will need to revise their Exchange Blueprint (Blueprint) under § 155.221(j)(1) to describe precisely how the state proposes to implement the Exchange DE option in compliance with related requirements. We believe that any costs of revising the Blueprint will be nominal, as this process involves logging into a CMS web interface that serves as the repository for all states' Exchange Blueprints to input additional information on the updated processes and controls the state will implement to manage its new Exchange DE program. The burden related to completing the Blueprint is currently approved under OMB Control Number 0938–1172 (Blueprint for Approval of Affordable State-based and State Partnership Insurance Exchanges (CMS–10416)). We sought comment on the burden associated with this activity, but did not receive any.

Prospective DE entities must contract with an independent third-party auditor to complete a security and privacy controls assessment, which must be submitted to HHS for review. Once approved, a DE entity must submit quarterly plans of action and milestones (POA&Ms) to HHS to document the identification and resolution of any new or existing security or privacy risks. We will prepare an ICR submission for review and approval by OMB through the normal PRA notice-and-comment process.

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule includes provisions related to FFE and SBE–FP user fees for the 2022 benefit year. It also includes changes related to acceptance of payments by issuers of individual market QHPs. It clarifies the regulation imposing network adequacy standards with regard to QHPs that do not differentiate benefits based on whether an enrollee receives services from an in-network or out-of-network provider. It also creates a new direct enrollment (DE) option for states served by State Exchanges, FFEs, and SBE–FPs. In addition, relating to State Innovation Waivers, this rule finalizes regulatory revisions codifying into section 1332 regulations policies initially announced in the section 1332 2018 Guidance, governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver.

B. Overall Impact

The Departments have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA), Public Law 96–354 (September 19, 1980), section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, 5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. An RIA must be prepared for rules with economically significant effects ($100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by OMB. The Departments have concluded that this rule is likely to have economic impacts of $100 million or more in at least one year, and therefore, meets the definition of ''significant rule'' under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The provisions in this final rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. The changes related to the Exchange DE option and section 1332 waivers will reduce regulatory burdens for states. Through the reduction in financial uncertainty for states and issuers and increased affordability for consumers, these provisions are expected to promote greater market stability and to increase access to affordable health coverage. In states that implement the Exchange DE option, there will be start-up costs for states, DE entities (including web-brokers, agents and brokers, and issuers), and the federal government related to start-up, approval, implementation, and oversight. However, consumers in such states will likely have more options to shop for coverage and an improved shopping experience. Some issuers may incur minimal costs to make operational changes in order to accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA.

Comment: A few commenters stated that the RIA in the proposed rule was inadequate.

Response: As explained in the proposed rule, the Departments are unable to quantify all the effects of the provisions of this rule. There are uncertainties regarding the impact of several provisions. For example, it is not certain how many states will implement the Exchange DE option or how many states will submit section 1332 waiver applications. Therefore, the Departments have included qualitative

discussions of costs and benefits related to the provisions in this final rule.

C. Impact Estimates of the Payment Notice Provisions and Accounting Statement

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including allowing consumers to have continued access to coverage and health care, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. Although we are unable to quantify all benefits and costs of this final rule, the effects in Table 1 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from some of the provisions of this rule.

For 2022, we are finalizing a reduction in the FFE user fee rate from 3.0 percent of total premiums charged to 2.25 percent of total premiums charged, and a reduction in the SBE–FP user fee rate from 2.5 percent of total premiums charged to 1.75 percent of total premiums charged. For the 2023 benefit year, we are finalizing the FFE–DE and SBE–FP–DE user fee rate of 1.5 percent of total premiums charged. While our current budget estimates may change in the future, we believe that it is important to keep the user fee in all markets at the lowest level possible to cover the costs of the Exchanges and keep premiums low for consumers and issuers. We expect transfers from the issuers to federal government to be reduced by approximately $270 million in 2022 and by approximately $60 million in 2023 due to changes in user fee rates and state transitions; transitions from FFE or SBE–FP to State Exchange, SBE–FP in 2022, or to FFE–DE in 2023 are included in the reduction in user fee transfers from issuers to federal government.

TABLE 1: Accounting Statement

Benefits:				
Qualitative: ● Continued access to coverage and heath care for consumers. ● Potential reduction in operational costs for the federal government if FFE or SBE-FP states elect to implement the FFE-DE or SBE-FP-DE option. ● Potential improved shopping experience for consumers in states with Exchanges that implement the Exchange DE option. This may result in a potential increase in enrollments in a state that implements this option. ● Potential improvements to the individual market risk pool through increased incentives for DE entities to enroll people who would otherwise not enroll—a potentially healthier group—in states that implement the Exchange DE option. ● Increased certainty for states to pursue section 1332 waivers, which could, in turn, help increase the number of states that apply for waivers to improve their individual insurance markets and increase affordable coverage options for their residents. ● Ease of administration of individual coverage HRAs and QSEHRAs when issuers accept payments made on behalf of enrollees.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$ 0.03 million	2020	7 percent	2021-2023
	$ 0.03 million	2020	3 percent	2021-2023
Quantitative: ● Regulatory familiarization costs of approximately $80,000 in 2021.				
Qualitative: ● Increased costs due to increases in providing medical services (if health insurance enrollment increases). ● Start-up costs for states seeking to transition to an SBE for future plan years in order to utilize the new Exchange DE option. These costs may potentially be higher as compared to start-up costs for states seeking to transition to an SBE without implementing the Exchange DE option, due to the additional interfaces to DE entities that must be implemented and managed. ● Increased operational costs for existing SBEs electing to implement the Exchange DE option for ongoing monitoring and oversight of the DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. ● Costs incurred by prospective DE entities (including web-brokers, agents and brokers, and issuers) and the federal government related to startup, approval, and implementation of the Exchange DE Option. ● Increase in administrative costs for issuers that need to make operational adjustments in order to accept premium payments from individual coverage HRAs or QSEHRAs made on behalf of enrollees. ● Potential increase in consumer confusion associated with a transition to an Exchange that implements the DE option. This may result in a potential reduction in enrollments through an Exchange that implements this option.				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	- $108.5 million	2020	7 percent	2021-2023
	- $109.4 million	2020	3 percent	2021-2023
Quantitative: ● Reduction in transfers from the issuers to the federal government by approximately $270 million in 2022 due to changes in user fee rates, and approximately $60 million in 2023, due to the availability of the DE option to FFE and SBE-FP states beginning with the 2023 benefit year.				
Qualitative: ● Pass-through funding amounts paid to states would increase if the number of states that apply for and receive 1332 waivers increases. Under a section 1332 waiver, a state may receive pass-through funding associated with the resulting elimination or reductions in federal spending on Exchange financial assistance (that is, PTC, CSR, or small business health insurance tax credits (SBTC) under section 45R of the Code), provided pursuant to PPACA that would have been paid on behalf of participants in the Exchange in the state in the calendar year in the absence of the waiver, but will not be paid as a result of the waiver.				

1. Exchange Direct Enrollment (DE) Option (§ 155.221)

We are finalizing the proposal to add § 155.221(j) to establish a new Exchange direct enrollment (DE) option by which states can use direct enrollment technology to transition to private sector-focused enrollment pathways operated by QHP issuers, web-brokers, and agents and brokers, instead of or in addition to a centralized eligibility and enrollment website operated by an Exchange. State Exchanges, as well as SBE–FP and FFE states can elect, subject to HHS approval, to implement the Exchange DE option. The impact of the new Exchange DE option will depend on the specific Exchange model and the number of states that take advantage of the new option. There are various stakeholders in states that elect to implement the Exchange DE option that could be impacted, including consumers, State Exchanges, web-brokers, issuers, and agents and brokers, as well as the federal government. However, we note that the FFEs' current direct enrollment pathways (Classic DE and EDE) generally reduce operational costs to the federal government while alleviating certain burdens on consumers.

The Exchange DE option may have varied impacts on consumers, and we solicited public comments to help us to understand how implementation of the Exchange DE option and a corresponding increase in the number of potential websites through which consumers could shop for QHP coverage might impact consumers and consumer behavior with respect to QHP enrollment.

At this time, we do not anticipate that any of the 15 current SBEs will implement the Exchange DE option in plan year 2022 because these states have not implemented direct enrollment interfaces with web-brokers or other direct enrollment entities similar to those implemented by the FFE. However, current SBEs that elect to implement the Exchange DE option will be responsible for meeting certain requirements for approval, in particular revising their Exchange Blueprint (Blueprint) under new § 155.221(j)(1) to describe precisely how the state proposes to implement the Exchange DE option. We believe that any costs of revising the Blueprint will be nominal, as this process involves logging into a CMS web interface that serves as the repository for all states' Exchange Blueprints to input additional information on the updated processes and controls the state will implement to manage its new Exchange DE program. However, we sought comment on the burden associated with this activity, noting that the Blueprint is currently approved under the PRA under OMB Control Number 0938–1172.

For states seeking to transition to an SBE in future plan years and implement the SBE–DE option, we anticipate that start-up costs may potentially be higher than the start-up costs for states seeking to transition to an SBE without implementing the Exchange DE option, due to the additional interfaces that must be implemented between the Exchange's eligibility platform and each approved DE entity and managed on an ongoing basis by the Exchange. States transitioning to an SBE–DE will be required to complete the Exchange Blueprint in the same manner as required prior to this final rule and will be required to meet all required minimum functions of an Exchange. In terms of implementation costs, these states can realize savings by virtue of not having to maintain and operate a consumer-facing enrollment website capable of handling all Exchange-related internet traffic for all state residents, instead relying on DE entities and their websites to provide the majority of the Exchange's consumer-facing enrollment functionality.

The costs associated with consumer-facing enrollment functionality may be relatively lower than those associated with building the back-end Exchange eligibility platform, interfaces with DE entities to accept Exchange applications and complete eligibility determinations, the connections required from an Exchange's back-end eligibility platform to the Federal Data Services Hub for eligibility verifications, connections from the Exchange's back-end eligibility platform to the respective state Medicaid agency for coordinating Medicaid and CHIP eligibility determinations, and the Exchange's data management and reporting functionality necessary to submit required eligibility and enrollment data regarding all Exchange enrollees to HHS and the IRS. Based on recent state transitions to the SBE model, the design, development, and implementation costs for an Exchange depend on a number of factors. Recent design, development, and implementation costs have ranged from $4 million for a smaller state, to almost $24 million for a larger state. As no SBE to date has implemented direct enrollment, however, we are not able to provide accurate cost estimates in this regard. States may be able to partner with existing federal DE partners who are already fully-compliant with federal operational requirements to achieve administrative savings related to the approval process for DE entities seeking to operate in their state. Any operational cost increases or savings may, in turn, affect an SBE's user fee and premium costs.

We do anticipate that an SBE electing the Exchange DE option will have increased operational costs for ongoing monitoring and oversight of the approved DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. However, any savings achieved through a decrease in call center volume or other consumer supports due to DE partners assisting consumers with enrollment would offset any increased operational costs. Any operational cost increases or savings stemming from implementation of the Exchange DE option could, in turn, affect an SBE's user fee and consumer premium costs.

We also anticipate that the Exchange DE option can have significant impacts on prospective DE entities (including web-brokers, agents and brokers, and issuers) and the federal government as a result of start-up, approval, and implementation costs. Such costs may be incurred by entities who enter a state's market as a new DE entity for the first time, or by existing DE entities that expand into new markets. We presume that DE entities will act rationally and enter a state's market or expand into new markets if the benefits exceed the costs. For the SBE–FP–DE and FFE–DE option, prospective federal DE entities pursuing approval to host their own DE platforms will incur a number of costs associated with startup and implementation activities, including costs to implement the appropriate privacy and security infrastructure, business controls, and with meeting eligibility application technical requirements related to ensuring the proper coordination with state Medicaid and CHIP programs.

In terms of privacy/security approval and startup costs, prospective DE entities operating through the SBE–FP–DE and FFE–DE option will be required to implement almost 300 security and privacy controls consistent with a system security and privacy plan provided by CMS. After control implementation, prospective DE entities must contract with an independent third-party auditor to complete a security and privacy controls assessment test plan, which must be submitted to CMS for review. Once approved, a DE entity must submit quarterly POA&Ms to CMS to document the identification and resolution of any new or existing security or privacy risks. DE entities must also incur costs to

contract with a third-party auditor to perform an annual assessment of their security and privacy posture consistent with continuous monitoring requirements published by CMS, and feedback provided on their quarterly POA&Ms.

In terms of approval and startup costs of implementing appropriate business controls, prospective DE entities that wish to serve an SBE–FP–DE or FFE–DE option state and host an eligibility application also will be required to implement a dynamic user interface (UI) that adapts to consumer scenarios based on complex business rules and integration with a range of application programming interfaces (APIs). They must also implement post-enrollment support functionality. After development, integration, and testing are complete, a prospective DE entity serving an SBE–FP–DE or FFE–DE option state must contract with a third-party auditor to evaluate its implementation consistent with business audit report toolkits provided by CMS. The audit consists of evaluation of the UI to ensure its consistency with program requirements, as well as completion of functional and integration testing. Once approved, a DE entity is required to implement CMS-initiated change requests to update its DE implementation as needed. In addition, DE entities are subject to periodic application audits to confirm their platforms continue to meet program requirements and remain functional.

There are additional technical startup and approval costs related to the eligibility application functionality that DE entities serving SBE–FP–DE or FFE–DE option states are required to implement. They must have the ability to provide the Exchange with all the information necessary for it to determine eligibility to enroll in QHPs, as well as to determine eligibility for APTC, CSRs, Medicaid, and CHIP. Consumers who complete an eligibility application on a DE entity's website must be provided with an eligibility determination notice (EDN) from the Exchange, and related information must display within the DE entity's website UI about consumers' eligibility. Therefore, if a consumer is determined eligible for Medicaid or CHIP after completing an eligibility application through a DE entity's website, they will receive the same information in their EDN about that eligibility and next steps as if they completed the application on *HealthCare.gov*.

We also anticipate that there will be costs specific to web-brokers and issuers that choose to enter into fee-based arrangements with other agents, brokers, or issuers, or that choose to enter new economic or legal arrangements with states, that help to offset the costs of the DE services provided. In terms of costs to issuers, generally any changes in issuer costs associated with the Exchange DE option could have downstream effects on premium rates. Issuers will be impacted by adjustments in Exchange user fees, and may have an incentive to promote direct enrollment if user fees are lower under the Exchange DE option, and the savings achieved through those lower user fees exceed the new costs of arrangements with web-brokers. Issuers may also be impacted if the Exchange DE option leads to shifts in consumer enrollment patterns, such as movement from a QHP offered by one issuer to another QHP. If issuers choose to build out standalone consumer-facing applications to enroll in coverage under the Exchange DE option, this would be another cost to consider that could impact them directly and have downstream impacts.

There are a number of additional anticipated costs to the federal government associated with the Exchange DE option beyond startup and approval. Under the FFE–DE and SBE–FP–DE option, for instance, we will continue to provide back-end eligibility services, notice and tax form generation, the processing of data matching and special enrollment verification issues, eligibility appeals, casework, advanced customer service, enrollment reconciliation, IRS reporting, and an alternate/backup consumer-facing eligibility and enrollment platform (as we do today). In addition, the *HealthCare.gov* website will continue to provide standardized comparative information for QHPs offered through an SBE–FP or FFE and will remain available for enrollment, as well to ensure there is an avenue to handle eligibility applications that approved DE partners are unable to process. Assuming an FFE–DE state chooses existing DE entities with whom HHS has partnered for the FFE's DE and EDE programs, we anticipate that there will be minimal increases in federal administrative costs associated with implementing the FFE–DE option since we have already implemented these programs. Any changes in payment amounts of the federal user fee for these services or any changes in issuer costs associated with the DE option may have downstream impacts on premiums, and therefore, federal tax expenditures on PTCs, which are benchmarked to premiums. We anticipate that any HHS costs associated with supporting the additional monitoring and oversight in states that elect to implement the SBE–DE option will be nominal given that SBEs will retain primary responsibility for overseeing their approved DE entities and HHS can leverage its existing SBE oversight mechanism [67] and associated processes to ensure that this is occurring.

We sought comment on this proposal, including any additional consumer, state, SBE, HHS, issuer, web-broker, or other costs, benefits or transfers that should be considered. We also sought data and information that would help us to quantify the potential impacts associated with this proposal. Comment summaries and our responses are included earlier in the preamble.

2. FFE and SBE–FP User Fees (§ 156.50)

We are finalizing an FFE user fee rate of 2.25 percent for the 2022 benefit year, which is lower than the 3.0 percent FFE user fee rate finalized for 2021 benefit year. We are also finalizing an SBE–FP user fee rate of 1.75 percent for the 2022 benefit year, which is lower than the 2.5 percent SBE–FP user fee rate we finalized for the 2021 benefit year. We are finalizing an FFE–DE and SBE–FP–DE user fee rate of 1.5 percent for the 2023 benefit year. Subject to HHS approval, SBE–FP or FFE states may implement the Exchange DE option starting in 2023. Based on our estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE–FP models to either the SBE–FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and the finalized user fee rates, we are estimating FFE and SBE–FP user fee transfers from issuers to the federal government will be lower by $270 million in 2022 compared to those estimated for the prior benefit year. Costs may be shifted to approved DE entities (including QHP issuers) that states elect to use, so there may not actually be any cost savings on the part of issuers in SBE or FFE states that elect the Exchange DE option. As such, there may not be an incentive for issuers in FFE–DE or SBE–FP–DE states to adopt these models solely as a result of the lower user fee rate. While there will be reduced transfers to the federal government in FFE–DE or SBE–FP–DE states, we expect that available user fee collections from current and prior years will be sufficient to fund Exchange operations. Based on our finalization of the FFE–DE and SBE–FP–DE user fee rates, transfers to the federal

[67] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smart_2018_9.pdf.*

government will be reduced by $60 million in 2023.

Comment: While some commenters supported the reduced user fee rates stating that these rates could lead to lower premiums, many other commenters expressed concern regarding the reduced user fee rates and the potential impact on Exchange operations, specifically how these rates could impact enrollment. However, two commenters specifically criticized the information provided in the RIA section of the proposed rule. Both commenters expressed concern that HHS had not sufficiently analyzed the financial and health impacts of the proposed user fee rate reductions, as HHS had not investigated how reduced Exchange operations, Navigator services, marketing and outreach, health plan oversight, call center and consumer appeals services, among others may translate into reduced enrollment, and the health costs associated. The second commenter further suggested that the proposed user fee rate would not be sufficient to enable the Exchange to reduce premiums.

Response: We are finalizing 2022 benefit year user fee rates at 2.25 percent for FFE issuers and 1.75 percent for SBE–FP issuers as proposed. We have addressed the general concern for reductions in user fees in the earlier preamble response sections. With respect to the specific comment of the RIA, we have sufficiently analyzed the financial and health impacts of the proposed user fee rate reductions and our internal analysis suggests that user fees will provide the necessary funding for the full functioning of Exchange operations including Navigator services, oversight functions, call center, and appeals services, among others for the 2022 benefit year. Based on prior years' additional collections and future projected changes in costs, enrollment, and premiums, we project that HHS can fully fund Federal platform costs associated with providing special benefits to these issuers.

3. State Innovation Waivers

The Departments are finalizing the policies, with modifications, to codify many of the policies and interpretations outlined in the 2018 Guidance into the section 1332 waiver implementing regulations governing waiver application procedures, monitoring and compliance, and periodic evaluations to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. As such, the Departments are finalizing changes to 31 CFR 33.108, 31 CFR 33.120, 31 CFR 33.128, 45 CFR 155.1308, 45 CFR 155.1320, and 45 CFR 155.1328. This final rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, nor evaluation in a way that would create any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans. The Departments are of the view that the increased certainty regarding the application requirements will allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application will not result in wasted resources and taxpayer dollars. This increased certainty could help increase the number of states that apply for waivers and increase state innovation, which in turn could lead to more affordable health coverage for individuals and families in states that consider implementing a section 1332 waiver program.

Comment: The Departments received many comments on the proposal and the potential impacts of the 2018 Guidance. Some commenters were concerned that finalization of the policy would increase health care costs, though the commenters did not define these costs further, and could potentially lead to increased premiums. A commenter stated that the Departments failed to analyze the distributional effects of the proposal, including its impact across the population and economy. The commenters asserted that the Departments failed to adequately identify and analyze the effects of codifying the policies in the 2018 Guidance in regulation.

Response: The Departments acknowledge that federal agencies, where appropriate, should analyze and consider the distributional effects of regulatory actions, which are the impacts of a regulatory action across the population and economy, divided up in various ways (for example, by income groups, race, sex, industrial sector, geography).[68] The Departments must analyze and determine whether each state waiver proposal complies with the section 1332 guardrails, which include comprehensiveness, affordability, coverage, and Federal deficit neutrality.

As explained earlier in section IV. of this final rule, a state's application and accompanying actuarial and economic analysis must appropriately model the impact of the waiver plan, including impacts on enrollment and affordability for individual market single risk pool coverage. Any increase in premiums in the individual market risk pool with the waiver, compared to a without-waiver scenario, would likely not meet the guardrails and would not be an approvable waiver application. To date, waivers have reduced premiums in comparison to premiums anticipated in the absence of the waivers.[69] In addition, the Departments maintain the discretion to reject any proposed waiver plan that meets the guardrails, such as if the Departments determine would cause more harm than good to the state's residents, or for example to a state's risk pool.[70] The Departments' approval letters for state waivers include information regarding the Departments' determination of whether a state's analysis and waiver plan satisfies the requirements of the section 1332 guardrails, as well as information on the projected impacts of waiver proposals.[71]

The Departments also acknowledge commenters' interest in the distributive impacts of incorporating the policies described in the 2018 Guidance into regulation text. As noted by commenters, OMB Circular A–4 is guidance issued by OMB and instructs that agencies should analyze the ''distributional effect'' of regulatory actions, which refers to the impact of a regulatory action across the population and economy, divided up in various ways (for example, income groups, race, sex, industrial sector, geography). However, the policies announced in the 2018 Guidance, specifically those that explain how the Departments will analyze compliance with the section 1332 guardrails, are not determinative of the specific waiver plans states may propose. Section 1332 waivers allow states to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The Departments have encouraged states to propose innovative approaches to meet the unique needs of their population through the flexibilities

[68] OMB Circular A–4, Regulatory Analysis (Sept. 17, 2003).

[69] Information about the pass-through amounts states received is available on HHS's CCIIO 1332 website, and information on the methodology and key components of the pass-through calculation is available under the ''pass-through funding tools and resources'' section and data brief on state relief and Empowerment Waivers, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-.*

[70] The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrail requirements.

[71] All section 1332 waiver approval letters available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-#Section_1332_State_Application_Waiver_Applications.*

Congress made available to states under section 1332 of PPACA. As such, the Departments are unable to predict or analyze the impact of various state waiver plans that have not yet been submitted, including the distributional effects on various segments of the population. Based on previous waiver applications, the Departments know that the impact of waivers vary widely based on the state's specific wavier plan. For example, the actual impact of the waiver on statewide average premiums compared to the estimated impact on statewide average premiums (that is, as estimated in the original state waiver application) for each waiver year varies based on the state's specific waiver program. In plan year 2020, states that implemented reinsurance waivers have lowered premiums ranging from 3.8 percent in Rhode Island to 37.1 percent in Alaska when comparing with and without the waivers, depending on a variety of factors of the states' plans and the composition of the state's population.[72]

A potential distributional impact for certain section 1332 waivers includes the substitution of pass-through funds from the federal government to the state in lieu of PTC, SBTC, or CSR, if a state waiver plan eliminates or reduces the amount of PTC, SBTC, or CSR that individuals and employers in the state receive (''pass-through funding''). [73] Pass-through funding amounts are adjusted to ensure that waivers remain deficit neutral, as required by statute. As discussed in the 2018 Guidance and consistent with the Departments' regulations, when applying for a section 1332 waiver, the state should include in the waiver application sufficient analysis and supporting data to inform the estimate of any pass-through funding amount; states with approved waivers must report additional data and information to support the annual estimate of pass-through funding. Furthermore, pass-through funding may be for the amount of federal financial assistance pursuant to the PPACA not paid due to an individual not qualifying for financial assistance or qualifying for a reduced level of financial assistance resulting from a waived provision as a direct result of the waiver plan.[74] Although pass-through funding payments would be operationalized by the federal government, the transfers, as categorized for purposes of this regulatory impact analysis, would flow from the individuals and employers who would otherwise receive PTC, SBTC, or CSR (not from the federal government) to the relevant states for the purposes of implementing the waiver plan.

The Departments are unable to estimate or determine how many or which states will apply for a section 1332 waiver once the policies described in the 2018 Guidance are codified in regulation. Based on our interactions with states that previously proposed or considered proposing section 1332 waiver plans, the Departments anticipate that more states will be able to take advantage of section 1332 waivers if approval standards are reasonable, appropriate, and sufficiently flexible to allow states to design waiver plans that are capable of addressing the specific needs and circumstances of their residents. The Departments are also of the view that, despite the significant investment of tax dollars and other state resources necessary to consider, design, and submit a section 1332 waiver proposal, more states will consider a waiver as a viable option to improve or address specific problems in their health care markets if they do not have to be concerned that the Departments' standards will change without notice or an opportunity to comment. For these reasons, the Departments are of the view that codifying the policies announced in the 2018 Guidance in rulemaking, as a general matter, will likely provide greater opportunities for states to lower premiums, provide greater health care support for state residents at a greater variety of income levels, and develop innovative strategies to address the needs of vulnerable populations.

The Departments note that the distributive impact of a state's particular waiver plan would be analyzed as part of the waiver application and review process. Specifically, as part of a state waiver application, final regulations at 31 CFR part 33 and 45 CFR part 155, subpart N, require a state to provide actuarial analyses and actuarial certifications, economic analyses, data and assumptions, targets, an implementation timeline, and other necessary information to support the state's estimates that the proposed waiver will comply with section 1332 requirements to satisfy the section 1332 waiver guardrails. The 2012 regulation also specified that data and assumptions used should include information on the age, income, health expenses, and current health insurance status of the relevant state population; the number of employers by number of employees and whether the employer offers insurance; cross tabulations of these variables; and an explanation of data sources and quality that the Departments would use to evaluate any waiver application and address regulatory impact across the population and economy. For example, state waiver applications' actuarial and economic analysis showed that enrollment increased when comparing the with and without-waiver scenarios over different age ranges and income levels for states that are implementing a reinsurance program.[75] Furthermore, the Departments complete a preliminary review of any waiver application received in accordance with 45 CFR 155.1308(c) and 3l CFR 33.108(c), and if an application does not have the aforementioned information the Secretaries can make a preliminary determination that the application is not complete. In that case, the waiver application would not be reviewed further unless additional information is provided.

Furthermore, section 1332(a)(4)(B) of PPACA provides that the Secretary of HHS and the Secretary of the Treasury shall issue regulations providing a process for public notice and comment at the state level, including public hearings, and a process for providing public notice and comment after the application is received by the Secretaries, that are both sufficient to ensure a meaningful level of public input. Current regulations at 31 CFR 33.112 and 45 CFR 155.1312 specify state public notice and participation requirements for proposed waiver requests, and 31 CFR 33.116(b) and 45 CFR 155.1316(b) specify the accompanying public notice and comment period requirements under the Federal public notice and approval process.[76] Under the current regulations

[72] *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf.*

[73] Information about the pass-through amounts states received is available on the CCIIO 1332 website and information on the methodology and key components of the pass-through calculation is available, under the ''pass-through funding tools and resources'' section and data brief on state relief and Empowerment Waivers ''here: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_State_Innovation_Waivers-.*

[74] The guidance on State Relief and Empowerment Waivers is available online at *https://www.federalregister.gov/documents/2018/10/24/2018-23182/state-reliefand-empowerment-waivers.*

[75] An example of information showing the distributional impact of a waiver on the population by age can be found in Table 3C. See *https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Delaware-1332-Waiver-Application-July-10-2019.pdf.*

[76] Also note that there is flexibility under 31 CFR 33.118 and 45 CFR 155.1318 for states to request, subject to approval by the Departments, modification from the normal public notice requirements during the COVID–19 PHE when a delay would undermine or compromise the purpose

at 31 CFR 33.112 and 45 CFR 155.1312, states are required to provide a public notice and comment period prior to submitting an application for a new section 1332 waiver. In addition, under section 1332(a)(4)(B)(iii) of PPACA and the existing implementing regulations at 31 CFR 33.116(b) and 45 CFR 155.1316(b), the Secretary of HHS and the Secretary of the Treasury are required to provide a Federal public notice and comment period following their preliminary determination that a state's section 1332 waiver application is complete. As such, the Departments are of the view that the public has a meaningful opportunity to provide comments on waiver proposals and to understand the distributional effects on various segments of the population prior to waiver approval.

4. Network Adequacy Standards (§ 156.230)

We are finalizing the proposal to revise § 156.230 to reflect the longstanding interpretation that plans that do not utilize a provider network are not required to comply with network adequacy standards to obtain QHP certification. We make no other changes to QHP certification requirements or requirements under the market reform provisions under title I of PPACA; plans that do not utilize a provider network must still comply with all other applicable QHP certification requirements to obtain QHP certification. Because the codified interpretation is the status quo, we do not anticipate any burden to result from finalization of this policy. We disagree with some commenters' assertions that finalization of this policy will create increased costs for consumers or a proliferation of plans that do not differentiate benefits based on whether enrollees receive covered services from in-network providers, which may not be advantageous for certain consumers. As we explain earlier in the preamble, the changes to the QHP network adequacy standard we are finalizing make no changes to QHP certification requirements. There have only been 12 such plans that did not utilize a provider network approved as QHPs, which were approved for sale in Wisconsin for plan year 2016. In the last five plan years, there have been no such plans approved for QHP certification. Accordingly, we do not expect this policy to result in increased consumer costs or any proliferation appreciable increases to such plans seeking QHP certification.

5. Enrollment Process for Qualified Individuals (§ 156.1240)

We are finalizing this policy with some minor modifications to the regulatory text and the adoption of additional language specifying that QHP issuers must also accept premium payments using a payment method described in § 156.1240(a)(2) that are made directly by enrollees who are enrolled in an individual coverage HRA or QSEHRA. We expect this approach will ease administration of individual coverage HRAs and QSEHRAs by altering the behavior of QHP issuers who do not yet accept premium payments using such payment methods. It will also make the individual coverage HRA and QSEHRA experience more seamless for employers and employees by ensuring that individual coverage HRAs and QSEHRAs may pay premiums for employees through direct payments to the issuer, rather than through reimbursements of premium payments to employees.

We received several comments asserting that finalizing these changes would place cost burdens on issuers and have addressed them earlier in the preamble. As discussed, we did not propose and are not finalizing a requirement for QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when such payments are made using a form of payment that is not described in § 156.1240(a)(2) or to accept aggregate payments from an individual coverage HRA or QSEHRA made on behalf of multiple enrollees.[77] While it may be possible that some issuers may incur administrative costs to implement operational changes necessary to comply with this requirement, such issuer costs should be minimal because QHP issuers, as a general matter, are already required to accept premium payments that are made using the forms of payment described in § 156.1240(a)(2). Accordingly, the rule we finalize here does not require issuers to incur additional costs to invest in information technology infrastructure that can generally accommodate roster, or list, billing.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, the Departments should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, the Departments assume that the this rule will be reviewed by all affected issuers, states, and some individuals and other entities that commented on the proposed rule. The Departments acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, the Departments consider the number of affected entities and commenters to be a fair estimate of the number of reviewers of this rule.

HHS is required to issue a portion of this rule each year under their regulations and the Departments estimate that approximately half of the remaining provisions would cause additional regulatory review burden that stakeholders do not already anticipate. The Departments also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for purposes of our estimate, the Departments assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that HHS is required to issue each year.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), the Departments estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits.[78] Assuming an average reading speed, the Departments estimate that it will take approximately 1 hour for staff to review the relevant portions of this final rule that causes unanticipated burden. The Departments assume that approximately 725 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately $110.74. Therefore, the Departments estimate that the total cost of reviewing this regulation is approximately $80,287 ($110.74 × 725 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, the Departments considered numerous alternatives. Below the Departments discuss the key regulatory alternatives that were considered.

As an alternative to the proposed reduction in user fee rates, we considered maintaining the FFE and SBE–FP user fee rates at their current 2021 levels. However, our analysis supported reducing the user fee rate. In

of the proposed waiver request and be contrary to the interest of consumers.

[77] 85 FR 78572, 78644.

[78] *https://www.bls.gov/oes/current/oes_nat.htm.*

light of the projected premium and enrollment increases, HHS believed that a reduction in FFE and SBE–FP user fees was warranted for 2022.

We considered including a requirement for states to submit and be approved for a State Innovation Waiver under section 1332 of PPACA as part of the proposed Exchange DE option described at new § 155.221(j). However, nothing under the plain terms of section 1311(d)(4) PPACA governing the functions of an Exchange requires an Exchange to host a single, consumer-facing enrollment website to receive applications or support plan shopping and selection.[79] Thus we concluded that there is no requirement in PPACA that must be waived to allow a state to implement the Exchange DE option, and requiring states to expend taxpayer dollars to file a waiver application would be unnecessary and unduly burdensome. We also considered aligning the implementation timeframe for all Exchange models interested in the Exchange DE option to plan year 2023; however, because we believe that this option could improve health insurance markets and that State Exchanges could implement the option by plan year 2022, we chose not to do so.

Regarding the section 1332 waiver policies in this rule, the Departments considered not proposing to codify the 2018 Guidance. Additionally, the Departments considered proposing the 2018 Guidance through separate notice and comment rulemaking. The Departments did not take either of these options because it would be contrary to the interest of states. Specifically, the Departments concluded that not proposing codifying the 2018 Guidance would lead to uncertainty for states considering section 1332 waiver applications, and the Departments concluded that separate notice and comment rulemaking was unnecessary because this rulemaking provided a public notice and comment period.

In this final rule, the Departments seek to provide certainty to states that the requirements and expectations of the section 1332 waiver program will not change abruptly during a period in which states are doing the work to prepare a waiver proposal. The Departments considered alternatives to the interpretations set forth in the 2018 Guidance, including interpretations that could further increase flexibility. However, the Departments determined that changing guidance and the criteria required for approval would increase regulatory uncertainty and make states less likely to submit section 1332 waivers. The Departments are of the view that finalizing these policies with modifications will help states that are interested in undertaking the complicated and potentially expensive work to design a waiver program that meets the four guardrails, as described in the 2018 Guidance. Codification of many of the policies described in the 2018 Guidance could also encourage more states to apply for section 1332 waivers. As discussed section IV.A. of this the preamble, this consideration is especially important because the process of developing and submitting a proposal may take significant time and taxpayer resources at the state level, and states do not want to undertake these efforts if the probability of success is low and the probability of the Departments changing requirements is high. As part of this rulemaking, the Departments substantively considered comments and determined that changes to 2018 Guidance were not warranted based on comments received.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

The provisions in this rule will affect health insurance issuers in the individual and small group markets. The Departments are of the view that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less are considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[80] The Departments are of the view that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report[81] submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 67 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. Therefore, the Departments do not expect the provisions of this rule to affect a substantial number of small entities.

The changes related to section 1332 waivers may have an impact on small businesses. Section 1332 allows a state to waive Part I of Subtitle D of Title I of the ACA (relating to establishing QHPs); Part II of Subtitle D of Title I of the ACA (relating to consumer choices and insurance competition through Exchanges); sections 36B of the Code and 1402 of the ACA (relating to premium tax credits and cost-sharing reductions for plans offered through Exchanges); section 4980H of the Code (relating to employer shared responsibility); and section 5000A of the Code (relating to individual shared responsibility). To date, the Departments have approved one waiver that impacts small businesses. Hawaii's waiver waived the small business health options program (SHOP) and related provisions in order to allow Hawaii to operate its own state program consistent with its state law. The state program, the Prepaid Health Care Act, requires virtually all employers to offer coverage to their employees and provides small employers premium assistance. As part of its the waiver, Hawaii waived the SBTC under section 45R of the Code. As such, the SBTC amounts that would otherwise be paid to small employers in Hawaii has been provided as a pass-through payment to the state, which it

[79] Section 1311(d)(4)(C) of PPACA requires only that ''[a]n Exchange shall, at a minimum . . . maintain an Internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans . . .''

[80] *https://www.sba.gov/document/support--table-size-standards.*

[81] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

used to support a state fund that helps small businesses cover their health care-related costs.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule under title XVIII, title XIX, or part B of title 42 of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, the Departments have determined that this rule will not affect small rural hospitals. Therefore, the Secretaries have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any federal mandate that may result in expenditures in any one year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $156 million. Although the Departments have not been able to quantify all costs, the Departments expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. In the Departments' view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, the Departments attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE–FPs, and the FFEs.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. Under the Congressional Review Act, the Office of Information and Regulatory Affairs designated this final rule as a ''major rule'' as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of $100 million or more.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This final rule primarily results in transfers and is thus not a regulatory or deregulatory action for the purposes of E.O. 13771.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements, Waivers for State Innovation.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of the

Treasury amends 31 CFR subtitle A as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

■ 1. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 2. Section 33.108 is amended by revising paragraphs (f)(3)(i), (f)(3)(iv) introductory text, and (f)(3)(iv)(A) through (C) to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of Health and Human Services, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

* * * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph (f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of Health and Human Services:

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the State plan will provide consumers access to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These coverage options must also satisfy the affordability requirement in paragraph (f)(3)(iv)(B) of this section;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the State plan will provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These coverage options must also satisfy the comprehensive coverage requirement in paragraph (f)(3)(iv)(A) of this section;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. Coverage refers to minimum essential coverage as defined in 26 U.S.C. 5000A(f) and 26 CFR 1.5000A–2, and health insurance coverage as defined in 45 CFR 144.103; and

* * * * *

■ 3. Section 33.120 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 33.120 Monitoring and compliance.

(a) * * *

(1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, as applicable, a State must comply with all applicable Federal laws, regulations, and interpretive policy statements, as well as interpretive guidance published by the Secretary and the Secretary of Health and Human Services, unless expressly waived. A State must, within the timeframes specified in law, regulation, interpretive policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of Health and Human Services will examine compliance with Federal and regulatory requirements consistent with § 33.108(f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of Health and Human Services when conducting implementation reviews under paragraph (b) of this section.

* * * * *

■ 4. Section 33.128 is amended by revising paragraph (a) to read as follows:

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with § 33.108(f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of Health and Human Services, as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 155 and 156 as set forth below.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 5. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 6. Section 155.221 is amended by—

■ a. Redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.

■ b. Adding a reserved paragraph (c);

■ c. In newly redesignated paragraphs (g) introductory text, (g)(6) and (7), and (h) by removing the reference to ''paragraph (e)'' and adding in its place a reference to ''paragraph (f)''; and

■ d. Adding paragraph (j).

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

* * * * *

(c) [Reserved]

* * * * *

(j) *Process for States to elect the Exchange direct enrollment option.* Subject to HHS approval, and in addition to or in lieu of the Exchange operating its own consumer-facing eligibility application and enrollment website, a State may elect for the State Exchange, State Exchange on the Federal platform, or federally-facilitated Exchange in the State to approve one or more enrollment entities described in paragraph (a) of this section to make available a non-Exchange online website to enroll qualified individuals in a QHP offered through the Exchange in the State in a manner that constitutes enrollment through the Exchange, as specified in paragraph (j)(1) or (2) of this section. Through the websites of these approved entities, consumers in the State apply for and enroll in coverage using an eligibility application as described in § 155.405, and receive eligibility determinations from the Exchange for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations from the Exchange for Medicaid and CHIP eligibility in accordance with §§ 155.302 and 155.405.

(1) *Direct enrollment option for a State Exchange.* A State may receive approval, under §§ 155.105(b) and 155.106(a), to operate a State Exchange using the direct enrollment option described in this paragraph (j). The State Exchange must meet all Federal statutory and regulatory requirements for the operation of an Exchange. An approved State Exchange that wishes to implement this option must submit a revised Exchange Blueprint in accordance with § 155.105(e). In order to obtain approval for the State Exchange to implement this option, the State must:

(i) Demonstrate to HHS operational readiness for the State Exchange to enroll qualified individuals in a QHP through approved direct enrollment entity websites in a manner that constitutes enrollment through the Exchange, including enabling individuals to apply for, and receive eligibility determinations from the Exchange for QHP enrollment and advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations of Medicaid and CHIP eligibility from the Exchange as described in § 155.302, using the eligibility application described in § 155.405;

(ii) Provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities; and

(iii) Ensure that a minimum of one direct enrollment entity approved by the State meets minimum Federal requirements for HHS approval to participate in the federally-facilitated Exchange direct enrollment program, including requirements at § 155.220 and this section, particularly § 155.220(c)(3)(i)(A) and (D) so that at least one approved web-broker in the state displays detailed information for all available QHPs and meets accessibility requirements under § 155.205(c) and is capable of enrolling all consumers in the State, including those who present complex eligibility scenarios. Where no direct enrollment entity approved by the State meets such minimum Federal requirements or possesses the capability to enroll all consumers in the State, the State must offer a consumer-facing website that meets such requirements and possesses such capability.

(2) *Direct enrollment option for a State with a federally-facilitated Exchange or State Exchange on the Federal platform.* Pursuant to a request from a State, the federally-facilitated Exchange or a State Exchange on the Federal platform may partner with the requesting State to implement the direct enrollment option described in this paragraph (j). The federally-facilitated Exchange or State-based Exchange on the Federal platform must meet all Federal statutory and regulatory requirements for the operation of an Exchange. In order to obtain approval for the federally-facilitated Exchange or State Exchange on the Federal platform in a State to implement this option, a State must:

(i) Coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the State, necessary for the federally-facilitated Exchange to operationalize the necessary changes to implement this option;

(ii) Execute a Federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the State;

(iii) Agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) of this subchapter; and

(iv) Perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act, including complying with reporting and compliance activities required by HHS and described in the Federal agreement.

■ 7. Section 155.1308 is amended by revising paragraphs (f)(3)(i), (f)(3)(iv) introductory text, and (f)(3)(iv)(A) through (C) to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of the Treasury, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

* * * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph (f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of the Treasury;

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement,

the Secretary and the Secretary of the Treasury, as applicable, must determine that the State plan will provide consumers access to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These coverage options must also satisfy the affordability requirement in paragraph (f)(3)(iv)(B) of this section;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the State plan will provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These coverage options must also satisfy the comprehensive coverage requirement in paragraph (f)(3)(iv)(A) of this section;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. Coverage refers to minimum essential coverage as defined in 26 U.S.C. 5000A(f) and 26 CFR 1.5000A–2, and health insurance coverage as defined in 45 CFR 144.103; and

* * * * *

■ 8. Section 155.1320 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 155.1320 Monitoring and compliance.

(a) * * *

(1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws, regulations, and interpretive policy statements, as well as interpretive guidance published by the Secretary and the Secretary of the Treasury, unless expressly waived. A State must, within the timeframes specified in law, regulation, interpretive policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of the Treasury will examine compliance with Federal and regulatory requirements consistent with § 155.1308(f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of the Treasury when conducting implementation reviews under paragraph (b) of this section.

* * * * *

■ 9. Section 155.1328 is amended by revising paragraph (a) to read as follows:

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with § 155.1308(f)(3)(iv) and interpretive guidance published by the Secretary and the Secretary of the Treasury, as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 10. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, and 26 U.S.C. 36B.

■ 11. Section 156.230 is amended by adding paragraph (f) to read as follows:

§ 156.230 Network adequacy standards.

* * * * *

(f) *Exception.* Paragraphs (a) through (e) of this section do not apply to a plan for which an issuer seeks QHP certification or to any certified QHP that does not use a provider network, meaning that the plan or QHP does not condition or differentiate benefits based on whether the issuer has a network participation agreement with the provider that furnishes covered services.

■ 12. Section 156.1240 is amended by adding paragraph (a)(3) to read as follows:

§ 156.1240 Enrollment process for qualified individuals.

(a) * * *

(3) For payments in the individual market made using a payment method described in paragraph (a)(2) of this section, accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA (as described in § 146.123(b) of this subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

* * * * *

Dated: January 8, 2021.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 12, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Dated: January 13, 2021.

David J. Kautter,

Assistant Secretary (Tax Policy), Department of the Treasury.

[FR Doc. 2021–01175 Filed 1–14–21; 4:15 pm]

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Part XI

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Chapter 1

Federal Acquisition Regulations; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2021–0051, Sequence No. 1]

Federal Acquisition Regulation; Federal Acquisition Circular 2021–04; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rule.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rule agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2021–04. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC.

DATES: For effective dates see the separate documents, which follow.

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207 or *zenaida.delgado@gsa.gov* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2021–04, FAR Case 2019–016.

RULES LISTED IN FAC 2021–04

Subject	FAR case
Maximizing Use of American-Made Goods, Products and Materials	2019–016

ADDRESSES: The FAC, including the SECG, is available via the internet at *https://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: A summary for the FAR rule follows. For the actual revisions and/or amendments by this FAR rule, refer to the specific item numbers and subjects set forth in the documents following this summary. FAC 2021–04 amends the FAR as follows:

Maximizing Use of American-Made Goods, Products, and Materials (FAR Case 2019–016)

This final rule strengthens domestic preferences under the Buy American statute by making adjustments to the required percentage of domestic content and the existing percentages for the price evaluation preferences in an effort to decrease the amount of foreign-sourced content in a U.S. manufactured product to promote economic and national security, help stimulate economic growth, and create jobs. The price evaluation preferences increase from 6 percent to 20 percent for large business and from 12 percent to 30 percent for small business; for DoD procurements there is no change to the DoD 50 percent amount. The domestic content requirement for iron and steel increases from 50 percent to 95 percent; for other end products and construction materials, the domestic content requirement increases from 50 percent to 55 percent. Foreign iron and steel is iron or steel products that are not produced in the United States. The rule implements E.O. 13881, Maximizing Use of American-Made Goods, Products, and Materials. This final rule will not have a significant economic impact on a substantial number of small entities.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2021–04 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2021–04 is effective January 19, 2021.

John M. Tenaglia,

Principal Director, Defense Pricing and Contracting, Department of Defense.

Jeffrey A. Koses,

Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

William G. Roets, II,

Acting Assistant Administrator, Office of Procurement, National Aeronautics and Space Administration.

[FR Doc. 2021–00708 Filed 1–15–21; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 12, 25, and 52

[FAC 2021–04; FAR Case 2019–016; Docket No. FAR–2019–0016, Sequence No. 1]

RIN 9000–AN99

Federal Acquisition Regulation: Maximizing Use of American-Made Goods, Products, and Materials

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement an Executive order (E.O.) addressing domestic preferences in Government procurement.

DATES: *Effective:* January 21, 2021.

Applicability: The changes in this rule apply to solicitations issued on or after February 22, 2021 and resultant contracts.

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207 or *zenaida.delgado@gsa.gov* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2021–04, FAR Case 2019–016.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule at 85 FR 56558 on September 14, 2020, to implement E.O. 13881, Maximizing Use of American-Made Goods, Products, and Materials (84 FR 34257, July 18, 2019). In order to implement the E.O., this final rule changes FAR clauses implementing the Buy American statute by increasing the—

1. Domestic content requirements; and
2. Price preference for domestic products.

Increased Domestic Content Requirements

Under E.O. 13881, and this final rule, in order to meet the definition of ''domestic construction material'' or ''domestic end product,'' the cost of

foreign iron and steel for iron and steel products must be less than 5 percent of the cost of all components in the product. For everything else, the domestic content requirement increases from 50 percent to more than 55 percent of the cost of all components. E.O. 13881 creates a new separate higher standard for iron and steel products. This distinction has existed for many years in domestic preference requirements governing certain Federal grant programs, such as the Federal Transit Administration's Buy America regulations applicable to grantees. Also, DoD procurements are affected by the increased domestic content requirements of E.O. 13881; the changes will be implemented in the Defense Federal Acquisition Regulation Supplement (DFARS) through DFARS Case 2019–D045, Maximizing Use of American-Made Goods.

Increased Price Preference for Domestic Offers

The Buy American statute does not prohibit the purchase of foreign end products or use of foreign construction material. Instead, it encourages the use of domestic end products and construction material by imposing a price preference for domestic end products and construction material. E.O. 13881 and this final rule increase the price preference from 6 percent to 20 percent for large businesses, and from 12 percent to 30 percent for small businesses. The E.O. does not impact the price preference for end products for DoD procurements, which is 50 percent for both large and small businesses, because the DoD percentage exceeds the requirements of the E.O.

Thirty-five respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes

This final rule makes the following significant changes from the proposed rule:

- *Definitions.* At FAR 25.003, the definitions of ''domestic construction material,'' ''domestic end product,'' and ''predominantly of iron or steel or a combination of both'' are revised; and a definition of ''foreign iron and steel'' is added.
  - The definitions of ''domestic construction material'' and ''domestic end product'' now specify that the cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of all foreign iron or steel components excluding commercially available off-the-shelf (COTS) fasteners. The definition specifies that the iron or steel components of unknown origin are treated as foreign. Also, the definition explains that if the construction material contains multiple components, the cost of all the materials used in the construction material is calculated in accordance with the definition of ''cost of components'' in FAR 25.003.
  - A definition of ''foreign iron and steel'' which includes language explaining ''produced in the United States'' is added to clarify the term as it is used in the revised definitions of ''domestic construction material'' and ''domestic end product''.
  - The definition of ''predominantly of iron or steel or a combination of both'' now clarifies what is meant by the phrase ''the cost of iron and steel.''
  - Conforming changes are made at FAR 25.101(a)(2)(ii) and 25.201(b)(2)(ii), as well as to FAR clauses 52.225–1, Buy American—Supplies; 52.225–3, Buy American—Free Trade Agreements—Israeli Trade Act; 52.225–9, Buy American—Construction Materials; and 52.225–11, Buy American—Construction Materials Under Trade Agreement.
- *COTS fasteners.* Revisions have been made throughout the FAR to clarify that the domestic content test does not apply to COTS fasteners. These revisions are made at FAR 25.001, 25.003, 25.101, 25.201, as well as in FAR clauses 52.225–1, Buy American-Supplies; 52.225–3, Buy American—Free Trade Agreements—Israeli Trade Act, and its alternates; 52.225–9, Buy American—Construction Materials; and 52.225–11, Buy American—Construction Materials Under Trade Agreement, and its alternate.

B. Analysis of Public Comments

1. Strong Support for the Rule

Comment: Most of the respondents strongly supported the proposed rule. One respondent noted positive factors regarding this rule as follows:

- Improves America's position from an economic standpoint.
- Helps increase jobs.
- Improves relationships with companies within our country.
- Interests other countries to do more trades and business with companies that have American-made products, goods, and materials.
- Improves our national image.

Response: Noted.

2. Domestic Content Test for COTS Items

2a. Remove the COTS Waiver for All Construction Materials

Comment: A few respondents stated that the rule should restore the domestic content test for all COTS construction material, not just for COTS construction iron and steel products. The respondents pointed out that there are instances where ''nonferrous'' construction materials compete with iron and steel products and in these instances, the rule provides an advantage to foreign nonferrous producers when they compete with U.S. producers of iron and steel products by not applying the domestic content test to the ''nonferrous'' construction material.

Response: This FAR change is required to implement E.O. 13881.

2b. Remove the COTS Waiver for Fasteners

Comment: Many respondents (using an essentially identical form letter) urged the Councils to remove the waiver of the domestic content test of the Buy American statute for the acquisition of COTS fasteners. These respondents stated that not doing so would not provide U.S. fastener manufacturers the same protection being offered to manufacturers of other iron and steel products.

Response: The Councils determined that requiring offerors to keep track of the origin of all fasteners could have a significant negative impact by creating an administrative burden on offerors that would outweigh any benefit to the American iron and steel industrial base. However, a clarification is made in FAR 25.001 to exclude only COTS fasteners.

2c. No Changes to Current COTS Waiver

Comment: A few respondents stated that the COTS waiver should remain as is and not subject iron and steel products to the additional rigor of the domestic content test. These respondents commented that contractors for COTS items have built their supply chains to comply with the existing COTS waiver and changing this paradigm will impede projects around the country, adversely impact these contractors, be administratively burdensome for them, and increase compliance costs that will eventually be borne by the Government. One of the

respondents stated that waiving some COTS items, but not others, would create a dissimilar application of the domestic content rule that is not in the public interest and should not be implemented in the FAR.

Response: As explained in the proposed rule, roll-back of the COTS waiver is necessary to give full effect to the E.O. 13881 requirement.

3. Definitions

Comment: One respondent stated that it was not clear why the longstanding practice of using cost of ''components'' has been replaced with ''content'' when determining whether an end product is a steel end product and the implications of this change. The respondent recommended defining the word ''content'' and providing examples of application of this new standard.

Response: The Councils note that the domestic content test is not applied to determine whether an item is wholly or predominantly of iron or steel or a combination of both, but to determine whether such a product is foreign or domestic. As explained in paragraph II.B.2.i of the proposed rule preamble, the term ''component test'' was replaced with ''domestic content test'' because of the wording of the E.O. regarding iron and steel. Per FAR 25.001(c)(1), this domestic content test is one of the two-part test elements used by the Buy American statute to define a ''domestic construction material'' or ''domestic end product.'' Regarding iron and steel end products, the E.O. states that the materials shall be considered to be of foreign origin if ''the cost of foreign iron and steel used in such iron and steel end products constitutes 5 percent or more of the cost of all the products used in such iron and steel end products.'' ''All the products used'' in an item would be the common meaning of ''content.'' The Councils do not consider it necessary to define ''content''.

However, the Councils added the explanation that the cost of all the materials used in a product is to be calculated consistent with the definition of ''cost of components'' at FAR 25.003, if the product contains multiple components. The Councils also specified that the cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners, both in the definitions of ''domestic construction material,'' and ''domestic end product.''

To determine whether a product that is wholly or predominantly of iron or steel or a combination of both is foreign or domestic, it is necessary to determine the following:

(i) Does the product consist wholly or ''predominantly of iron or steel or a combination of both'' (as defined in FAR 25.003)?

(ii) Is any of the iron or steel content not produced in the United States?

(iii) Is the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product, and a good faith estimate of the cost of all foreign iron or steel components (excluding COTS fasteners), less than 5 percent of the cost of all the components used in the end product (or construction material)? If the product contains multiple components, the cost is to be calculated consistent with the definition of ''cost of components'' at FAR 25.003.

See the following examples:

• *A steel beam.* For purposes of this example, this steel beam consists wholly of steel. The cost of all material in the beam, excluding final manufacture, overhead costs, and profit, is $50. If the steel beam is rolled from steel bloom, then the steel beam probably contains either all domestic steel, or all foreign steel. However, if the beam is welded or riveted from separate steel plates, then it is conceivable that some of the steel plates could have been formed from steel not produced in the United States. If the cost of the foreign steel plates used to make the beam equals or exceeds $2.50 (*i.e.,* 5 percent of the cost of all the components used in the product), then the entire beam is a foreign construction material.

• *A steel safe.* The steel safe may include other components such as a combination lock, a dehumidifier, or drawers. The safe costs $1,000 and the cost of all components in the safe is $500. If the cost of the steel plates or other steel mill products (excluding COTS fasteners) utilized in the manufacture of the safe exceeds $250 (*i.e.,* 50 percent of the total cost of all the components as defined in FAR 25.003), then the safe consists predominantly of steel. If the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the safe and a good faith estimate of the cost of all foreign iron or steel components (excluding COTS fasteners) is less than $25 (*i.e.,* 5 percent of the cost of all the components used in the product), then the safe is a domestic end product.

• *A refrigerator.* The refrigerator consists of many components and materials. The exterior cabinet and door and the inner cabinet of this refrigerator are steel. The refrigerator also includes insulation, cooling system, refrigerant, and fixtures. The refrigerator costs $2,000 and the cost of all components in the refrigerator is $1,000. If the cost of the steel plates or other steel mill products (excluding COTS fasteners) utilized in the manufacture of the refrigerator does not exceed $500 (*i.e.,* 50 percent of the total cost of all the components as defined in FAR 25.003), then the refrigerator does not consist predominantly of steel.

Comment: One respondent recommended clarifying the meaning of ''metallurgical processes'' and providing a list of representative metallurgical functions such as smelting, melting, pouring, rolling, casting, and other similar processes. The respondent based the recommendation on their interpretation of the existing guidance and the proposed rule, suggesting that raw steel and iron material for a steel end product may enter the United States and after undergoing all manufacturing processes for its intended final use, it would then be considered ''produced in the U.S.'' both for purposes of being a domestic component (if it is a component in an end product) or a domestic end product itself (if solely from one foreign material). The respondent's interpretation also suggested that if ''the steel came with any foreign manufacturing outside the original metallurgical process, the item would be considered foreign, even if all subsequent manufacturing occurred in the U.S.'' One respondent suggested defining ''manufactured in the United States'' under the Buy American statute's two-part test using a more stringent standard where all steelmaking processes, including the melting and pouring of the steel (*i.e.,* the actual steelmaking), occur in the United States. Other respondents requested the rule provide a clear, explicit definition of ''foreign iron and steel'' to prevent any adverse or unintended consequences.

Response: The exception relating to metallurgical processes involving refinement of steel additives does not apply to any of the metallurgical processes involved in the making of the steel itself. Steel is defined in FAR 25.003 as an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements. These other elements (*e.g.,* manganese, silicon, copper, aluminum, chromium, cobalt, molybdenum, nickel, niobium, titanium, tungsten, vanadium) are termed steel additives, and as such,

are added to the steel alloy to create steel with different properties (*e.g.,* stainless steel). Therefore, whatever metallurgical processes are used to separate and concentrate and reduce the ore to metal, then refine to increase the grade or purity of a steel additive (such as titanium or tungsten) can occur anywhere, prior to adding these other metals to produce the steel alloy in the United States. As stated in the proposed rule, in order to be domestic, all manufacturing processes of the iron or steel (other than the additives) must take place in the United States. In the final rule, language is added from the definition of ''produced in the United States'' from E.O. 13788, Buy American and Hire American (82 FR 18837) to better explain how the iron or steel is considered domestic. For clarity, the final rule moves the explanation of what it means to produce iron or steel in the United States from the definition of ''domestic construction material'' and ''domestic end product'' to a new, separate definition in FAR 25.003 for the term ''foreign iron and steel.'' The definition of ''foreign iron and steel'' is based on the existing description of ''iron or steel components'' at FAR 25.602–1(a)(1)(ii), consistent with the intent articulated in the proposed rule.

Comment: One respondent recommended that ''good faith'' be further defined to include a subjective and objective standard for a ''reasonable business person without legal knowledge or training''.

Response: The term ''good faith'' is used in many instances in the FAR and other agency regulations. The Councils concluded that ''a good faith estimate'' should be sufficient; and that adding the suggested language will not make the standard any clearer.

Comment: One respondent stated that requiring nothing more than a ''good faith assurance'' to calculate the cost of foreign components could lead to abuse or fraud in calculating the cost of foreign components, which would undermine the purpose of E.O. 13881. The respondent commented that because the origin of the iron and steel products should be readily discernible, the final rule should require suppliers to track the domestic content in iron and steel products and subject this accounting to periodic audit. Another respondent submitted a similar comment.

Response: The Councils agree that the origin of the iron and steel components should be readily discernible. As such, the final rule has been revised to clarify that contractors are to make a ''good faith estimate'' only for the cost of all foreign iron or steel components, other than the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product. It is highly likely that current procedures will yield the needed information for the offeror to make the required determinations in this rule. The cost of the iron and steel items are included in invoices and already used to determine whether an end product or construction material is foreign.

Comment: A few respondents stated that defining ''predominantly of iron or steel'' based on cost of the components, as opposed to weight, volume, and cost, opens a loophole that will allow manufacturers and contractors to evade the domestic content requirements through creative accounting practices.

Response: The Councils reiterate that basing the predominance on cost, rather than weight or volume, is consistent with the requirement of the E.O. that the ''cost'' of foreign iron and steel be limited to less than 5 percent of the ''cost'' of all components. Therefore, the final rule remains unchanged regarding the basis for determining whether an item is predominantly of iron or steel.

Comment: One respondent stated that the proposed rule's definition of ''fasteners'' was overly broad and by exempting fasteners from the domestic content requirements, the rule creates an opportunity for abuse of this ''loophole.'' The respondent requested the definition of ''fasteners'' be modified to reflect the qualifiers the Councils provided in the proposed rule, *i.e.,* that the fasteners being exempted were those that were ''small'' or ''inexpensive.''

Response: The Councils have clarified the text in the final rule to state that the fasteners being exempted from the domestic content requirement are those that are COTS items.

Comment: One respondent stated that requiring iron and steel products to contain 95 percent domestic content is too onerous and burdensome on manufacturers. The respondent commented that the 95 percent requirement should be reduced or phased in over time. Alternatively, the respondent also suggested that in determining whether a predominantly of iron or steel product is domestic, manufacturers should be allowed to use the cost of non-iron and non-steel components of the item; this way, manufacturers can mitigate the 95 percent requirement, while still incentivizing domestic purchase of non-steel components. Another respondent had a similar comment, pointing out that the Environmental Protection Agency allows for 5 percent of the total ''project'' cost to be foreign iron and steel products instead of 5 percent of the total cost of the individual product.

Response: This FAR change is required to implement E.O. 13881, which increased the domestic content requirement for iron and steel end products to 95 percent. However, the Councils note that the proposed rule presented the requirement as whether 5 percent of the cost of all the components was foreign iron or steel, not whether 5 percent of the cost of only the iron or steel components were foreign iron or steel; thereby, giving credit to the non-iron and non-steel components of the end item as requested by the respondent.

Comment: One respondent stated their interpretation that the proposed rule encompassed steel subcomponents, not just steel components. Due to lack of visibility into the cost of these steel subcomponents by manufacturers, the respondent requested the rule consider exempting the cost of subcomponents from the calculations. Another respondent had a similar comment, pointing out that the Federal Transit Administration's policy explicitly exempts subcomponents from country-of-origin consideration, including iron and steel components.

Response: The Councils confirm that the intent of the proposed rule was to include the cost of subcomponents in the domestic content calculations. However, the Councils did not add ''subcomponents'' in the FAR text because the definition of ''components'' at FAR 25.003 is written broadly enough to already cover subcomponents. In acknowledging the difficulty contractors may have to know, definitively, the cost of all subcomponents in iron or steel items, the Councils clarify in the final rule that contractors are to make a ''good faith estimate'' of the cost of all foreign iron or steel components, other than the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product.

4. Outside the Scope of This Rule

Comment: Two respondents provided comments regarding marketing their specific businesses, and two respondents provided comments of a political nature.

Response: These comments did not address the rule and, as such, are outside the scope of this rule.

Comment: One respondent recommended that if no domestic offers are received on an acquisition conducted using full and open competition, then the procurement officer should confirm with at least two

other manufacturers within the same NAICS code their non-interest in the procurement.

Response: The Councils concluded the recommendation would add a significant burden on contracting officers, and is not necessary for implementation of the E.O.

Comment: One respondent recommended defining ''manufactured'' and adopting a clear non-shift approach to the items specified in the procurement document for all purchases (aside from systems).

Response: This recommendation is not necessary for implementation of the E.O. The Councils note that definitions of ''manufacture'' have been considered in the past and rejected. Although the FAR does not define ''manufacture,'' it does define ''place of manufacture,'' at FAR 52.225–18, as ''the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government.''

Comment: One respondent recommended removing the Buy American statute's exception for ''Goods for Use Outside the United States'' and using an evaluation factor instead.

Response: The exception for articles, materials, or supplies for use outside the United States is included in the Buy American statute (41 U.S.C. 8302(a)(2)(A) and 8303(b)(1)(A)).

The Balance of Payments Program provided a preference for U.S. products and services for overseas use, and its restrictions were similar to the restrictions of the Buy American statute, which apply only within the United States. Purchases of supplies for use outside the United States, and construction materials for construction contracts performed outside the United States, were covered by the Balance of Payments Program in FAR subpart 25.3, as a matter of policy, until it was removed in 2002. Only a few civilian agencies make purchases for use outside the United States. Furthermore, even fewer civilian agencies award construction contracts that are performed outside the United States. The Balance of Payments Program applied to purchases valued at more than the simplified acquisition threshold and had little impact for civilian agency acquisitions of supplies in excess of the Trade Agreements Act threshold, because the civilian agencies do not apply the Balance of Payments Program when the Trade Agreements Act applies. Therefore, because there was no statutory requirement for the Balance of Payments Program, and because elimination of this Program for civilian agencies would reduce administrative burdens on both the Government and the public, without significant impact on the Government's international balance of payments, the Balance of Payments Program was eliminated for civilian agencies. The rationale for elimination of this Program for civilian agencies has not changed. Note that DoD has retained the Balance of Payments Program for acquisitions of supplies for use outside the United States or construction projects to be performed overseas.

5. Oppose the Rule

Comment: Some respondents urged the Councils not to increase the iron and steel content requirements beyond their current levels because of the limited availability of U.S. sources for components, which will result in increased costs and a decrease in competition. Some of these respondents also stated that Buying American should be an incentive, not a requirement.

Response: This FAR change implements the content requirements established in E.O. 13881.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This final rule does not add any new provisions or clauses, nor change the applicability of existing provisions or clauses, to contracts at or below the SAT and contracts for the acquisition of commercial items, including COTS items.

However, this rule applies the domestic content test of the Buy American statute, as implemented by E.O. 13881, to COTS items that consist wholly or predominantly of iron or steel (excluding COTS fasteners). In accordance with 41 U.S.C. 1907, since 2008, the domestic content test of the Buy American statute has been waived for COTS items, in part due to the complexity and cost of keeping track of components in a world of global sourcing where the Government is not a market driver. But absent restoration of the domestic content test, the E.O. 13881 requirement regarding iron and steel construction material would have very little effect. As such, the Administrator for Federal Procurement Policy has determined that it would not be in the best interest of the Federal Government to exempt iron and steel products (excluding COTS fasteners) that are COTS items from the applicability of the content test for foreign iron and steel under the Buy American statute.

The domestic content waiver for COTS items would continue to apply to COTS iron and steel fasteners, such as nuts, bolts, pins, rivets, nails, clips, and screws, which are generally so small, inexpensive, and comingled that trying to keep track of the origin of all fasteners would create an administrative burden on offerors that would outweigh any benefit to the American iron and steel industrial base.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a significant regulatory action and, therefore, was not subject to the review of the Office of Information and Regulatory Affairs under section 6(b) of E.O. 12866. This rule is not a major rule under 5 U.S.C. 804.

V. Expected Impact of the Final Rule

The FAR clauses implementing the Buy American statute apply to a narrow set of procurements. Also, because the FAR Council is leaving the COTS items exception in place for most COTS items, the heightened domestic content requirements will not be applicable to those procurements.

With this rule's implementation, domestic industries supplying domestic end products are likely to benefit from a competitive advantage. Based on the E.O., it is unclear if the pool of qualified suppliers would be reduced, resulting in less competition (and a possible increase in prices that the Government will pay to procure these products).

At least three arguments point to the possibility that any increased burden, on contractors in particular, could be small if not *de minimis:* (1) Familiarization costs should be low; (2) some, if not many, contractors may already be able to meet the more stringent threshold; and (3) costs incurred by contractors that adjust their supply chains so that their end products qualify as domestic will enjoy a larger price preference that should help to offset these costs over time. Each of these arguments is explained below.

First, DoD, GSA, and NASA do not anticipate significant costs from contractors' familiarization with this

rule given the history of rulemaking and E.O.s in this area. The basic mechanics of the Buy American statute (*e.g.,* definitions, how and when the price preference is used to favor domestic end products, certifications required of offerors to demonstrate end products are domestic) remain unchanged and continue to reflect processes that are decades old.

Second, some, if not many, contractors may already be able to comply with the lower foreign content requirement needed to meet the definition of ''domestic end product'' under E.O. 13881 and this rule. Laws such as the SECURE Technology Act, Public Law 115–390, which requires a series of actions to strengthen the Federal infrastructure for managing supply chain risks, are placing a significantly increased emphasis on Federal agencies and Federal Government contractors to identify and reduce risk in their supply chains. One way to reduce supply chain risk is to increase domestic sourcing of content. In addition, in the context of iron and steel, many existing laws already require more stringent content. For example, the Recovery Act required that all construction material for a project for the construction, alteration, maintenance, or repair of a public building or a public work in the United States, consisting wholly or predominantly of iron or steel, had to be produced in the United States when using Recovery Act funds, to the extent consistent with trade agreements (see FAR 25.602–1, implementing section 1605 of the Recovery Act). In addition, Federal contractors who also work on subawards funded under Federal grants may, in some cases, find that the steel, iron, and manufactured goods used in the project be produced in the United States, as is the case for certain funding administrated by the Federal Transit Administration for public transportation projects (see 49 U.S.C. 5323(j)). Accordingly, it is possible that the Federal market for iron and steel has already done significant retooling and could meet the requirements of E.O. 13881 with minor additional effort.

Third, it is anticipated that some contractors' products and construction materials may not meet the definitions of ''domestic construction material,'' and ''domestic end product'' unless the contractors take steps to adjust their supply chains to increase the domestic content. Contractors that make a business decision not to modify their supply chains will still be able to propose in response to Federal contract solicitations but will no longer enjoy a price preference. Contractors that sell to civilian agencies and retool their supply sources to meet the more stringent threshold will have a more generous price preference applied to their products. These stronger preferences, which are designed as an incentive to encourage more domestic sourcing, may help to offset costs of meeting the new standards.

This rule has the potential to slightly increase the estimated percentage of foreign offers. It can only impact products that are made in the United States as follows: Iron or steel products where the cost of foreign iron and steel is 5 percent or more of the cost of all components in the product; or other products, other than COTS items, that have a content of 45 to 50 percent foreign components. Offerors of such products have an option to increase the domestic content and continue to offer domestic products, in which case they may benefit from the increased preference for domestic products, or they may continue to offer the same product, which will now be evaluated as foreign. The Councils do not have any data on how many currently domestic products would fall into this category. Nor do the Councils have any knowledge as to which option an offeror of such products would select since this is a business decision for each offeror to make. Regarding the increased price preference for domestic offers, the Councils note that robust competition among vendors offering domestic products will decrease the extent to which the Government could pay an additional 20 to 30 percent for domestic products above and beyond the cost of otherwise equivalent foreign products.

Therefore, based on public comments received, DoD, GSA, and NASA have concluded that the initial assessment is correct that the cost impact of this rule is not significant, and any impact is predominantly positive.

VI. Executive Order 13771

This rule is not subject to E.O. 13771, Reducing Regulation and Controlling Regulatory Costs, because this rule has a *de minimis* impact on the public (see section V. of this preamble).

VII. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule strengthens domestic preferences under the Buy American statute by making adjustments to the required percentage of domestic content and the existing percentages for the price evaluation preferences in an effort to decrease the amount of foreign-sourced content in a U.S. manufactured product to promote economic and national security, help stimulate economic growth, and create jobs. The objective of this rule is to implement E.O. 13881, Maximizing Use of American-Made Goods, Products, and Materials (84 FR 34257, July 18, 2019).

There were no significant issues raised by the public comments in response to the initial regulatory flexibility analysis.

DoD, GSA, and NASA examined data from the Federal Procurement Data System for fiscal years (FY) 2017, 2018, and 2019, for new awards with a foreign place of performance for construction valued over the micro-purchase threshold and awards for supplies to unique small businesses. This rule will apply to only the 8 percent of foreign construction awards that were made to small businesses, and only 14 percent of foreign supply awards were made to small businesses.

Buy american statute	FY 2017	FY 2018	FY 2019	Median
	SB/total	SB/total	SB/total	SB (%)
Construction	18/217 = 8%	13/223 = 6%	15/199 = 8%	8
Supplies	153/1,200 = 13%	164/1,161 = 14%	164/1,048 = 16%	14

This rule is covered under the existing information collection requirements associated with the Buy American statute. The rule will strengthen domestic preferences under the Buy American statute and provide small businesses the opportunity and incentive to deliver U.S. manufactured products from domestic suppliers. It is expected that this rule will benefit U.S. small business manufacturers, including those of iron or steel.

There are no available alternatives to the rule to accomplish the desired objective of the statute.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory

Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply; however, these changes to the FAR do not impose additional information collection requirements to the paperwork burden previously approved under the Office of Management and Budget Control Number 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry.

List of Subjects in 48 CFR Parts 12, 25, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 12, 25, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 12, 25, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 12—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 12.505 by revising paragraph (a) to read as follows:

12.505 Applicability of certain laws to contracts for the acquisition of COTS items.

* * * * *

(a)(1) The portion of 41 U.S.C. 8302, American Materials Required for Public Use, paragraph (a)(1) that reads ''substantially all from articles, materials, or supplies mined, produced, or manufactured in the United States,'' Buy American—Supplies, domestic content test, except as provided in 25.101(a)(2)(ii) (see 52.225–1 and 52.225–3).

(2) The portion of 41 U.S.C. 8303, Contracts for Public Works, paragraph (a)(2) that reads ''substantially all from articles, materials, or supplies mined, produced, or manufactured in the United States,'' Buy American—Construction Materials, domestic content test, except as provided in 25.201(b)(2)(ii)(see 52.225–9 and 52.225–11).

* * * * *

PART 25—FOREIGN ACQUISITION

■ 3. Amend section 25.001 by revising paragraph (c)(1) to read as follows:

25.001 General.

* * * * *

(c) * * *

(1) The Buy American statute uses a two-part test to define a ''domestic end product'' or ''domestic construction material'' (manufactured in the United States and a domestic content test). The domestic content test has been waived for acquisition of commercially available off-the-shelf (COTS) items, except a product that consists wholly or predominantly of iron or steel or a combination of both (excluding COTS fasteners) (see 25.101(a) and 25.201(b)).

* * * * *

■ 4. Amend section 25.003 by—

■ a. Revising the definitions ''Domestic construction material'' and ''Domestic end product''; and

■ b. Adding in alphabetical order the definitions ''Fastener'', ''Foreign iron and steel'', ''Predominantly of iron or steel or a combination of both'', and ''Steel''.

The revisions and additions read as follows:

25.003 Definitions.

* * * * *

Domestic construction material means—

(1) For use in subparts other than 25.6—

(i) For construction material that does not consist wholly or predominantly of iron or steel or a combination of both—

(A) An unmanufactured construction material mined or produced in the United States; or

(B) A construction material manufactured in the United States, if—

(*1*) The cost of the components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic. Components of unknown origin are treated as foreign; or

(*2*) The construction material is a commercially available off-the-shelf (COTS) item; or

(ii) For construction material that consists wholly or predominantly of iron or steel or a combination of both, a construction material manufactured in the United States if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all the components used in such construction material. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the construction material contains multiple components, the cost of all the materials used in such construction material is calculated in accordance with the definition of ''cost of components'' in this section; or

(2) For use in subpart 25.6, see the definition in 25.601.

Domestic end product means—

(1) For an end product that does not consist wholly or predominantly of iron or steel or a combination of both—

(i) An unmanufactured end product mined or produced in the United States;

(ii) An end product manufactured in the United States, if—

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind as those that the agency determines are not mined, produced, or manufactured in sufficient and reasonably available commercial quantities of a satisfactory quality are treated as domestic. Components of unknown origin are treated as foreign. Scrap generated, collected, and prepared for processing in the United States is considered domestic; or

(B) The end product is a COTS item; or

(2) For an end product that consists wholly or predominantly of iron or steel or a combination of both, an end product manufactured in the United States, if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all the components used in the end product. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the end product and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the end product contains multiple components, the cost of all the materials used in such end product is calculated in accordance with the definition of ''cost of components'' in this section.

* * * * *

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

* * * * *

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

* * * * *

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

* * * * *

■ 5. Amend section 25.100 by—
■ a. Removing from the end of paragraph (a)(2) ''and'';
■ b. Redesignating paragraph (a)(3) as paragraph (a)(4);
■ c. Adding a new paragraph (a)(3); and
■ d. Revising the newly redesignated paragraph (a)(4).

The addition and revision read as follows:

25.100 Scope of subpart.

(a) * * *

(3) Executive Order 13881, July 15, 2019; and

(4) Waiver of the domestic content test of the Buy American statute for acquisition of commercially available off-the-shelf (COTS) items in accordance with 41 U.S.C. 1907, but see 25.101(a)(2)(ii).

* * * * *

■ 6. Amend section 25.101 by—
■ a. Removing from paragraph (a) introductory text ''statute uses'' and adding ''statute and E.O. 13881 use'' in its place;
■ b. Revising paragraph (a)(2);
■ c. Removing from paragraph (b) ''component test'' and adding ''domestic content test'' in its place; and
■ d. Removing from paragraph (c) ''Subpart 25.5'' and adding ''subpart 25.5'' in its place.

The revision reads as follows:

25.101 General.

(a) * * *

(2)(i) Except for an end product that consists wholly or predominantly of iron or steel or a combination of both, the cost of domestic components must exceed 55 percent of the cost of all the components. In accordance with 41 U.S.C. 1907, this domestic content test of the Buy American statute has been waived for acquisitions of COTS items (see 12.505(a)) (but see paragraph (a)(2)(ii) of this section).

(ii) For an end product that consists wholly or predominantly of iron or steel or a combination of both, the cost of foreign iron and steel must constitute less than 5 percent of the cost of all the components used in the end product (see the definition of ''foreign iron and steel'' at 25.003). The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the end product and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. This domestic content test of the Buy American statute has not been waived for acquisitions of COTS items in this category, except for COTS fasteners.

* * * * *

25.105 [Amended]

■ 7. Amend section 25.105 by—
■ a. Removing from paragraph (b)(1) ''6 percent'' and adding ''20 percent'' in its place; and
■ b. Removing from paragraph (b)(2) ''12 percent'' and ''Subpart 19.5'' and adding ''30 percent'' and ''subpart 19.5'' in their places, respectively.

■ 8. Amend section 25.200 by—
■ a. Removing from the end of paragraph (a)(2) ''and'';
■ b. Redesignating paragraph (a)(3) as paragraph (a)(4);
■ c. Adding a new paragraph (a)(3); and
■ d. Revising the newly redesignated paragraph (a)(4).

The addition and revision read as follows:

25.200 Scope of subpart.

(a) * * *

(3) Executive Order 13881, July 15, 2019; and

(4) Waiver of the domestic content test of the Buy American statute for acquisitions of commercially available off-the-shelf (COTS) items in accordance with 41 U.S.C. 1907, but see 25.201(b)(2)(ii).

* * * * *

■ 9. Revise section 25.201 to read as follows:

25.201 Policy.

(a) Except as provided in 25.202, use only domestic construction materials in construction contracts performed in the United States.

(b) The Buy American statute restricts the purchase of construction materials that are not domestic construction materials. For manufactured construction materials, the Buy American statute and E.O. 13881 use a two-part test to define domestic construction materials.

(1) The article must be manufactured in the United States; and

(2)(i) Except for construction material that consists wholly or predominantly of iron or steel or a combination of both, the cost of domestic components must exceed 55 percent of the cost of all the components. In accordance with 41 U.S.C. 1907, this domestic content test of the Buy American statute has been waived for acquisitions of COTS items (see 12.505(a)).

(ii) For construction material that consists wholly or predominantly of iron or steel or a combination of both, the cost of foreign iron and steel must constitute less than 5 percent of the cost of all the components used in such construction material (see the definition of ''foreign iron and steel'' at 25.003). The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. This domestic content test of the Buy American statute has not been waived for acquisitions of COTS items in this category, except for COTS fasteners.

25.204 [Amended]

■ 10. Amend section 25.204 in paragraph (b) by removing ''6 percent'' and adding ''20 percent'' in its place.

■ 11. Amend section 25.504–1 by—
■ a. Revising the table in paragraph (a)(1);
■ b. Removing from paragraph (a)(2) ''12 percent'' and ''$11,200'' and adding ''30 percent'' and ''$13,000'' in their places, respectively; and
■ c. Removing from paragraph (b)(2) ''12 percent'' and ''$11,424'' and adding ''30 percent'' and ''$13,260'' in their places, respectively.

The revision reads as follows:

25.504–1 Buy American statute.

(a)(1) * * *

Offer A	$16,000	Domestic end product, small business.

Offer B	$15,700	Domestic end product, small business.
Offer C	$10,000	U.S.-made end product (not domestic), small business.

* * * * *

■ 12. Amend section 25.504–2 by revising the table to read as follows:

25.504–2 WTO GPA/Caribbean Basin Trade Initiative/FTAs.

* * * * *

Offer A	$304,000	U.S.-made end product (not domestic).
Offer B	$303,000	U.S.-made end product (domestic), small business.
Offer C	$300,000	Eligible product.
Offer D	$295,000	Noneligible product (not U.S.-made).

* * * * *

■ 13. Amend section 25.504–3 by—

■ a. Revising the entry ''Offer B'' in the table in paragraph (a);

■ b. Revising the entry ''Offer B'' in the table in paragraph (b); and

■ c. Revising entries ''Offer B'' and ''Offer C'' in the table in paragraph (c).

The revisions read as follows:

25.504–3 FTA/Israeli Trade Act.

(a) * * *

* * * * *

Offer B	$100,000	Eligible product.

* * * * *

(b) * * *

* * * * *

Offer B	$103,000	Noneligible product.

* * * * *

(c) * * *

* * * * *

Offer B	$103,000	Eligible product.
Offer C	100,000	Noneligible product.

* * * * *

■ 14. Amend section 25.504–4 by—

■ a. In paragraph (a)—

■ i. Revising the table;

■ ii. In STEP 1, Items 3 and 5, removing ''6 percent'' and adding ''20 percent'' in their places, respectively; and

■ iii. Revising STEP 2 and 3.

■ b. Revising paragraph (b).

The revisions read as follows:

25.504–4 Group award basis.

(a) * * *

Item	Offers		
	A	B	C
1	DO = $55,000	EL = $56,000	NEL = $50,000
2	NEL = 13,000	EL = 10,000	EL = 13,000
3	NEL = 11,500	DO = 12,000	DO = 10,000
4	NEL = 24,000	EL = 28,000	NEL = 22,000
5	DO = 18,000	NEL = 10,000	DO = 14,000
Total	121,500	116,000	109,000

* * * * *

STEP 2: Evaluate Offer C against the tentative award pattern for Offers A and B:

Item	Offers		
	Low offer	Tentative award pattern from A and B	C
1	A	DO = $55,000	*NEL = $60,000
2	B	EL = 10,000	EL = 13,000
3	B	DO = 12,000	DO = 10,000
4	A	NEL = 24,000	NEL = 22,000
5	B	*NEL = 12,000	DO = 14,000
Total		113,000	119,000

* Offer + 20 percent.

On a line item basis, apply a factor to any noneligible offer if the other offer for that line item is domestic.

For Item 1, apply a factor to Offer C because Offer A is domestic and the acquisition was not covered by the WTO GPA. The evaluated price of Offer C, Item 1, becomes $60,000 ($50,000 plus 20 percent). Apply a factor to Offer B, Item 5, because it is a noneligible product and Offer C is domestic. The evaluated price of Offer B is $12,000 ($10,000 plus 20 percent). Evaluate the remaining items without applying a factor.

STEP 3: The tentative unrestricted award pattern from Offers A and B is lower than the evaluated price of Offer C. Award the combination of Offers A and B. Note that if Offer C had not specified all-or-none award, award would be made on Offer C for line items 3 and 4, totaling an award of $32,000.

(b) *Example 2.*

Item	Offers		
	A	B	C
1	DO = $50,000	EL = $50,500	NEL = $50,000

Item	Offers		
	A	B	C
2	NEL = 10,300	NEL = 10,000	EL = 10,200
3	EL = 20,400	EL = 21,000	NEL = 20,200
4	DO = 10,500	DO = 10,300	DO = 10,400
Total	91,200	91,800	90,800

Problem: The solicitation specifies award on a group basis. Assume the Buy American statute applies and the acquisition cannot be set aside for small business concerns. All offerors are large businesses.

Analysis: (see 25.503(c))

STEP 1: Determine which of the offers are domestic (see 25.503(c)(1)):

	Domestic (percent)	Determination
A	$50,000 (Offer A1) + $10,500 (Offer A4) = $60,500	Domestic.
	$60,500/$91,200 (Offer A Total) = 66.3%	
B	$10,300 (Offer B4)/$91,800 (Offer B Total) $ = 11.2%	Foreign.
C	$10,400 (Offer C4)/$90,800 (Offer C Total) = 11.5%	Foreign.

STEP 2: Determine whether foreign offers are eligible or noneligible offers (see 25.503(c)(2)):

	Domestic + eligible (percent)	Determination
A	N/A (Both Domestic)	Domestic.
B	$50,500 (Offer B1) + $21,000 (Offer B3) + $10,300 (Offer B4) = $81,800	Eligible.
	$81,800/$91,800 (Offer B Total) = 89.1%	
C	$10,200 (Offer C2) + $10,400 (Offer C4) = $20,600	Noneligible.
	$20,600/$90,800 (Offer C Total) = 22.7%	

STEP 3: Determine whether to apply an evaluation factor (see 25.503(c)(3)). The low offer (Offer C) is a foreign offer. There is no eligible offer lower than the domestic offer. Therefore, apply the factor to the low offer. Addition of the 20 percent factor (use 30 percent if Offer A is a small business) to Offer C yields an evaluated price of $108,960 ($90,800 + 20 percent). Award on Offer A (see 25.502(c)(4)(ii)). Note that, if Offer A were greater than Offer B, an evaluation factor would not be applied, and award would be on Offer C (see 25.502(c)(3)).

25.601 [Amended]

■ 15. Amend section 25.601 by removing the definition ''Steel''.

25.604 [Amended]

■ 16. Amend section 25.604 in paragraph (c)(2) by removing ''6 percent'' and adding ''20 percent'' in its place.

25.605 [Amended]

■ 17. Amend section 25.605 by—

■ a. Removing from paragraph (a)(2) ''6 percent'' and adding ''20 percent'' in its place; and

■ b. Removing from paragraph (a)(3) ''.06'' and adding ''.20'' in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 18. Amend section 52.212–3 by—

■ a. Revising the date of the provision; and

■ b. Revising paragraphs (f)(1), (g)(1)(i), the first sentence of (g)(1)(ii), and (g)(1)(iii) introductory text.

The revisions read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offeror Representations and Certifications—Commercial Items (Jan 2021)

* * * * *

(f) * * *

(1)(i) The Offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product.

(ii) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(iii) The terms ''domestic end product,'' ''end product,'' ''foreign end product,'' and ''United States'' are defined in the clause of this solicitation entitled ''Buy American-Supplies.''

* * * * *

(g)(1) * * *

(i)(A) The Offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (iii) of this provision, is a domestic end product.

(B) The terms ''Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product,'' ''domestic end product,'' ''end product,'' ''foreign end product,'' ''Free Trade Agreement country,'' ''Free Trade Agreement country end product,'' ''Israeli end product,'' and ''United States'' are defined in the clause of this solicitation entitled ''Buy American—Free Trade Agreements—Israeli Trade Act.''

(ii) The Offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled ''Buy American—Free Trade Agreements—Israeli Trade Act.''

* * * * *

(iii) The Offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled ''Buy American—Free Trade Agreements—Israeli Trade Act.'' The Offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

* * * * *

■ 19. Amend section 52.212–5 by—

■ a. Revising the date of the clause; and
■ b. Removing from paragraphs (b)(48) and (b)(49)(i) through (iv) ''(MAY 2014)'' and adding ''(JAN 2021)'' in their places, respectively.

The revision reads as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (Jan 2021)

* * * * *

■ 20. Amend section 52.213–4 by—
■ a. Revising the date of the clause; and
■ b. Removing from paragraph (b)(1)(xvii) introductory text ''(MAY 2014)'' and adding ''(JAN 2021)'' in its place.

The revision reads as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (Jan 2021)

* * * * *

■ 21. Amend section 52.225–1 by—
■ a. Revising the date of the clause;
■ b. In paragraph (a):
■ i. Removing from paragraph (1)(i) in the definition ''Commercially available off-the-shelf (COTS) item'' ''FAR'' and adding ''Federal Acquisition Regulation (FAR)'' in its place;
■ ii. Revising the definition ''*Domestic end product*'';
■ iii. Adding in alphabetical order the definitions ''*Fastener*'' ''*Foreign iron and steel*'' ''*Predominantly of iron or steel or a combination of both*'' and ''*Steel*''; and
■ c. Revising paragraph (b).

The revisions and additions read as follows:

52.225–1 Buy American—Supplies.

* * * * *

Buy American—Supplies (Jan 2021)

(a) * * *

Domestic end product means—

(1) For an end product that does not consist wholly or predominantly of iron or steel or a combination of both—

(i) An unmanufactured end product mined or produced in the United States;

(ii) An end product manufactured in the United States, if—

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind as those that the agency determines are not mined, produced, or manufactured in sufficient and reasonably available commercial quantities of a satisfactory quality are treated as domestic. Components of unknown origin are treated as foreign. Scrap generated, collected, and prepared for processing in the United States is considered domestic; or

(B) The end product is a COTS item; or

(2) For an end product that consists wholly or predominantly of iron or steel or a combination of both, an end product manufactured in the United States, if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all the components used in the end product. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the end product and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the end product contains multiple components, the cost of all the materials used in such end product is calculated in accordance with the definition of ''cost of components''.

* * * * *

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

* * * * *

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

* * * * *

(b) 41 U.S.C. chapter 83, Buy American, provides a preference for domestic end products for supplies acquired for use in the United States. In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for an end product that is a COTS item (see 12.505(a)(1)), except that for an end product that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the end product, excluding COTS fasteners.

* * * * *

■ 22. Amend section 52.225–2 by—
■ a. Revising the date of the provision and paragraphs (a) and (b);
■ b. Removing from paragraph (c) ''Part'' and adding ''part'' in its place.

The revisions read as follows:

52.225–2 Buy American Certificate.

* * * * *

Buy American Certificate (Jan 2021)

(a)(1) The Offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product.

(2) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(3) The terms ''domestic end product,'' ''end product,'' and ''foreign end product'' are defined in the clause of this solicitation entitled ''Buy American—Supplies.''

(b) Foreign End Products:

Line item No.	Country of origin

[*List as necessary.*]

* * * * *

■ 23. Amend section 52.225–3 by—
■ a. Revising the date of the clause;
■ b. In paragraph (a):
■ i. Removing from paragraph (1)(i) in the definition ''Commercially available off-the-shelf (COTS) item'' ''FAR'' and adding ''Federal Acquisition Regulation (FAR)'' in its place;
■ ii. Revising the definition ''*Domestic end product*''; and
■ iii. Adding in alphabetical order the definitions ''*Fastener*'' ''*Foreign iron and* steel'' ''*Predominantly of iron or steel or a combination of both*'' and ''*Steel*'';
■ c. Revising the second sentence of paragraph (c);
■ d. Revising the date in the introductory text and the second sentence of paragraph (c) of Alternate I;
■ e. Revising the date in the introductory text and the second sentence of paragraph (c) of Alternate II and adding a period to the end of paragraph (c); and
■ f. Revising the date in the introductory text and the second sentence of paragraph (c) of Alternate III.

The revisions and additions read as follows:

52.225–3 Buy American—Free Trade Agreements—Israeli Trade Act.

* * * * *

Buy American—Free Trade Agreements—Israeli Trade Act (Jan 2021)

(a) * * *

Domestic end product means—

(1) For an end product that does not consist wholly or predominantly of iron or steel or a combination of both—

(i) An unmanufactured end product mined or produced in the United States;

(ii) An end product manufactured in the United States, if—

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind as those that the agency determines are not mined, produced, or manufactured in sufficient and reasonably available commercial quantities of a satisfactory quality are treated as domestic. Components of unknown origin are treated as foreign. Scrap generated, collected, and prepared for processing in the United States is considered domestic; or

(B) The end product is a COTS item; or

(2) For an end product that consists wholly or predominantly of iron or steel or a combination of both, an end product manufactured in the United States, if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all the components used in the end product. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the end product and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the end product contains multiple components, the cost of all the materials used in such end product is calculated in accordance with the definition of ''cost of components''.

* * * * *

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

* * * * *

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

* * * * *

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

* * * * *

(c) * * * In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for an end product that is a COTS item (see 12.505(a)(1)), except that for an end product that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the end product, excluding COTS fasteners. * * *

Alternate I (Jan 2021) * * *

(c) * * * In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for an end product that is a COTS item (see 12.505(a)(1)), except that for an end product that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the end product, excluding COTS fasteners. * * *

Alternate II (Jan 2021) * * *

(c) * * * In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for an end product that is a COTS item (see 12.505(a)(1)), except that for an end product that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the end product, excluding COTS fasteners. * * *

Alternate III (Jan 2021) * * *

(c) * * * In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for an end product that is a COTS item (see 12.505(a)(1)), except that for an end product that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the end product, excluding COTS fasteners. * * *

■ 24. Amend section 52.225–4 by—

■ a. Revising the date of the provision;

■ b. Revising paragraph (a);

■ c. In paragraph (b) introductory text removing ''offeror'' and adding ''Offeror'' in its place;

■ d. Revising the first and second sentences of paragraph (c);

■ e. Removing from paragraph (d) ''Part'' and adding ''part'' in its place;

■ f. In Alternate I by—

■ i. Revising the date of the Alternate; and

■ ii. Removing from paragraph (b) introductory text ''offeror'' and adding ''Offeror'' in its place;

■ g. In Alternate II by—

■ i. Revising the date of the Alternate; and

■ ii. Removing from paragraph (b) introductory text ''offeror'' and adding ''Offeror'' in its place; and

■ h. In Alternate III by—

■ i. Revising the date of the Alternate; and

■ ii. Removing from paragraph (b) introductory text ''offeror'' and adding ''Offeror'' in its place, and removing from the second paragraph of (b) ''Products (Other'' and adding ''Products (other'' in its place.

The revisions read as follows:

52.225–4 Buy American—Free Trade Agreements—Israeli Trade Act Certificate.

* * * * *

Buy American—Free Trade Agreements—Israeli Trade Act Certificate (Jan 2021)

(a)(1) The Offeror certifies that each end product, except those listed in paragraph (b) or (c) of this provision, is a domestic end product.

(2) The terms ''Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product,'' ''domestic end product,'' ''end product,'' ''foreign end product,'' ''Free Trade Agreement country,'' ''Free Trade Agreement country end product,'' ''Israeli end product,'' and ''United States'' are defined in the clause of this solicitation entitled ''Buy American—Free Trade Agreements—Israeli Trade Act.''

* * * * *

(c) The Offeror shall list those supplies that are foreign end products (other than those listed in paragraph (b) of this provision) as defined in the clause of this solicitation entitled ''Buy American—Free Trade Agreements—Israeli Trade Act.'' The Offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

* * * * *

Alternate I (Jan 2021) * * *

Alternate II (Jan 2021) * * *

Alternate III (Jan 2021) * * *

■ 25. Amend section 52.225–9 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a):

■ i. Removing from paragraph (1)(i) in the definition ''Commercially available off-the-shelf (COTS) item'' ''FAR'' and adding ''Federal Acquisition Regulation (FAR)'' in its place;

■ ii. Revising the definition ''*Domestic construction material*''; and

■ iii. Adding in alphabetical order the definitions ''*Fastener*'' ''*Foreign iron and steel*'' ''*Predominantly of iron or steel or a combination of both*'' and ''*Steel*'';

■ c. Revising paragraph (b)(1);

■ d. Removing from paragraph (b)(3)(i) ''6 percent'' and adding ''20 percent'' in its place; and

■ e. Revising paragraph (d).

The revisions and additions read as follows:

52.225–9 Buy American—Construction Materials.

* * * * *

Buy American—Construction Materials (Jan 2021)

(a) * * *

Domestic construction material means—

(1) For construction material that does not consist wholly or predominantly of iron or steel or a combination of both—

(i) An unmanufactured construction material mined or produced in the United States; or

(ii) A construction material manufactured in the United States, if—

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic. Components of unknown origin are treated as foreign; or

(B) The construction material is a COTS item; or

(2) For construction material that consists wholly or predominantly of iron or steel or a combination of both, a construction material manufactured in the United States if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all components used in such construction material. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the construction material contains multiple components, the cost of all the materials used in such construction material is calculated in accordance with the definition of ''cost of components''.

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

* * * * *

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

* * * * *

(b) * * * (1) This clause implements 41 U.S.C. chapter 83, Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction materials, excluding COTS fasteners. (See FAR 12.505(a)(2)). The Contractor shall use only domestic construction material in performing this contract, except as provided in paragraphs (b)(2) and (b)(3) of this clause.

* * * * *

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON

Construction material description	Unit of measure	Quantity	Price (dollars) *
Item 1:			
Foreign construction material.			
Domestic construction material.			
Item 2:			
Foreign construction material.			
Domestic construction material.			

[Include all delivery costs to the construction site and any applicable duty (whether or not a duty-free entry certificate is issued)].*
[List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.]
[Include other applicable supporting information.]

(End of clause)

■ 26. Amend section 52.225–11 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a):

■ i. Removing from paragraph (1)(i) in the definition ''Commercially available off-the-shelf (COTS) item'' ''FAR'' and adding ''Federal Acquisition Regulation (FAR)'' in its place;

■ ii. Revising the definition ''*Domestic construction material*'';

■ iii. Adding in alphabetical order the definitions ''*Fastener*'' ''*Foreign iron and* steel'' ''*Predominantly of iron or steel or a combination of both*'' and ''*Steel*'';

■ c. Revising paragraph (b)(1);

■ d. Removing from paragraph (b)(4)(i) ''6 percent'' and adding ''20 percent'' in its place;

■ e. Revising paragraph (d);

■ f. In Alternate I—

■ i. Revising the date of the Alternate; and

■ ii. Revising paragraph (b)(1).

The revisions and additions read as follows:

52.225–11 Buy American—Construction Materials Under Trade Agreements.

* * * * *

Buy American—Construction Materials Under Trade Agreements (Jan 2021)

(a) * * *

Domestic construction material means—

(1) For construction material that does not consist wholly or predominantly of iron or steel or a combination of both—

(i) An unmanufactured construction material mined or produced in the United States; or

(ii) A construction material manufactured in the United States, if—

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic. Components of unknown origin are treated as foreign; or

(B) The construction material is a COTS item; or

(2) For construction material that consists wholly or predominantly of iron or steel or a combination of both, a construction material manufactured in the United States if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all components used in such construction material. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the

construction material contains multiple components, the cost of all the materials used in such construction material is calculated in accordance with the definition of ''cost of components''.

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

* * * * *

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

* * * * *

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

* * * * *

(b) * * * (1) This clause implements 41 U.S.C. chapter 83, Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction material, excluding COTS fasteners. (See FAR 12.505(a)(2)). In addition, the Contracting Officer has determined that the WTO GPA and Free Trade Agreements (FTAs) apply to this acquisition. Therefore, the Buy American restrictions are waived for designated country construction materials.

* * * * *

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON

Construction material description	Unit of measure	Quantity	Price (dollars) *
Item 1:			
Foreign construction material.			
Domestic construction material.			
Item 2:			
Foreign construction material.			
Domestic construction material.			

[Include all delivery costs to the construction site and any applicable duty (whether or not a duty-free entry certificate is issued)].*
[List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.]
[Include other applicable supporting information.]

(End of clause)

Alternate I (Jan 2021) * * *

(b) * * * (1) This clause implements 41 U.S.C. chapter 83, Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction material, excluding COTS fasteners. (See FAR 12.505(a)(2)). In addition, the Contracting Officer has determined that the WTO GPA and all the Free Trade Agreements except the Bahrain FTA, NAFTA, and the Oman FTA apply to this acquisition. Therefore, the Buy American statute restrictions are waived for designated country construction materials other than Bahrainian, Mexican, or Omani construction materials.

* * * * *

■ 27. Amend section 52.225–21 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a) in the definition ''Steel'' removing ''.02'' and adding ''0.02'' in its place;

■ c. Removing from paragraph (b)(4)(i)(B) ''6 percent'' and adding ''20 percent'' in its place;

■ d. Removing from paragraph (c) heading ''*Section*'' and adding ''*section*'' in its place; and

■ e. In paragraph (d):

■ i. Removing from the first undesignated paragraph following the table ''reponse'' and adding ''response'' in its place; and

■ ii Removing from the second undesignated paragraph following the table ''**Include*'' and adding ''*[*Include*'' in its place.

The revision reads as follows:

52.225–21 Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials.

* * * * *

Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials (Jan 2021)

* * * * *

■ 28. Amend section 52.225–22 by—

■ a. Revising the date of the provision;

■ b. Removing from paragraph (b) ''offeror'' and adding ''Offeror'' in its place wherever it appears;

■ c. Removing from paragraph (c)(1)(ii) ''6 percent'' and adding ''20 percent'' in its place;

■ d. Removing from paragraph (c)(3) ''offeror'' and adding ''Offeror'' in its place; and

■ e. Removing from paragraphs (d)(1), (2), and (3) introductory text ''offeror'' and adding ''Offeror'' in their places, respectively.

The revision reads as follows:

52.225–22 Notice of Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials.

* * * * *

Notice of Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials (Jan 2021)

* * * * *

■ 29. Amend section 52.225–23 by—

■ a. Revising the date of the clause;

■ b. In paragraph (a), in the definition ''*Steel*'' removing ''.02'' and adding ''0.02'' in its place; and

■ c. Removing from paragraph (b)(4)(i)(B) ''6 percent'' and adding ''20 percent'' in its place.

The revision reads as follows:

52.225–23 Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements.

* * * * *

Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements (Jan 2021)

* * * * *

■ 30. Amend section 52.225–24 by—

■ a. Revising the date of the provision;

■ b. Removing from paragraph (b) ''offeror'' and adding ''Offeror'' in its place wherever it appears;

■ c. Removing from paragraph (c)(1)(ii) ''6 percent'' and adding ''20 percent'' in its place;

■ d. Removing from paragraph (c)(3) ''offeror'' and adding ''Offeror'' in its place; and

■ e. Removing from paragraphs (d)(1), (2), and (3) introductory text ''offeror'' and adding ''Offeror'' in their places, respectively.

The revision reads as follows:

52.225–24 Notice of Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements.

* * * * *

Notice of Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements (Jan 2021)

* * * * *

[FR Doc. 2021–00710 Filed 1–15–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2021–0051, Sequence No. 1]

Federal Acquisition Regulation; Federal Acquisition Circular 2021–04; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rule appearing in Federal Acquisition Circular (FAC) 2021–04, which amends the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding this rule by referring to FAC 2021–04, which precedes this document.

DATES: January 19, 2021.

ADDRESSES: The FAC, including the SECG, is available via the internet at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207 or *zenaida.delgado@gsa.gov* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2021–04, FAR Case 2019–016. An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared.

RULES LISTED IN FAC 2021–04

Subject	FAR case
* Maximizing Use of American-Made Goods, Products and Materials	2019–016

ADDRESSES: The FAC, including the SECG, is available via the internet at *https://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: A summary for the FAR rule follows. For the actual revisions and/or amendments made by this FAR rule, refer to the specific subject set forth in the document following this summary. FAC 2021–04 amends the FAR as follows:

Maximizing Use of American-Made Goods, Products, and Materials (FAR Case 2019–016)

This final rule strengthens domestic preferences under the Buy American statute by making adjustments to the required percentage of domestic content and the existing percentages for the price evaluation preferences in an effort to decrease the amount of foreign-sourced content in a U.S. manufactured product to promote economic and national security, help stimulate economic growth, and create jobs. The price evaluation preferences increase from 6 percent to 20 percent for large business and from 12 percent to 30 percent for small business; for DoD procurements there is no change to the DoD 50 percent amount. The domestic content requirement for iron and steel increases from 50 percent to 95 percent; for other end products and construction materials, the domestic content requirement increases from 50 percent to 55 percent. Foreign iron and steel is iron or steel products that are not produced in the United States. The rule implements E.O. 13881, Maximizing Use of American-Made Goods, Products, and Materials. This final rule will not have a significant economic impact on a substantial number of small entities.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2021–00711 Filed 1–15–21; 8:45 am]

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FEDERAL REGISTER

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Part XII

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 53

Tax on Excess Tax-Exempt Organization Executive Compensation; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 53

[TD 9938]

RIN 1545–BO99

Tax on Excess Tax-Exempt Organization Executive Compensation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document sets forth final regulations under section 4960 of the Internal Revenue Code (Code), which imposes an excise tax on remuneration in excess of $1,000,000 and any excess parachute payment paid by an applicable tax-exempt organization to any covered employee. The regulations affect certain tax-exempt organizations and certain entities that are treated as related to those organizations.

DATES: *Effective Date:* These final regulations are effective on January 15, 2021.

Applicability Dates: For dates of applicability, see § 53.4960–6.

FOR FURTHER INFORMATION CONTACT: William McNally at (202) 317–5600 or Patrick Sternal at (202) 317–5800 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Foundation and Similar Excise Tax Regulations (26 CFR part 53) by adding final regulations under section 4960. Section 4960 was added to the Code by section 13602 of the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2054, 2157 (TCJA). Section 4960(a) generally provides that an applicable tax-exempt organization (ATEO) that pays to a covered employee remuneration in excess of $1 million for a taxable year or any excess parachute payment is subject to an excise tax on the amount of the excess remuneration (as described in section IV of the Summary of Comments and Explanation of Revisions, titled ''Excess Remuneration'') plus excess parachute payments paid during that taxable year at a rate equal to the rate of tax imposed on corporations under section 11 (currently 21 percent). Section 4960 is effective for taxable years beginning after December 31, 2017.

An ATEO is defined in section 4960(c)(1) as any organization that for the taxable year is exempt from taxation under section 501(a) as well as certain other tax-exempt organizations. A covered employee is defined in section 4960(c)(2) as any employee (including any former employee) of an ATEO if the employee is one of the five highest-compensated employees of the organization for the taxable year or any preceding taxable year beginning after December 31, 2016. Section 4960(c)(4)(A) provides that remuneration paid to a covered employee by an ATEO includes any remuneration paid with respect to employment of such employee by any related person or governmental entity. Section 4960(c)(4)(B) defines a related person or governmental entity as an entity that controls, or is controlled by, the ATEO; is controlled by one or more persons that control the ATEO; or is a supported or supporting organization as described in sections 509(f)(3) and 509(a)(3), respectively. An excess parachute payment is defined in section 4960(c)(5)(A) as an amount equal to the excess of any parachute payment over the portion of the base amount (as described in section V.D. of the Summary of Comments and Explanation of Revisions, titled ''Three-Times-Base-Amount Test'') allocated to such payment; section 4960(c)(5)(B) defines a parachute payment as any payment in the nature of compensation to a covered employee if the payment is contingent on the employee's separation from employment with the employer and the aggregate present value of such payments exceeds 3-times the base amount.

On December 31, 2018, the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS) issued Notice 2019–09 (2019–04 I.R.B. 403), setting forth initial guidance on the application of section 4960. On June 11, 2020, the Treasury Department and the IRS published proposed regulations on section 4960 in the **Federal Register** (REG–122345–18, 85 FR 35746) (the proposed regulations). The statutory provisions and the initial guidance provided by Notice 2019–09 are described in detail in the proposed regulations.

The Treasury Department and the IRS received written comments on the proposed regulations. No public hearing was requested or held. All written comments received in response to the proposed regulations are available at *www.regulations.gov* or upon request. Comments received that are outside of the scope of the proposed regulations generally are not addressed in this preamble but may be considered in connection with future guidance projects. After consideration of the relevant comments received, the proposed regulations under section 4960 are adopted as final regulations as modified by this Treasury Decision. The major areas of comment and the revisions to the proposed regulations are discussed in the Summary of Comments and Explanation of Revisions. With respect to provisions in the proposed regulations on which no comments were received or for which comments were received prior to the issuance of the proposed regulations, the preamble to the proposed regulations may provide additional information.

Summary of Comments and Explanation of Revisions

These final regulations provide guidance on the excise tax imposed by section 4960 and the entities that are subject to the tax.

I. Scope of Final Regulations

These final regulations retain the basic approach and structure of the proposed regulations, with certain revisions. These final regulations restate certain statutory definitions and define various terms set forth in section 4960. These final regulations also provide rules for determining: The amount of remuneration paid for a taxable year for purposes of identifying covered employees and calculating the excise tax; whether excess remuneration has been paid and in what amount; whether a parachute payment has been paid and in what amount; the allocation of liability for the excise tax among related organizations; and the date of applicability of these final regulations. These definitions and rules apply solely for purposes of section 4960.

II. Definitions

A. Applicable Tax-Exempt Organization

These final regulations adopt the definition of ''applicable tax-exempt organization'' or ''ATEO'' as set forth in the proposed regulations. Consistent with section 4960(c)(1), the proposed regulations provided that an ''applicable tax-exempt organization'' or ''ATEO'' includes an organization that is exempt from tax under section 501(a); is a farmers' cooperative organization described in section 521(b)(1); has income excluded from taxation under section 115(1); or is a political organization described in section 527(e)(1).

In response to comments on Notice 2019–09 regarding the applicability of the excise tax imposed by section 4960 to certain Federal instrumentalities, section II.A. of the Explanation of Provisions of the proposed regulations, titled ''Applicable Tax-Exempt Organization,'' stated that the Treasury

Department and the IRS consider all Federal instrumentalities described in section 501(c)(1) to be included in the statutory ATEO definition as an organization exempt from tax under section 501(a) and thus subject to section 4960. However, the Treasury Department and the IRS requested comments regarding the application of section 4960 to Federal instrumentalities. One commenter requested that these final regulations confirm that Federal instrumentalities described under section 501(c)(1)(A)(i), for which the enabling acts provide for exemption from all current and future Federal taxes are not subject to tax under section 4960. These final regulations do not address this issue but reserve § 53.4960–1(b)(3) and § 53.4960–4(a)(5) for future rules to address these Federal instrumentalities. The Treasury Department and the IRS will continue to consider whether section 4960 should apply to Federal instrumentalities for which the enabling acts provide for exemption from all current and future Federal taxes. Until further guidance is issued, a Federal instrumentality for which an enabling act provides for exemption from all current and future Federal taxes may treat itself as not subject to tax under section 4960 as an ATEO or related organization. However, if that Federal instrumentality is a related organization of an ATEO, remuneration it pays must be taken into account by that ATEO.

B. Applicable Year

Section 4960(a)(1) refers to remuneration paid ''for the taxable year,'' but does not specify which taxpayer's taxable year is referenced, what it means for remuneration to be paid ''for'' a taxable year, or how to measure remuneration if an ATEO and a related organization have different taxable years. The proposed regulations provided that remuneration is treated as paid for a taxable year if it is paid during the applicable year, and that the applicable year is defined as the calendar year ending with or within an ATEO's taxable year. The proposed regulations provided rules for determining the applicable year of an organization with respect to the taxable year in which the organization becomes an ATEO or ceases to be an ATEO, including rules addressing short applicable years that may arise in these situations and rules addressing related organizations with different taxable years. No comments were received on those proposed rules, and these final regulations adopt those rules without change.

C. Employee

Section 4960(a) imposes a tax on excess remuneration and any excess parachute payment paid by an ATEO for the taxable year with respect to employment of a covered employee. Section 4960(c)(2) defines a ''covered employee'' as an employee (including any former employee) of the ATEO who meets certain other conditions. Accordingly, the excise tax imposed by section 4960(a) applies only with respect to a current or former employee of the ATEO.

The proposed regulations defined ''employee'' by reference to the definition of ''employee'' for purposes of Federal income tax withholding in section 3401(c) and the regulations thereunder. Specifically, the proposed regulations cross-referenced the definition of ''employee'' in § 31.3401(c)–1, which includes common-law employees, officers or elected or appointed officials of governments, or agencies or instrumentalities thereof, and certain officers of corporations. The proposed regulations restated certain rules from § 31.3401(c)–1 that are particularly relevant to section 4960, including the rules that a member of a board of directors of a corporation is not an employee of the corporation (in the member's capacity as a director), and that an officer is an employee of the entity for which the officer serves as an officer (unless the officer performs no services or only minor services and neither receives, nor is entitled to receive, any remuneration for such services). For further discussion, see section II.E. of this Summary of Comments and Explanation of Revisions, titled ''Covered Employee.'' No comments were received on those proposed rules, and these final regulations adopt those provisions of the proposed regulations without change.

One commenter requested clarification regarding the source of the remuneration that is considered for purposes of applying the minor services exception to the rule that treats a corporation's officer as an employee. The minor services exception in Prop. § 53.4960–1(e)(1) incorporated the standard in § 31.3401(c)–1 and provided that ''an officer of a corporation who as such does not perform any services or performs only minor services and who neither receives, nor is entitled to receive, any remuneration is not considered to be an employee of the corporation solely due to the individual's status as an officer of the corporation.'' The commenter stated that it is unclear whether an individual qualifies for the exception if he or she receives remuneration from a related person or governmental entity for services performed for an organization other than the ATEO and also volunteers his or her time as an officer of the ATEO (and performs no services or only minor services for the ATEO). The commenter recommended that these final regulations clarify that the relevant remuneration for purposes of meeting the minor services exception is only remuneration paid by the ATEO. The minor services exception applies if an individual is not paid (nor is entitled to be paid) remuneration based ''solely'' on the individual's status as an officer. Thus, the source of the remuneration is not relevant, but rather the standard is whether the individual received any remuneration for the minor services as an officer regardless of the source of the remuneration. Therefore, the Treasury Department and the IRS have concluded that this clarification of the minor services exception in these final regulations is unnecessary.

For a discussion of how this definition of ''employee'' and other rules address employees of non-ATEO related organizations performing limited or temporary services for the related ATEO (in particular, while also receiving compensation from the non-ATEO related organization), see section II.E.5. of this Summary of Comments and Explanation of Revisions, titled ''Volunteer Services and Other Exceptions.''

D. Employer

Section 4960(b) provides that the employer is liable for the tax imposed under section 4960(a). Similar to the definition of ''employee,'' the proposed regulations defined ''employer'' by reference to the definition of ''employer'' for purposes of Federal income tax withholding in section 3401(d) and the regulations thereunder, without regard to the special rules in section 3401(d)(1) and (2). Accordingly, control of the payment of wages would not be relevant for determining whether an entity is the employer for section 4960 purposes. Further, the proposed regulations provided that a person or governmental entity does not avoid status as an employer of an employee by using a third-party payor to pay remuneration to that employee. Third-party payors include a payroll agent, an agent under section 3504, a common paymaster, a statutory employer under section 3401(d)(1), or a certified professional employer organization under section 7705 (which is an ''employer'' only for purposes of subtitle

C of the Code). Similarly, consistent with existing principles for determining the employer, under certain facts and circumstances, a management company may also be acting as a third-party payor for the employees of its ATEO client, rather than as the common law employer of the employees. Thus, the proposed regulations provided that remuneration that is paid to an individual by a separate organization for services the individual performed as an employee of the ATEO would be remuneration paid by the ATEO to its employee for purposes of section 4960, whether or not the separate organization is related to the ATEO. In addition, the proposed regulations provided that the sole owner of an entity that is disregarded as separate from its owner under § 301.7701–2(c)(2)(i) would be treated as the employer of any employee of the disregarded entity, notwithstanding that the entity is regarded for subtitle C purposes under § 301.7701–2(c)(2)(iv). No comments were received on these provisions of the proposed regulations, and these final regulations adopt them without change.

E. Covered Employee

1. In General

Section 4960(c)(2) defines ''covered employee'' as any individual who is one of the five highest-compensated employees of the ATEO for a taxable year or was a covered employee of the ATEO (or any predecessor) for any preceding taxable year beginning after December 31, 2016. Thus, once an employee is a covered employee of an ATEO, the employee continues to be a covered employee for all subsequent taxable years of that ATEO. The proposed regulations provided that whether an employee is one of the five highest-compensated employees of an ATEO is determined separately for each ATEO and not for an entire group of related organizations. As a result, a group of related ATEOs could have more than five ''five highest-compensated employees'' for a taxable year. Similarly, an employee could be a covered employee of more than one ATEO in a related group of organizations for a taxable year. No comments were received on these provisions of the proposed regulations, and these final regulations adopt them without change.

2. Aggregation of Remuneration Paid by the ATEO and Its Related Organizations for Purposes of Determining the Five Highest-Compensated Employees

For purposes of determining whether an employee is one of an ATEO's five highest-compensated employees for a taxable year, the proposed regulations provided that remuneration paid by the ATEO during the ATEO's applicable year is aggregated with remuneration paid by any related organization during the ATEO's applicable year, including remuneration paid by a related taxable organization or governmental entity, for services performed as an employee of that related organization. Remuneration for which a deduction is disallowed under section 162(m) generally is not considered for purposes of determining whether excess remuneration is paid for a taxable year, but that remuneration is considered for purposes of determining an ATEO's five highest-compensated employees.

One commenter suggested that, for purposes of determining an ATEO's five highest-compensated employees, these final regulations should consider only remuneration paid (directly or indirectly) by an ATEO for services provided by an employee to the ATEO, rather than aggregating all remuneration paid to the individual for services the individual provides as an employee of the ATEO and as an employee of any related organization, including a related non-ATEO (for example, a taxable organization). The commenter reasoned that aggregating remuneration for purposes of determining covered employee status is not required by the statutory text and is unnecessary to comply with Congressional intent to achieve parity between ATEOs and publicly held corporations that are subject to the section 162(m) deduction disallowance for compensation paid to a covered employee in excess of $1 million. The commenter also reasoned that because only an ATEO can have a ''covered employee'' under section 4960(c)(2), the reference to the ''five highest-compensated employees *of the organization*'' (emphasis in comment) in section 4960(c)(2)(A) should be read to include only compensation paid by the ATEO, directly or indirectly (for example, by reimbursing another entity), for services provided by the employee to the ATEO, regardless of the payor. The commenter asserted that the language in section 4960(c)(4)(A), which provides that ''remuneration *of a covered employee* by an [ATEO] shall include any remuneration paid with respect to employment of such employee by any related person or governmental entity'' (emphasis in comment) should not override a plain reading of section 4960(c)(2), which refers only to employment with the ATEO. The commenter further reasoned that section 4960(c)(4)(A) applies after a determination of the ATEO's covered employees has already been made, and thus it is circular to read section 4960(c)(4)(A) as requiring inclusion of remuneration paid to a covered employee of an ATEO by a related person or governmental entity for purposes of determining an ATEO's highest-compensated employees (and, thus, its covered employees).

While the Treasury Department and the IRS acknowledge that alternative interpretations as to whether sections 4960(c)(2) and (c)(4)(A) take into account remuneration paid by a related organization for purposes of determining an ATEO's covered employees may be reasonable, for the reasons set forth below, these final regulations adopt the relevant provisions of the proposed regulations without change and do not adopt the commenter's recommendation. Section 4960 does not define the ''five highest-compensated employees'' of an ATEO. The ambiguity in this term is highlighted by the fact that the only provision in the statute that references ''compensation'' is section 4960(c)(2), which defines ''covered employee'' as one of the ''5 highest compensated employees''; the statute otherwise uses the defined terms ''remuneration'' and ''parachute payment'' for purposes of determining the excise tax imposed by section 4960. In addition, there is no discussion in the legislative history describing how Congress intended an ATEO to determine its five highest-compensated employees. The Treasury Department and the IRS have concluded that the commenter's suggested interpretation—that only remuneration paid by the ATEO for services performed for the ATEO should be considered for purposes of determining who is a covered employee—would raise significant tax administration issues and the potential for abuse in circumstances in which an individual provides services to, and receives compensation from, the ATEO and one or more related organizations during the applicable year. In these cases, it may be difficult to determine the proper allocation of the compensation among the organizations to which the individual provides the services and whether the allocation was properly based on the value of the services provided. Due to the highly factual nature of this analysis and the potential for differing conclusions on one or more of these issues, the commenter's suggested rule would result in an unpredictable standard to be applied by taxpayers and the IRS and would raise the potential for abusive

mischaracterizations of the nature of the services and compensation provided.

The commenter further asserted that the requirement to aggregate compensation paid by the ATEO and all related organizations is not required to ensure parity with the rules for identifying covered employees under section 162(m). Under §§ 1.162–27(c)(2)(ii) and 1.162–33(c)(1)(ii)(B), the amount of compensation used to identify the covered employees who are the three most highly compensated executive officers (other than the principal executive officer and the principal financial officer) for the taxable year is determined pursuant to the executive compensation disclosure rules under the Securities Exchange Act of 1934. Under 17 CFR 229.402(a)(2), the amount of compensation paid to an employee by a publicly held corporation is measured by reference to remuneration paid by the registrant and remuneration paid by the registrant's subsidiaries, and is not limited to remuneration for services provided to the registrant. Although the provisions of sections 4960 and 162(m) are similar in many respects, there is no indication in the legislative history that sections 162(m) and 4960 are intended to apply in the same manner in all situations. Further, the section 162(m) and section 4960 statutory language and the application of the rules differ significantly in many respects that would not allow that strict parity. Regardless of the conclusion that the sections 162(m) and 4960 rules do not allow for strict parity, the Treasury Department and the IRS have concluded that the aggregation of compensation paid by all related entities in identifying covered employees is more analogous to the rules under section 162(m) than considering only remuneration for services provided to the ATEO.

Thus, while the Treasury Department and the IRS considered several alternatives for determining the ATEO's five highest-compensated employees, including the alternative proposed by the commenter, the Treasury Department and the IRS ultimately concluded that including remuneration paid by all related organizations is appropriate and that it is more administrable to use a single standard for identifying covered employees and computing the excise tax, if any, imposed by section 4960(a)(1). However, to mitigate the effect of requiring the aggregation of remuneration paid by an ATEO and all related organizations for purposes of determining the ATEO's covered employees, these final regulations retain the limited hours, nonexempt funds, and limited services exceptions (discussed in section II.E.5. of this Summary of Comments and Explanation of Revisions, titled ''Volunteer Services and Other Exceptions'').

3. Remuneration for Medical Services

Consistent with section 4960(c)(3)(B) and the proposed regulations, these final regulations provide that for purposes of identifying an ATEO's five highest-compensated employees for a taxable year, remuneration paid during the applicable year for medical services is not taken into account. For a discussion of the rules for determining the remuneration paid for medical or veterinary services and for allocating remuneration to medical and non-medical services, see section II.F. of this Summary of Comments and Explanation of Revisions, titled ''Medical Services.''

4. Covered Employee Status Continues for All Subsequent Taxable Years

In accordance with section 4960(c)(2), the proposed regulations provided that a covered employee includes any employee (including any former employee) of an ATEO who was a covered employee of the organization (or a predecessor) for any preceding taxable year beginning after December 31, 2016. In response to the proposed regulations, one commenter suggested that the Treasury Department and the IRS reconsider the rule that an individual who is a covered employee of an ATEO (or of a predecessor ATEO) for one taxable year remains a covered employee of that ATEO (and any successor ATEOs) for all subsequent taxable years. The commenter suggested that an ATEO should be relieved of the burden of continuing to include an employee among its covered employees when a consolidation or restructuring of a tax-exempt organization results in changes to the employee's job responsibilities and compensation, if it no longer furthers the purpose of the statute to include the employee among its covered employees. The commenter asserted that the requirement that an individual remain a covered employee for all subsequent years, even after the employment relationship has ended, creates a potentially excessive administrative burden for the ATEO. These final regulations do not adopt this suggestion because that rule would be inconsistent with the statutory language.

5. Volunteer Services and Other Exceptions

The proposed regulations provided certain exceptions to the definition of ''covered employee'' and the rules for identifying the five highest-compensated employees of an ATEO. Several commenters supported the inclusion of the exceptions provided in Prop. § 53.4960–1(d)(2)(ii), (iii), and (iv). These final regulations adopt these exceptions with certain modifications in response to comments as discussed later in this section.

The exceptions to the definition of ''covered employee'' in the proposed regulations were provided in response to comments on Notice 2019–09 expressing concern that the rules for identifying an ATEO's five highest-compensated employees in the notice would subject a non-ATEO to the excise tax on remuneration it pays to an employee who performs limited or temporary services for a related ATEO and who typically receives remuneration only from the non-ATEO. The exceptions were intended to ensure that certain employees of a related non-ATEO providing services as an employee of an ATEO are not treated as one of the five highest-compensated employees of the ATEO, and thus considered a covered employee, if certain conditions related to the individuals' remuneration or hours of service are met. To avoid manipulation of the rules through the deferral of compensation, in determining whether an employee is one of the five highest-compensated employees, the proposed regulations provided that a grant of a legally binding right to vested remuneration is considered to be remuneration paid, and any grant of a legally binding right to nonvested remuneration by the ATEO (or a related ATEO), for example under a deferred compensation plan or arrangement, disqualifies the ATEO from claiming a relevant exception. No comments were received on those proposed rules, and these final regulations adopt those rules without change.

a. No Remuneration and Non-Employment Exceptions

The proposed regulations provided that the remuneration paid to an individual who is never an employee of an ATEO is not considered for purposes of section 4960. For example, an individual who, under all the facts and circumstances, performs services for an ATEO solely as a bona fide independent contractor is not an employee of the ATEO, and thus is not considered for purposes of determining the ATEO's five highest-compensated employees. Similarly, an individual who, under all the facts and circumstances, performs services solely as a bona fide employee of a related organization, including a related organization that provides services to the ATEO, is not an

employee of the ATEO, and thus is not considered for purposes of determining the ATEO's five highest-compensated employees. No comments were received on those provisions of the proposed regulations, and these final regulations adopt them without change.

The proposed regulations further provided that, for purposes of determining an ATEO's five highest-compensated employees for a taxable year, an employee is disregarded if neither the ATEO nor any related organization pays remuneration or grants a legally binding right to nonvested remuneration for services the individual performed as an employee of the ATEO or any related organization. Thus, if none of an ATEO's employees received remuneration from the ATEO or from a related organization, then the ATEO has no covered employees. Benefits excluded from gross income are not considered remuneration, including expense allowances and reimbursements under an accountable plan (see § 1.62–2) and most insurance for liability arising from service with an ATEO, such as directors and officers liability insurance (see § 1.132–5(r)(3)). These final regulations adopt these provisions of the proposed regulations without change.

In section II.E.2. of the Explanation of Provisions of the proposed regulations, titled ''Volunteer Services and Similar Exceptions,'' the Treasury Department and the IRS requested comments on whether certain taxable benefits, such as employer-provided parking in excess of the value excluded under section 132, should be disregarded for purposes of determining whether an individual receives remuneration for services and what standards should apply to identify those benefits. No comments were received on this issue. Because taxable fringe benefits that are wages within the meaning of section 3401(a) are included in the statutory definition of remuneration, these final regulations adopt the provisions of the proposed regulations providing that these amounts are considered for purposes of determining an ATEO's five highest-compensated employees and for purposes of applying the exceptions from covered employee status. For a discussion of comments received on the exclusion of taxable fringe benefits from the definition of remuneration for purposes other than the determination of the five highest-compensated employees, see section III.A. of this Summary of Comments and Explanation of Revisions, titled ''In General'' under ''Remuneration.''

b. Limited Hours Exception

These final regulations adopt the ''limited hours'' exception as provided in the proposed regulations for purposes of determining an ATEO's five highest-compensated employees. Under this exception, an employee of an ATEO is disregarded for purposes of determining the ATEO's five highest-compensated employees for a taxable year if neither the ATEO nor any related ATEO pays remuneration or grants a legally binding right to nonvested remuneration to the employee for services performed for the ATEO and the employee performs only limited hours of service for the ATEO. For purposes of this exception, an ATEO is not treated as paying an amount paid to an individual by a related organization that employs the individual, so long as the ATEO does not reimburse the payor. An employee qualifies for this exception only if the hours of service the employee performs as an employee of the ATEO and all related ATEOs comprise 10 percent or less of the employee's total hours of service for the ATEO and all related organizations during the applicable year. For purposes of this rule, an employee who performs fewer than 100 hours of service as an employee of an ATEO (and all related ATEOs) during an applicable year is treated as having worked no more than 10 percent of the employee's total hours for the ATEO (and all related ATEOs).

One commenter recommended that these final regulations replace the 10 percent hours of service threshold in the limited hours exception with the 50 percent hours of service threshold that is used for the nonexempt funds exception (discussed later in this section) because the 10 percent threshold fails to capture many common arrangements between ATEOs and taxable related organizations controlled by the ATEO (''controlled taxable related organizations'') that are not structured to avoid the excise tax imposed by section 4960. These final regulations do not adopt this suggestion because the limited hours exception was intended to address arrangements in which services are sufficiently limited so that the arrangements resemble volunteer arrangements. This exception therefore has a much lower hours of service threshold than the nonexempt funds exception but may be used by a broader group of ATEOs. Further, the Treasury Department and the IRS have concluded that adopting the commenter's suggestion would be inconsistent with the legislative intent of section 4960. As explained in section II.E.2 of the Explanation of Provisions of the proposed regulations, titled ''Volunteer Services and Similar Exceptions,'' the legislative history indicates that Congress intended to tax excessive compensation paid to covered employees from tax-exempt funds.[1] Consistent with this intent, the proposed regulations provided a nonexempt funds exception, which applies if certain criteria are satisfied, but does not apply if an ATEO's controlled taxable related organization pays remuneration to an employee of the ATEO. The Treasury Department and the IRS reasoned that a controlled taxable related organization that pays remuneration to an employee for services provided to an ATEO uses the ATEO's funds to do so, either because the controlled taxable related organization's assets are, effectively, the ATEO's assets, or because the payment reduces the related organization's assets, which in turn reduces the value of the ATEO's interest in the related organization. The Treasury Department and the IRS consider the funds of an ATEO's controlled taxable related organization as, in substance, equivalent to tax-exempt funds, and thus the use of such funds to compensate an individual for services provided to an ATEO is in substance the use of tax-exempt funds.[2]

One commenter expressed concern about the ''cliff'' nature of the proposed limited hours exception (as well as the nonexempt funds and limited services exceptions), noting that exceeding the thresholds even slightly may result in the employee being a covered employee for the applicable year and all subsequent applicable years. The commenter recommended that these final regulations allow a 3-year (or longer) measurement period to qualify for the limited hours exception or the other exceptions, primarily to prevent the ATEO from inadvertently failing to satisfy the exception.

A 3-year measurement period would reduce the potential for inadvertent failures for an employer intending to be at or below the threshold for every applicable year. However, for an employer that intends to meet the limited hours exception during only one applicable year, the suggested 3-year standard would effectively raise the 10 percent hours of service limit to 30 percent and create a new ''cliff'' at that

[1] H. Rep. 115–409, 115th Cong., 1st Sess. 333 (Nov. 13, 2017).

[2] In a similar context, § 53.4958–4(a)(2) treats excessive compensation paid to a disqualified person with respect to an applicable tax-exempt organization by a controlled entity of the organization as excessive compensation paid by the organization, and thus as an excess benefit transaction.

30 percent threshold. In addition, permitting a 3-year measurement period would create additional complexity and burdens for taxpayer compliance and tax administration. For these reasons, the Treasury Department and the IRS do not adopt this suggestion. However, the modification to the nonexempt funds exception described later in this section, expanding the measurement period to two applicable years, is intended to address some of the commenter's concerns with respect to inadvertent failures to meet the requirements of the nonexempt funds exception.

Another commenter recommended that Example 5 in the provisions of the proposed regulations, which illustrated the application of the limited hours exception (Prop. § 53.4960–1(d)(3)(v)), be modified to eliminate from the facts that ATEO 5 does not control CORP 3, as control of another corporation by an ATEO is irrelevant for purposes determining whether the requirements of this exception are met, and thus irrelevant to the conclusion in that example. The commenter further suggested that this fact be moved to Example 8 in the proposed regulations, which illustrated the application of the separate nonexempt funds exception (Prop. § 53.4960–1(d)(3)(viii)), since control of another corporation by an ATEO is relevant for determining whether the requirements of that exception are met, and thus relevant to the conclusion in that example. The Treasury Department and the IRS agree with the commenter's suggestion, and modified Example 5 in these final regulations describing the limited hours exception (§ 53.4960–1(d)(3)(v)) accordingly. However, because of changes to the nonexempt funds exception as described later in this Summary of Comments and Explanation of Revisions, these final regulations replace Example 8 (§ 53.4960–1(d)(3)(viii)) with a new example.

c. Nonexempt Funds Exception

As previously discussed, the proposed regulations also provided a ''nonexempt funds'' exception for employees of a related non-ATEO organization who may perform a large portion of their overall services as an employee of the ATEO under certain circumstances. Under the nonexempt funds exception, an employee is disregarded for purposes of determining an ATEO's five highest-compensated employees for a taxable year provided that none of the ATEO, any related ATEO, or any controlled taxable related organization, pays the employee of the ATEO any remuneration or grants a legally binding right to nonvested remuneration to the employee. When applying these requirements for the nonexempt funds exception, the ATEO is not treated as paying remuneration that is paid by a related organization that also employs the individual, so long as the ATEO does not reimburse the payor. Further, to prevent indirect payment of remuneration by the ATEO, a related ATEO, or controlled taxable related organization, no related organization that paid remuneration to the individual may provide services for a fee to the ATEO, related ATEO, or any controlled taxable related organization.

To satisfy the nonexempt funds exception, the proposed regulations also stated that the employee must have provided services primarily to a taxable related organization or other non-ATEO (other than a controlled taxable related organization of the ATEO) during the applicable year. For this purpose, an employee is treated as having provided services primarily to the taxable related organization or other non-ATEO (other than a controlled taxable related organization of the ATEO) only if the employee provided services to the taxable related organization or other non-ATEO for more than 50 percent of the employee's total hours worked for the ATEO and all related organizations (including ATEOs) during the applicable year.

One commenter expressed concern that, for purposes of the nonexempt funds exception, the requirement limiting the employee's hours worked for the ATEO and all related ATEOs to not more than 50 percent of the total hours worked for the ATEO and all related organizations during an applicable year was too restrictive and may result in inadvertent failures. The Treasury Department and the IRS acknowledge the issues presented by this comment. These final regulations modify the exception by expanding the measurement period from one applicable year to two applicable years (that is, the current applicable year and the preceding applicable year are treated as a single measurement period) for purposes of determining whether an employee provided services to the ATEO and all related ATEOs for not more than 50 percent of the employee's total hours worked as an employee of the ATEO and all related organizations during the applicable year and the prior applicable year. This modification provides additional flexibility for situations in which an employee ''rotates'' to an ATEO for a period that extends longer than six months, or when an employee unexpectedly provides services beyond six months in an applicable year.

Another commenter recommended that the nonexempt funds exception be modified to prohibit the provision of services for a fee to a taxable entity only if the ATEO actually owns a controlling interest in the taxable entity, as opposed to being attributed the ownership interest under the section 318 attribution principles, which were incorporated into the definitions of a related organization and control. The commenter asserted that the related organizations requirement under the proposed nonexempt funds exception (Prop. § 53.4960–1(d)(2)(iii)(A)(3)), which incorporates the section 318 attribution principles, is unduly restrictive, and would have unintended results, as illustrated by the following example. An individual who is the sole shareholder of two taxable corporations (Corporation 1 and Corporation 2) also controls an ATEO (by having the power to appoint a majority of the ATEO's board of directors); Corporation 1 provides administrative services for a fee to Corporation 2; employee of Corporation 1 provides services only to Corporation 1 and does not provide any services to the ATEO. Under these facts, Corporation 2 is deemed to be controlled by the ATEO because, for purposes of determining whether an ATEO controls an organization under Prop. § 53.4960–1(i)(2)(vii)(B)(2), if a person controls an ATEO, the ATEO is treated as owning a percentage of the stock owned by that person in accordance with the percentage of directors of the ATEO that are controlled by that person. Because the related organizations requirement prohibits the payment of a fee by a related organization to a controlled taxable related organization for services performed by an employee of the controlled taxable related organization, and because Corporation 1 is providing services for a fee to Corporation 2, which is deemed to be controlled by the ATEO, no employee of Corporation 1 could meet the requirements of the proposed nonexempt funds exception. The commenter suggested that this result is inappropriate because the sharing of services between two taxable corporations in which an ATEO has no actual ownership interest would not circumvent the legislative intent of section 4960. The Treasury Department and the IRS agree with the commenter's recommendation. Accordingly, these final regulations modify the attribution rules as they apply for purposes of determining eligibility for the nonexempt funds exception by disregarding the application of downward attribution in applying

section 318(a)(3) to corporations and other entities and in applying section 318 principles to nonstock organizations. This modification applies only for purposes of applying the nonexempt funds exception and does not apply for purposes of determining whether an organization is a related organization generally.

d. Limited Services Exception

The proposed regulations provided a ''limited services'' exception, under which an employee is not considered for purposes of determining an ATEO's five highest-compensated employees for a taxable year if, during the applicable year, the ATEO paid less than 10 percent of the employee's total remuneration during the applicable year for services performed as an employee of the ATEO and all related organizations. However, if an employee would not be considered for purposes of determining the five highest-compensated employees of any ATEO in an ATEO's group of related organizations because no ATEO in the group paid at least 10 percent of the total remuneration paid by the group during the applicable year, then this exception does not apply to the ATEO that paid the employee the most remuneration during that applicable year. No comments were received on that proposed rule, and these final regulations retain that rule without change.

F. Medical Services

Section 4960(c)(3)(B) provides that remuneration for purposes of section 4960 does not include the portion of any remuneration paid to a licensed medical professional (including a veterinarian) that is for the performance of medical or veterinary services by such professional. Section 4960(c)(5)(C)(iii) provides a substantially similar exception from the definition of ''parachute payment.'' The proposed regulations provided rules relating to medical services and licensed medical professionals. No comments were received on those rules in the proposed regulations, and these final regulations adopt the rules in the proposed regulations without change. For further discussion of these rules, see section II.F. of the Explanation of Provisions of the proposed regulations, titled ''Medical Services.''

These final regulations also adopt the rule in the proposed regulations that a ''licensed medical professional'' is an individual who is licensed under state or local law to perform medical services. In addition to doctors, nurses, and veterinarians, a licensed medical professional generally would include dentists and nurse practitioners and may include other medical professionals, depending on the applicable state or local law. For a discussion of other issues related to remuneration for medical or veterinary services, including a rule for allocating remuneration received for a combination of medical and non-medical services, see section III.B. of this Summary of Comments and Explanation of Revisions, titled ''Remuneration Related to Medical Services.''

G. Predecessor Organization

Section 4960(c)(2)(B) provides that a covered employee includes any employee who was a covered employee of the ATEO (or any predecessor) for any preceding taxable year beginning after December 31, 2016. Because a covered employee, under section 4960(c)(2), must be (or have been) an employee of an ATEO, the predecessor must also have been an ATEO at the time the individual was employed by the predecessor to be a covered employee. Thus, an individual who is a covered employee of an ATEO (or of an ATEO predecessor of an ATEO) for one taxable year remains a covered employee of that ATEO (and any successor ATEOs) for subsequent taxable years.

The proposed regulations defined ''predecessor'' by reference to several enumerated categories of organizational changes, including acquisitions, mergers, other reorganizations, and changes in tax-exempt status. A predecessor ATEO ordinarily is an ATEO that has transferred, by any of several legal means, its assets and operations to another pre-existing or newly created ATEO (the successor of the predecessor ATEO). No comments were received with respect to the proposed rules. These final regulations adopt the definition of predecessor as provided in the proposed regulations without change. For further information concerning these rules, see section II.G. of the Explanation of Provisions of the proposed regulations, titled ''Predecessor Organization.''

H. Related Organization

Section 4960(c)(4)(A) provides that remuneration paid to a covered employee by an ATEO includes any remuneration paid with respect to employment of the employee by any related person or governmental entity,[3] and includes in the definition of ''remuneration'' any remuneration paid by the employer ATEO, related ATEOs, and related non-ATEOs (including taxable entities, nonprofit entities that are not ATEOs, and governmental entities that are not ATEOs). Section 4960(c)(4)(B) defines a ''related organization'' of an ATEO as a person or governmental entity that controls, or is controlled by, the ATEO; is controlled by one or more persons that control the ATEO; is a supported organization or a supporting organization (as defined in sections 509(f)(3) and 509(a)(3), respectively) during the taxable year of the ATEO, or, in the case of an ATEO that is a voluntary employees' beneficiary association described in section 501(c)(9) (VEBA), establishes, maintains, or makes contribution to the VEBA.

Section 4960(c)(4) does not define ''control'' for purposes of identifying related organizations. To determine which persons are related organizations under section 4960(c)(4)(B), the proposed regulations generally adopted the definition of ''control'' set forth in section 512(b)(13)(D) and § 1.512(b)–1(l)(4). Section II.H. of the Explanation of Provisions of the proposed regulations, titled ''Related Organization,'' explained that this standard (and its ''greater than 50 percent'' threshold) was intended to align the definition of ''related organization'' for purposes of section 4960 with the definition of ''related organization'' for purposes of the annual reporting requirements on Form 990, ''Return of Organization Exempt From Income Tax,'' and with other exempt organization control tests.

One commenter recommended that these final regulations instead define ''control'' based on the controlled group rules in section 414(b) and (c) and the regulations thereunder, which include an 80 percent control test. The commenter suggested that the section 414(b) and (c) controlled group test was more appropriate for a number of reasons: The purpose of section 414(b) and (c) is to treat related parties as a single employer (the same purpose as section 4960(c)(4)(C)), whereas the purpose of section 512(b)(13) is to tax abusive transactions; the regulations under section 512(b)(13) do not reflect statutory revisions; the control definition under section 512(b)(13) is overinclusive; and using the Form 990 test for control does not reduce administrative burdens because the Form 990 rules for identifying an ATEO's highest-compensated employees and calculating compensation differ significantly from the section 4960 rules.

[3] The proposed and final regulations refer to related persons and governmental entities collectively as related organizations.

These final regulations do not adopt the suggestion in this comment. Instead, these final regulations adopt the rules in the proposed regulations, which align the definition of control with the definition in the Form 990 instructions, which, in turn, is generally based on the section 512(b)(13) standards. The Treasury Department and the IRS have concluded that this definition of control is more appropriate and administrable because the Form 990 control definition and the section 512(b)(13) rules are familiar to and used by exempt organizations. Similarly, an 80 percent control threshold, while used in section 414(b) and (c), as well as in regulations under section 162(m), generally is not a standard used for purposes of tax administration related to exempt organizations, whereas the 50 percent control threshold is a control test familiar to exempt organizations. See, for example, the instructions to Form 990; §§ 1.509(a)–4(g)(1)(i); 1.509(a)–4(j)(1); 56.4911–7(b); 53.4941(d)–1(b)(5); 53.4943–3(b)(3)(ii); 53.4958–4(a)(2)(ii)(B); and 53.4968–3(b). In addition, section 509(a)(3) supporting organizations and their section 509(f)(3) supported organizations are defined as related organizations under section 4960(c)(4)(B); the adoption of an 80 percent control threshold would be incongruous with the lower standards of control for such organizations under § 1.509(a)–4 (particularly in the case of Type III supporting organizations, for which control is not required). Further, the legislative history states that the purpose for enacting section 4960 is to deter ''excessive compensation,''[4] indicating an intent to deter arguably abusive practices, and the Treasury Department and the IRS have determined that use of a higher control threshold would allow potentially abusive compensation arrangements among organizations that are related to a lesser degree.[5] For these reasons, and the reasons set forth in section II.H. of the Explanation of Provisions of the proposed regulations, titled ''Related Organization,'' these final regulations adopt the rules regarding the overall definition of ''control'' in the proposed regulations without change.

To determine control of a nonstock organization, the proposed regulations provided rules similar to other regulations dealing with control of tax-exempt organizations (§§ 1.512(b)–1(l)(4)(i)(b), 53.4958–4(a)(2)(ii)(B)(1)(iii), and 1.414(c)–5(b))[6] that provide that a person is considered to control a nonstock organization under either a ''removal power'' test or a ''representative'' test. No comments were received addressing the ''removal power'' test, and the final regulations adopt these rules from the proposed regulations without change. Comments were received on the ''representative'' test, and in particular the manner in which the proposed regulations would address certain situations involving ''accidental control.''

Under the representative test, a person or governmental entity generally controls a nonstock organization if more than 50 percent of the nonstock organization's directors or trustees are also trustees, directors, officers, agents, or employees of the person or governmental entity. Unlike the representative test in §§ 1.512(b)–1(l)(4)(i)(b), 53.4958–4(a)(2)(ii)(B)(1)(iii), and 1.414(c)–5(b), the proposed regulations expressly included an officer of the person or governmental entity as a representative for purposes of determining control of a nonstock organization.

In response to Notice 2019–09, a commenter raised the issue of ''accidental control'' presented by the representative test in which, for example, control of an organization by an employer may be found because a few lower-level employees of the employer serve on the board of directors of the organization. The proposed regulations addressed this issue by permitting a nonstock organization (or its putative controlling person or governmental entity) to qualify for an exception from control status if the employees of the person or governmental entity that are directors or trustees of the nonstock organization are not trustees, directors, officers, or employees with the powers of a director or officer, of the person or governmental entity and are not acting as representatives of the person or governmental entity in their service with the nonstock organization. A nonstock organization that relies on this exception must report its reliance on this exception on the applicable Form 990 and provide supporting details.

Another commenter on the proposed regulations stated that compliance with this exception to avoid ''accidental control'' under the representative test places additional reporting burdens on exempt organizations and recommended that these final regulations remove ''employees'' altogether from the list of deemed representatives and instead focus the representative test on the actual decision-makers in the organization. The commenter suggested that an expansive list of deemed representatives, including employees, is more justifiable with an 80 percent control threshold. These final regulations do not adopt the commenter's suggestions. The Treasury Department and the IRS have concluded that a rule that treats as non-officers any employees not defined as officers under the organization's organizing documents may be subject to abuse because employees frequently function as officers, even if they do not have that title. Further, a rule that treats any employee without the title of officer as a non-officer would be inconsistent with other Code provisions addressing exempt organizations, which generally treat as an officer any person with similar powers. See, for example, sections 4946(b)(1), 4955(f)(2)(A), 4958(f)(2), 4965(d)(1), and 4966(d)(3)(A). In addition, an employee of an organization (such as a department head) may serve *ex officio* on the board of another organization, and, in substance, serve in a representative capacity. Similarly, the facts of other arrangements in which an employee serves on another organization's board may demonstrate that the employee is serving as a representative of the employer. Finally, the percentage threshold of control is not necessarily relevant to the determination of whether the individual is serving in a representative capacity—an employer with less than a specific threshold percentage may still have reasons to have an employee represent its interests on another organization's board of directors. For these reasons, these final regulations adopt without change the representative rules in the proposed regulations.

The proposed regulations also addressed the status of foreign organizations as ATEOs, excluding them from ATEO status if described in section 4948(b) and the regulations thereunder. The Treasury Department and the IRS requested comments on whether a foreign related organization described in section 4948(b) should be exempt from tax imposed by section 4960(c)(4)(C) and, if so, whether remuneration paid by such an organization should nonetheless be taken into account for purposes of determining excess

[4] H. Rep. 115–409, supra, at 333.

[5] The imposition of excise tax under section 4960 is not determinative as to whether the remuneration paid to the covered employee is excessive or unreasonable compensation for purposes of sections 4941 or 4958. Similarly, there is no presumption, inference, or basis for concluding that remuneration paid to a covered employee that is not subject to excise tax under section 4960 is reasonable compensation for purposes of determining liability for excise tax under sections 4941 or 4958.

[6] See also the representative test in section 4911(f)(2)(B)(i) for determining affiliated organizations.

remuneration and allocating liability among the ATEO and related organizations that are subject to the excise tax imposed by section 4960. No comments were received on these issues. However, the Treasury Department and the IRS have concluded that it is appropriate to address these issues in these final regulations.

Chapter 42 of the Code applies generally to private foundations and other tax-exempt organizations and the excise taxes in chapter 42 generally are payable by exempt organizations and in some cases by persons associated with them. However, under section 4948(b), sections 507 and 508 and chapter 42 do not apply to a foreign organization that has not received substantial support (other than gross investment income) from United States sources. Section 509(d) defines support for purposes of chapter 42 as including gifts, gross receipts from an activity that is not an unrelated trade or business under section 513, net income from unrelated business activities, gross investment income, tax revenues levied for the benefit of the organization, and the value of services or facilities furnished by a governmental unit without charge—a breadth of items that support a tax-exempt organization. Section 4948(b) is thus concerned with foreign private foundations (including entities treated as private foundations for purposes of chapter 42) and other tax-exempt organizations that have received sufficient support from United States sources to warrant subjection to taxation and various prohibitions under chapter 42. Therefore, the Treasury Department and the IRS have determined that it is appropriate to exclude from taxation under section 4960 as a related organization any foreign organization that is both described in section 4948(b) and is either exempt from tax under section 501(a) [7] or a taxable private foundation.[8] Such organizations excluded from the excise tax imposed by section 4960 are referred to as ''section 4948(b) related organizations.''

While chapter 42 taxes are inapplicable to section 4948(b) related organizations, those organizations' activities that otherwise would have resulted in chapter 42 taxes may have other consequences. For example, section 4948(c) in certain circumstances imposes loss of exemption on an exempt organization described in section 4948(b) that engages in activities that would result in chapter 42 taxes for domestic organizations. Therefore, the Treasury Department and the IRS have determined that the remuneration paid to a covered employee of an ATEO by a section 4948(b) related organization must be taken into account by the ATEO and any related organizations subject to the excise tax imposed by section 4960 for purposes of determining an ATEO's (and related organizations') liability under section 4960 and the ATEO's five highest-compensated employees, even though the section 4948(b) related organization is not subject to the excise tax imposed by section 4960 on the excess remuneration that is otherwise allocable to that organization. These final regulations also clarify that for purposes of applying the exclusion from status as an ATEO or a related organization, whether the foreign organization meets the requirements of section 4948(b) is determined at the end of the organization's taxable year.

III. Remuneration

A. In General

Consistent with section 4960(c)(3)(A), the proposed regulations defined ''remuneration'' as wages under section 3401(a) (meaning generally amounts subject to Federal income tax withholding), but excluding designated Roth contributions under section 402A(c) and including amounts required to be included in gross income under section 457(f). Remuneration does not include certain retirement benefits, including payments that are contributions to or distributions from a trust described in section 401(a); payments under or to an annuity plan described in section 403(a) at the time of payment; payments described in section 402(h)(1) and (2) if, at the time of the payment, it is reasonable to believe that the employee will be entitled to an exclusion under that section for the payment; payments under an arrangement to which section 408(p) applies; or payments under or to an eligible deferred compensation plan described in section 457(b) and maintained by an eligible employer described in section 457(e)(1)(A) (governmental employer) at the time of payment. See section 3401(a)(12). Remuneration includes a parachute payment, but excess remuneration does not include a parachute payment that is an excess parachute payment. These final regulations adopt these rules provided in the proposed regulations without change.

One commenter recommended that, for purposes of computing the excise tax, section 4960(c)(4)(A) should be interpreted to include only remuneration related to the employment of an employee by an ATEO, which would include remuneration paid by a related person or related governmental entity with respect to an ATEO or by any other third party, but only if the payment related to the employee's employment by the ATEO. The commenter stated that this suggested interpretation would ensure that all remuneration with respect to a covered employee's employment by an ATEO, including remuneration paid by a related organization of an ATEO with respect to services performed for the ATEO, would be included in computing the tax under section 4960(a). The commenter asserted that the suggested interpretation would avoid the unintended result, caused by the proposed regulations, of subjecting to the excise tax remuneration that is paid by persons who are not ATEOs for an individual's services that are unrelated to an ATEO.

The Treasury Department and the IRS have concluded that the more natural reading of the statute is that remuneration paid to a covered employee of an ATEO includes remuneration paid by a related organization with respect to services performed as an employee for the related organization. In addition, adoption of the commenter's suggestion could raise the potential for abuse because it relies on an ability to identify the specific recipient of services that an employee provides to multiple entities and determine the relative value of the services or allocate the compensation to the entities under a reasonable allocation method. Specifically, given the facts and circumstances analysis that in many cases may be difficult and burdensome to administer, adoption of the suggestion could provide an opening for related taxpayers to coordinate their activities to mischaracterize the employer of an individual with respect to some or all services provided to a related organization, or to misallocate portions of the total remuneration paid by the related taxpayers to the individual as paid for services provided as an employee of a related organization, so that all the related entities avoid any liability under section 4960 while still providing what would otherwise be excess remuneration to the individual as an employee of an ATEO. While this type of identification and allocation may be needed for other tax purposes, including in some cases the

[7] Some types of exempt organizations are limited to domestic organizations, such as section 501(c)(10) fraternal organizations.

[8] A private foundation that loses its exemption under section 501(c)(3) remains a taxable private foundation until its private foundation status is terminated under section 507. See sections 509(b) and 4940(b).

allocation of liability under section 4960, those applications do not involve a situation such as this in which all the entities may benefit from the mischaracterizations through the avoidance of the potential liability. Thus, the interpretation provided in these final regulations also is consistent with the exercise of authority in section 4960(d) to prevent avoidance of the tax imposed by section 4960 by providing compensation through a third party. Further, adoption of the commenter's suggestion could raise issues regarding the role of section 4960(c)(6), the statutory provision coordinating the application of section 162(m) and section 4960, given the impact that adoption of the suggestion would have on the scope of circumstances to which that provision may apply. For these reasons, these final regulations do not limit the application of section 4960(c)(4)(A) to remuneration paid solely with respect to employment by an ATEO or for services provided to an ATEO, as suggested by the commenter.

The commenter also suggested that these final regulations not treat remuneration paid by a related organization as paid by the ATEO if a covered employee is not employed by an ATEO at any time during an applicable year. For example, in circumstances in which a covered employee of an ATEO performs services for a related non-ATEO but provides no services for the ATEO during an applicable year, the commenter suggested that compensation for those services not be treated as remuneration under section 4960. These final regulations do not adopt this suggestion. Section 4960(c)(2)(B) provides that once an individual is a covered employee of an ATEO (or any predecessor), the employee remains a covered employee for all subsequent years. Section 4960(c)(4)(A) provides that ''remuneration of a covered employee by an [ATEO]'' includes ''any remuneration paid with respect to employment of such employee by any related person or governmental entity.'' The Treasury Department and the IRS have concluded that the better interpretation of section 4960(c)(2)(B) and (c)(4)(A), when read together, is that compensation paid to a covered employee by a related organization during an applicable year is remuneration for purposes of section 4960, even if the covered employee does not perform services as an employee of the ATEO during the applicable year. In addition, the commenter's suggestion also raises administrability issues similar to those that would arise if only remuneration for services provided to the ATEO were taken into account. If an employee provides services to different members of a group of related organizations from year to year, it may be difficult to determine what remuneration is allocable to services provided to each group member. Therefore, the commenter's suggestion would be similarly difficult and burdensome to administer and could raise the potential for abuse.

The same commenter also suggested that these final regulations apply the substance of the limited hours and nonexempt funds exceptions for purposes of determining remuneration paid. These final regulations do not adopt this suggestion because the Treasury Department and the IRS have concluded that the statute does not provide the authority to apply these exceptions to the definition of remuneration. The statute does not define compensation for purposes of identifying the five highest-compensated employees, and thus the statute permits flexibility in the rules for determining the five highest-compensated employees. In contrast, section 4960(c)(3)(A) defines remuneration as wages within the meaning of section 3401(a) (with certain specified modifications) paid by an ATEO and section 4960(c)(4)(A) provides that ''remuneration of a covered employee by an [ATEO] shall include any remuneration paid with respect to employment of such employee by any related person or governmental entity.'' These statutory provisions do not provide the flexibility to adopt the commenter's suggestion to include the exceptions applicable to the determination of a covered employee in the definition of remuneration.

Another commenter requested that these final regulations limit the scope of the definition of remuneration to include only regular employee wages, as defined in section 3401(a), and to exclude taxable fringe benefits from the section 4960 definition of remuneration. The commenter asserted that certain taxable fringe benefits, such as paid parking above the excludable limit and reimbursement of childcare expenses, are not the type of remuneration that was intended to be taxed under section 4960. The commenter further suggested that the inclusion of taxable fringe benefits in remuneration would have an adverse effect on certain employers' ability to attract and retain key employees. These final regulations do not adopt this commenter's suggestion because it would be inconsistent with the statutory provisions. Section 4960(c)(3)(A) defines remuneration as amounts that are ''wages'' within the meaning of section 3401(a). Section 3401(a) defines ''wages'' as all remuneration for services performed by an employee for his employer, including the cash value of all remuneration (including benefits) paid in any medium other than cash, with certain specific exclusions. Taxable fringe benefits, including parking above the excludable limit and reimbursement of childcare expenses, are not excluded from wages under section 3401(a). In addition, section 4960(c)(3) specifically excludes other type of wages, such as designated Roth contributions and remuneration for medical services, indicating a legislative intent for all other types of wages to be included. For these reasons, the Treasury Department and the IRS have determined that providing further exclusions such as those suggested would be inconsistent with the statute and these final regulations do not adopt this suggestion.

The proposed regulations clarified that remuneration includes any amount includible in gross income as compensation under section 7872 and the regulations thereunder. For example, under § 1.7872–15(e)(1)(i), a below-market split-dollar loan between an employer and employee generally is treated as a compensation-related loan, and thus any imputed transfer from the employer to the employee generally is a payment of compensation. Although section 7872(f)(9) provides that no amount shall be withheld under chapter 24 of the Code with respect to any amount treated as transferred or retransferred under section 7872(a) or received under section 7872(b), those amounts are ''remuneration . . . for services performed by an employee for his employer'' within the meaning of section 3401(a) and are not specifically excluded from wages under section 3401(a). Thus, those amounts are remuneration as defined in section 4960(c)(3)(A). ATEOs that are private foundations or section 509(a)(3) supporting organizations should consider, before entering into these arrangements, that loans (including transactions treated as loans for Federal tax purposes, such as split-dollar arrangements) to certain employees may constitute an act of self-dealing under section 4941 or an excess benefit transaction under section 4958(c)(3).

A commenter recommended that these final regulations, or alternatively the preamble to these final regulations, confirm that remuneration does not include amounts that are not includible in gross income pursuant to the $10,000 de minimis exception under section 7872(c)(3). Under that exception, the

foregone interest attributable to any day on which the aggregate outstanding amount of loans between the borrower and lender does not exceed $10,000 is not includible in gross income. These final regulations adopt the commenter's suggestion and clarify that, in accordance with section 7872, these de minimis amounts are not remuneration for purposes of section 4960. Other than this comment that resulted in this clarification, no further comments were received on those provisions of the proposed regulations, and these final regulations adopt them without further changes.

B. Remuneration Related to Medical Services

Remuneration that is paid to a licensed medical professional for medical services is excluded from the definition of ''remuneration'' for purposes of section 4960. (See section II.F. of the Summary of Comments and Explanation of Revisions, titled ''Medical Services,'' for a further discussion of the scope of this exception.) When an employer pays remuneration to an employee for both medical services (including related services, such as medical recordkeeping) and other services, the employer must allocate that remuneration between remuneration paid for medical services or for other services. These final regulations adopt the proposed regulations, with minor clarifications, and permit taxpayers to use a reasonable, good faith method to allocate remuneration between these two categories of services. For this purpose, taxpayers may rely on a reasonable allocation set forth in an employment agreement allocating remuneration between medical services and other services. If some or all of the remuneration is not reasonably allocated in an employment agreement, taxpayers must use another reasonable method of allocation. For example, allocating remuneration to medical services based on the portion of the total hours the employee worked for the employer providing medical services (determined based on records such as patient, insurance, Medicare/Medicaid billing records, or internal time reporting mechanisms) would be a reasonable method.

In section III.B. of the Explanation of Provisions of the proposed regulations, titled ''Remuneration Related to Medical Services,'' the Treasury Department and the IRS requested comments on other reasonable methods of allocating remuneration between medical services and other services. One commenter recommended that an employer be permitted to make a reasonable, good faith allocation between remuneration for providing medical services and remuneration for providing nonmedical services, not only with respect to current remuneration but also with respect to contributions and earnings under a deferred compensation plan. These final regulations adopt this recommendation and clarify that an employer may make a reasonable, good faith allocation between remuneration for medical and nonmedical services, regardless of the form of compensation, and that an employer may apply the same principles with respect to contributions and earnings under a deferred compensation plan.

C. When Remuneration Is Treated as Paid

The proposed regulations addressed when remuneration is treated as paid for purposes of section 4960. The flush language at the end of section 4960(a) provides that, for purposes of section 4960(a), remuneration is treated as paid when there is no substantial risk of forfeiture of the rights to the remuneration within the meaning of section 457(f)(3)(B). Although section 4960(a) cross-references the definition of ''substantial risk of forfeiture'' in section 457(f)(3)(B), the rule under section 4960(a) providing that remuneration is treated as paid when there is no substantial risk of forfeiture of the rights to the remuneration is neither limited to remuneration that is otherwise subject to section 457(f) nor limited to amounts paid pursuant to a nonqualified deferred compensation arrangement. The proposed regulations provided that, for purposes of section 4960(a), all forms of remuneration except for ''regular wages'' as described in the next paragraph are treated as paid when the remuneration is not subject to a substantial risk of forfeiture. These final regulations adopt this payment timing rule provided in the proposed regulations with certain modifications, as discussed in further detail in this section.

To clarify when remuneration that is never subject to a substantial risk of forfeiture is treated as paid, the proposed regulations provided that remuneration that is a ''regular wage'' within the meaning of § 31.3402(g)–1(a)(ii) is treated as paid at the time of actual or constructive payment. A ''regular wage'' is defined in § 31.3402(g)–1(a)(ii) as remuneration ''paid at a regular hourly, daily, or similar periodic rate (and not an overtime rate) for the current payroll period or at a predetermined fixed determinable amount for the current payroll period.'' These final regulations adopt these rules provided in the proposed regulations without change. Because the final regulations provide that remuneration that is a regular wage within the meaning of § 31.3402(g)–1(a)(1)(ii) is treated as paid when actually or constructively paid, an employer will not need to determine amounts of regular wages that vested in the preceding year for purposes of section 4960. For example, if a pay period begins December 25, 2022, and ends January 7, 2023, and the salary for that period is not actually paid until January 14, 2023, then the salary for the pay period is treated as paid in 2023, and the employer need not treat any amount as remuneration paid in 2022 due to vesting in 2022.

The proposed regulations treated an amount that is not regular wages as paid when it is no longer subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B) and referred to such an amount as ''vested.'' The Treasury Department and the IRS issued proposed regulations under section 457(f) in 2016 (81 FR 40548 (June 22, 2016)), upon which taxpayers may rely for periods before the applicability date of the final section 457(f) regulations. Under Prop. § 1.457–12(e)(1), an amount of compensation is subject to a substantial risk of forfeiture only if entitlement to the amount is conditioned on the future performance of substantial services, or upon the occurrence of a condition that is related to a purpose of the compensation if the possibility of forfeiture is substantial. See Prop. § 1.457–12(e)(3) for examples of the rules relating to substantial risk forfeiture. These final regulations adopt the rules provided in the proposed regulations, including the definition of ''substantial risk of forfeiture'' in Prop. § 1.457–12(e)(1). Any changes to the proposed regulations under section 457(f) when finalized will be considered for purposes of section 4960, and further guidance may be issued, if appropriate, including any transition guidance that may be needed to take into account periods before and after the applicability date of the definition of substantial risk of forfeiture under the final section 457(f) regulations.

In section III.C. of the Explanation of Provisions of the proposed regulations, titled ''When Remuneration Is Treated as Paid,'' the Treasury Department and the IRS invited comments regarding any burdens that could be avoided through a short-term deferral rule and how such a rule could be designed to avoid permitting inappropriate avoidance of the tax. One commenter recommended that these final regulations extend the

rule for ''regular wages'' as defined in § 31.3402(g)–1(a) to amounts that are not treated as deferred compensation under § 1.409A–1(b)(4) or Prop. § 1.457–12(d)(2) because such amounts are paid within the ''short-term deferral'' period. The commenter suggested that other remuneration that falls outside the definition of ''regular wages'' be treated as remuneration when actually or constructively paid, including benefits under bona fide severance pay plans and death and disability plans, as well as annual bonuses, long-term incentive pay, business expense reimbursements, and noncash fringe benefits. The commenter noted that such amounts are treated as wages for other reporting purposes, including Federal Insurance Contributions Act (FICA) wage reporting, when actually or constructively paid, and thus the rules under the proposed regulations result in a timing mismatch. The commenter asserted that this recommendation would substantially reduce the administrative burden and potential for errors created by the broad timing rule in the proposed regulations, yet affect a limited range of remuneration.

Another commenter recommended that these final regulations provide that the short-term deferral exception to the definition of deferred compensation for section 457(f) apply to section 4960 such that the year of inclusion for income tax purposes matches the year of inclusion for section 4960 purposes. The commenter interpreted the statutory reference to wages under section 3401(a) and amounts included in income under section 457(f) as providing not only a substantive rule but also a timing rule, meaning the amount must either be wages within the meaning of section 3401(a) paid during that year or be an amount included in income under section 457(f) during that year in order to be treated as remuneration paid in that year. According to the commenter, since amounts that meet the definition of a short-term deferral for purposes of section 457(f) are neither wages under section 3401(a) nor includible in income under section 457(f) in the year of vesting, those amounts should be treated as remuneration for purposes of section 4960 only in the year actually paid.

Further, the commenter noted that applying a short-term deferral rule would simplify administration for employers because the determination of remuneration would more closely track the determination of wages for Form W–2, ''Wage and Tax Statement,'' reporting. The commenter acknowledged the concern stated in section III.C. of the Explanation of Provisions of the proposed regulations, titled ''When Remuneration Is Treated as Paid,'' that a short-term deferral rule would permit an ATEO to select the year in which remuneration would be subject to tax under section 4960, but observed that an individual may become a covered employee during the section 457(f) short-term deferral period after the year of vesting, and thus the proposed rule could actually result in amounts not being subject to the excise tax. The commenter also observed that treating short-term deferrals as remuneration in the year of vesting requires that those amounts be present-valued and that earnings be included in remuneration in the subsequent year, resulting in additional complexity for ATEOs. Finally, the commenter suggested that an employer be permitted to include an amount in remuneration in the year of vesting or include the amount in the year of payment, as is permitted for FICA tax purposes under § 31.3121(v)(2)–1(b)(3)(iii), and require that employers apply consistent treatment of amounts with respect to its selection of the timing of FICA taxation of short-term deferrals and timing of the treatment as remuneration for purposes of section 4960.

These final regulations do not adopt the commenter's suggestions to apply a ''short-term deferral'' rule. Rather, these final regulations adopt the applicable provisions of the proposed regulations without change. Under section 4960(c)(3), an amount must either be wages under section 3401(a) or be includible in income under section 457(f) in order to be remuneration under section 4960. However, the rules under section 4960(c)(3) determine whether an amount is remuneration, not when the remuneration is considered to be paid. The flush language at the end of section 4960(a) provides that, for purposes of section 4960(a), remuneration is treated as paid when there is no substantial risk of forfeiture, as defined in section 457(f)(3)(B), of the rights to the remuneration. Section 3401(a) primarily focuses on whether, not when, amounts are includible in wages; the basic timing rule for wage inclusion appears in regulations under section 3402(a), not section 3401(a). Specifically, § 31.3402(a)–1(b) provides that wages are paid when actually or constructively paid and explains what it means for an amount to be constructively paid. Thus, the cross-reference to section 3401(a) (and not section 3402(a)) in section 4960(c)(3) establishes the scope of the term ''remuneration'' without regard to timing, but the flush language in section 4960(a) establishes the timing rule that applies to all forms of remuneration. In addition to being inconsistent with the statutory language addressing the timing of the payment of remuneration, allowing a short-term deferral rule similar to the rule in § 1.409A–1(b)(4) and Prop. § 1.457–12(d)(2) could permit an employer to determine the taxable year in which the amount is treated as paid, which could be used not only to manipulate the application of section 4960(a) to the remuneration paid, but also to manipulate the identification of covered employees.

This application of the statutory language results in circumstances in which the amount of remuneration paid for purposes of section 4960 is not the same as the amount reported in any box on Form W–2 for an applicable year. However, as described later in this section, these final regulations address the administrative burden of calculating the present value of vested but unpaid amounts by expanding the ability to include at vesting the full amount that is to be paid in circumstances in which there is a short delay between vesting and payment.

These final regulations adopt the rule set forth in the proposed regulations that provided that an amount of remuneration treated as paid generally is the present value of the remuneration on the date on which the covered employee vests in the right to payment of the remuneration. The employer must determine the present value using reasonable actuarial assumptions regarding the amount, time, and probability that the payment will be made. These final regulations do not provide rules for the determination of present value. However, an employer may determine the present value using the rules set forth in Prop. § 1.457–12(c)(1). The Treasury Department and the IRS anticipate that final regulations addressing the determination of present value for purposes of section 4960 will be issued when final regulations under section 457(f) are issued. Until actually or constructively paid or otherwise includible in gross income of the employee, any amount treated as paid at vesting is referred to as ''previously paid remuneration.''

To reduce the administrative burden of determining the present value of remuneration in certain circumstances that would involve minimal discounting, these final regulations adopt the rule provided in the proposed regulations that the employer may treat the entire amount to be paid on a future date (without making a present valuation determination) as the present value on the date of vesting. However, these final regulations do not limit the

application of this rule to amounts that are paid under a nonaccount balance plan described in § 1.409A–1(c)(2)(i)(C), but instead this rule applies to any vested amount that is scheduled to be paid within 90 days. For example, an employer is not required to discount an annual bonus of $10,000 that vests on December 31, 2022, and is scheduled to be paid on February 15, 2023, to reflect the delay in actual payment, but instead may treat $10,000 as remuneration paid in 2022.

D. Earnings and Losses

These final regulations generally adopt the proposed regulations and provide specific rules for the treatment of earnings and losses on previously paid remuneration. In general, these rules are intended to minimize administrative burdens in determining the amount of earnings and losses treated as paid for an applicable year, as well as in determining the amount of earnings and losses across multiple compensation arrangements.

The proposed regulations provided that net earnings on previously paid remuneration are treated as vested (and therefore paid) on the last day of the applicable year in which they are accrued unless otherwise actually or constructively paid before that date. For example, the present value of vested remuneration accrued to an employee's account under an account balance plan described in § 1.409A–1(c)(2)(i)(A) (under which the earnings and losses attributed to the account are based solely on a predetermined actual investment or a reasonable market interest rate) is treated as paid on the date accrued to the employee's account and, until subsequently actually or constructively paid, is treated as previously paid remuneration. In addition, at the end of each applicable year in which there is previously paid remuneration remaining in the covered employee's account balance, the present value of any net earnings accrued on that previously paid remuneration (the increase in present value due to the application of a predetermined actual investment or a reasonable market interest rate) is treated as remuneration paid in that applicable year. This remuneration is then treated as previously paid remuneration for subsequent applicable years until actually or constructively paid.

Similarly, the proposed regulations provided that the present value of a vested, fixed amount of remuneration under a nonaccount balance plan described in § 1.409A–1(c)(2)(i)(C) is treated as paid on the date of vesting and subsequently treated as previously paid remuneration until actually or constructively paid. In addition, at the end of each applicable year in which previously paid remuneration remains as part of the covered employee's benefit under the plan, the net increase in the present value of that amount during the year due solely to the passage of time constitutes earnings and is treated as remuneration paid. For this purpose, earnings and losses from one plan or arrangement are aggregated with earnings and losses from any other plan or arrangement in which the employee participates that is provided by the same employer (but not across arrangements provided by related but separate employers). For purposes of determining earnings and losses, previously paid remuneration under a plan or arrangement is reduced by the amount actually or constructively paid under the plan or arrangement. These final regulations further illustrate the operation of these rules through examples.

One commenter recommended that these final regulations permit, but not require, related employers to determine net earnings on previously paid remuneration on an aggregate basis by treating all earnings and losses on the previously paid remuneration of related employers as paid by the ATEO. The commenter explained that in groups of related taxable and tax-exempt organizations, related organizations often provide separate deferred compensation plans to their employees. Therefore, an individual employee who works (or has worked) for multiple related employers might have several deferred compensation plans, which often differ considerably, with some being nonaccount balance plans and others being account balance plans that may offer very different investment options. As a result, an individual employee might accrue significant earnings in a year under some deferred compensation plans but incur significant losses in others. The commenter therefore suggested that these final regulations permit aggregation of losses with earnings among related employers to avoid the inappropriate inflation of remuneration in certain circumstances. Any concerns about manipulation due to permitting aggregation could be addressed by requiring employers to aggregate (or not aggregate) earnings and losses consistently from year to year, with changes allowed only infrequently—for example, every 3 years—unless in response to changes in the composition of the group of related organizations.

These final regulations do not adopt the commenter's suggestion to permit the aggregation of earnings and losses among related organizations. The commenter's suggestions would be feasible among related organizations only if they agreed to either aggregate or disaggregate arrangements as to all employees and also to coordinate and integrate their remuneration calculations across the separate plans and arrangements that each employer established to permit timely and accurate calculations for each covered employee (and employees that may become covered employees) who participated in more than one employer arrangement. Even if this was feasible for a particular year, the regulatory framework would need to account for the entry and departure of members of the group of related organizations and how the aggregation or disaggregation would account for those events. This regime would be complex and burdensome for taxpayers and the IRS to administer and is not warranted due to the limited potential benefits. In addition, the aggregation of earnings and losses across related employers would implicate the statutory allocation of the liability for the tax on excess remuneration under section 4960(c)(4)(C), since the aggregation of earnings and losses would impact the relative remuneration paid by the separate employers.

E. Request for a Grandfathering Rule

One commenter suggested that these final regulations provide for grandfathering of employee remuneration contracts executed on or before November 2, 2017, so that amounts paid under such contracts would not be treated as remuneration for purposes of section 4960. The commenter reasoned that the grandfathering of employee remuneration contracts executed on or before November 2, 2017, would help certain employers in overcoming challenges in hiring executives, and that the legislative history of the TCJA failed to consider the differences between tax-exempt employers and their taxable counterparts. The final regulations do not adopt the commenter's suggested rule. Section 13602(c) of TCJA, which added section 4960 to the Code, did not provide for a grandfathering rule and there is no indication in the legislative history that Congress intended that one be adopted by regulation. In contrast, section 13601 of TCJA amended section 162(m) of the Code and provided an explicit grandfathering rule. Under these circumstances, the Treasury Department and the IRS do not find it appropriate to provide a grandfathering rule. However, these final regulations

provide rules that have the effect of grandfathering remuneration that vested before the taxpayer's first taxable year beginning after December 31, 2017.

Section III.E. of the Explanation of Provisions of the proposed regulations, titled ''Request for a Grandfather Rule,'' explained that one of the consequences of treating remuneration as paid at the time the remuneration vests is that any remuneration that vested prior to the first day of the first taxable year of the ATEO beginning after December 31, 2017, is not considered remuneration for purposes of section 4960. One commenter recommended that the Treasury Department and the IRS explicitly reflect this rule in these final regulations. In response to this comment, these final regulations provide that any vested remuneration, including vested but unpaid earnings accrued on deferred amounts, that is treated as paid before the effective date of section 4960 (January 1, 2018, for a calendar year employer) is not subject to the excise tax imposed under section 4960(a)(1). All earnings on those vested amounts that accrue or vest after the effective date, however, are treated as remuneration paid for purposes of section 4960(a)(1).

Similarly, for an employee who has vested compensation from years prior to the taxable year in which the employee first became a covered employee, these final regulations adopt the rule in the proposed regulations providing that vested remuneration (including vested but unpaid earnings) that would have been treated as remuneration paid for a taxable year before the taxable year in which an employee first became a covered employee under section 4960 is not remuneration subject to the excise tax imposed by section 4960(a)(1) for the first taxable year in which the employee becomes a covered employee or any subsequent year. However, subsequent earnings that accrue on those vested amounts when the employee is a covered employee are treated as remuneration paid for purposes of section 4960(a)(1).

F. Remuneration Paid to a Covered Employee for Which a Deduction Is Disallowed Under Section 162(m)

Section 4960(c)(6) provides that remuneration for which a deduction is disallowed under section 162(m) is not taken into account for purposes of section 4960. Thus, remuneration that is paid to a covered employee of an ATEO who is also a covered employee of a related ''publicly held corporation'' or an applicable individual of a related ''covered health insurance provider'' (as defined in section 162(m)(2) and (m)(6)(C), respectively), for which a deduction is disallowed under section 162(m), generally is not treated as remuneration for purposes of determining whether remuneration has been paid. However, that remuneration is taken into account for purposes of determining the ATEO's five highest-compensated employees. See section II.E. of this Summary of Comments and Explanation of Revisions, titled ''Covered Employee.''

As discussed in section III.F. of the Explanation of Provisions of the proposed regulations, titled ''Remuneration Paid to a Covered Employee for Which a Deduction Is Disallowed Under Section 162(m),'' the application of this provision raises significant issues stemming largely from the difference in timing between the payment of remuneration under section 4960 (when the right to the amount vests), and the availability of a deduction that may be restricted by section 162(m) (generally when the amount is paid). Section III.F. of the Explanation of Provisions of the proposed regulations, titled ''Remuneration Paid to a Covered Employee for Which a Deduction Is Disallowed Under Section 162(m),'' described two possible approaches for addressing these circumstances and requested comments on those approaches. The Treasury Department and the IRS continue to consider the issues raised by this provision in section 4960(c)(6) requiring coordination with section 162(m), including the comments submitted, but have not yet determined the appropriate manner of implementation. Accordingly, these final regulations do not address the coordination of sections 4960 and 162(m) in these circumstances, but instead reserve a section of these final regulations as a place for future guidance.

Until that future guidance is issued, taxpayers may use a reasonable, good faith approach with respect to the coordination of sections 4960 and 162(m) in circumstances in which it is not known whether a deduction for the remuneration will be disallowed under section 162(m) by the due date (including any extension) of the relevant Form 4720. For this purpose, a reasonable, good faith approach must have a reasonable basis for anticipating that the compensation that a particular employee will be paid in the future may be subject to the deduction limitations of section 162(m). For example, it is not reasonable for this purpose to anticipate that an ATEO may become a public corporation by the date the compensation will be paid absent facts indicating that is a realistic potentiality. Additionally, until further guidance is issued, the two approaches regarding deferred compensation described in section III.F. of the Explanation of Provisions of the proposed regulations, titled ''Remuneration Paid to a Covered Employee for Which a Deduction Is Disallowed Under Section 162(m),'' will be treated as reasonable, good faith approaches. However, a third approach suggested by a commenter, under which section 162(m) would not disallow a taxpayer's deduction for remuneration that the taxpayer treated as excess remuneration under section 4960 in a previous taxable year, will not be treated as a reasonable, good faith approach, because such an approach would be inconsistent with section 162(m) and the regulations thereunder.

IV. Excess Remuneration

In general, the excise tax imposed under section 4960(a)(1) is based on the remuneration paid (other than any excess parachute payment) by an ATEO for the taxable year with respect to employment of any covered employee in excess of $1 million. Consistent with the proposed regulations, these final regulations refer to this amount as ''excess remuneration.'' The $1 million threshold provided in section 4960(a)(1) is not adjusted for inflation, and an amount subject to tax under section 4960(a)(2) as an excess parachute payment is not subject to tax under section 4960(a)(1) as excess remuneration.

As provided in section 4960(c)(4)(C), if an individual performs services as an employee for two or more related organizations during an applicable year, one or more of which is an ATEO, each employer is liable for its proportionate share of the excise tax. These final regulations adopt the rules provided in the proposed regulations for allocating liability for the excise tax among the employers. For this purpose, remuneration that is paid by a separate organization (whether related to the ATEO or not) for services performed as an employee of the ATEO is treated as remuneration paid by the ATEO. For a further discussion of when amounts are treated as paid by an ATEO, see section VI of this Summary of Comments and Explanation of Revisions, titled ''Calculation, Reporting, and Payment of the Tax.''

V. Excess Parachute Payments

A. In General

The proposed regulations set forth rules with respect to excess parachute payments under section 4960. No

comments were received on these rules, and these final regulations adopt them without change. Section 4960(a)(2) imposes an excise tax on any excess parachute payment. Section 4960(c)(5)(A) provides that ''excess parachute payment'' means an amount equal to the excess of any parachute payment over the portion of the base amount allocated to such payment. Section 4960(c)(5)(B) provides that ''parachute payment'' means any payment in the nature of compensation to (or for the benefit of) a covered employee if the payment is contingent on the employee's separation from employment with the employer and the aggregate present value of the payments in the nature of compensation to (or for the benefit of) the individual that are contingent on the separation equals or exceeds an amount equal to 3-times the base amount. Under section 4960(c)(5)(C), certain retirement plan payments, certain payments to licensed medical professionals, and payments to an individual who is not a ''highly compensated employee'' (HCE) as defined in section 414(q) are not excess parachute payments.[9]

The excess parachute payment rules under section 4960 are modeled after section 280G, but section 4960(c)(5)(B) defines ''parachute payment'' differently than section 280G(b)(2). The section 4960 definition refers to payments contingent on an employee's separation from employment, whereas the section 280G definition refers to payments contingent on a change in the ownership or effective control of a corporation (or in the ownership of a substantial portion of the assets of the corporation). While these final regulations incorporate many of the concepts found in the rules under § 1.280G–1, with modifications to reflect the statutory differences between sections 280G and 4960, they do not incorporate other rules under § 1.280G–1 because those rules address issues that do not arise under section 4960. In addition, many provisions in these final regulations do not have parallel rules under § 1.280G–1 because they address issues that arise under section 4960, but not under section 280G.

The following sections provide a general overview of these final regulations for purposes of calculating the excise tax imposed under section 4960(a)(2), noting certain similarities and differences between these final regulations and the rules under § 1.280G–1. For more information concerning these rules, including additional similarities and differences with the rules under section 280G, see section V of the Explanation of Provisions of the proposed regulations, titled ''Excess Parachute Payments.''

B. Definitions Related to Excess Parachute Payments

These final regulations define ''excess parachute payment'' and the term ''parachute payment'' for purposes of section 4960. Any payment in the nature of compensation made by an ATEO (or any predecessor or related organization) to a covered employee that is contingent on the employee's separation from employment is taken into account for purposes of the parachute payment calculation, assuming no exclusion applies. Those combined payments constitute a parachute payment if the aggregate present value of all such payments made to an individual equals or exceeds 3-times the individual's base amount. A parachute payment is an excess parachute payment to the extent it exceeds one-times the individual's base amount allocated to the payment.

These final regulations define a ''payment in the nature of compensation'' based on § 1.280G–1, Q/A–11 and Q/A–14. In general, any payment arising out of an employment relationship is a payment in the nature of compensation. A payment in the nature of compensation is reduced, however, by any consideration paid by the covered employee in exchange for the payment.

C. Payments Contingent on a Separation From Employment

1. In General

Although section 4960 does not define what it means for a payment to be contingent on a separation from employment, these final regulations generally treat a payment as contingent on an employee's separation from employment only if there is an involuntary separation from employment. If the payment is subject to a substantial risk of forfeiture (defined in a manner consistent with section 457(f)) that lapses upon an involuntary separation from employment, and the separation causes the risk of forfeiture to lapse, the payment is contingent on separation from employment.

2. Requirement of Involuntary Separation From Employment

Separation from employment (whether voluntary or involuntary) often is used in compensation arrangements as a trigger to pay vested compensation. For example, it is typical for a nonqualified deferred compensation plan to provide that a payment or a series of payments will be made or begin upon a separation from employment, including separation from employment resulting from death or disability. The vested amounts that are to be paid after a separation from employment generally are not treated as contingent on a separation from employment because the amounts will never be subject to forfeiture or otherwise not paid (even if an employee does not voluntarily or involuntarily terminate employment during the employee's lifetime, the payments will be made upon the employee's death). In these cases, the separation from employment functions only as a payment timing event and is neither a contingent event that may not occur nor a precondition to entitlement to the payment.

3. Definition of ''Involuntary Separation From Employment''

If an amount is payable solely upon an involuntary separation from employment, then it is a payment contingent on an event that may not occur and that is a precondition to entitlement to the payment. The definition of an ''involuntary separation from employment'' set forth in these final regulations is modeled after the definition of an ''involuntary separation from service'' in § 1.409A–1(n)(1), which also was the model for the definition of an ''involuntary severance from employment'' under Prop. § 1.457–11(d)(2). A separation from employment for good reason is treated as an involuntary separation from employment for purposes of section 4960 if certain conditions are met. For this purpose, these regulations generally adopt the standards set forth in § 1.409A–1(n)(2) and Prop. § 1.457–11(d)(2)(ii).

These final regulations generally adopt the standards of the section 409A regulations for purposes of determining whether there has been a separation from employment, except that for purposes of section 4960 a bona fide change from employee to independent contractor status is treated as a

[9] Under section 414(q), a ''highly compensated employee'' generally is defined as any employee who was a five-percent owner at any time during the year or the preceding year or who had compensation from the employer in the preceding year in excess of an inflation-adjusted amount. Notice 2019–59 (2019–47 I.R.B. 1091) and Notice 2020–79 (2020–46 I.R.B 1014), provide that the inflation-adjusted amounts for 2020 and 2021 are $130,000 and $130,000, respectively. See section 414(q) and the regulations thereunder for additional rules, including the availability of an election to treat no more than the top 20 percent of an employer's employees as highly compensated employees by reason of their compensation.

separation from employment. Because the section 409A regulations do not provide a standard for determining when an involuntary change of status from employee to independent contractor results in a separation from employment, in section V.C.3. of the Explanation of Provisions of the proposed regulations, titled ''Definition of 'Involuntary Separation from Employment,' '' the Treasury Department and the IRS requested comments on whether additional guidance is needed on this issue. No comments were received in response to that request. Consistent with the proposed regulations, these final regulations provide that a separation from employment occurs in the case of a bona fide and involuntary change of status from employee to independent contractor in circumstances in which the change in status otherwise meets the requirements for an involuntary separation from employment.

With respect to when an employee otherwise has terminated employment, these final regulations adopt rules based on the section 409A regulations. Specifically, these regulations adopt the standards of § 1.409A–1(h)(1)(ii), providing that an anticipated reduction in the level of services of more than 80 percent is treated as a separation from employment, an anticipated reduction in the level of services of less than 50 percent is not treated as a separation from employment, and the treatment of an anticipated reduction between these two levels will depend on the facts and circumstances. The measurement of the anticipated reduction in the level of services is based on the average level of bona fide services performed over the immediately preceding 3 years (or shorter period for an employee employed for less than 3 full prior years). However, these regulations do not adopt the rule in § 1.409A–1(h)(1)(ii), under which an employer may modify the level of the anticipated reduction in future services that will be considered to result in a separation from employment.

4. When a Payment Is Contingent on Separation From Employment

In defining when a payment is contingent on separation from employment, these final regulations do not focus solely on whether the payment would not have been made but for a separation from employment, but also take into consideration whether the separation from employment accelerates the right to payment or the lapse of a substantial risk of forfeiture with respect to the right to payment. Generally, if the payment or the lapse of a substantial risk of forfeiture is accelerated as a result of an involuntary separation from employment (such as a payment that otherwise would have vested and been paid had the employee remained employed for a subsequent period), then the value of any accelerated payment plus the value of any lapse of the substantial risk of forfeiture is treated as contingent on a separation from employment (since the employer would not have provided the increased value in the absence of an involuntary separation from employment).

However, if the lapse of the substantial risk of forfeiture is dependent on an event other than the performance of services, such as the attainment of a performance goal, and if that event does not occur prior to the employee's separation from employment, but the payment vests due to the employee's involuntary separation from employment, then the full amount of the payment is treated as contingent on the separation from employment.

As discussed in section V.C.4. of the Explanation of Provisions of the proposed regulations, titled ''When a Payment Is Contingent on Separation from Employment,'' a payment the right to which is not subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B) at the time of an involuntary separation from employment generally is not contingent on a separation from employment (since the right to the payment is not triggered by the separation from employment). However, the increased value of a payment accelerated due to the involuntary separation from employment, and the value of accelerated vesting due to the involuntary separation from employment, each generally are treated as a payment contingent on a separation from employment. In addition, a payment for damages due to the breach of an employment agreement that is related to an involuntary separation from employment generally constitutes a payment contingent on a separation from employment, and a payment for compliance with a noncompetition agreement or similar arrangement may, in certain situations, constitute a payment contingent on a separation from employment.

Actual or constructive payment of an amount that was previously includible in gross income is not a payment contingent on a separation from employment. For example, a payment of deferred compensation after an involuntary separation from employment that vested based on years of service completed before the involuntary separation from employment generally is not a payment that is contingent on a separation from employment because the separation from employment may affect the time of, but not the right to, the payment (although the value of an acceleration of the payment may be contingent on a separation from employment).

Unlike Q/A–25 and Q/A–26 of § 1.280G–1, these regulations do not provide a presumption that a payment made pursuant to an agreement entered into or modified within 12 months of a separation from employment is a payment that is contingent on a separation from employment. However, as discussed later in this section, if the facts and circumstances demonstrate that either the vesting or the payment of an amount would not have occurred but for the involuntary nature of the separation from employment, the amount will be treated as a payment contingent on a separation from employment.

In addition, these final regulations do not provide a rule similar to § 1.280G–1, Q/A–9 (exempting reasonable compensation for services rendered on or after a change in ownership or control from the definition of ''parachute payment''), which would exclude reasonable compensation for services provided after a separation from employment. In most cases, the issue of whether payments made after a separation from employment are reasonable compensation for services will not arise because the employee will not provide services after the separation from employment. However, if the employee continues to provide services (including as a bona fide independent contractor) after an involuntary separation from employment, payments for those services are not contingent on the involuntary separation from employment to the extent those payments are reasonable and are not made due to the involuntary nature of the separation from employment.

Notwithstanding the foregoing, if the facts and circumstances demonstrate that either vesting or payment of an amount (whether before or after an involuntary separation from employment) would not have occurred but for the involuntary nature of the separation from employment, the amount will be treated as contingent on a separation from employment. For example, an employer's exercise of discretion to accelerate vesting of an amount shortly before an involuntary separation from employment may indicate that the acceleration of vesting was due to the involuntary nature of the separation from employment and was

therefore contingent on the employee's separation from employment.

In section V.C.4. of the Explanation of Provisions of the proposed regulations, titled ''When a Payment Is Contingent on Separation from Employment,'' the Treasury Department and the IRS requested comments on whether there are additional types of payments made in connection with separation from employment and the extent to which these final regulations under section 4960 should be modified to ensure appropriate classification of those payments as contingent or not contingent on separation from employment. No comments were received in response to this request, and no modifications have been made in the final regulations.

D. Three-Times-Base-Amount Test

Section 4960(c)(5) provides rules for determining the tax on any excess parachute payment imposed under section 4960(a)(2). Section 4960(c)(5)(B) provides that a payment is a parachute payment only if the aggregate present value of the payments in the nature of compensation to (or for the benefit of) an individual that are contingent on a separation from employment equals or exceeds an amount equal to 3-times the base amount. Section 4960(c)(5)(D) provides that rules similar to the rules of section 280G(b)(3) apply for purposes of determining the base amount, and section 4960(c)(5)(E) provides that rules similar to the rules of section 280G(d)(3) and (4) apply for purposes of present value determinations. Section 280G(b)(3) provides that ''base amount'' means an individual's annualized includible compensation for the base period. Section 280G(d)(2) defines ''base period'' as the period consisting of the 5 most-recent taxable years of the service provider ending before the date on which the change in ownership or control occurs or the portion of such period during which the individual performed personal services for the corporation.

These final regulations provide that the ''base amount'' is the average annual compensation as an employee of the ATEO (including services performed as an employee of a predecessor or related organization) for the taxable years in the ''base period.'' The base period is the 5 most-recent taxable years during which the individual was an employee of the ATEO (or predecessor or related organization) or the portion of the 5-year period during which the employee was an employee of the ATEO (or predecessor or related organization).

These final regulations provide rules for determining whether a payment is an excess parachute payment, including rules for applying the 3-times-base-amount test. The rules for determining the base amount, base period, and present value, including determining the present value of payments that are contingent on uncertain future events, are based on the rules under § 1.280G–1, Q/A–30 through Q/A–36 (substituting an involuntary separation from employment for a change in control). These final regulations describe when a payment in the nature of compensation is considered made for purposes of section 4960(a)(2), based on the rules in § 1.280G–1, Q/A–11 through Q/A–14. Consistent with the rules provided under § 1.280G–1, Q/A–12(a), these final regulations provide that the transfer of section 83 property generally is considered a payment made in the taxable year in which the fair market value of the property would be includible in the gross income of the covered employee under section 83, disregarding any election made by the employee under section 83(b) or (i). In addition, similar to the rules provided under § 1.280G–1, Q/A–13(a), these regulations generally provide that stock options are treated as property transferred on the date of vesting (regardless of whether the option has a ''readily ascertainable value'' as defined in § 1.83–7(b)). For purposes of determining the timing and amount of any payment related to an option, the principles of § 1.280G–1, Q/A–13 and Rev. Proc. 2003–68 (2003–2 C.B. 398) apply.

E. Computation of Excess Parachute Payments

Consistent with section 4960(c)(5)(A), these final regulations provide that an ''excess parachute payment'' is an amount equal to the excess of any parachute payment over the portion of the base amount allocated to the payment. The portion of the base amount allocated to any parachute payment is the amount that bears the same ratio to the base amount as the present value of the parachute payment bears to the aggregate present value of all parachute payments to be made to the covered employee. The rules on allocation of the base amount in these regulations are based on § 1.280G–1, Q/A–38.

VI. Calculation, Reporting, and Payment of the Tax

ATEOs (and any related non-ATEO organizations) are liable for the excise tax imposed by section 4960 only if they pay a covered employee sufficient remuneration to trigger the tax. An ATEO is not subject to the excise tax under section 4960(a)(1) unless the ATEO (together with any related organizations) pays more than $1 million of remuneration to a covered employee for a taxable year. An ATEO cannot make an excess parachute payment subject to the excise tax under section 4960(a)(2) if the employer does not have any HCEs under section 414(q) [10] for the taxable year. If both of these situations apply to an ATEO, the ATEO is not liable for any excise tax under section 4960 for that taxable year.

These final regulations generally adopt the proposed rules regarding the entity that is liable for the excise tax under section 4960 and how that excise tax is calculated. These regulations provide that the employer, as determined under section 3401(d), without regard to paragraph (d)(1) or (d)(2), is liable for the excise tax imposed under section 4960. Further, as authorized by section 4960(d), a payment by the employer may be treated as remuneration or a parachute payment if, based on the facts and circumstances, the payment is structured such that it has the effect of avoiding the tax applicable under section 4960. For example, the excise tax under section 4960 would apply with respect to an individual who is an employee of an ATEO or related organization but who is incorrectly classified as an independent contractor. Similarly, the excise tax under section 4960 would apply to an amount paid to a limited liability company or other entity owned all or in part by an employee (or owned by another entity unrelated to the ATEO or related organization) for services performed by an employee of the ATEO or related organization if the arrangement would otherwise have the effect of avoiding the tax applicable under section 4960. For a further discussion of the definition of ''employer'' see section II.D. of this Summary of Comments and Explanation of Revisions, titled ''Employer.''

A. Calculation of Tax on Excess Remuneration

An individual may perform services as an employee of an ATEO and as an employee of one or more related organizations during the same applicable year, in which case remuneration paid for the taxable year is aggregated for purposes of determining whether excess remuneration has been paid. To address these cases, these final regulations adopt the proposed rules for allocating liability for the excise tax among the related employers. As provided in

[10] See footnote 9.

section 4960(c)(4)(C), in any case in which an ATEO includes remuneration from one or more related organizations as separate employers of the individual in determining the excise tax imposed by section 4960(a), each employer is liable for its proportionate share of the excise tax. In contrast, a payment to an individual for performing services as an employee of an ATEO that is made by a third-party payor (whether the payor is related to the ATEO or not) is remuneration paid by the ATEO for section 4960 purposes and thus is included with any remuneration paid directly by the ATEO (and the related liability is not allocated to the other organization). If a covered employee is employed by one employer when the legally binding right to the remuneration is granted and by a different employer at vesting, then the covered employee's employer at vesting is treated as paying the remuneration, provided the employment relationship is bona fide and not a means to avoid tax under section 4960. A related organization may become (or cease to be) related during the applicable year, in which case only remuneration the related organization pays (or is treated as paying due to vesting) to the ATEO's covered employee during the portion of the applicable year that it is a related organization is treated as paid by the ATEO for the taxable year, as provided in section 4960(c)(4)(A).

If an employee is a covered employee of more than one ATEO, these final regulations provide that each ATEO calculates its liability under section 4960(a)(1), taking into account remuneration paid to the employee by the organizations to which it is related. These regulations also provide that, rather than owing tax as both an ATEO and a related organization for the same remuneration paid to a covered employee, each employer is liable only for the greater of the excise tax for which it would be liable as an ATEO or the excise tax it would be liable for as a related organization with respect to that covered employee (and if there is more than one related group of organizations, then for the group that results in the greatest amount of tax). These regulations provide that these same allocation principles apply in the case of the allocation of liability in situations involving an ATEO or related organization with a short taxable year, and should be applied in a manner that avoids, to the extent possible, duplicative taxation of remuneration paid to the same individual. Because the application of the allocation rules may prove complicated in situations involving short taxable years, especially if those situations also involve multiple short taxable years or differing taxable years among the group constituting the ATEO and its related organizations, the regulations further provide that the Commissioner may prescribe guidance of general applicability addressing how the allocation rules apply in particular circumstances involving short taxable years.

Under section 4960(b) and (c)(4)(C), the employer or employers are liable for the excise tax imposed by section 4960. Related organizations must obtain information from each other on remuneration paid to covered employees in order to calculate the tax and their share of the liability. One commenter noted that there may be situations in which an employer is unable to obtain complete information on the remuneration and benefits paid by other employers. The commenter requested guidance on relief from penalties or interest for an error if the employer made a bona fide attempt to obtain the necessary information when it became aware of the error and requested guidance on what would be a bona fide attempt for this purpose. If an ATEO or related organization fails to pay tax it is liable for due to failure to obtain information on remuneration paid by other organizations within the related group, it may be liable for a civil penalty under section 6651 (and in some cases, criminal penalties). Section 6651 includes an exception for reasonable cause. Guidance as to reasonable cause for penalty relief, and therefore the guidance requested by this commenter, is beyond the scope of these final regulations, and therefore is not addressed in these final regulations.

B. Calculation of Tax on an Excess Parachute Payment

These final regulations adopt the proposed regulations with respect to the rules for the calculation of tax on an excess parachute payment. With respect to the calculation of, and liability for, the tax on excess parachute payments, the proposed regulations differed in one respect from the guidance provided in Q/A–1 of Notice 2019–09. Notice 2019–09 provided that an ATEO or related organization may be liable for the tax on an excess parachute payment based on the aggregate parachute payments made by the ATEO and its related organizations, including parachute payments based on separation from employment from a related organization. As in the proposed regulations, these final regulations provide that only an excess parachute payment paid by an ATEO is subject to the excise tax on excess parachute payments. However, consistent with the provision in section 4960(c)(5)(D) that rules similar to section 280G(b)(3) apply for purposes of determining the base amount under section 4960, payments from all related organizations (including payments from non-ATEOs) are considered for purposes of determining the base amount and total payments in the nature of compensation that are contingent on the covered employee's separation from employment with the employer. See § 1.280G–1, Q/A–34. Generally, this means that a covered employee's base amount calculation includes remuneration from the ATEO and all related organizations, and that a covered employee's parachute payment calculation includes all payments (made by the ATEO and all related organizations) that are contingent on the employee's involuntary separation from employment. However, only an ATEO is subject to the excise tax on excess parachute payments it makes to a covered employee. A non-ATEO that pays an amount that would otherwise be an excess parachute payment is not subject to the excise tax. These regulations further provide that, based on the facts and circumstances, the Commissioner may reallocate excess parachute payments to an ATEO if it is determined that excess parachute payments were made by a non-ATEO for the purpose of avoiding the tax under section 4960. Step by step instructions for calculating the tax on excess parachute payments were provided in section VI.B. of the Explanation of Provisions of the proposed regulations, titled ''Calculation of Tax on an Excess Parachute Payment.''

C. Reporting and Payment of the Tax

These final regulations adopt without change the rules provided in the proposed regulations relating to the reporting and payment of the excise tax. Under §§ 53.6011–1 and 53.6071–1, the excise tax under section 4960 is reported on Form 4720, ''Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,'' which is the form generally used for reporting and paying chapter 42 taxes. The reporting and payment of any applicable taxes are due when payments of chapter 42 taxes are ordinarily due (the 15th day of the 5th month after the end of the taxpayer's taxable year—May 15 for a calendar year employer), subject to an extension of time for filing returns and making payments [11] that generally

[11] The tentative tax, an estimate, must be paid by the due date of Form 4720 without extensions and

Continued

applies. Because section 6655 has not been amended to include section 4960, no quarterly payments of estimated excise tax imposed by section 4960 are required under section 6655.

These final regulations require that the excise tax imposed by section 4960 be reported and paid in the form and manner prescribed by the Commissioner, and § 53.6011–1 requires that every person (including a governmental entity) liable for the excise tax imposed by section 4960 shall file Form 4720, ''Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code.'' Notice 2019–09, Q/A–33(a) required each employer liable for the excise tax imposed by section 4960 to file a separate Form 4720 to report its share of liability. Two commenters recommended allowing related employers to file a joint Form 4720, as has been permitted in § 53.6011–1(c) for private foundations and their disqualified persons and foundation managers. In addition to being beyond the scope of these regulations, permitting joint filing of Form 4720 is incompatible with electronic filing of Form 4720 that is required for certain tax-exempt organizations under the Taxpayer First Act, Public Law 116–25. See Notice 2021–01.

These final regulations also provide that an employer may elect to prepay the excise tax imposed under section 4960(a)(2) for excess parachute payments in the year of separation from employment or any taxable year prior to the year in which the parachute payment is actually paid. This prepayment rule for the tax applicable to excess parachute payments is similar to the rule in § 1.280G–1, Q/A–11(c), under which a disqualified employee may elect to prepay the excise tax under section 4999 based on the present value of the excise tax that would be owed by the employee when the parachute payments are actually made.

VII. Applicability Date

These final regulations were proposed to apply to taxable years beginning after December 31 of the calendar year in which the Treasury decision adopting these rules as final regulations is published in the **Federal Register**. The Treasury Department and the IRS requested comments on the burdens anticipated and the timeframe expected to be necessary to implement these final regulations (taking into account that the statutory provisions are already effective).

One commenter recommended that these final regulations apply to taxable years beginning after December 31 of the calendar year that ends at least six months after the date on which these final regulations are published in the **Federal Register** in order for ATEOs and related organization to have sufficient time to understand and apply these final regulations. The Treasury Department and the IRS agree with this recommendation, and therefore these final regulations apply to taxable years beginning after December 31, 2021 (with the first applicable year generally being the 2022 calendar year).

The guidance provided in these final regulations and the proposed regulations generally is consistent with the guidance provided in Notice 2019–09. Until the applicability date of these final regulations, taxpayers may rely on the guidance provided in Notice 2019–09 in its entirety or on the proposed regulations in their entirety. Alternatively, taxpayers may choose to apply these final regulations to taxable years beginning after December 31, 2017, and on or before December 31, 2021, provided they apply the final regulations in their entirety and in a consistent manner.

Until the applicability date of these final regulations, taxpayers may also base their positions upon a reasonable, good faith interpretation of the statute that includes consideration of any relevant legislative history. Whether a taxpayer's position that is inconsistent with Notice 2019–09, the proposed regulations, or these final regulations constitutes a reasonable, good faith interpretation of the statute generally will be determined based upon all of the relevant facts and circumstances, including whether the taxpayer has applied the position consistently and the extent to which the taxpayer has resolved interpretive issues based on consistent principles and in a consistent manner. Notwithstanding the previous sentence, the preamble to Notice 2019–09 describes certain positions that the Treasury Department and the IRS have concluded are not consistent with a reasonable, good faith interpretation of the statutory language, and the proposed regulations and these final regulations reflect this view. For a description of each of these positions, see section VII of the Explanation of Provisions of the proposed regulations, titled ''Proposed Applicability Date.''

Special Analyses

I. Regulatory Planning and Review

Executive Orders 13771, 13563, and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Executive Order 13771 designation for this rule is ''regulatory.''

The regulations have been designated as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations. The Office of Information and Regulatory Affairs (OIRA) has designated the rulemaking as significant under section 1(c) of the Memorandum of Agreement. Accordingly, OMB has reviewed the regulations.

A. Background

1. The Excise Tax Under Section 4960

Section 4960 was added to the Code by TCJA. Section 4960(a) subjects excess remuneration above $1 million and excess parachute payments that an ATEO pays to a covered employee to an excise tax equal to the rate of tax imposed on corporations under section 11 (21 percent for 2020). Before TCJA, compensation paid by tax-exempt organizations was not subject to an excise tax, although section 4958 applies an excise tax to penalize excess benefit transactions in which an ''applicable tax-exempt organization'' (as defined in section 4958) provides a benefit to a disqualified person that exceeds the reasonable fair market value of the services received.

Section 4960 defines an ''ATEO'' as any organization which is exempt from taxation under section 501(a), is a farmers' cooperative organization described in section 521(b)(1), has income excluded from taxation under section 115(1), or is a political organization described in section 527(e)(1). Covered employees of an ATEO include the five highest-compensated employees of the organization for the taxable year and any employee or former employee who was a covered employee of the organization (or predecessor) for any

may be paid with Form 8868, ''Application for Automatic Extension of Time To File an Exempt Organization Return.''

preceding taxable year beginning after December 31, 2016.

''Remuneration'' means ''wages'' as defined in section 3401(a) (excluding designated Roth contributions) and includes amounts required to be included in gross income under section 457(f). Section 4960 excludes from remuneration any amount paid to a licensed medical professional for medical or veterinary services provided. Remuneration also includes payments with respect to employment of a covered employee by any person or government entity related to the ATEO. A person or governmental entity is treated as related to the ATEO if that person or governmental entity controls, or is controlled by, the ATEO, is controlled by one or more persons which control the ATEO, is a ''supported organization'' (as defined in section 509(f)(3)) during the taxable year with respect to the ATEO, is a supporting organization described in section 509(a)(3) during the taxable year with respect to the ATEO, or in the case of an organization which is a voluntary employees' beneficiary association (VEBA) under section 501(c)(9), established, maintains, or makes contribution to such VEBA.

2. Notice 2019–09 and the Proposed and Final Regulations

Notice 2019–09 provided taxpayers with initial guidance on the application of section 4960, including that taxpayers may base their positions on a reasonable, good faith interpretation of the statute until further guidance is issued. On June 11, 2020, the Treasury Department and the IRS published proposed regulations on section 4960 in the **Federal Register** (REG–122345–18, 85 FR 35746) (the proposed regulations). The Treasury Department and the IRS received comments responding to the proposed regulations, which were considered in these final regulations, published here. The comments primarily discussed the treatment of employees of a related organization who also provide services to the ATEO, suggesting various exceptions for these situations. Comments also addressed the possibility of a grandfather rule for compensation to be paid under arrangements in place prior to the effective date of section 4960, treatment of deferred compensation as remuneration, the definition of ''control,'' and which organizations are ATEOs.

B. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

C. Affected Entities

The final regulations affect an estimated 261,000 ATEOs and 77,000 non-ATEO related organizations of ATEOs that in historical filings report substantial executive compensation.[12] Of the roughly 261,000 such ATEOs based on filings for tax year 2017, 239,000 are section 501(a) exempt organizations (including 23,000 private foundations), 19,000 are section 115 state and local instrumentalities, 2,000 are section 527 political organizations, 600 are exempt farmers' cooperative organizations described in section 521(b)(1), and 200 are federal instrumentalities (although the Treasury Department and the IRS will continue to consider whether federal instrumentalities are ATEOs).

D. Economic Analysis

This section describes the key economic effects of the provisions of these final regulations.

1. Clarifications

Most provisions of these final regulations clarify aspects of the excise tax imposed by section 4960, minimizing the burdens entities bear to comply with section 4960, and have little other economic impact. Clarifications reduce uncertainty, lowering the effort required to infer which organizations, employees, and payments are subject to the excise tax and the potential for conflict if entities and tax administrators interpret provisions differently. Examples of provisions of these final regulations that are primarily clarifications include the definition of ''control,'' treatment of deferred compensation and vesting, and which organizations are ATEOs.

2. ''Volunteer'' Exceptions

Several commenters expressed concern that highly-paid employees of a non-ATEO performing services for a related ATEO without receiving compensation from the ATEO may be subject to the excise tax. To avoid the excise tax, individuals might cease performing such services, or ATEOs might dissolve their relationships with related non-ATEOs, reducing donations from related non-ATEOs.

The final regulations include exceptions to the definitions of ''employee'' and ''covered employees'' (specifically to the rules for determining the five highest compensated employees for purposes of identifying covered employees) to address such situations. With respect to the first exception, the regulations define ''employee'' consistent with section 3401(c), in particular adopting the rule that a director is not an employee in the capacity as a director and an officer performing minor or no services and not receiving any remuneration for those services is not an employee.

The general rule provides that employees of a related non-ATEO are not considered for purposes of determining the five highest-compensated employees if they are never employees of the ATEO. In addition, individuals who receive no remuneration (or grant of a legally binding right to remuneration) from the ATEO or a related organization cannot be among the ATEO's five highest-compensated employees.

Under the exceptions, an ATEO's five highest-compensated employees also exclude an employee of the ATEO who receives no remuneration from the ATEO and performs only limited hours of service for the ATEO, which means that no more than 10 percent of total annual hours worked for the ATEO and related organizations are for services performed for the ATEO. An employee who performs fewer than 100 hours of services as an employee of an ATEO and its related ATEOs is treated as having worked less than 10 percent of total hours for the ATEO and related ATEOs. An employee who is not compensated by an ATEO, related ATEO, or any taxable related organization controlled by the ATEO and who primarily (more than 50 percent of total hours worked) provides services to a related non-ATEO is also disregarded. In response to comments on the proposed regulations expressing concern that this exception did not provide sufficient flexibility for situations in which an employee of a non-ATEO performs services for a related ATEO as a temporary assignment, these final regulations provide that the 50 percent of total hours worked threshold can be computed over a period of two consecutive years, rather than a single year. This modification expands the exception to provide additional flexibility. An employee is also disregarded if an ATEO paid less than 10 percent of the employee's total remuneration for services performed for the ATEO and all related organizations, and the ATEO had at least one related ATEO during the applicable year. Additionally, if neither the ATEO nor any related ATEO paid more than 10 percent of the employee's total

[12] The methods and data used to estimate the number of affected entities are discussed in detail in the Paperwork Reduction Act special analysis.

remuneration, then the ATEO that paid the highest percent of remuneration does not meet this exception.

Consider, for example, a corporate employee making $2 million per year who spends 5 percent of her time (roughly one day each month) working for the corporation's foundation, a related ATEO, without receiving compensation from the ATEO and who would be a covered employee of the ATEO absent the exceptions. Without the exceptions, her compensation in excess of $1 million from the corporation, which is a related party of the foundation, is subject to a 21 percent excise tax, or $210,000 in excise tax liability. The exceptions (either of the first two could apply here) remove that liability and the incentive it provides to stop providing such services or to dissolve the relationship between the ATEO and the related organization. The exceptions support a transfer of substantial value (5 percent of the employee's salary, or $100,000) that might otherwise not take place.

Commenters on the proposed regulations suggested other ways in which the exceptions could be expanded. The Treasury Department and the IRS considered these suggested expansions of the exceptions and concluded that the suggestions were inconsistent with the statute and legislative history or would enable organizations to circumvent the excise tax in situations where an individual performs services for an ATEO on more than a volunteer basis, creating the potential for abuse and increasing the costs of administering the excise tax. Therefore, these final regulations do not adopt the suggested expansions of the exceptions.

The exceptions in these final regulations may have a substantial impact on donations relative to a no-action baseline, although the magnitude of the potential impact depends on how often the exceptions apply and on how responsive organizations and employees are to the excise tax, both of which are uncertain.

The exceptions apply only in particular circumstances: For example, the employee must be employed by a related organization (typically an organization that controls or is controlled by the ATEO), the employee must be highly compensated, and the employee's work for the ATEO must be sufficiently minimal. Historically, many ATEOs report employees with compensation from related organizations. An estimated 8,500 ATEOs filing Form 990 in tax year 2017 reported both compensation of $500,000 or more for any person and any compensation from related organizations. These ATEOs are estimated to have an average of 18 non-ATEO related organizations based on information reported on Form 990 Schedule R, yielding an estimated 154,000 non-ATEO related organizations, of which half, or 77,000, are estimated to employ a covered employee of the ATEO. The fraction of the 154,000 non-ATEO related organizations with employees to whom the exceptions apply (and who are thus not covered employees of the ATEO) is uncertain, but perhaps half the related organizations, or 77,000, have such an employee.

This entity count omits a substantial number of private foundations which may have employees who receive no compensation from the ATEO but who are highly compensated by related organizations, because while the ATEO count used in these estimates includes approximately 100 private foundations that have historically reported employee compensation of $500,000 or more on Form 990–PF, Form 990–PF (unlike Form 990) does not include information on employee compensation received from related organizations. The exceptions are particularly likely to apply to donations to foundations related to non-ATEO businesses, as companies are highly likely to be related organizations of a company's foundation, many family foundations are controlled by the same family that controls a private business, and executives of the related business often provide services to the foundation without payment from the foundation. Because of these facts, looking at pre-TCJA tax forms may underestimate the number of entities potentially affected by the exceptions. In the U.S. in 2015, there were about 2,000 company foundations responsible for $5.5 billion in giving, and 42,000 family foundations.[13] It is reasonable to assume that about half of these foundations, or 22,000, have a related business with an employee to whom the exceptions apply.

Under reasonable assumptions about the response of donated services to the excise tax, the exceptions may restore substantial donations (transfers) of services that the excise tax could potentially otherwise eliminate. Totaling both private foundations and other ATEOs, roughly 99,000 related organizations are estimated to have employees to whom the exceptions apply. If the excise tax would have reduced services that are donated under the exceptions by an average of just over $5,000 per related organization, the total transfer reduction exceeds $500 million.

Absent the exceptions, organizations may also avoid the excise tax by dissolving the relationship between the ATEO and non-ATEO, which may affect donations of money as well as services. Considering only corporate foundations and setting aside other ATEOs, if such dissolutions would lead to a two percent reduction in the $5.5 billion in corporate giving that would otherwise take place through related foundations, the reduction exceeds $100 million. The Treasury Department and the IRS requested but did not receive comments on the impact of the exceptions on the dissolution of relationships between ATEOs and related organizations.

It is plausible that these final regulations restore substantial economic activity relative to regulatory alternatives, under which the excise tax would discourage highly-compensated employees of related non-ATEOs from providing services to a related ATEO without compensation from the ATEO and discourage relationships between ATEOs and non-ATEOs.

3. Summary

This analysis suggests that these final regulations will reduce compliance burden on affected entities by providing clarifications and, through the exceptions, increase services provided to ATEOs without compensation from the ATEO by a small but potentially economically significant amount ($100 million or more), relative to regulatory alternatives. The Treasury Department and the IRS requested but did not receive comments on the economic impact of these proposed regulations (in particular, comments providing data, other evidence, or models that provide insight).

II. Paperwork Reduction Act

The collections of information in these final regulations are in § 53.4960–1(d), (h), and (i); § 53.4960–2(a), (c) and (d); and § 53.4960–4(a) and (d). This information is required to determine an ATEO's ''covered employees'' as defined in section 4960(c)(2); to calculate remuneration in excess of $1 million as described in section 4960(c)(3); to determine remuneration from related organizations and allocation of liability as described in section 4960(c)(4); and to determine any excess parachute payments to covered employees described in section 4960(c)(5).

The IRS intends that the burden of the collections of information will be reflected in the burden associated with Form 4720, under OMB approval

[13] *http://data.foundationcenter.org/.*

number 1545–0047. The burden associated with Form 4720 is included in the aggregated burden estimates for OMB control number 1545–0047, which represents a total estimated burden time for all forms and schedules of 52.450 million hours and total estimated burden in dollars of $1.497 billion (estimated for fiscal year 2021). The overall burden estimates provided for 1545–0047 are aggregate amounts that relate to all information collections associated with that OMB control number. This estimate is therefore unrelated to the future calculations needed to assess the burden imposed by these regulations. To guard against over-counting the burden imposed, the Treasury Department and the IRS urge readers to recognize that these burden estimates are aggregates for the applicable types of filers. For purposes of the Paperwork Reduction Act, the Treasury Department and the IRS have not estimated the burden, including that of any new information collections, related to the requirements under these final regulations. Future burden estimates under OMB control number 1545–0047 would capture changes made by TCJA and changes that arise out of discretionary authority exercised in the regulations.

The expected burden associated with section 4960 compliance (including Form 4720 preparation and filing) for ATEOs as described in section 4960(c)(1) and related organizations as described in section 4960(c)(4)(B) is listed below:

Estimated number of respondents: 337,888.

Estimated average annual burden hours per response: 0.20 hours.

Estimated total annual burden: $3,569,632 (2020).

Estimated frequency of collection: Annual.

In the proposed regulations, the Treasury Department and the IRS requested comments on all aspects of information collection burdens related to the proposed regulations, including estimates for how much time it would take to comply with the paperwork burdens previously described in this section for each relevant form and ways for the IRS to minimize the paperwork burden. The Treasury Department and the IRS did not receive any comments on these issues. Revisions (if any) to these forms that reflect the information collections included in these final regulations will be made available for public comment at *https://apps.irs.gov/app/picklist/list/draftTaxForms.html* and will not be finalized until after these forms have been approved by OMB under the PRA. Comments on these forms can be submitted at *https://www.irs.gov/forms-pubs/comment-on-tax-forms-and-publications.*

The current status of the PRA submissions related to section 4960 are provided in the following table.

Form	Type of filer	OMB No.(s)	Status
Form 4720	Tax-exempt organizations and their related organizations, including for-profit and government entities.	1545–0047	Published in the **Federal Register** on 11/12/20. Public comment period closes on 1/11/21.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law.

Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. chapter 6), it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities. In the proposed regulations, the Treasury Department and the IRS invited comments on the impact this rule would have on small entities. The Treasury Department and the IRS did not receive any comments on this issue.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA) (13 CFR 121.201), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of ''small entity.'') The Treasury Department and the IRS estimate that these final regulations will affect 324,000 small entities, 73,000 of which are proprietary firms meeting the size standards of the SBA and 251,000 of which are nonprofit organizations that are not dominant in their fields or small government jurisdictions with a population of less than 50,000.

The Treasury Department and the IRS estimated the number of ATEOs, based primarily on Form 990 data for filers with at least one employee (and thus having a burden, at a minimum, of maintaining annual lists of covered employees), as 261,118, and the number of non-ATEO related organizations employing at least one covered employee of an ATEO as 76,770, for a total of 337,888 affected entities. The SBA defines a small business as an independent business having fewer than 500 employees. (See A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Appendix B [14]). Tax data available to the Treasury Department and the IRS include employee counts for only half the affected entities, as employee counts are included on Form 990, but not on other forms including Form 990–EZ and 990–PF. An examination of tax data from 2016 shows that for filers for whom employee counts were available and who had at least one employee, 96.5 percent had fewer than 500 employees. Similarly, there are no bright lines in the available data to distinguish small nonprofit organizations that are not dominant in their field. An examination of non-tax data shows that a similar proportion, approximately 96 percent, of all incorporated cities, towns, and villages in 2014 had a population of less than 50,000, which may serve as a proxy for small government jurisdictions generally.[15] By applying the 96 percent estimate to all entities affected by section 4960, the Treasury Department and the IRS estimate that 324,000 small entities are affected by these regulations. However, the Treasury Department and the IRS have determined that the rules regarding an ATEO's covered employees will not have a significant economic impact on affected small entities as described later in this discussion of the RFA.

Section 4960 imposes the excise tax on ATEOs and their related organizations to the extent they pay certain compensation to a covered employee. Because covered employee

[14] *https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/.*

[15] See *https://www.statista.com/statistics/241695/number-of-us-cities-towns-villages-by-population-size/.*

status is permanent, every ATEO must determine its five highest-compensated employees for the taxable year—even if the ATEO is not subject to the tax for that taxable year—and maintain a list of covered employees. Accordingly, these final rules likely will affect a substantial number of small entities, especially nonprofit entities that are not dominant in their fields.

The Treasury Department and the IRS estimate that the vast majority of ATEOs, particularly small ATEOs, can determine their five highest-compensated employees for the taxable year under the method provided in these final rules very quickly and at negligible cost using information already collected in the normal course of business. The time necessary to determine an ATEO's five highest-compensated employees is positively correlated with the size of the entity (that is, the smaller the entity, the less time such a determination should take). Larger ATEOs may need more time, but it is estimated that this determination will take less than seven hours. The burden for making this determination is estimated to fall on the small number of larger ATEOs. Putting these two groups together, the total estimated cost for all 261,118 ATEOs to make these determinations is $1,255,760 per year, averaging $4.81 per ATEO. Thus, it is hereby certified that these final regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA).

Pursuant to section 7805(f) of the Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities and no comments were received.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This final rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (titled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications that are not required by the statute and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

VI. Congressional Review Act

The Administrator of OIRA has determined that this is a major rule for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*) (CRA). Under section 801(3) of the CRA, a major rule takes effect 60 days after the rule is published in the **Federal Register**.

Notwithstanding this requirement, section 808(2) of the CRA allows agencies to dispense with the requirements of section 801 when the agency for good cause finds that such procedure would be impracticable, unnecessary, or contrary to the public interest and the rule shall take effect at such time as the agency promulgating the rule determines. Pursuant to section 808(2) of the CRA, the Treasury Department and the IRS find, for good cause, that a 60-day delay in the effective date is unnecessary and contrary to the public interest.

Following the addition of section 4960 to the Code by TCJA, the Treasury Department and the IRS published the proposed regulations setting forth guidance on all aspects of the law, including certain exceptions to the definition of ''employee'' and ''covered employee'' for purposes of identifying covered employees. The majority of comments received in response to the proposed regulations requested additional clarifications or modifications of the rules for these exceptions. In response, these final regulations include certain clarifications and modifications to the proposed rules. The clarifications and modifications in these final regulations reduce both uncertainty and the burden associated with application of these rules.

In response to certain commenter requests that the applicability date of the final regulations be delayed after publication of the regulations as final in the **Federal Register** so that ATEOs and related organizations have sufficient time to understand and apply these final regulations, these final regulations apply to taxable years beginning after December 31, 2021. However, until the applicability date, taxpayers may choose to apply these final regulations to taxable years beginning after December 31, 2017, and on or before December 31, 2021, provided the taxpayer applies them in their entirety and in a consistent manner. Therefore, ATEOs and related organizations that wish to apply these regulations prior to the applicability date will need to know that these final regulations are effective before incurring necessary costs to timely comply with these final regulations. In particular, certainty that these rules are effective is essential to taxpayers so that they can determine whether and to what extent the excise tax imposed by section 4960 applies to an organization and which employees are covered employees, given that taxpayers will begin preparing their 2020 tax returns in early 2021. Further, for these potentially affected taxpayers, certainty with respect to these rules is necessary for them to proceed with several aspects of their operations, including employee hiring and retention, designing of compensatory arrangements, recordkeeping, and maintaining relationships between related non-ATEOs and ATEOs—including with respect to donating of services. Further, the COVID–19 pandemic has affected many ATEOs, and providing additional clarification regarding these rules, in particular with respect to the exceptions for purposes of determining covered employees, will better enable ATEOs and related organizations to perform financial and operational planning tasks for the tax year as they anticipate the easing of restrictions that have severely impacted their operations during the COVID–19 pandemic. Consistent with Executive Order 13924 (May 19, 2020), the Treasury Department and the IRS have therefore determined that an expedited effective date of these final regulations will provide critical guidance on what the law requires for taxpayers to determine whether the excise tax imposed by section 4960 applies, which employees may be considered to be covered employees, and what actions are required under the law as a result. Accordingly, the Treasury Department and the IRS have determined that the rules in this Treasury decision will take effect on the date of filing for public inspection in the **Federal Register**.

Statutory Authority

The regulations are adopted pursuant to the authority contained in sections 7805 and 4960.

Drafting Information

The principal authors of the regulations are William McNally and Patrick Sternal of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of the regulations.

Statement of Availability

IRS Revenue Procedures, Revenue Rulings, Notices, and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 53

Excise taxes, Foundations, Investments, Lobbying, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, the Department of the Treasury and the Internal Revenue Service amend 26 CFR parts 1 and 53 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.338–1 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 1.338–1 General principles; status of old target and new target.

* * * * *

(b) * * *

(2) * * *

(i) The rules applicable to employee benefit plans (including those plans described in sections 79, 104, 105, 106, 125, 127, 129, 132, 137, and 220), qualified pension, profit-sharing, stock bonus and annuity plans (sections 401(a) and 403(a)), simplified employee pensions (section 408(k)), tax qualified stock option plans (sections 422 and 423), welfare benefit funds (sections 419, 419A, 512(a)(3), and 4976), voluntary employees' beneficiary associations (section 501(c)(9) and the regulations thereunder), and tax on excess tax-exempt organization executive compensation (section 4960) and the regulations in part 53 under section 4960;

* * * * *

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

■ **Par. 3.** The authority citation for part 53 is revised to read in part as follows:

Authority: 26 U.S.C. 7805; 4960.

* * * * *

■ **Par. 4.** Sections 53.4960–0 through 53.4960–6 are added to read as follows:

* * * * *

53.4960–0 Table of contents.
53.4960–1 Scope and definitions.
53.4960–2 Determination of remuneration paid for a taxable year.
53.4960–3 Determination of whether there is a parachute payment.
53.4960–4 Liability for tax on excess remuneration and excess parachute payments.
53.4960–5 Coordination with section 162(m) [reserved].
53.4960–6 Applicability date.

* * * * *

§ 53.4960–0 Table of contents.

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§ 53.4960–1 Scope and definitions.

(a) *Scope.* This section provides definitions for purposes of section 4960, this section, and §§ 53.4960–2 through 53.4960–6. Section 53.4960–2 provides definitions and rules for determining the amount of remuneration paid for a taxable year. Section 53.4960–3 provides definitions and rules for determining whether a parachute payment is paid. Section 53.4960–4 provides definitions and rules for calculating the amount of excess remuneration paid for a taxable year, excess parachute payments paid in a taxable year, and liability for the excise tax. Section 53.4960–5 is reserved for rules on the coordination of sections 4960 and 162(m). Section 53.4960–6 provides rules regarding the applicability date for the regulations in §§ 53.4960–1 through 53.4960–5. The rules and definitions provided in this section through § 53.4960–6 apply solely for purposes of section 4960 unless specified otherwise.

(b) *Applicable tax-exempt organization*—(1) *In general. Applicable tax-exempt organization* or *ATEO* means any organization that is one of the following types of organizations:

(i) *Section 501(a) organization.* The organization is exempt from taxation under section 501(a) (except as provided in paragraph (b)(2) or (b)(3) of this section);

(ii) *Section 521 farmers' cooperative.* The organization is a farmers' cooperative organization described in section 521(b)(1);

(iii) *Section 115(1) organization.* The organization has income excluded from taxation under section 115(1); or

(iv) *Section 527 political organization.* The organization is a political

organization described in section 527(e)(1).

(2) *Certain foreign organizations.* Any foreign organization described in section 4948(b) that either is exempt from tax under section 501(a) or is a taxable private foundation (section 4948(b) organization) is not an ATEO. A foreign organization is an organization not created or organized in the United States or in any possession thereof, or under the law of the United States, any State, the District of Columbia, or any possession of the United States. See section 4948(b) and § 53.4948–1. For purposes of this paragraph (b)(2) and the application of section 4960 to a taxable year, an organization's status as a section 4948(b) organization is determined at the end of its taxable year.

(c) *Applicable year*—(1) *In general. Applicable year* means the calendar year ending with or within the ATEO's taxable year. See § 53.4960–4 regarding how an ATEO's applicable year affects the liability of related organizations.

(2) *Examples.* The following examples illustrate the rules of paragraph (c)(1) of this section.

(i) *Example 1 (Calendar year taxpayer)*—(A) *Facts.* ATEO 1 uses the calendar year as its taxable year and became an ATEO before 2022.

(B) *Conclusion.* ATEO 1's applicable year for its 2022 taxable year is the period from January 1, 2022, through December 31, 2022 (that is, the 2022 calendar year).

(ii) *Example 2 (Fiscal year taxpayer)*—(A) *Facts.* ATEO 2 uses a taxable year that starts July 1 and ends June 30 and became an ATEO before 2022.

(B) *Conclusion.* ATEO 2's applicable year for the taxable year beginning July 1, 2022, and ending June 30, 2023, is the 2022 calendar year.

(3) *Short applicable years*—(i) *In general.* An ATEO may have an applicable year that does not span the entire calendar year for the initial taxable year that the organization is an ATEO or for the taxable year in which the taxpayer ceases to be an ATEO. The beginning and end dates of the applicable year in the case of an ATEO's change in status depend on when the change in status occurs.

(ii) *Initial year of ATEO status.* For the taxable year in which an ATEO first becomes an ATEO, *applicable year* means the period beginning on the date the ATEO first becomes an ATEO and ending on the last day of the calendar year ending with or within such taxable year (or, if earlier, the date of termination of ATEO status, as described in paragraph (c)(3)(ii)(A) of this section). If the taxable year in which an ATEO first becomes an ATEO ends before the end of the calendar year in which the ATEO first becomes an ATEO, then there is no applicable year for the ATEO's first taxable year; however, for the ATEO's next taxable year, *applicable year* means the period beginning on the date the ATEO first becomes an ATEO and ending on December 31 of the calendar year (or, if earlier, the date of termination of ATEO status, as described in paragraph (c)(3)(ii)(A) of this section).

(iii) *Year of termination of ATEO status*—(A) *Termination on or before the close of the calendar year ending with or within the taxable year of termination.* If an ATEO has a termination of ATEO status during the taxable year and the termination of ATEO status occurs on or before the close of the calendar year ending with or within such taxable year, then, for the taxable year of termination of ATEO status, applicable year means the period starting January 1 of the calendar year of the termination of ATEO status and ending on the date of the termination of ATEO status.

(B) *Termination after the close of the calendar year ending in the taxable year of termination.* If an ATEO has a termination of ATEO status during the taxable year and the termination of ATEO status occurs after the close of the calendar year ending within such taxable year, then, for the taxable year of the termination of ATEO status, *applicable year* means both the calendar year ending within such taxable year and the period beginning January 1 of the calendar year of the termination of ATEO status and ending on the date of the termination of ATEO status. Both such applicable years are treated as separate applicable years. See § 53.4960–4(b)(2)(ii) for rules regarding calculation of the tax in the event there are multiple applicable years associated with a taxable year.

(4) *Examples.* The following examples illustrate the rules of paragraph (c)(3) of this section. For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO and any entity referred to as ''CORP'' is not an ATEO.

(i) *Example 1 (Taxable year of formation ending after December 31)*—(A) *Facts.* ATEO 1, ATEO 2, and CORP 1 are related organizations that all use a taxable year that starts July 1 and ends June 30. ATEO 1 is recognized as a section 501(c)(3) organization by the IRS on May 8, 2023, effective as of October 1, 2022. ATEO 2 became an ATEO in 2017.

(B) *Conclusion (ATEO 1).* ATEO 1's applicable year for the taxable year beginning October 1, 2022, and ending June 30, 2023, is the period beginning October 1, 2022, and ending December 31, 2022. For purposes of determining the amount of remuneration paid by ATEO 1 and all related organizations for ATEO 1's taxable year beginning October 1, 2022, and ending June 30, 2023, (including for purposes of determining ATEO 1's covered employees), only remuneration paid between October 1, 2022, and December 31, 2022, is taken into account. Thus, any remuneration paid by ATEO 1, ATEO 2, and CORP 1 before October 1, 2022, is disregarded for purposes of ATEO 1's applicable year associated with its initial taxable year.

(C) *Conclusion (ATEO 2).* ATEO 2's applicable year for its taxable year beginning July 1, 2022, and ending June 30, 2023, is the 2022 calendar year. Thus, any remuneration paid by ATEO 1, ATEO 2, and CORP 1 during the 2022 calendar year is taken into account for purposes of determining ATEO 2's covered employees and remuneration paid for ATEO 2's taxable year ending June 30, 2023.

(ii) *Example 2 (Taxable year of formation ending before December 31)*—(A) *Facts.* Assume the same facts as in paragraph (c)(4)(i)(A) of this section (Example 1), except that ATEO 1 is recognized as a section 501(c)(3) organization effective as of March 15, 2023.

(B) *Conclusion.* ATEO 1 has no applicable year for the taxable year starting March 15, 2023, and ending June 30, 2023, because no calendar year ends (or termination of ATEO status occurs) with or within the taxable year. ATEO 1's applicable year for the taxable year ending June 30, 2024, is the period beginning March 15, 2023, and ending December 31, 2023. For purposes of determining the amount of remuneration paid by ATEO 1 and all related organizations for ATEO 1's taxable year ending June 30, 2024 (including for purposes of determining ATEO 1's covered employees), only remuneration paid between March 15, 2023, and December 31, 2023, is taken into account. The conclusion for ATEO 2 is the same as in paragraph (c)(4)(i)(C) of this section (Example 1).

(iii) *Example 3 (Termination before the close of the calendar year ending in the taxable year of termination)*—(A) *Facts.* Assume the same facts as in paragraph (c)(4)(i)(A) of this section (Example 1). In addition, ATEO 1 has a termination of ATEO status on September 30, 2024.

(B) *Conclusion.* For ATEO 1's taxable year beginning July 1, 2024, and ending September 30, 2024, ATEO 1's applicable year is the period beginning

January 1, 2024, and ending September 30, 2024.

(iv) *Example 4 (Termination after the close of the calendar year ending in the taxable year of termination)*—(A) *Facts.* Assume the same facts as in paragraph (c)(4)(i)(A) of this section (Example 1). In addition, ATEO 1 has a termination of ATEO status on March 31, 2025.

(B) *Conclusion.* For ATEO 1's taxable year beginning July 1, 2024, and ending March 31, 2025, ATEO 1 has two applicable years: the 2024 calendar year, and the period beginning on January 1, 2025, and ending on March 31, 2025.

(d) *Covered employee*—(1) *In general.* For each taxable year, *covered employee* means any individual who is one of the five highest-compensated employees of the ATEO for the taxable year or was a covered employee of the ATEO (or any predecessor) for any preceding taxable year beginning after December 31, 2016.

(2) *Five highest-compensated employees*—(i) *In general.* Except as otherwise provided in this paragraph (d)(2), an individual is one of an ATEO's five highest- compensated employees for the taxable year if the individual is among the five employees of the ATEO with the highest amount of remuneration paid during the applicable year, as determined under § 53.4960–2. However, remuneration for which the deduction is disallowed by reason of section 162(m) is taken into account for purposes of determining an ATEO's five highest-compensated employees. The five highest-compensated employees of an ATEO for the taxable year are identified on the basis of the total remuneration paid during the applicable year to the employee for services performed as an employee of the ATEO or any related organization. An ATEO may have fewer than five highest-compensated employees for a taxable year if it has fewer than five employees other than employees who are disregarded under paragraphs (d)(2)(ii) through (iv) of this section. For purposes of this paragraph (d)(2), a grant of a legally binding right (within the meaning of § 1.409A–1(b)) to vested remuneration is considered to be remuneration paid as of the date of grant, as described in § 53.4960–2(c)(2), and a person or governmental entity is considered to grant a legally binding right to nonvested remuneration if the person or governmental entity grants a legally binding right to remuneration that is not vested within the meaning of § 53.4960–2(c)(2). An employee is disregarded for purposes of determining an ATEO's five highest-compensated employees for a taxable year if, during the applicable year, neither the ATEO nor any related organization paid remuneration or granted a legally binding right to nonvested remuneration to the individual for services the individual performed as an employee of the ATEO or any related organization.

(ii) *Limited hours exception*—(A) *In general.* An individual is disregarded for purposes of determining an ATEO's five highest-compensated employees for a taxable year if all of the following requirements are met:

(*1*) *Remuneration requirement.* Neither the ATEO nor any related ATEO paid remuneration or granted a legally binding right to nonvested remuneration to the individual for services the individual performed as an employee of the ATEO during the applicable year; and

(*2*) *Hours of service requirement.* The individual performed services as an employee of the ATEO and all related ATEOs for no more than 10 percent of the total hours the individual worked as an employee of the ATEO and any related organizations during the applicable year. An ATEO may instead make this determination based on the total days the individual worked as an employee of the ATEO and all related ATEOs as a percentage of the total days worked as an employee of the ATEO and all related organizations, provided that for purposes of the calculation, any day that the individual worked at least one hour as an employee of the ATEO or a related ATEO is treated as a day worked as an employee of the ATEO and not for any other organization.

(B) *Certain payments disregarded.* For purposes of paragraph (d)(2)(ii)(A)(*1*) of this section, a payment of remuneration made to the individual by a related organization that is an employer of the individual and for which the related organization is neither entitled to reimbursement by the ATEO nor entitled to any other consideration from the ATEO is not considered remuneration paid by the ATEO under § 53.4960–2(b)(1), and a payment of remuneration made to the individual by a related organization is not treated as remuneration paid by the ATEO under § 53.4960–2(b)(2).

(C) *Safe harbor.* For purposes of paragraph (d)(2)(ii)(A)(*2*) of this section, an individual is treated as having performed services as an employee of the ATEO and all related ATEOs for no more than 10 percent of the total hours the individual worked as an employee of the ATEO and all related organizations during the applicable year if the employee performed no more than 100 hours of service as an employee of the ATEO and all related ATEOs during the applicable year.

(iii) *Nonexempt funds exception*—(A) *In general.* An individual is disregarded for purposes of determining an ATEO's five highest-compensated employees for a taxable year if all the following requirements are met:

(*1*) *Remuneration requirement.* Neither the ATEO, nor any related ATEO, nor any taxable related organization controlled by the ATEO, or by one or more related ATEOs, either alone or together with the ATEO, paid remuneration or granted a legally binding right to nonvested remuneration to the individual for services the individual performed as an employee of an ATEO during the applicable year and the preceding applicable year. For this purpose, whether a taxable related organization is controlled by the ATEO (or one or more related ATEOs) is determined without regard to paragraph (i)(2)(vii)(B)(*2*) of this section and without regard to section 318(a)(3) for purposes of applying paragraph (i)(2)(vii)(A) of this section, so that an interest in a corporation or nonstock entity is not attributed downward in determining control of the corporation or nonstock entity;

(*2*) *Hours of service requirement.* The individual performed services as an employee of the ATEO and any related ATEOs for not more than 50 percent of the total hours worked as an employee of the ATEO and any related organizations during the applicable year and the preceding applicable year. An ATEO may instead make this determination based on the total days the individual worked as an employee of the ATEO and all related ATEOs as a percentage of the total days worked as an employee of the ATEO and all related organizations, provided that for purposes of the calculation, any day that the individual worked at least one hour as an employee of the ATEO or a related ATEO is treated as a day worked as an employee of the ATEO and not for any other organization; and

(*3*) *Related organizations requirement.* No related organization that paid remuneration or granted a legally binding right to nonvested remuneration to the individual during the applicable year and the preceding applicable year provided services for a fee to the ATEO, to any related ATEO, or to any taxable related organization controlled by the ATEO or by one or more related ATEOs, either alone or together with the ATEO, during the applicable year and the preceding applicable year. For purposes of this paragraph (d)(2)(iii)(A)(*3*), whether a taxable related organization is controlled by the ATEO (or one or more related ATEOs) is determined without regard to paragraph (i)(2)(vii)(B)(*2*) of

this section and without regard to section 318(a)(3) for purposes of applying paragraph (i)(2)(vii)(A) of this section, so that an interest in a corporation or nonstock entity is not attributed downward in determining control of the corporation or nonstock entity.

(B) *Certain payments disregarded.* For purposes of paragraph (d)(2)(iii)(A)(*1*) of this section, a payment of remuneration made to an individual by a related organization that is an employer of the individual and for which the related organization is neither entitled to reimbursement by the ATEO nor entitled to any other consideration from the ATEO is not considered remuneration paid by the ATEO under § 53.4960–2(b)(1) and a payment of remuneration made to the individual by a related organization is not treated as paid by the ATEO under § 53.4960–2(b)(2).

(iv) *Limited services exception.* An individual is disregarded for purposes of determining an ATEO's five highest-compensated employees for a taxable year even though the ATEO paid remuneration to the individual if, disregarding § 53.4960–2(b)(2), all of the following requirements are met:

(A) *Remuneration requirement.* The ATEO did not pay 10 percent or more of the individual's total remuneration for services performed as an employee of the ATEO and all related organizations during the applicable year; and

(B) *Related ATEO requirement.* The ATEO had at least one related ATEO during the applicable year and one of the following conditions applies:

(*1*) *Ten percent remuneration condition.* A related ATEO paid at least 10 percent of the remuneration paid by the ATEO and any related organizations during the applicable year; or

(*2*) *Less remuneration condition.* No related ATEO paid at least 10 percent of the total remuneration paid by the ATEO and any related organizations and the ATEO paid less remuneration to the individual than at least one related ATEO during the applicable year.

(3) *Examples.* The following examples illustrate the rules of this paragraph (d). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO, any entity referred to as ''CORP'' is not an ATEO and is not a publicly held company within the meaning of section 162(m)(2) unless otherwise stated, and each taxpayer uses the calendar year as its taxable year.

(i) *Example 1 (Employee of two related ATEOs)*—(A) *Facts.* ATEO 1 and ATEO 2 are related organizations and have no other related organizations. Both employ Employee A during calendar year 2022 and pay remuneration to Employee A for Employee A's services. During 2022, Employee A performed services for 1,000 hours as an employee of ATEO 1 and 1,000 hours as an employee of ATEO 2.

(B) *Conclusion.* Employee A may be a covered employee of both ATEO 1 and ATEO 2 as one of the five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(i) of this section because the exceptions in paragraphs (d)(2)(ii) through (iv) of this section do not apply. Because they are related organizations, ATEO 1 and ATEO 2 must each include the remuneration paid to Employee A by the other during each of their applicable years in determining their respective five highest-compensated employees for taxable year 2022.

(ii) *Example 2 (Employee of an ATEO and a related non-ATEO)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(i) of this section (*Example 1*), except that ATEO 1 is instead CORP 1.

(B) *Conclusion (CORP 1).* For taxable year 2022, CORP 1 is not an ATEO and therefore does not need to identify covered employees.

(C) *Conclusion (ATEO 2).* Employee A may be a covered employee of ATEO 2 as one of its five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(i) of this section because no exception in paragraphs (d)(2)(ii) through (iv) of this section applies. ATEO 2 must include the remuneration paid to Employee A by CORP 1 during its applicable year in determining ATEO 2's five highest-compensated employees for taxable year 2022.

(iii) *Example 3 (Amounts for which a deduction is disallowed under section 162(m) are taken into account for purposes of determining the five highest-compensated employees)*—(A) *Facts.* CORP 2 is a publicly held corporation within the meaning of section 162(m)(2) and is a related organization of ATEO 3. ATEO 3 is a corporation that is part of CORP 2's affiliated group (as defined in section 1504, without regard to section 1504(b)) and has no other related organizations. Employee B is a covered employee (as defined in section 162(m)(3)) of CORP 2 and an employee of ATEO 3. In 2022, CORP 2 paid Employee B $8 million of remuneration for services provided as an employee of CORP 2 and ATEO 3 paid Employee B $500,000 of remuneration for services provided as an employee of ATEO 3. $7.5 million of the remuneration is compensation for which a deduction is disallowed pursuant to section 162(m)(1).

(B) *Conclusion.* The $7.5 million of remuneration for which a deduction is disallowed under section 162(m)(1) is taken into account for purposes of determining ATEO 3's five highest-compensated employees. Thus, ATEO 3 is treated as paying Employee B $8.5 million of remuneration for purposes of determining its five highest-compensated employees.

(iv) *Example 4 (Employee disregarded due to receiving no remuneration)*—(A) *Facts.* Employee C is an officer of ATEO 4 who performs more than minor services for ATEO 4. In 2022, neither ATEO 4 nor any related organization paid remuneration or granted a legally binding right to any nonvested remuneration to Employee C. ATEO 4 paid premiums for insurance for liability arising from Employee C's service with ATEO 4, which is properly treated as a working condition fringe benefit excluded from gross income under § 1.132–5.

(B) *Conclusion.* Even though Employee C is an employee of ATEO 4, Employee C is disregarded for purposes of determining ATEO 4's five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(i) of this section because neither ATEO 4 nor any related organization paid Employee C any remuneration (nor did they grant a legally binding right to nonvested remuneration) in applicable year 2022. The working condition fringe benefit is not wages within the meaning of section 3401(a), as provided in section 3401(a)(19), and thus is not remuneration within the meaning of § 53.4960–2(a).

(v) *Example 5 (Limited hours exception)*—(A) *Facts.* ATEO 5 and CORP 3 are related organizations. ATEO 5 has no other related organizations. Employee D is an employee of CORP 3. As part of Employee D's duties at CORP 3, Employee D serves as an officer of ATEO 5. Only CORP 3 paid remuneration (or granted a legally binding right to nonvested remuneration) to Employee D and ATEO 5 did not reimburse CORP 3 for any portion of Employee D's remuneration in any manner. During 2022, Employee D provided services as an employee for 2,000 hours to CORP 3 and 200 hours to ATEO 5.

(B) *Conclusion.* Even though Employee D is an employee of ATEO 5 because Employee D provided more than minor services as an officer, Employee D is disregarded for purposes of determining ATEO 5's five highest-compensated employees for taxable year 2022. Employee D is disregarded under

paragraph (d)(2)(ii) of this section because only CORP 3 paid Employee D any remuneration or granted a legally binding right to nonvested remuneration in applicable year 2022 and Employee D provided services as an employee of ATEO 5 for 200 hours, which is not more than ten percent of the 2,200 total hours (2,000 + 200 = 2,200) worked as an employee of ATEO 5 and all related organizations.

(vi) *Example 6 (Limited hours exception)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(v) of this section (*Example 5*), except that ATEO 5 also provides a reasonable allowance for expenses incurred by Employee D in executing Employee D's duties as an officer of ATEO 5, which is properly excluded from gross income under an accountable plan described in § 1.62–2.

(B) *Conclusion.* The conclusion is the same as in paragraph (d)(3)(v)(B) of this section (*Example 5*). Specifically, even though Employee D is an employee of ATEO 5 because Employee D provided more than minor services for ATEO 5, Employee D is disregarded for purposes of determining ATEO 5's five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(ii) of this section because the expense allowance under the accountable plan is excluded from wages within the meaning of section 3401(a), as provided in § 31.3401(a)-4, and thus is not remuneration within the meaning of § 53.4960–2(a).

(vii) *Example 7 (No exception applies due to source of payment)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(v) of this section (*Example 5*), except that ATEO 5 has a contractual arrangement with CORP 3 to reimburse CORP 3 for the hours of service Employee D provides to ATEO 5 during applicable year 2022 by paying an amount equal to the total remuneration received by Employee D from both ATEO 5 and CORP 3, multiplied by a fraction equal to the hours of service Employee D provided ATEO 5 over Employee D's total hours of service to both ATEO 5 and CORP 3.

(B) *Conclusion.* Employee D may be one of ATEO 5's five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(i) of this section because the exceptions in paragraphs (d)(2)(ii) through (iv) of this section do not apply. Pursuant to the contractual arrangement between CORP 3 and ATEO 5, ATEO 5 reimburses CORP 3 for a portion of Employee D's remuneration during applicable year 2022; thus, the exceptions under paragraphs (d)(2)(ii) and (iii) of this section do not apply. Further, while ATEO 5 paid Employee D less than 10 percent of the total remuneration from ATEO 5 and all related organizations (200 hours of service to ATEO 5/2,200 hours of service to ATEO 5 and all related organizations = 9 percent), it had no related ATEO; thus, the limited services exception under paragraph (d)(2)(iv) of this section does not apply.

(viii) *Example 8 (Nonexempt funds exception for part-time services)*—(A) *Facts.* ATEO 6 and CORP 4 are related organizations. ATEO 6 has no other related organizations and does not control CORP 4. During applicable year 2022, Employee E provided 2,000 hours of services as an employee of CORP 4 and 0 hours of services as an employee of ATEO 6; during applicable year 2023, Employee E provided 1,100 hours of services as an employee of CORP 4 and 900 hours of services as an employee of ATEO 6; during applicable year 2024, Employee E provided 1,100 hours of services as an employee of CORP 4 and 900 hours of services as an employee of ATEO 6. ATEO 6 neither paid any remuneration to Employee E nor paid a fee for services to CORP 4 during any applicable year. No exception under paragraphs (d)(2)(i), (ii), or (iv) applies to Employee E.

(B) *Conclusion (2023).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2023 under paragraph (d)(2)(iii) of this section because for applicable years 2022 and 2023, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (900 hours/4,000 hours), and ATEO 6 neither paid any remuneration to Employee E nor paid a fee for services to CORP 4 during applicable years 2022 and 2023.

(C) *Conclusion (2024).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2024 under paragraph (d)(2)(iii) of this section because for applicable years 2023 and 2024, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (1,800 hours/4,000 hours), and ATEO 6 neither paid any remuneration to Employee E nor paid a fee for services to CORP 4 during applicable years 2023 and 2024.

(ix) *Example 9 (Nonexempt funds for full-time services in one applicable year)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(viii) of this section (*Example 8),* except that during applicable year 2022, Employee E provided services as an employee for 2,000 hours to CORP 4 and for 0 hours to ATEO 6; during applicable year 2023, Employee E provided services as an employee for 0 hours to CORP 4 and 2,000 hours to ATEO 6; and during applicable year 2024, Employee E resumes employment with CORP 4 so that Employee E provided services as an employee for 2,000 hours to CORP 4 and 0 hours to ATEO 6.

(B) *Conclusion (2023).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2023 under paragraph (d)(2)(iii) of this section because for applicable years 2022 and 2023, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (2,000 hours/4,000 hours), and ATEO 6 neither paid any remuneration to Employee E nor paid a fee for services to CORP 4 during applicable years 2022 and 2023.

(C) *Conclusion (2024).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2024 under paragraph (d)(2)(iii) of this section because for applicable years 2023 and 2024, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (2,000 hours/4,000 hours for ATEO 6 and CORP 4), and ATEO 6 neither paid any remuneration to Employee E nor paid a fee for services to CORP 4 during applicable years 2023 and 2024.

(x) *Example 10 (Nonexempt funds exception for full-time services across two applicable years)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(viii)(A) of this section (*Example 8),* except that during applicable year 2022, Employee E provided services as an employee for 2,000 hours to CORP 4 and for 0 hours to ATEO 6; during applicable year 2023, Employee E provided services as an employee for 600 hours to CORP 4 and for 1,400 hours to ATEO 6; and during applicable year 2024, Employee E provided services as an employee for 1,400 hours to CORP 4 and for 600 hours to ATEO 6.

(B) *Conclusion (2023).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2023 under paragraph (d)(2)(iii) of this section because for applicable years 2022 and 2023, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (1,400 hours/4,000 hours), and ATEO 6 neither

paid any remuneration to Employee E, nor paid a fee for services to CORP 4 during applicable years 2022 and 2023.

(C) *Conclusion (2024).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2024 under paragraph (d)(2)(iii) of this section because for applicable years 2023 and 2024, Employee E provided services as an employee of ATEO 6 for not more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (2,000 hours/4,000 hours), and ATEO 6 neither paid any remuneration to Employee E, nor paid a fee for services to CORP 4 during applicable years 2023 and 2024.

(xi) *Example 11 (Failure under the nonexempt funds exception)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(viii)(A) of this section (*Example 8),* except that during applicable year 2022, Employee E provided services as an employee for 2,000 hours to CORP 4 and for 0 hours to ATEO 6; during applicable year 2023, Employee E provided services as an employee for 600 hours to CORP 4 and for 1,400 hours to ATEO 6; and during applicable year 2024, Employee E provided services as an employee for 1,300 hours to CORP 4 and for 700 hours to ATEO 6.

(B) *Conclusion (2023).* Employee E is disregarded for purposes of determining ATEO 6's five highest-compensated employees for taxable year 2023 under paragraph (d)(2)(iii) of this section because for applicable years 2022 and 2023, Employee E provided services as an employee of ATEO 6 for less than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (1,400 hours/4,000 hours), and ATEO 6 neither paid any remuneration to Employee E, nor paid a fee for services to CORP 4 during applicable years 2022 and 2023.

(C) *Conclusion (2024).* Employee E may be a covered employee of ATEO 6 as one of its five highest-compensated employees for taxable year 2024 because the requirements under paragraph (d)(2)(iii) are not met and no other exception applies. For applicable years 2023 and 2024, Employee E provided services as an employee of ATEO 6 for more than 50 percent of the total hours Employee E provided services as an employee of ATEO 6 and CORP 4 (2,100 hours/4,000 hours).

(xii) *Example 12 (Limited services exception)*—(A) *Facts.* ATEO 7, ATEO 8, ATEO 9, and ATEO 10 are a group of related organizations, none of which have any other related organizations. During 2022, Employee F is an employee of ATEO 7, ATEO 8, ATEO 9, and ATEO 10. During applicable year 2022, ATEO 7 paid 5 percent of Employee F's remuneration, ATEO 8 paid 10 percent of Employee F's remuneration, ATEO 9 paid 25 percent of Employee F's remuneration, and ATEO 10 paid 60 percent of Employee F's remuneration. No exception under paragraph (d)(2)(i), (ii), or (iii) applies to Employee F for any of ATEO 7, ATEO 8, ATEO 9, or ATEO 10.

(B) *Conclusion (ATEO 7).* Employee F is disregarded for purposes of determining ATEO 7's five highest-compensated employees for taxable year 2022 under paragraph (d)(2)(iv) of this section because ATEO 7 paid less than 10 percent of Employee F's total remuneration from ATEO 7 and all related organizations during applicable year 2022, and another related ATEO paid at least 10 percent of that total remuneration.

(C) *Conclusion (ATEO 8, ATEO 9, and ATEO 10).* Employee F may be a covered employee of ATEO 8, ATEO 9, and ATEO 10 as one of their respective five highest-compensated employees for their taxable years 2022 because each of those ATEOs paid 10 percent or more of Employee F's remuneration during the 2022 applicable year. Thus, the limited services exception under paragraph (d)(2)(iv) of this section does not apply.

(xiii) *Example 13 (Limited services exception if no ATEO paid at least 10 percent of remuneration)*—(A) *Facts.* Assume the same facts as in paragraph (d)(3)(xii) of this section (*Example 12*), except that for applicable year 2022, ATEO 7 paid 6 percent of F's remuneration, ATEO 8, ATEO 9, and ATEO 10 each paid 5 percent of Employee F's remuneration, and Employee F also works as an employee of CORP 5, a related organization of ATEO 7, ATEO 8, ATEO 9, and ATEO 10 that paid 79 percent of Employee F's remuneration for applicable year 2022.

(B) *Conclusion (ATEO 7).* Employee F may be one of ATEO 7's five highest-compensated employees for taxable year 2022. Although ATEO 7 did not pay Employee F 10 percent or more of the total remuneration paid by ATEO 7 and all of its related organizations, no related ATEO paid more than 10 percent of Employee F's remuneration, and ATEO 7 did not pay less remuneration to Employee F than at least one related ATEO. Thus, the limited services exception under paragraph (d)(2)(iv) of this section does not apply, and Employee F may be one of ATEO 7's five highest-compensated employees because ATEO 7 paid Employee F more remuneration than any other related ATEO.

(C) *Conclusion (ATEO 8, ATEO 9, and ATEO 10).* Employee F is disregarded for purposes of determining the five highest-compensated employees of ATEO 8, ATEO 9, and ATEO 10 for taxable year 2022 under paragraph (d)(2)(iv) of this section because none paid 10 percent or more of Employee F's total remuneration, each had no related ATEO that paid at least 10 percent of Employee F's total remuneration, and each paid less remuneration than at least one related ATEO (ATEO 7).

(e) *Employee*—(1) *In general. Employee* means an employee as defined in section 3401(c) and § 31.3401(c)–1. Section 31.3401(c)–1 generally defines an employee as any individual performing services if the relationship between the individual and the person for whom the individual performs services is the legal relationship of employer and employee. As set forth in § 31.3401(c)–1, this includes common law employees, as well as officers and employees of government entities, whether or not elected. An employee generally also includes an officer of a corporation, but an officer of a corporation who as such does not perform any services or performs only minor services and who neither receives, nor is entitled to receive, any remuneration is not considered to be an employee of the corporation solely due to the individual's status as an officer of the corporation. Whether an individual is an employee depends on the facts and circumstances.

(2) *Directors.* A director of a corporation (or an individual holding a substantially similar position in a corporation or other entity) in the individual's capacity as such is not an employee of the corporation. See § 31.3401(c)–1(f).

(3) *Trustees.* The principles of paragraph (e)(2) of this section apply by analogy to a trustee of any arrangement classified as a trust for Federal tax purposes in § 301.7701–4(a).

(f) *Employer*—(1) *In general. Employer* means an employer within the meaning of section 3401(d), without regard to section 3401(d)(1) or (2), meaning generally the person or governmental entity for whom the services were performed as an employee. Whether a person or governmental entity is the employer depends on the facts and circumstances, but a person does not cease to be the employer through use of a payroll agent under section 3504, a common paymaster under section 3121(s), a person described in section 3401(d)(1) or (2), a certified professional employer

organization under section 7705, or any similar arrangement.

(2) *Disregarded entities.* In the case of a disregarded entity described in § 301.7701–3, § 301.7701–2(c)(2)(iv) does not apply; thus, the sole owner of the disregarded entity is treated as the employer of any individual performing services as an employee of the disregarded entity.

(g) *Medical services*—(1) *Medical and veterinary services*—(i) *In general. Medical services* means services directly performed by a licensed medical professional (as defined in paragraph (g)(2) of this section) for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; services provided for the purpose of affecting any structure or function of the human or animal body; and other services integral to providing such medical services. For purposes of section 4960, teaching and research services are not medical services except to the extent that they involve the services performed to directly diagnose, cure, mitigate, treat, or prevent disease or affect a structure or function of the body. Administrative services may be integral to directly providing medical services. For example, documenting the care and condition of a patient is integral to providing medical services, as is accompanying another licensed professional as a supervisor while that medical professional provides medical services. However, managing an organization's operations, including scheduling, staffing, appraising employee performance, and other similar functions that may relate to a particular medical professional or professionals who perform medical services, is not integral to providing medical services. See § 53.4960–2(a)(2)(ii) for rules regarding allocating remuneration paid to a medical professional who performs both medical services and other services.

(ii) *Examples.* The following examples illustrate the rules of this paragraph (g):

(A) *Example 1 (Administrative tasks that are integral to providing medical services)*—(*1*) *Facts.* Employee A is a doctor who is licensed to practice medicine in the state in which Employee A's place of employment is located. In the course of Employee A's practice, Employee A treats patients and performs some closely-related administrative tasks, such as examining and updating patient records.

(*2*) *Conclusion.* Employee A's administrative tasks are integral to providing medical services and thus are medical services.

(B) *Example 2 (Administrative tasks that are not integral to providing medical services)*—(*1*) *Facts.* Assume the same facts as in paragraph (g)(1)(ii)(A)(*1*) of this section (Example 1), except that Employee A also performs additional administrative tasks such as analyzing the budget, authorizing capital expenditures, and managing human resources for the organization by which Employee A is employed.

(*2*) *Conclusion.* Employee A's additional administrative tasks are not integral to providing medical services and thus are not medical services.

(C) *Example 3 (Teaching duties that are and are not medical services)*—(*1*) *Facts.* Employee B is a medical doctor who is licensed to practice medicine in the state in which her place of employment, a university hospital, is located. Employee B's duties include overseeing and teaching a group of resident physicians who have restricted licenses to practice medicine. Those duties include supervising and instructing the resident physicians while they treat patients and instruction in a classroom setting.

(*2*) *Conclusion.* Employee B's supervision and instruction of resident physicians during the course of patient treatment are necessary for the treatment, and thus are medical services. Employee B's classroom instruction is not necessary for patient treatment, and thus is not medical services.

(D) *Example 4 (Research services that are and are not medical services)*—(*1*) *Facts.* Employee C is a licensed medical doctor who is employed to work on a research trial. Employee C provides an experimental treatment to patients afflicted by a disease and performs certain closely-related administrative tasks that ordinarily are performed by a medical professional in a course of patient treatment. As part of the research trial, Employee C also compiles and analyzes patient results and prepares reports and articles that would not ordinarily be prepared by a medical professional in the course of patient treatment.

(*2*) *Conclusion.* Employee C's services that are ordinarily performed by a medical professional in a course of treatment, including closely-related administrative tasks, are medical services. Because the compilation and analysis of patient results and the formulation of reports and articles are neither services ordinarily performed by a medical professional in a course of treatment nor necessary for such treatment, these services are not medical services.

(2) *Definition of licensed medical professional. Licensed medical professional* means an individual who is licensed under applicable state or local law to perform medical services, including as a doctor, nurse, nurse practitioner, dentist, veterinarian, or other licensed medical professional.

(h) *Predecessor*—(1) *Asset acquisitions.* If an ATEO (acquiror) acquires at least 80 percent of the operating assets or total assets (determined by fair market value on the date of acquisition) of another ATEO (target), then the target is a predecessor of the acquiror. For an acquisition of assets that occurs over time, only assets acquired within a 12-month period are taken into account to determine whether at least 80 percent of the target's operating assets or total assets were acquired. However, this 12-month period is extended to include any continuous period that ends or begins on any day during which the acquiror has an arrangement to acquire directly or indirectly, assets of the target. Additions to the assets of target made as part of a plan or arrangement to avoid the application of this subsection to acquiror's purchase of target's assets are disregarded in applying this paragraph. This paragraph (h)(1) applies for purposes of determining whether an employee is a covered employee under paragraph (d)(1) of this section only with respect to a covered employee of the target who commences the performance of services for the acquiror (or a related organization with respect to the acquiror) within the period beginning 12 months before and ending 12 months after the date of the transaction as defined in paragraph (h)(7) of this section.

(2) *Corporate reorganizations.* A predecessor of an ATEO includes another separate ATEO the stock or assets of which are acquired in a corporate reorganization as defined in section 368(a)(1)(A), (C), (D), (E), (F), or (G) (including by reason of section 368(a)(2)).

(3) *Predecessor change of form or of place of organization.* An ATEO that restructured by changing its organizational form or place of organization (or both) is a predecessor of the restructured ATEO.

(4) *ATEO that becomes a non-ATEO*—(i) *General rule.* An organization is a predecessor of an ATEO if it ceases to be an ATEO and then again becomes an ATEO effective on or before the predecessor end date. The *predecessor end date* is the date that is 36 months following the date that the organization's Federal information return under section 6033 (or, for an

ATEO described in paragraph (b)(1)(ii) or (iii) of this section, its Federal income tax return under section 6011(a)) is due (or would be due if the organization were required to file), excluding any extension, for the last taxable year for which the organization previously was an ATEO. If the organization becomes an ATEO again effective after the predecessor end date, then the former ATEO is treated as a separate organization that is not a predecessor of the current ATEO.

(ii) *Intervening changes or entities.* If an ATEO that ceases to be an ATEO (former ATEO) would be treated as a predecessor to an organization that becomes an ATEO before the predecessor end date (successor ATEO), and if the former ATEO would be treated as a predecessor to each intervening entity (if such intervening entities had been ATEOs) under the rules of this paragraph (h), then the former ATEO is a predecessor of the successor ATEO. For example, if ATEO 1 loses its tax-exempt status and then merges into Corporation X, Corporation X then merges into Corporation Y, and Corporation Y becomes an ATEO before the predecessor end date, then ATEO 1 is a predecessor of Corporation Y.

(5) *Predecessor of a predecessor.* A reference to a predecessor includes any predecessor or predecessors of such predecessor, as determined under these rules.

(6) *Elections under sections 336(e) and 338.* For purposes of this paragraph (h), when an ATEO organized as a corporation makes an election to treat as an asset purchase either the sale, exchange, or distribution of stock pursuant to regulations under section 336(e) or the purchase of stock pursuant to regulations under section 338, the corporation that issued the stock is treated as the same corporation both before and after such transaction.

(7) *Date of transaction.* For purposes of this paragraph (h), the date that a transaction is treated as having occurred is the date on which all events necessary to complete the transaction described in the relevant provision have occurred.

(i) *Related organization*—(1) *In general. Related organization* means any person or governmental entity, domestic or foreign, that meets any of the following tests:

(i) *Controls or controlled by test.* The person or governmental entity controls, or is controlled by, the ATEO;

(ii) *Controlled by same persons test.* The person or governmental entity is controlled by one or more persons that control the ATEO;

(iii) *Supported organization test.* The person or governmental entity is a supported organization (as defined in section 509(f)(3)) with respect to the ATEO;

(iv) *Supporting organization test.* The person or governmental entity is a supporting organization described in section 509(a)(3) with respect to the ATEO; or

(v) *VEBA test.* With regard to an ATEO that is a voluntary employees' beneficiary association (VEBA) described in section 501(c)(9), the person or governmental entity establishes, maintains, or makes contributions to such VEBA.

(2) *Control*—(i) *In general.* Control may be direct or indirect. For rules concerning application of the principles of section 318 in applying this paragraph (i)(2), see paragraph (i)(2)(vii) of this section.

(ii) *Stock corporation.* A person or governmental entity controls a stock corporation if it owns (by vote or value) more than 50 percent of the stock in the stock corporation.

(iii) *Partnership.* A person or governmental entity controls a partnership if it owns more than 50 percent of the profits interests or capital interests in the partnership, determined in accordance with the rules and principles of § 1.706–1(b)(4)(ii) for a partner's interest in the profits of a partnership and § 1.706–1(b)(4)(iii) for a partner's interest in the capital of a partnership.

(iv) *Trust.* A person or governmental entity controls a trust if it owns more than 50 percent of the beneficial interests in the trust, determined by actuarial value.

(v) *Nonstock organization*—(A) *In general.* A person or governmental entity controls a nonstock organization if more than 50 percent of the trustees or directors of the nonstock organization are either representatives of, or directly or indirectly controlled by, the person or governmental entity. A *nonstock organization* is a nonprofit organization or other organization without owners and includes a governmental entity.

(B) *Control of a trustee or director of a nonstock organization.* A person or governmental entity controls a trustee or director of the nonstock organization if the person or governmental entity has the power (either at will or at regular intervals) to remove such trustee or director and designate a new one.

(C) *Representatives.* Trustees, directors, officers, employees, or agents of a person or governmental entity are deemed representatives of the person or governmental entity. However, an employee of a person or governmental entity (other than a trustee, director, or officer, or an employee who possesses at least the authority commonly exercised by an officer) who is a director or trustee of a nonstock organization (or acting in that capacity) will not be treated as a representative of the person or governmental entity if the employee does not act as a representative of the person or governmental entity and that fact is reported in the form and manner prescribed by the Commissioner in forms and instructions.

(vi) *Brother-sister related organizations.* Under paragraph (i)(1)(ii) of this section, an organization is a related organization with respect to an ATEO if one or more persons control both the ATEO and the other organization. In the case of control by multiple persons, the control tests described in this paragraph (i)(2) of this section apply to the persons as a group. For example, if 1,000 individuals who are members of both ATEO 1 and ATEO 2 elect a majority of the board members of each organization, then ATEO 1 and ATEO 2 are related to each other because the same group of 1,000 persons controls both ATEO 1 and ATEO 2.

(vii) *Section 318 principles*—(A) *In general.* Section 318 (relating to constructive ownership of stock) applies in determining ownership of stock in a corporation. The principles of section 318 also apply for purposes of determining ownership of interests in a partnership or in a trust with beneficial interests. For example, applying the principles of section 318(a)(1)(A), an individual is considered to own the partnership interest or trust interest owned, directly or indirectly, by or for the family members specified in such section.

(B) *Nonstock organizations*—(*1*) *Attribution of ownership interest from a nonstock organization to a controlling person.* If a person or governmental entity controls a nonstock organization, the person or governmental entity is treated as owning a percentage of the stock (or partnership interest or beneficial interest in a trust) owned by the nonstock organization in accordance with the percentage of trustees or directors of the nonstock organization that are representatives of, or directly or indirectly controlled by, the person or governmental entity.

(*2*) *Attribution of ownership interest from a controlling person to a nonstock organization.* If a person or governmental entity controls a nonstock organization, the nonstock organization is treated as owning a percentage of the stock (or partnership interest or beneficial interest in a trust) owned by the person or governmental entity in

accordance with the percentage of trustees or directors of the nonstock organization that are representatives of, or directly or indirectly controlled by, the person or governmental entity.

(*3*) *Indirect control of a nonstock organization through another nonstock organization.* If a person or governmental entity controls one nonstock organization that controls a second nonstock organization, the person or governmental entity is treated as controlling the second nonstock organization if the product of the percentage of trustees or directors of the first nonstock organization that are representatives of, or directly or indirectly controlled by, the person or governmental entity, multiplied by the percentage of trustees or directors of the second nonstock organization that are representatives of, or directly or indirectly controlled by, the person or governmental entity or first nonstock organization, exceeds 50 percent. Similar principles apply to successive tiers of nonstock organizations.

(*4*) *Attribution of control of nonstock organization to family member.* An individual's control of a nonstock organization or of a trustee or director of a nonstock organization is attributed to the members of the individual's family (as set forth in section 318(a)(1) and the regulations thereunder), subject to the limitation of section 318(a)(5)(B) and the regulations thereunder.

(3) *Examples.* The following examples illustrate the principles of this paragraph (i). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO and any entity referred to as ''CORP'' is not an ATEO.

(i) *Example 1 (Related through a chain of control)*—(A) *Facts.* ATEO 1, ATEO 2, and ATEO 3 are nonstock organizations. ATEO 3 owns 80 percent of the stock (by value) of corporation CORP 1. Eighty percent of ATEO 2's directors are representatives of ATEO 1. In addition, 80 percent of ATEO 3's directors are representatives of ATEO 1.

(B) *Conclusion.* ATEO 1 is a related organization with respect to ATEO 2 (and vice versa) because more than 50 percent of ATEO 2's directors are representatives of ATEO 1; thus, ATEO 1 controls ATEO 2. Based on the same analysis, ATEO 1 is also a related organization with respect to ATEO 3 (and vice versa). CORP 1 is a related organization with respect to ATEO 3 because, as the owner of more than 50 percent of CORP 1's stock, ATEO 3 controls CORP 1. Applying the principles of section 318, ATEO 1 is deemed to own 64 percent of the stock of CORP 1 (80 percent of ATEO 3's stock in CORP 1). Thus, CORP 1 is a related organization with respect to ATEO 1 because ATEO 1 controls CORP 1. ATEO 2 is a related organization with respect to ATEO 3, ATEO 3 is a related organization with respect to ATEO 2, and CORP 1 is a related organization with respect to ATEO 2 because ATEO 2, ATEO 3, and CORP 1 are all controlled by the same person (ATEO 1).

(ii) *Example 2 (Not related through a chain of control)*—(A) *Facts.* ATEO 4, ATEO 5, and ATEO 6 are nonstock organizations. Sixty percent of ATEO 5's directors are representatives of ATEO 4. In addition, 60 percent of ATEO 6's directors are representatives of ATEO 5, but none are representatives of ATEO 4.

(B) *Conclusion.* ATEO 4 is a related organization with respect to ATEO 5 (and vice versa) because more than 50 percent of ATEO 5's directors are representatives of ATEO 4; thus, ATEO 4 controls ATEO 5. Based on the same analysis, ATEO 6 is a related organization with respect to ATEO 5 (and vice versa). Applying the principles of section 318, ATEO 4 is deemed to control 36 percent of ATEO 6's directors (60 percent of ATEO 5's 60 percent control over ATEO 6). Because less than 50 percent of ATEO 6's directors are representatives of ATEO 4, and absent any facts suggesting that ATEO 4 directly or indirectly controls ATEO 6, ATEO 4 and ATEO 6 are not related organizations with respect to each other.

§ 53.4960–2 Determination of remuneration paid for a taxable year.

(a) *Remuneration*—(1) *In general.* For purposes of section 4960, *remuneration* means any amount that is wages as defined in section 3401(a), excluding any designated Roth contribution (as defined in section 402A(c)) and including any amount required to be included in gross income under section 457(f). Remuneration includes amounts includible in gross income as compensation for services as an employee pursuant to a below-market loan described in section 7872(c)(1)(B)(i) (compensation-related loans) but does not include amounts excepted by section 7872(c)(3) ($10,000 de minimis exception). For example, see § 1.7872–15(e)(1)(i). Director's fees paid by a corporation to a director of the corporation are not remuneration, provided that if the director is also an employee of the corporation, the director's fees are excluded from remuneration only to the extent that they do not exceed fees paid to a director who is not an employee of the corporation or any related organization or, if there is no such director, they do not exceed reasonable director's fees. Remuneration does not include any amount that vested or was paid by a taxpayer before the start of the taxpayer's first taxable year that began on or after January 1, 2018.

(2) *Exclusion of remuneration for medical services*—(i) *In general. Remuneration* does not include the portion of any remuneration paid to a licensed medical professional that is for the performance of medical services by such professional.

(ii) *Allocation of remuneration for medical services and non-medical services.* If, during an applicable year, an employer pays a covered employee remuneration for providing both medical services and non-medical services, the employer must make a reasonable, good faith allocation between the remuneration for medical services and the remuneration for non-medical services. For example, if a medical doctor receives current remuneration (or vests in remuneration under a deferred compensation plan) for providing medical services and administrative or management services, the employer must make a reasonable, good faith allocation between the remuneration for the medical services and the remuneration for the administrative or management services. For this purpose, if an employment agreement or similar written arrangement sets forth the remuneration to be paid for particular services, that allocation of remuneration applies unless the facts and circumstances demonstrate that the amount allocated to medical services is unreasonable for those services or that the allocation was established for purposes of avoiding application of the excise tax under section 4960. If some or all of the remuneration is not reasonably allocated in an employment agreement or similar arrangement, an employer may use any reasonable allocation method. For example, an employer may use a representative sample of records, such as patient, insurance, and Medicare/Medicaid billing records or internal time reporting mechanisms to determine the time spent providing medical services, and then allocate remuneration to medical services in the proportion such time bears to the total hours the employee worked for the employer (and any related employer) for purposes of making a reasonable allocation of remuneration. Similarly, if some or all of the remuneration is not reasonably allocated in an employment agreement or other similar arrangement, an employer may use salaries or other remuneration paid by the employer or similarly situated employers for duties

comparable to those the employee performs (for example, hospital administrator and physician) for purposes of making a reasonable allocation between remuneration for providing medical services and for providing non-medical services.

(iii) *Examples.* The following examples illustrate the rules of this paragraph (a)(2). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO.

(A) *Example 1 (Allocation based on employment agreement)*—(*1*) *Facts.* Employee A is a covered employee of ATEO 1. Employee A is a licensed medical professional who provides patient care services for ATEO 1 and also provides management and administrative services to ATEO 1 as the manager of a medical practice group within ATEO 1. The employment agreement between ATEO 1 and Employee A specifies that of Employee A's salary, 30 percent is allocable to Employee A's services as manager of the medical practice group and 70 percent is allocable to Employee A's services as a medical professional providing patient care services. The facts regarding Employee A's employment indicate the employment agreement provides a reasonable allocation and that the allocation was not established for purposes of avoiding application of the excise tax.

(*2*) *Conclusion.* Consistent with Employee A's employment agreement, ATEO 1 must allocate 30 percent of Employee A's salary to the provision of non-medical services and 70 percent of Employee A's salary to the provision of medical services. Accordingly, only the 30 percent portion of Employee A's salary allocated to the other, non-medical services is remuneration for purposes of paragraph (a) of this section.

(B) *Example 2 (Allocation based on billing records)*—(*1*) *Facts.* Assume the same facts as in paragraph (a)(2)(iii)(A) of this section (Example 1), except that the employment agreement does not allocate Employee A's salary between medical and non-medical services performed by Employee A. Based on a representative sample of insurance and Medicare billing records, as well as time reports that Employee A submits to ATEO 1, ATEO 1 determines that Employee A spends 50 percent of her work hours providing patient care and 50 percent of her work hours performing administrative and management services. ATEO 1 allocates 50 percent of Employee A's remuneration to medical services.

(*2*) *Conclusion.* ATEO 1's allocation of Employee A's salary is a reasonable, good faith allocation. Accordingly, only the 50 percent portion of Employee A's remuneration allocated to the non-medical services is remuneration for purposes of paragraph (a) of this section.

(b) *Source of payment.* For purposes of this section, the determination of the source of a payment of remuneration may involve the application of one or both of two separate rules described in this paragraph (b). Paragraph (b)(1) of this section addresses payments by a third party for services performed as an employee of a separate employer entity, while paragraph (b)(2) of this section addresses the application of section 4960(c)(4)(A) to treat certain remuneration paid by a related organization (after application of paragraph (b)(1) of this section, if applicable) as paid by the ATEO.

(1) *Remuneration paid by a third party for employment by an employer.* Remuneration paid (or a grant of a legally binding right to nonvested remuneration) by a third-party payor (whether a related organization, payroll agent, agent designated under section 3504, certified professional employer organization under section 7705, or other entity) during an applicable year for services performed as an employee of an employer is remuneration paid (or payable) by the employer, except as otherwise provided in § 53.4960–1(d)(2)(ii) and (iii).

(2) *Remuneration paid by a related organization for employment by the related organization.* Pursuant to section 4960(c)(4)(A), remuneration paid (or a grant of a legally binding right to nonvested remuneration) by a related organization to an ATEO's employee during an applicable year for services performed as an employee of the related organization is treated as remuneration paid (or payable) by the ATEO, except as otherwise provided in § 53.4960–1(d)(2)(ii) and (iii).

(c) *Applicable year in which remuneration is treated as paid*—(1) *In general.* Remuneration that is a regular wage within the meaning of § 31.3402(g)–1(a)(1)(ii) is treated as paid on the date it is actually or constructively paid and all other remuneration is treated as paid on the first date on which the remuneration is vested.

(2) *Vested remuneration.* Remuneration is *vested* if it is not subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B) (regardless of whether the arrangement under which the remuneration is to be paid is deferred compensation described in section 457(f) or 409A). In general, an amount is subject to a substantial risk of forfeiture if entitlement to the amount is conditioned on the future performance of substantial services or upon the occurrence of a condition that is related to a purpose of the remuneration if the possibility of forfeiture is substantial. Except as provided in paragraph (c)(1) of this section, remuneration that is never subject to a substantial risk of forfeiture is considered paid on the first date the service provider has a legally binding right to the payment. For purposes of this section, a *plan* means a plan within the meaning of § 1.409A–1(c), an *account balance plan* means an account balance plan within the meaning of § 1.409A–1(c)(2)(i)(A), and a *nonaccount balance plan* means a nonaccount balance plan within the meaning of § 1.409A–1(c)(2)(i)(C). Net earnings on previously paid remuneration (described in paragraph (d)(2) of this section) that are not subject to a substantial risk of forfeiture are vested (and, thus, treated as paid) at the earlier of the date actually or constructively paid to the employee or the close of the applicable year in which they accrue. For example, the present value of a principal amount accrued to an employee's account under an account balance plan (under which the earnings and losses attributed to the account are based solely on a predetermined actual investment as determined under § 31.3121(v)(2)–1(d)(2)(i)(B) or a reasonable market interest rate) is treated as paid on the date vested, but the present value of any net earnings subsequently accrued on that amount (the increase in value due to the predetermined actual investment or a reasonable market interest rate) is treated as paid at the close of the applicable year in which they accrue. Similarly, while the present value of an amount accrued under a nonaccount balance (including earnings that accrued while the amount was nonvested) is treated as paid on the date it is first vested, the present value of the net earnings on that amount (the increase in the present value) is treated as paid at the close of the applicable year in which they accrue.

(3) *Change in related status during the year.* If a taxpayer becomes or ceases to be a related organization with respect to an ATEO during an applicable year, then only the remuneration paid by the taxpayer to an employee with respect to services performed as an employee of the related organization during the portion of the applicable year during which the employer is a related organization is treated as paid by the ATEO. If an amount is treated as paid due to vesting in the year the taxpayer becomes or ceases to be a related

organization with respect to the ATEO, then the amount is treated as paid by the ATEO only if the amount becomes vested during the portion of the applicable year that the taxpayer is a related organization with respect to the ATEO.

(d) *Amount of remuneration treated as paid*—(1) *In general.* For each applicable year, the amount of remuneration treated as paid by the employer to a covered employee is the sum of regular wages within the meaning of § 31.3402(g)–1(a)(1)(ii) actually or constructively paid during the applicable year and the present value (as determined under paragraph (e) of this section) of all other remuneration that vested during the applicable year. The amount of remuneration that vests during an applicable year is determined on an employer-by-employer basis with respect to each covered employee.

(2) *Earnings and losses on previously paid remuneration*—(i) *In general.* The amount of net earnings or losses on previously paid remuneration paid by an employer is determined on an employee-by-employee basis, such that amounts accrued with regard to one employee do not affect amounts accrued with regard to a different employee. Similarly, losses accrued on previously paid remuneration from one employer do not offset earnings accrued on previously paid remuneration from another employer. The amount of net earnings or losses on previously paid remuneration paid by the employer is determined on a net aggregate basis for all plans maintained by the employer in which the employee participates for each applicable year. For example, losses under an account balance plan may offset earnings under a nonaccount balance plan for the same applicable year maintained by the same employer for the same employee.

(ii) *Previously paid remuneration*—(A) *New covered employee.* For an individual who was not a covered employee for any prior applicable year, *previously paid remuneration* means, for the applicable year for which the individual becomes a covered employee, the present value of vested remuneration that was not actually or constructively paid or otherwise includible in the employee's gross income before the start of the applicable year plus any remuneration that vested during the applicable year but that is not actually or constructively paid or otherwise includible in the employee's gross income before the close of the applicable year.

(B) *Existing covered employee.* For an individual who was a covered employee for any prior applicable year, *previously paid remuneration* means, for each applicable year, the amount of remuneration that the employer treated as paid in the applicable year or for a prior applicable year but that is not actually or constructively paid or otherwise includible in the employee's gross income before the close of the applicable year. Actual or constructive payment or another event causing an amount of previously paid remuneration to be includible in the employee's gross income thus reduces the amount of previously paid remuneration.

(iii) *Earnings. Earnings* means any increase in the vested present value of previously paid remuneration as of the close of the applicable year, regardless of whether the plan denominates the increase as earnings. For example, an increase in the vested account balance of a nonqualified deferred compensation plan based solely on the investment return of a predetermined actual investment (and disregarding any additional contributions) constitutes earnings. Similarly, an increase in the vested present value of a benefit under a nonqualified nonaccount balance plan due solely to the passage of time (and disregarding any additional benefit accruals) constitutes earnings. However, an increase in an account balance of a nonqualified deferred compensation plan due to a salary reduction contribution or an employer contribution does not constitute earnings (and therefore may not be offset with losses). Likewise, an increase in the benefit under a nonaccount balance plan due to an additional year of service or an increase in compensation that is reflected in a benefit formula does not constitute earnings.

(iv) *Losses. Losses* means any decrease in the vested present value of previously paid remuneration as of the close of the applicable year, regardless of whether the plan denominates that decrease as losses.

(v) *Net earnings. Net earnings* means, for each applicable year, the amount (if any) by which the earnings accrued for the applicable year on previously paid remuneration exceeds the sum of the losses accrued on previously paid remuneration for the applicable year and any net losses carried forward from a previous taxable year.

(vi) *Net losses. Net losses* means, for each applicable year, the amount (if any) by which the sum of the losses accrued on previously paid remuneration for the applicable year and any net losses carried forward from a previous taxable year exceed the earnings accrued for the applicable year on previously paid remuneration. Losses may only be used to offset earnings and thus do not reduce the remuneration treated as paid for an applicable year except to the extent of the earnings accrued for that applicable year. However, with regard to a covered employee, an employer may carry net losses forward to the next applicable year and offset vested earnings for purposes of determining net earnings or losses for that subsequent applicable year. For example, if a covered employee who participates in a nonaccount balance plan and an account balance plan vests in an amount of earnings under the nonaccount balance plan and has losses under the account balance plan that exceed the vested earnings treated as remuneration under the nonaccount balance plan, those excess losses are carried forward to the next applicable year and offset vested earnings for purposes of determining net earnings or losses for that applicable year. If, for the next applicable year, there are not sufficient earnings to offset the entire amount of losses carried forward from the previous year (and any additional losses), the offset process repeats for each subsequent applicable year until there are sufficient earnings for the applicable year to offset any remaining losses carried forward.

(3) *Remuneration paid for a taxable year before the employee becomes a covered employee*—(i) *In general.* In accordance with the payment timing rules of paragraph (c) of this section, any remuneration that is vested but is not actually or constructively paid or otherwise includible in an employee's gross income as of the close of the applicable year for the taxable year immediately preceding the taxable year in which the employee first becomes a covered employee of an ATEO is treated as previously paid remuneration for the taxable year in which the employee first becomes a covered employee. Net losses on this previously paid remuneration from any preceding applicable year do not carry forward to subsequent applicable years. However, net earnings and losses that vest on such previously paid remuneration in subsequent applicable years are treated as remuneration paid for a taxable year for which the employee is a covered employee.

(ii) *Examples.* The following examples illustrate the rules of this paragraph (d)(3). For purposes of these examples, assume any organization described as ''ATEO'' is an ATEO.

(A) *Example 1 (Earnings on pre-covered employee remuneration)*—(*1*) *Facts.* ATEO 1 uses a taxable year

beginning July 1 and ending June 30. Employee A becomes a covered employee of ATEO 1 for the taxable year beginning July 1, 2023, and ending June 30, 2024. During the 2022 applicable year, Employee A vests in $1 million of nonqualified deferred compensation. As of December 31, 2022, the present value of the amount deferred under the plan is $1.1 million. During the 2023 applicable year, ATEO 1 pays Employee A $1 million in regular wages. The present value as of December 31, 2023, of Employee A's nonqualified deferred compensation is $1.3 million.

(*2*) *Conclusion (Taxable year beginning July 1, 2022, and ending June 30, 2023).* ATEO 1 pays Employee A $1.1 million of remuneration in the 2022 applicable year. This is comprised of $1 million of vested nonqualified deferred compensation, and $100,000 of earnings, all of which is treated as paid for the taxable year beginning July 1, 2022, and ending June 30, 2023.

(*3*) *Conclusion (Taxable year beginning July 1, 2023, and ending June 30, 2024).* ATEO 1 pays Employee A $1.2 million of remuneration in the 2023 applicable year. This is comprised of $1 million regular wages and $200,000 of earnings ($1.3 million present value as of December 31, 2023, minus $1.1 million previously paid remuneration as of December 31, 2022).

(B) *Example 2 (Losses on pre-covered employee remuneration)*—(*1*) *Facts.* Assume the same facts as in paragraph (d)(3)(ii)(A) of this section (Example 1), except that the present value of the nonqualified deferred compensation as of December 31, 2022, is $900,000.

(*2*) *Conclusion (Taxable year beginning July 1, 2022, and ending June 30, 2023).* ATEO 1 pays Employee A $1 million of remuneration in the 2022 applicable year. This is comprised of $1 million of vested nonqualified deferred compensation. The present value of all vested deferred compensation as of December 31 of the 2022 applicable year ($900,000) is treated as previously paid remuneration for the next applicable year (as Employee A is a covered employee for the next taxable year). The $100,000 of losses accrued while Employee A was not a covered employee do not carry forward to the next applicable year.

(*3*) *Conclusion (Taxable year beginning July 1, 2023, and ending June 30, 2024).* ATEO 1 pays Employee A $1.4 million of remuneration in the 2023 applicable year. This is comprised of $1 million cash and $400,000 of earnings ($1.3 million present value as of December 31, 2023, minus $900,000 previously paid remuneration).

(e) *Calculation of present value*—(1) *In general.* The employer must determine present value using reasonable actuarial assumptions regarding the amount, time, and probability that a payment will be made. For this purpose, a discount for the probability that an employee will die before commencement of benefit payments is permitted, but only to the extent that benefits will be forfeited upon death. The present value may not be discounted for the probability that payments will not be made (or will be reduced) because of the unfunded status of the plan; the risk associated with any deemed or actual investment of amounts deferred under the plan; the risk that the employer, the trustee, or another party will be unwilling or unable to pay; the possibility of future plan amendments; the possibility of a future change in the law; or similar risks or contingencies. The present value of the right to future payments as of the vesting date includes any earnings that have accrued as of the vesting date that are not previously paid remuneration.

(2) *Treatment of future payment amount as present value for certain amounts.* For purposes of determining the present value of remuneration that is scheduled to be actually or constructively paid within 90 days of vesting, the employer may treat the future amount that is to be paid as the present value at vesting.

(f) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO, any entity referred to as ''CORP'' is not an ATEO, and all taxpayers use the calendar year as their taxable year.

(1) *Example 1 (Account balance plan)*—(i) *Facts.* Employee A is a covered employee of ATEO 1. Employee A participates in a nonqualified deferred compensation plan (the NQDC plan) in which the account balance is adjusted based on the investment returns on predetermined actual investments. On January 1, 2022, ATEO 1 credits $100,000 to Employee A's account under the plan, subject to the requirement that Employee A remain employed through June 30, 2024. On June 30, 2024, the vested account balance is $110,000. Due to earnings or losses on the account balance, the closing account balance on each of the following dates is: $115,000 on December 31, 2024, $120,000 on December 31, 2025, $100,000 on December 31, 2026, and $110,000 on December 31, 2027. During 2028, Employee A defers an additional $10,000 under the plan, all of which is vested at the time of deferral. On December 31, 2028, the closing account balance is $125,000. In 2029, ATEO 1 pays $10,000 to Employee A under the plan. On December 31, 2029, the closing account balance is $135,000 due to earnings on the account balance.

(ii) *Conclusion (2022 and 2023 applicable years—nonvested amounts).* For 2022 and 2023, ATEO 1 is not treated as paying Employee A any remuneration attributable to Employee A's participation in the NQDC plan because the amount deferred under the plan remains subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B).

(iii) *Conclusion (2024 applicable year—amounts in year of vesting).* For 2024, ATEO 1 is treated as paying Employee A $115,000 of remuneration attributable to Employee A's participation in the NQDC plan, including $110,000 of remuneration on June 30, 2024, when the amount becomes vested, and an additional $5,000 of remuneration on December 31, 2024, which is earnings on the previously paid remuneration ($110,000).

(iv) *Conclusion (2025 applicable year—earnings).* For 2025, ATEO 1 is treated as paying Employee A $5,000 of remuneration attributable to Employee A's participation in the NQDC plan, which is the additional earnings on the previously paid remuneration ($115,000) as of December 31, 2025.

(v) *Conclusion (2026 applicable year—losses).* For 2026, ATEO 1 is not treated as paying Employee A any remuneration attributable to Employee A's participation in the NQDC plan because the present value of the previously paid remuneration ($120,000) decreased to $100,000 as of December 31, 2026. The $20,000 loss for 2026 does not reduce any amount previously treated as remuneration but is available for carryover to subsequent taxable years to offset earnings.

(vi) *Conclusion (2027 applicable year—recovery of losses).* For 2027, ATEO 1 is not treated as paying Employee A any remuneration attributable to Employee A's participation in the NQDC plan because the present value of the previously paid remuneration ($120,000) was $110,000 as of December 31, 2027. Due to increases on the account balance, ATEO 1 recovers $10,000 of the $20,000 of losses carried over from 2026. The net losses as of December 31, 2027, are $10,000, and none of the $10,000 in earnings during 2027 is treated as remuneration paid in 2027.

(vii) *Conclusion (2028 applicable year—no recovery of losses against additional deferrals of compensation).*

For 2028, ATEO 1 is treated as paying Employee A $10,000 of remuneration attributable to Employee A's participation in the NQDC plan. The additional $10,000 deferral is vested and thus is treated as remuneration paid on the date credited to Employee A's account. This credit increases the amount of previously paid remuneration from $120,000 to $130,000. Additionally, due to earnings, ATEO 1 recovers $5,000 of the $10,000 loss carried over from 2027, none of which was remuneration paid for 2026, so that as of December 31, 2028, the net loss available for carryover to 2029 is $5,000.

(viii) *Conclusion (2029 applicable year—distributions, recovery of remainder of losses through earnings and additional earnings).* For 2029, ATEO 1 is treated as paying Employee A $15,000 of remuneration attributable to Employee A's participation in the NQDC plan. The $10,000 payment reduces the amount of previously paid remuneration (from $130,000 to $120,000) and the account balance (from $125,000 to $115,000). The present value of the vested account balance increases by $20,000 (from $115,000 to $135,000) as of December 31, 2029. Therefore, due to earnings, ATEO 1 recovers the remaining $5,000 loss carried over from 2028 (the difference between the $120,000 previously paid remuneration before earnings and the $115,000 account balance before earnings) and is treated as paying Employee A an additional $15,000 of remuneration as earnings (the difference between the $135,000 account balance after earnings and the $120,000 previously paid remuneration after loss recovery).

(2) *Example 2 (Nonaccount balance plan with earnings)*—(i) *Facts.* ATEO 2 and CORP 2 are related organizations. Employee B is a covered employee of ATEO 2 and is also employed by CORP 2. On January 1, 2022, CORP 2 and Employee B enter into an agreement under which CORP 2 will pay Employee B $100,000 on December 31, 2025, if B remains employed by CORP 2 through January 1, 2024. Employee B remains employed by CORP 2 through January 1, 2024. On January 1, 2024, the present value based on reasonable actuarial assumptions of the $100,000 to be paid on December 31, 2025, is $75,000. On December 31, 2024, the present value of the $100,000 future payment increases to $85,000 due solely to the passage of time. On December 31, 2025, CORP 2 pays Employee B $100,000.

(ii) *Conclusion (2022 and 2023 applicable years—nonvested amounts).* For 2022 and 2023, CORP 2 is not treated as paying Employee B any remuneration attributable to the agreement because the amount deferred under the agreement remains subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B).

(iii) *Conclusion (2024 applicable year—amounts in year of vesting).* For 2024, CORP 2 is treated as paying Employee B $75,000 of remuneration attributable to the agreement on January 1, 2024, which is the present value on that date of the $100,000 payable on December 31, 2025. In addition, CORP 2 is treated as paying Employee B $10,000 of remuneration attributable to the agreement on December 31, 2024, which is earnings based on the increase in the present value of the previously paid remuneration (from $75,000 to $85,000) as of December 31, 2024.

(iv) *Conclusion (2025 applicable year—earnings and distribution of previously paid remuneration).* For 2025, CORP 2 is treated as paying Employee B $15,000 in remuneration attributable to the agreement on December 31, 2025, which is earnings based on the increase in the present value of the previously paid remuneration (from $85,000 to $100,000) as of December 31, 2025. In addition, the $100,000 payment is treated as reducing the amount of previously paid remuneration ($100,000) to zero.

(3) *Example 3 (Treatment of amount payable as present value at vesting)*—(i) *Facts.* Employee C is a covered employee of ATEO 3. Under an agreement between ATEO 3 and Employee C, ATEO 3 agrees to pay Employee C $100,000 two months after the date Employee C meets a specified performance goal that is a substantial risk of forfeiture within the meaning of section 457(f)(3)(B). Employee C meets the performance goal on November 30, 2022, and ATEO 3 pays Employee C $100,000 on January 31, 2023. In accordance with § 53.4960–2(e)(2), because the payment is to be made within 90 days of vesting, ATEO 3 elects to treat the full payment amount as the amount of remuneration paid at vesting.

(ii) *Conclusion (2022 applicable year—election to treat amount payable within 90 days as paid at vesting).* For taxable year 2022, ATEO 3 is treated as paying Employee C $100,000 of remuneration attributable to the agreement. Employee C vests in the $100,000 payment in 2022 upon meeting the performance goal. Under the general rule, ATEO 3 would be treated as paying for the taxable year 2022 the present value as of November 30, 2022, of $100,000 payable on January 31, 2023 (two months after the date of vesting), with adjustments to the present value as of the end of the year. However, because ATEO 3 elected to treat the full $100,000 amount payable within 90 days of vesting as the remuneration paid, the $100,000 payable to Employee C in 2023 is treated as remuneration paid in 2022 (and no additional amount related to the $100,000 paid on January 31, 2023, is treated as remuneration paid in 2023).

(4) *Example 4 (Aggregation of remuneration from related organizations)*—(i) *Facts.* Employee D is a covered employee of ATEO 4 and also an employee of CORP 4 and CORP 5. ATEO 4, CORP 4, and CORP 5 are related organizations. ATEO 4, CORP 4, and CORP 5 each pay Employee D $200,000 of salary during 2022 and 2023. On January 1, 2022, ATEO 4 promises to pay Employee D $120,000 on December 31, 2023, under a nonaccount balance plan, the right to which is vested and the present value of which is $100,000 on January 1, 2022. On January 1, 2022, CORP 4 and CORP 5 each contribute $100,000 on Employee D's behalf to account balance plans of CORP 4 and CORP 5, respectively, under which all amounts deferred are vested. On December 31, 2022, the present value of the amounts deferred under the ATEO 4 plan is $110,000, the present value of the amounts deferred under the CORP 4 plan is $120,000, and the present value of the amounts deferred under the CORP 5 plan maintained is $90,000. On December 31, 2023, the present value of the amounts deferred under the ATEO 4 plan is $120,000, the present value of the amounts deferred under the CORP 4 plan is $130,000, and the present value of the amounts deferred under the CORP 5 plan is $110,000.

(ii) *Conclusion (2022 applicable year).* For 2022, before aggregation of remuneration paid by related organizations, ATEO 4 is treated as paying Employee D $310,000 of remuneration ($200,000 salary + $100,000 upon vesting of deferred amounts + $10,000 net earnings on vested deferred amounts). CORP 4 is treated as paying Employee D $320,000 of remuneration ($200,000 salary + $100,000 upon vesting of deferred amounts + $20,000 net earnings on vested deferred amounts). CORP 5 is treated as paying Employee D $300,000 of remuneration ($200,000 salary + $100,000 upon vesting of deferred amounts) and has $10,000 of net losses on vested deferred amounts, which are carried forward to 2023. Thus, ATEO 4 is treated as paying $930,000 of remuneration to Employee D for the applicable year.

(iii) *Conclusion (2023 applicable year).* For 2023, before aggregation of remuneration paid by related organizations, ATEO 4 is treated as paying Employee D $210,000 of remuneration ($200,000 salary + $10,000 earnings on previously paid remuneration). CORP 4 is treated as paying Employee D $210,000 of remuneration ($200,000 salary + $10,000 net earnings on previously paid remuneration). CORP 5 is treated as paying Employee D $210,000 of remuneration ($200,000 salary + $10,000 net earnings on previously paid remuneration after taking into account the loss carryforward). Thus, ATEO 4 is treated as paying $630,000 of remuneration to Employee D for the applicable year.

(5) *Example 5 (Treatment of regular wages for a pay period spanning applicable years)*—(i) *Facts.* ATEO 5 pays its employees' salaries in accordance with a two-week payroll period that begins Sunday of the first week and ends Saturday of the second week. Payment occurs the Friday following the end of the payroll period. The last payroll period of 2023 ends on December 31, 2023. For the last payroll period, Employee E earns $8,000 of salary. In addition, ATEO 5 awards Employee E a $10,000 bonus that vests on December 31, 2023. ATEO 5 pays Employee E $18,000 on Friday, January 5, 2024, reflecting Employee E's salary for the last payroll period of 2023 and the bonus, the right to which vested on December 31, 2023.

(ii) *Conclusion (Regular wages).* The $8,000 of salary is regular wages within the meaning of § 31.3402(g)–1(a)(1)(ii) because it is an amount paid at a periodic rate for the current payroll period. Thus, $8,000 is treated as remuneration paid on January 5, 2024 (when it is actually or constructively paid), and, therefore, is treated as remuneration paid in ATEO 5's 2024 applicable year.

(iii) *Conclusion (Amounts other than regular wages).* The $10,000 bonus is not regular wages within the meaning of § 31.3402(g)–1(a)(1)(ii) because it is not an amount paid at a periodic rate for the current payroll period. Thus, $10,000 is treated as remuneration paid on December 31, 2023 (when it is vested) and, therefore, is treated as remuneration paid in ATEO 5's 2023 applicable year.

§ 53.4960–3 Determination of whether there is a parachute payment.

(a) *Parachute payment*—(1) *In general.* Except as otherwise provided in paragraph (a)(2) of this section (relating to payments excluded from the definition of a parachute payment), *parachute payment* means any payment in the nature of compensation made by an ATEO (or a predecessor of the ATEO) or a related organization to (or for the benefit of) a covered employee if the payment is contingent on the employee's separation from employment with the employer, and the aggregate present value of the payments in the nature of compensation to (or for the benefit of) the individual that are contingent on the separation equals or exceeds an amount equal to 3-times the base amount.

(2) *Exclusions.* The following payments are not parachute payments:

(i) *Certain qualified plans.* A payment that is a contribution to or a distribution from a plan described in section 401(a) that includes a trust exempt from tax under section 501(a), an annuity plan described in section 403(a), a simplified employee pension (as defined in section 408(k)), or a simple retirement account described in section 408(p);

(ii) *Certain annuity contracts.* A payment made under or to an annuity contract described in section 403(b) or a plan described in section 457(b);

(iii) *Compensation for medical services.* A payment made to a licensed medical professional for the performance of medical services performed by such professional; and

(iv) *Payments to non-HCEs.* A payment made to an individual who is not a highly compensated employee (HCE) as defined in paragraph (a)(3) of this section.

(3) *Determination of HCEs for purposes of the exclusion from parachute payments.* For purposes of this section, *highly compensated employee* or *HCE* means, with regard to an ATEO that maintains a qualified retirement plan or other employee benefit plan described in § 1.414(q)–1T, Q/A–1, any person who is a highly compensated employee within the meaning of section 414(q) and, with regard to an ATEO that does not maintain such a plan, any person who would be a highly compensated employee within the meaning of section 414(q) if the ATEO did maintain such a plan. For purposes of determining the group of highly compensated employees for a determination year, consistent with § 1.414(q)–1T, Q/A–14(a)(1), the determination year calculation is made on the basis of the applicable plan year under § 1.414(q)–1T, Q/A–14(a)(2) of the plan or other entity for which a determination is made, and the look-back year calculation is made on the basis of the 12-month period immediately preceding that year. For an ATEO that does not maintain a plan described in § 1.414(q)–1T, Q/A–1, the rules are applied by analogy, substituting the calendar year for the plan year. Thus, for example, in 2022, an ATEO that does not maintain such a plan must use its employees' 2021 annual compensation (as defined in § 1.414(q)–1T, Q/A–13, including any of the safe harbor definitions if applied consistently to all employees) to determine which employees are HCEs for 2022, if any, for purposes of section 4960. If an employee is an HCE at the time of separation from employment, then for purposes of section 4960 any parachute payment that is contingent on the separation from employment (as defined in paragraph (d) of this section) is treated as paid to an HCE so that the exception from the term parachute payment under paragraph (a)(2)(iv) of this section does not apply, even if the payment occurs during one or more later taxable years (that is, taxable years after the taxable year during which the employee separated from employment).

(b) *Payment in the nature of compensation*—(1) *In general.* Any payment—in whatever form—is a payment in the nature of compensation if the payment arises out of an employment relationship, including holding oneself out as available to perform services and refraining from performing services. Thus, for example, a payment made under a covenant not to compete or a similar arrangement is a payment in the nature of compensation. A payment in the nature of compensation includes (but is not limited to) wages and salary, bonuses, severance pay, fringe benefits, life insurance, pension benefits, and other deferred compensation (including any amount characterized by the parties as interest or earnings thereon). A payment in the nature of compensation also includes cash when paid, the value of the right to receive cash, the value of accelerated vesting, or a transfer of property. The vesting of an option, stock appreciation right, or similar form of compensation as a result of a covered employee's separation from employment is a payment in the nature of compensation. However, a payment in the nature of compensation does not include attorney's fees or court costs paid or incurred in connection with the payment of any parachute payment or a reasonable rate of interest accrued on any amount during the period the parties contest whether a parachute payment will be made.

(2) *Consideration paid by covered employee.* Any payment in the nature of compensation is reduced by the amount of any money or the fair market value of any property (owned by the covered

employee without restriction) that is (or will be) transferred by the covered employee in exchange for the payment.

(c) *When payment is considered to be made*—(1) *In general.* A payment in the nature of compensation is considered made in the taxable year in which it is includible in the covered employee's gross income or, in the case of fringe benefits and other benefits that are excludable from income, in the taxable year the benefits are received. In the case of taxable non-cash fringe benefits provided in a calendar year, payment is considered made on the date or dates the employer chooses, but no later than December 31 of the calendar year in which the benefits are provided, except that when the fringe benefit is the transfer of personal property (either tangible or intangible) of a kind normally held for investment or the transfer of real property, payment is considered made on the actual date of transfer. If the fringe benefit is neither a transfer of personal property nor a transfer of real property, the employer may, in its discretion, treat the value of the benefit actually provided during the last two months of the calendar year as paid during the subsequent calendar year. However, an employer that treats the value of a benefit paid during the last two months of a calendar year as paid during the subsequent calendar year under this rule must treat the value of that fringe benefit as paid during the subsequent calendar year with respect to all employees who receive it.

(2) *Transfers of section 83 property.* A transfer of property in connection with the performance of services that is subject to section 83 is considered a payment made in the taxable year in which the property is transferred or would be includible in the gross income of the covered employee under section 83, disregarding any election made by the employee under section 83(b) or (i). Thus, in general, such a payment is considered made at the later of the date the property is transferred (as defined in § 1.83–3(a)) to the covered employee or the date the property becomes substantially vested (as defined in § 1.83–3(b) and (j)). The amount of the payment is the compensation as determined under section 83, disregarding any amount includible in income pursuant to an election made by an employee under section 83(b).

(3) *Stock options.* An option (including an option to which section 421 applies) is treated as property that is transferred when the option becomes vested (regardless of whether the option has a readily ascertainable fair market value as defined in § 1.83–7(b)). For purposes of determining the timing and amount of any payment related to the option, the principles of § 1.280G–1, Q/A–13 and any method prescribed by the Commissioner in published guidance of general applicability under § 601.601(d)(2) apply.

(d) *Payment contingent on an employee's separation from employment*—(1) *In general.* A payment is contingent on an employee's separation from employment if the facts and circumstances indicate that the employer would not make the payment in the absence of the employee's involuntary separation from employment. A payment generally would be made in the absence of the employee's involuntary separation from employment if it is substantially certain at the time of the involuntary separation from employment that the payment would be made whether or not the involuntary separation occurred. A payment the right to which is not subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B) at the time of an involuntary separation from employment generally is a payment that would have been made in the absence of an involuntary separation from employment (and is therefore not contingent on a separation from employment), except that the increased value of an accelerated payment of a vested amount described in paragraph (f)(3) of this section resulting from an involuntary separation from employment is not treated as a payment that would have been made in the absence of an involuntary separation from employment. A payment the right to which is no longer subject to a substantial risk of forfeiture within the meaning of section 457(f)(3)(B) as a result of an involuntary separation from employment, including a payment the vesting of which is accelerated due to the separation from employment as described in paragraph (f)(3) of this section, is not treated as a payment that would have been made in the absence of an involuntary separation from employment (and thus is contingent on a separation from employment). A payment does not fail to be contingent on a separation from employment merely because the payment is conditioned upon the execution of a release of claims, noncompetition or nondisclosure provisions, or other similar requirements. See paragraph (d)(3) of this section for the treatment of a payment made pursuant to a covenant not to compete. If, after an involuntary separation from employment, the former employee continues to provide certain services as a nonemployee, payments for services rendered as a nonemployee are not payments that are contingent on a separation from employment to the extent those payments are reasonable and are not made on account of the involuntary separation from employment. Whether services are performed as an employee or nonemployee depends upon all the facts and circumstances. See § 53.4960–1(e). For rules on determining whether payments are reasonable compensation for services, the rules of § 1.280G–1, Q/A–40 through Q/A–42 (excluding Q/A–40(b) and Q/A–42(b)), and Q/A–44 are applied by analogy (substituting involuntary separation from employment for change in ownership or control).

(2) *Employment agreements*—(i) *In general.* If a covered employee involuntarily separates from employment before the end of a contract term and is paid damages for breach of contract pursuant to an *employment agreement*, the payment of damages is treated as a payment that is contingent on a separation from employment. An *employment agreement* is an agreement between an employee and employer that describes, among other things, the amount of compensation or remuneration payable to the employee for services performed during the term of the agreement.

(ii) *Example.* The following example illustrates the rules of this paragraph (d)(2). For purposes of this example, assume any entity referred to as ''ATEO'' is an ATEO.

(A) *Example*—(*1*) *Facts.* Employee A, a covered employee, has a 3-year employment agreement with ATEO 1. Under the agreement, Employee A will receive a salary of $200,000 for the first year and, for each succeeding year, an annual salary that is $100,000 more than the previous year. The agreement provides that, in the event of A's involuntary separation from employment without cause, Employee A will receive the remaining salary due under the agreement. At the beginning of the second year of the agreement, ATEO 1 involuntarily terminates Employee A's employment without cause and pays Employee A $700,000 representing the remaining salary due under the employment agreement ($300,000 for the second year of the agreement plus $400,000 for the third year of the agreement).

(*2*) *Conclusion.* The $700,000 payment is treated as a payment that is contingent on a separation from employment.

(3) *Noncompetition agreements.* A payment under an agreement requiring a covered employee to refrain from performing services (for example, a

covenant not to compete) is a payment that is contingent on a separation from employment if the payment would not have been made in the absence of an involuntary separation from employment. For example, a payment contingent on compliance in whole or in part with a covenant not to compete negotiated as part of a severance arrangement arising from an involuntary separation from employment is contingent on a separation from employment. Similarly, one or more payments contingent on compliance in whole or in part with a covenant not to compete not negotiated as part of a severance arrangement arising from an involuntary separation from employment but that provides for a payment specific to an involuntary separation from employment (and not voluntary separation from employment) is contingent on a separation from employment. Payments made under an agreement requiring a covered employee to refrain from performing services that are contingent on separation from employment are not treated as paid in exchange for the performance of services and are not excluded from parachute payments.

(4) *Payment of amounts previously included in income or excess remuneration.* Actual or constructive payment of an amount that was previously included in gross income of the employee is not a payment contingent on a separation from employment. For example, payment of an amount included in income under section 457(f)(1)(A) due to the lapsing of a substantial risk of forfeiture on a date before the separation from employment generally is not a payment that is contingent on a separation from employment, even if the amount is paid in cash or otherwise to the employee because of the separation from employment. In addition, actual or constructive receipt of an amount treated as excess remuneration under § 53.4960–4(b)(1) is not a payment that is contingent on a separation from employment (and thus is not a parachute payment), even if the amount is paid to the employee because of the separation from employment.

(5) *Window programs.* A payment under a window program is contingent on a separation from employment. A *window program* is a program established by an employer in connection with an impending separation from employment to provide separation pay if the program is made available by the employer for a limited period of time (no longer than 12 months) to employees who separate from employment during that period or to employees who separate from service during that period under specified circumstances. A payment made under a window program is treated as a payment that is contingent on an employee's separation from employment notwithstanding that the employee may not have had an involuntary separation from employment.

(6) *Anti-abuse provision.* Notwithstanding paragraphs (d)(1) through (5) of this section, if the facts and circumstances demonstrate that either the vesting or the payment of an amount (whether before or after an employee's involuntary separation from employment) would not have occurred but for the involuntary nature of the separation from employment, the payment of the amount is contingent on a separation from employment. For example, an employer's exercise of discretion to accelerate vesting of an amount shortly before an involuntary separation from employment may indicate that the acceleration of vesting was due to the involuntary nature of the separation from employment and was therefore contingent on the employee's separation from employment. Similarly, payment of an amount in excess of an amount otherwise payable (for example, increased salary), shortly before or after an involuntary separation from employment, may indicate that the amount was paid because the separation was involuntary and was therefore contingent on the employee's separation from employment. If an ATEO becomes a predecessor as a result of a reorganization or other transaction described in § 53.4960–1(h), any payment to an employee by a successor organization that is contingent on the employee's separation from employment with the predecessor ATEO is treated as paid by the predecessor ATEO.

(e) *Involuntary separation from employment*—(1) *In general. Involuntary separation from employment* means a separation from employment due to the independent exercise of the employer's unilateral authority to terminate the employee's services, other than due to the employee's implicit or explicit request, if the employee was willing and able to continue performing services as an employee. An involuntary separation from employment may include an employer's failure to renew a contract at the time the contract expires, provided that the employee was willing and able to execute a new contract providing terms and conditions substantially similar to those in the expiring contract and to continue providing services. The determination of whether a separation from employment is involuntary is based on all the facts and circumstances.

(2) *Separation from employment for good reason*—(i) *In general.* Notwithstanding paragraph (e)(1) of this section, an employee's voluntary separation from employment is treated as an involuntary separation from employment if the separation occurs under certain bona fide conditions (referred to herein as a separation from employment for good reason).

(ii) *Material negative change required.* A separation from employment for good reason is treated as an involuntary separation from employment if the relevant facts and circumstances demonstrate that it was the result of unilateral employer action that caused a material negative change to the employee's relationship with the employer. Factors that may provide evidence of such a material negative change include a material reduction in the duties to be performed, a material negative change in the conditions under which the duties are to be performed, or a material reduction in the compensation to be received for performing such services.

(iii) *Deemed material negative change.* An involuntary separation from employment due to a material negative change is deemed to occur if the separation from employment occurs within 2 years following the initial existence of one or more of the following conditions arising without the consent of the employee:

(A) *Material diminution of compensation.* A material diminution in the employee's base compensation;

(B) *Material diminution of responsibility.* A material diminution in the employee's authority, duties, or responsibilities;

(C) *Material diminution of authority of supervisor.* A material diminution in the authority, duties, or responsibilities of the supervisor to whom the employee is required to report, including a requirement that an employee report to a corporate officer or employee instead of reporting directly to the board of directors (or similar governing body) of an organization;

(D) *Material diminution of budget.* A material diminution in the budget over which the employee retains authority;

(E) *Material change of location.* A material change in the geographic location at which the employee must perform services; or

(F) *Other material breach.* Any other action or inaction that constitutes a material breach by the employer of the

agreement under which the employee provides services.

(3) *Separation from employment.* Except as otherwise provided in this paragraph, separation from employment has the same meaning as separation from service as defined in § 1.409A–1(h). Pursuant to § 1.409A–1(h), an employee generally separates from employment with the employer if the employee dies, retires, or otherwise has a termination of employment with the employer or experiences a sufficient reduction in the level of services provided to the employer. For purposes of applying the rules regarding reductions in the level of services set forth in the definition of termination of employment in § 1.409A–1(h)(1)(ii), the rules are modified for purposes of this paragraph such that an employer may not set the level of the anticipated reduction in future services that will give rise to a separation from employment, meaning that the default percentages set forth in § 1.409A–1(h)(1)(ii) apply in all circumstances. Thus, an anticipated reduction of the level of service of less than 50 percent is not treated as a separation from employment, an anticipated reduction of more than 80 percent is treated as a separation from employment, and the treatment of an anticipated reduction between those two levels is determined based on the facts and circumstances. The measurement of the anticipated reduction of the level of service is based on the average level of service for the prior 36 months (or shorter period for an employee employed for less than 36 months). In addition, an employee's separation from employment is determined without regard to § 1.409A–1(h)(2) and (5) (application to independent contractors), since, for purposes of this section, only an employee may have a separation from employment, and a change from bona fide employee status to bona fide independent contractor status is also a separation from employment. See § 53.4960–2(a)(1) regarding the treatment of an employee who also serves as a director of a corporation (or in a substantially similar position). The definition of separation from employment also incorporates the rules under § 1.409A–1(h)(1)(i) (addressing leaves of absence, including military leaves of absence), § 1.409A–1(h)(4) (addressing asset purchase transactions), and § 1.409A–1(h)(6) (addressing employees participating in collectively bargained plans covering multiple employers). The definition further incorporates the rules of § 1.409A–1(h)(3), under which an employee separates from employment only if the employee has a separation from employment with the employer and all employers that would be considered a single employer under section 414(b) and (c), except that the ''at least 80 percent'' rule under section 414(b) and (c) is used, rather than replacing it with ''at least 50 percent.'' However, for purposes of determining whether there has been a separation from employment, a purported ongoing employment relationship between a covered employee and an ATEO or a related organization is disregarded if the facts and circumstances demonstrate that the purported employment relationship is not bona fide, or the primary purpose of the establishment or continuation of the relationship is avoidance of the application of section 4960.

(f) *Accelerated payment or accelerated vesting resulting from an involuntary separation from employment*—(1) *In general.* If a payment or the lapse of a substantial risk of forfeiture is accelerated as a result of an involuntary separation from employment, generally only the value due to the acceleration of payment or vesting is treated as contingent on a separation from employment, as described in paragraphs (f)(3) and (4) of this section, except as otherwise provided in this paragraph (f). For purposes of this paragraph (f), the terms *vested* and *substantial risk of forfeiture* have the same meaning as provided in § 53.4960–2(c)(2).

(2) *Nonvested payments subject to a non-service vesting condition.* If (without regard to a separation from employment) vesting of a payment would depend on an event other than the performance of services, such as the attainment of a performance goal, and that vesting event does not occur prior to the employee's separation from employment and the payment vests due to the employee's involuntary separation from employment, the full amount of the payment is treated as contingent on the separation from employment.

(3) *Vested payments.* If an involuntary separation from employment accelerates actual or constructive payment of an amount that previously vested without regard to the separation, the portion of the payment, if any, that is contingent on the separation from employment is the amount by which the present value of the accelerated payment exceeds the present value of the payment absent the acceleration. The payment of an amount otherwise due upon a separation from employment (whether voluntary or involuntary) is not treated as an acceleration of the payment unless the payment timing was accelerated due to the involuntary nature of the separation from employment. If the value of the payment absent the acceleration is not reasonably ascertainable, and the acceleration of the payment does not significantly increase the present value of the payment absent the acceleration, the present value of the payment absent the acceleration is the amount of the accelerated payment (so the amount contingent on the separation from employment is zero). If the present value of the payment absent the acceleration is not reasonably ascertainable but the acceleration significantly increases the present value of the payment, the future value of the payment contingent on the separation from employment is treated as equal to the amount of the accelerated payment. For purposes of this paragraph (f)(3), the acceleration of a payment by 90 days or less is not treated as significantly increasing the present value of the payment. For rules on determining present value, see paragraph (f)(6) and paragraphs (h), (i) and (j) of this section.

(4) *Nonvested payments subject to a service vesting condition*—(i) *In general.* If an involuntary separation from employment accelerates vesting of a payment, the portion of the payment that is contingent on separation from employment is the amount described in paragraph (f)(3) of this section (if any) plus the value of the lapse of the obligation to continue to perform services described in paragraph (f)(4)(ii) of this section (but the amount cannot exceed the amount of the accelerated payment, or, if the payment is not accelerated, the present value of the payment), to the extent that all of the following conditions are satisfied with respect to the payment:

(A) *Vesting trigger.* The payment vests as a result of an involuntary separation from employment;

(B) *Vesting condition.* Disregarding the involuntary separation from employment, the vesting of the payment was contingent only on the continued performance of services for the employer for a specified period of time; and

(C) *Services condition.* The payment is attributable, at least in part, to the performance of services before the date the payment is made or becomes certain to be made.

(ii) *Value of the lapse of the obligation to continue to perform services.* The value of the lapse of the obligation to continue to perform services is one percent of the amount of the accelerated payment multiplied by the number of full months between the date that the employee's right to receive the payment

is vested and the date that, absent the acceleration, the payment would have been vested. This paragraph (f)(4)(ii) applies to the accelerated vesting of a payment in the nature of compensation even if the time when the payment is made is not accelerated. In that case, the value of the lapse of the obligation to continue to perform services is one percent of the present value of the future payment multiplied by the number of full months between the date that the individual's right to receive the payment is vested and the date that, absent the acceleration, the payment would have been vested.

(iii) *Accelerated vesting of equity compensation.* For purposes of this paragraph (f)(4), the acceleration of the vesting of a stock option or stock appreciation right (or similar arrangement) or the lapse of a restriction on restricted stock or a restricted stock unit (or a similar arrangement) is considered to significantly increase the value of the payment.

(5) *Application to benefits under a nonqualified deferred compensation plan.* In the case of a payment of benefits under a nonqualified deferred compensation plan, paragraph (f)(3) of this section applies to the extent benefits under the plan are vested without regard to the involuntary separation from employment, but the payment of benefits is accelerated due to the involuntary separation from employment. Paragraph (f)(4) of this section applies to the extent benefits under the plan are subject to the conditions described in paragraph (f)(4)(i) of this section. For any other payment of benefits under a nonqualified deferred compensation plan (such as a contribution made due to the employee's involuntary separation from employment), the full amount of the payment is contingent on the employee's separation from employment.

(6) *Present value.* For purposes of this paragraph (f), the present value of a payment is determined based on the payment date absent the acceleration and the date on which the accelerated payment is scheduled to be made. The amount that is treated as contingent on the separation from employment is the amount by which the present value of the accelerated payment exceeds the present value of the payment absent the acceleration.

(7) *Examples.* See § 1.280G Q/A–24(f) for examples that may be applied by analogy to illustrate the rules of this paragraph (f).

(g) *Three-times-base-amount test for parachute payments*—(1) *In general.* To determine whether payments in the nature of compensation made to a covered employee that are contingent on the covered employee separating from employment with the ATEO are parachute payments, the aggregate present value of the payments must be compared to the individual's base amount. To do this, the aggregate present value of all payments in the nature of compensation that are made or to be made to (or for the benefit of) the same covered employee by an ATEO (or any predecessor of the ATEO) or related organization and that are contingent on the separation from employment must be determined. If this aggregate present value equals or exceeds the amount equal to 3-times the individual's base amount, the payments are parachute payments. If this aggregate present value is less than the amount equal to 3-times the individual's base amount, the payments are not parachute payments. See paragraphs (f)(6), (h), (i), and (j) of this section for rules on determining present value.

(2) *Examples.* The following examples illustrate the rules of this paragraph (g). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO.

(i) *Example 1 (Parachute payment)*—(A) *Facts.* Employee A is a covered employee and an HCE of ATEO 1. Employee A's base amount is $200,000. Payments in the nature of compensation that are contingent on a separation from employment with ATEO 1 totaling $800,000 are made to Employee A on the date of Employee A's separation from employment.

(B) *Conclusion.* The payments are parachute payments because they have an aggregate present value at the time of the separation from employment of $800,000, which is at least equal to 3-times Employee A's base amount of $200,000 ($3 \times \$200,000 = \$600,000$).

(ii) *Example 2 (No parachute payment)*—(A) *Facts.* Assume the same facts as in paragraph (g)(2)(i) of this section (Example 1), except that the payments contingent on Employee A's separation from employment total $580,000.

(B) *Conclusion.* Because the aggregate present value of the payments ($580,000) is not at least equal to 3-times Employee A's base amount ($600,000), the payments are not parachute payments.

(h) *Calculating present value*—(1) *In general.* Except as otherwise provided in this paragraph (h), for purposes of determining if a payment contingent on a separation from employment exceeds 3-times the base amount, the present value of a payment is determined as of the date of the separation from employment or, if the payment is made prior to that date, the date on which the payment is made.

(2) *Deferred payments.* For purposes of determining whether a payment is a parachute payment, if a payment in the nature of compensation is the right to receive payments in a year (or years) subsequent to the year of the separation from employment, the value of the payment is the present value of the payment (or payments) calculated on the basis of reasonable actuarial assumptions and using the applicable discount rate for the present value calculation that is determined in accordance with paragraph (i) of this section.

(3) *Health care.* If the payment in the nature of compensation is an obligation to provide health care (including an obligation to purchase or provide health insurance), then, for purposes of this paragraph (h) and for applying the 3-times-base-amount test under paragraph (g) of this section, the present value of the obligation is calculated in accordance with generally accepted accounting principles. For purposes of paragraph (g) of this section and this paragraph (h), the obligation to provide health care is permitted to be measured by projecting the cost of premiums for health care insurance, even if no health care insurance is actually purchased. If the obligation to provide health care is made in coordination with a health care plan that the employer makes available to a group, then the premiums used for purposes of this paragraph (h)(3) may be the allocable portion of group premiums.

(i) *Discount rate.* Present value generally is determined by using a discount rate equal to 120 percent of the applicable Federal rate (determined under section 1274(d) and the regulations in part 1 under section 1274(d)), compounded semiannually. The applicable Federal rate to be used is the Federal rate that is in effect on the date as of which the present value is determined, using the period until the payment is expected to be made as the term of the debt instrument under section 1274(d). See paragraph (h) of this section for rules with respect to the date as of which the present value is determined. However, for any payment, the employer and the covered employee may elect to use the applicable Federal rate that is in effect on the date on which the parties entered into the contract that provides for the payment if that election is set forth in writing in the contract.

(j) *Present value of a payment to be made in the future that is contingent on an uncertain future event or condition*—

(1) *Treatment based on the estimated probability of payment.* In certain cases, it may be necessary to apply the 3-times-base-amount test to a payment that is contingent on separation from employment at a time when the aggregate present value of all the payments is uncertain because the time, amount, or right to receive one or more of the payments is also contingent on the occurrence of an uncertain future event or condition. In that case, the employer must reasonably estimate whether it will make the payment. If the employer reasonably estimates there is a 50-percent or greater probability that it will make the payment, the full amount of the payment is considered for purposes of the 3-times-base-amount test and the allocation of the base amount. If the employer reasonably estimates there is a less than 50-percent probability that the payment will be made, the payment is not considered for either purpose.

(2) *Correction of incorrect estimates.* If an ATEO later determines that an estimate it made under paragraph (j)(1) of this section was incorrect, it must reapply the 3-times-base-amount test to reflect the actual time and amount of the payment. In reapplying the 3-times-base-amount test (and, if necessary, reallocating the base amount), the ATEO must determine the aggregate present value of payments paid or to be paid as of the date described in paragraph (h) of this section using the discount rate described in paragraph (i) of this section. This redetermination may affect the amount of any excess parachute payment for a prior taxable year. However, if, based on the application of the 3-times-base-amount test without regard to the payment described in this paragraph (j), an ATEO has determined it will pay an employee an excess parachute payment or payments, then the 3-times-base-amount test does not have to be reapplied when a payment described in this paragraph (j) is made (or becomes certain to be made) if no base amount is allocated to that payment under § 53.4960–4(d)(5).

(3) *Initial option value estimate.* To the extent provided in published guidance of general applicability under § 601.601(d)(2), an initial estimate of the value of an option subject to paragraph (c) of this section is permitted to be made, with the valuation subsequently redetermined and the 3-times-base-amount test reapplied. Until guidance is published under section 4960, published guidance of general applicability described in § 601.601(d)(2) that is issued under section 280G applies by analogy.

(4) *Examples.* See § 1.280G–1, Q/A–33(d) for examples that may be applied by analogy to illustrate the rules of this paragraph (j).

(k) *Base amount*—(1) *In general.* A covered employee's base amount is the average annual compensation for services performed as an employee of the ATEO (including compensation for services performed for a predecessor of the ATEO), and/or, if applicable, a related organization, with respect to which there has been a separation from employment, if the compensation was includible in the gross income of the individual for taxable years in the base period (including amounts that were excluded under section 911) or that would have been includible in the individual's gross income if the individual had been a United States citizen or resident. See paragraph (l) of this section for the definition of base period and for examples of base amount computations.

(2) *Short or incomplete taxable years.* If the base period of a covered employee includes a short taxable year or less than all of a taxable year of the employee, compensation for the short or incomplete taxable year must be annualized before determining the average annual compensation for the base period. In annualizing compensation, the frequency with which payments are expected to be made over an annual period must be taken into account. Thus, any amount of compensation for a short or incomplete taxable year that represents a payment that will not be made more often than once per year is not annualized.

(3) *Excludable fringe benefits.* Because the base amount includes only compensation that is includible in gross income, the base amount does not include certain items that may constitute parachute payments. For example, payments in the form of excludable fringe benefits or excludable health care benefits are not included in the base amount but may be treated as parachute payments.

(4) *Section 83(b) income.* The base amount includes the amount of compensation included in income under section 83(b) during the base period.

(l) *Base period*—(1) *In general.* The base period of a covered employee is the covered employee's 5 most-recent taxable years ending before the date on which the separation from employment occurs. However, if the covered employee was not an employee of the ATEO for this entire 5-year period, the individual's base period is the portion of the 5-year period during which the covered employee performed services for the ATEO, a predecessor, or a related organization.

(2) *Determination of base amount if employee separates from employment in the year hired.* If a covered employee commences services as an employee and experiences a separation from employment in the same taxable year, the covered employee's base amount is the annualized compensation for services performed for the ATEO (or a predecessor or related organization) that was not contingent on the separation from employment and either was includible in the employee's gross income for that portion of the employee's taxable year prior to the employee's separation from employment (including amounts that were excluded under section 911) or would have been includible in the employee's gross income if the employee had been a United States citizen or resident.

(3) *Examples.* The following examples illustrate the rules of paragraph (k) of this section and this paragraph (l). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO, any entity referred to as ''CORP'' is not an ATEO, and all employees are HCEs of their respective employers.

(i) *Example 1 (Calculation with salary deferrals)*—(A) *Facts.* Employee A, a covered employee of ATEO 1, receives an annual salary of $500,000 per year during the 5-year base period. Employee A defers $100,000 of salary each year under a nonqualified deferred compensation plan (none of which is includible in Employee A's income until paid in cash to Employee A).

(B) *Conclusion.* Employee A's base amount is $400,000 (($400,000 × 5)/5).

(ii) *Example 2 (Calculation for less-than-5-year base period)*—(A) *Facts.* Employee B, a covered employee of ATEO 1, was employed by ATEO 1 for 2 years and 4 months preceding the year in which Employee B separates from employment. Employee B's compensation includible in gross income was $100,000 for the 4-month period, $420,000 for the first full year, and $450,000 for the second full year.

(B) *Conclusion.* Employee B's base amount is $390,000 (((3 × $100,000) + $420,000 + $450,000)/3). Any compensation Employee B receives in the year of separation from employment is not included in the base amount calculation.

(iii) *Example 3 (Calculation for less-than-5-year base period with signing bonus)*—(A) *Facts.* Assume the same facts as in paragraph (l)(3)(ii)(A) of this section (Example 2), except that Employee B also received a $60,000 signing bonus when Employee B's

employment with ATEO 1 commenced at the beginning of the 4-month period.

(B) *Conclusion.* Employee B's base amount is $410,000 ((($60,000 + (3 × $100,000)) + $420,000 + $450,000)/3). Pursuant to paragraph (k)(2) of this section, because the bonus is a payment that will not be paid more often than once per year, the bonus is not taken into account in annualizing Employee B's compensation for the 4-month period.

(iv) *Example 4 (Effect of non-employee compensation)*—(A) *Facts.* Employee C, a covered employee of ATEO 1, was not an employee of ATEO 1 for the full 5-year base period. In 2024 and 2025, Employee C is only a director of ATEO 1 and receives $30,000 per year for services as a director. On January 1, 2026, Employee C becomes an officer and covered employee of ATEO 1. Employee C's includible compensation for services as an officer of ATEO 1 is $250,000 for each of 2026 and 2027, and $300,000 for 2028. In 2028, Employee C separates from employment with ATEO 1.

(B) *Conclusion.* Employee C's base amount is $250,000 ((2 × $250,000)/2). The $30,000 of director's fees paid to Employee C in each of 2024 and 2025 is not included in Employee C's base amount calculation because it was not for services performed as an employee of ATEO 1.

§ 53.4960–4 Liability for tax on excess remuneration and excess parachute payments.

(a) *Liability, reporting, and payment of excise taxes*—(1) *Liability.* For each taxable year, with respect to each covered employee, the taxpayer is liable for tax at the rate imposed under section 11 on the sum of the excess remuneration allocated to the taxpayer under paragraph (c) of this section and, if the taxpayer is an ATEO, any excess parachute payment paid by the taxpayer or a predecessor during the taxable year.

(2) *Reporting and payment.* The excise tax imposed by section 4960 is reported as provided in §§ 53.6011–1(b) and 53.6071–1(i) and paid in the form and manner prescribed by the Commissioner.

(3) *Arrangements between an ATEO and a related organization.* Calculation of, and liability for, the excise tax imposed by section 4960 is separate from, and unaffected by, any arrangement that an ATEO and any related organization may have for bearing the cost of any liability for the excise tax imposed by section 4960.

(4) *Certain foreign related organizations.* A related organization that is a foreign organization described in section 4948(b) that either is exempt from tax under section 501(a) or is a taxable private foundation (section 4948(b) related organization) is not liable for the excise tax imposed by section 4960. A foreign organization is an organization not created or organized in the United States or in any possession thereof, or under the law of the United States, any State, the District of Columbia, or any possession of the United States. See section 4948(b) and § 53.4948–1. For purposes of this paragraph (a)(4) and the application of section 4960 to a taxable year, an organization's status as a section 4948(b) related organization is determined at the end of its taxable year. However, remuneration that the section 4948(b) related organization pays to a covered employee of an ATEO must be taken into account by the ATEO and other related organizations for purposes of section 4960 generally, including for purposes of determining the five highest-compensated employees and the total remuneration paid to a covered employee. For example, if an ATEO and its related organization that is a section 4948(b) related organization each paid $600,000 remuneration to a covered employee during the applicable year, then the related organization would not be liable for the tax that would otherwise be allocable to it, and the ATEO would be liable for tax on $100,000 (50 percent of the $200,000 excess remuneration paid to the employee).

(5) [Reserved]

(b) *Amounts subject to tax*—(1) *Excess remuneration*—(i) *In general. Excess remuneration* means the amount of remuneration paid by an ATEO to any covered employee during an applicable year in excess of $1 million, as determined under § 53.4960–2.

(ii) *Exclusion for excess parachute payments.* Excess remuneration does not include any amount that is an excess parachute payment as defined in paragraph (b)(2) of this section.

(2) *Excess parachute payment. Excess parachute payment* means an amount equal to the excess (if any) of the amount of any parachute payment paid by an ATEO, a predecessor of the ATEO, or a related organization, or on behalf of any such person, during the taxable year over the portion of the base amount allocated to such payment.

(c) *Calculation of liability for tax on excess remuneration*—(1) *In general.* For each taxable year, an employer is liable for the tax on excess remuneration paid in the applicable year ending with or within the employer's taxable year. If, for the taxable year, remuneration paid during an applicable year by an ATEO or one or more related organizations to a covered employee is taken into account in determining the tax imposed on excess remuneration for that taxable year, then each employer is liable for the tax in an amount that bears the same ratio to the total tax determined under section 4960(a) as the amount of remuneration paid by the employer to the covered employee (including remuneration paid by the employer as described in § 53.4960–2(b)(1), but disregarding remuneration treated as paid by the employer under § 53.4960–2(b)(2)), bears to the total amount of remuneration paid by the ATEO under § 53.4960–2 (including remuneration treated as paid by the ATEO under § 53.4960–2(b)(2)).

(2) *Calculation if liability is allocated from more than one ATEO with regard to an individual.* If liability for the tax on excess remuneration is allocated to an employer from more than one ATEO in a taxable year with regard to an individual that is a covered employee of each ATEO, then the employer is liable for the tax only in the capacity in which it is liable for the greatest amount of the tax with respect to that individual for the taxable year. For example, assume ATEO 1 is a related organization to both ATEO 2 and ATEO 3 and pays excess remuneration to Employee D, and Employee D is a covered employee of ATEO 1, ATEO 2, and ATEO 3. In this case, ATEO 1's liability for the tax on excess remuneration to Employee D is the highest of its liability as an ATEO, as a related organization to ATEO 2, or as a related organization to ATEO 3.

(3) *Calculation if liability is allocated from an ATEO with a short applicable year.* If liability for the tax on excess remuneration paid to an individual is allocated to an employer from an ATEO with a short applicable year under § 53.4960–1(c)(3), then the liability with respect to the excess remuneration paid to that individual is allocated in accordance with the principles of this paragraph (c) adjusted as necessary to avoid, to the extent possible, duplication of application of the excise tax. The Commissioner may provide additional guidance of general applicability, published in the Internal Revenue Bulletin (see § 601.601(d)(2) of this chapter), on the application of this paragraph (c)(3) to particular circumstances, including circumstances involving an ATEO with a short applicable year that has one or more related organizations and the ATEO's short applicable year and the preceding applicable year both end with or within the related organization's taxable year, such that the ATEO and related organizations are liable for the tax for

multiple applicable years ending with or within the employer's taxable year.

(4) *Examples.* The following examples illustrate the rules of this paragraph (c). For purposes of these examples, assume that the rate of excise tax under section 4960 is 21 percent, that any entity that is referred to as ''ATEO'' is an ATEO, that any entity referred to as ''CORP'' is not an ATEO and is not a publicly held corporation within the meaning of section 162(m)(2) or a covered health insurance provider within the meaning of section 162(m)(6)(C), that no related organization is a section 4948(b) related organization, all taxpayers use the calendar year as their taxable year unless otherwise stated, and that no parachute payments are made in any of the years at issue.

(i) *Example 1 (Remuneration from multiple employers)*—(A) *Facts.* ATEO 1 and CORP 1 are related organizations. Employee A is a covered employee of ATEO 1 and an employee of CORP 1. In the 2022 applicable year, ATEO 1 pays Employee A $1.2 million of remuneration, and CORP 1 pays A $800,000 of remuneration. Remuneration paid by each employer is for services performed by Employee A solely as an employee of that employer.

(B) *Conclusion.* For the 2022 taxable year, ATEO 1 is treated as paying Employee A $2 million of remuneration, $1 million of which is excess remuneration. The total excise tax is $210,000 (21 percent × $1 million). ATEO 1 paid ⅗ of Employee A's total remuneration ($1.2 million/$2 million); thus, ATEO 1 is liable for ⅗ of the excise tax, which is $126,000. CORP 1 paid ⅖ of Employee A's total remuneration ($800,000/$2 million); thus, CORP 1 is liable for ⅖ of the excise tax, which is $84,000.

(ii) *Example 2 (Application when taxpayers have different taxable years)*—(A) *Facts.* Assume the same facts as in paragraph (c)(4)(i) of this section (*Example 1*), except that CORP 2 uses a taxable year beginning July 1 and ending June 30.

(B) *Conclusion.* The conclusion is the same as the conclusion in paragraph (c)(4)(i) of this section (*Example 1*), except that ATEO 1 is liable for the tax for its taxable year starting January 1, 2022, and ending December 31, 2022, and CORP 1 is liable for the tax for its taxable year beginning July 1, 2022, and ending June 30, 2023 (the taxable year with or within which ATEO 1's 2022 applicable year ends).

(iii) *Example 3 (Multiple liabilities for same applicable year due to multiple ATEOs)*—(A) *Facts.* The following facts are all with respect to the 2023 applicable year: ATEO 5 owns 60 percent of the stock of CORP 2. Sixty percent of ATEO 4's directors are representatives of ATEO 3. In addition, 60 percent of ATEO 5's directors are representatives of ATEO 4, but none are representatives of ATEO 3. Employee B is a covered employee of ATEO 3, ATEO 4, and ATEO 5 and is an employee of CORP 2. ATEO 3, ATEO 4, ATEO 5, and CORP 2 each pay Employee B $1.2 million of remuneration in the applicable year. ATEO 4's related organizations are ATEO 3 and ATEO 5. ATEO 3's only related organization is ATEO 4. ATEO 5's related organizations are ATEO 4 and CORP 2.

(B) *Calculation (ATEO 3).* Under ATEO 3's calculation as an ATEO for the 2023 applicable year, ATEO 3 is treated as paying Employee B a total of $2.4 million in remuneration ($1.2 million from ATEO 3 + $1.2 million from ATEO 4). The total excise tax is $294,000 (21 percent × $1.4 million). ATEO 3 and ATEO 4 each paid ½ of Employee B's total remuneration ($1.2 million/$2.4 million); thus, under ATEO 3's calculation, ATEO 3 and ATEO 4 each would be liable for ½ of the excise tax, which is $147,000.

(C) *Calculation (ATEO 4).* Under ATEO 4's calculation as an ATEO for the 2023 applicable year, ATEO 4 is treated as paying Employee B a total of $3.6 million in remuneration for the 2022 applicable year ($1.2 million from ATEO 3 + $1.2 million from ATEO 4 + $1.2 million from ATEO 5). The total excise tax is $546,000 (21 percent × $2.6 million). ATEO 3, ATEO 4, and ATEO 5 each paid ⅓ of the total remuneration to Employee B ($1.2 million/$3.6 million); thus, under ATEO 4's calculation, ATEO 3, ATEO 4, and ATEO 5 each would be liable for ⅓ of the excise tax, which is $182,000.

(D) *Calculation (ATEO 5).* Under ATEO 5's calculation as an ATEO for the 2023 applicable year, ATEO 5 is treated as paying Employee B a total of $3.6 million in remuneration ($1.2 million from ATEO 4 + $1.2 million from ATEO 5 + $1.2 million from CORP 2). The total excise tax is $546,000 (21 percent × $2.6 million). ATEO 4, ATEO 5, and CORP 2 each paid ⅓ of the total remuneration to Employee B ($1.2 million/$3.6 million); thus, under ATEO 5's calculation, ATEO 4, ATEO 5, and CORP 2 each would be liable for ⅓ of the excise tax, which is $182,000.

(E) *Conclusion (Liability of ATEO 3).* For the 2023 applicable year, ATEO 3 is liable for $182,000 of excise tax as a related organization under ATEO 4's calculation, which is greater than the $147,000 of excise tax under ATEO 3's own calculation. Thus, ATEO 3's excise tax liability with respect to Employee B is $182,000 for its 2023 taxable year.

(F) *Conclusion (Liability of ATEO 4).* For the 2023 applicable year, ATEO 4 is liable as a related organization for $147,000 of excise tax according to ATEO 3's calculation, for $182,000 according to ATEO 4's own calculation, and for $182,000 according to ATEO 5's calculation. Thus, ATEO 4's excise tax liability with respect to Employee B is $182,000 for its 2023 taxable year.

(G) *Conclusion (Liability of ATEO 5).* For the 2023 applicable year, ATEO 5 is liable as a related organization for $182,000 of excise tax under ATEO 4's calculation, and is liable for $182,000 of excise tax under ATEO 5's own calculation. Thus, ATEO 5's excise tax liability with respect to Employee B is $182,000 for its 2023 taxable year.

(H) *Conclusion (Liability of CORP 2).* For the 2023 applicable year, CORP 2 is liable as a related organization for $182,000 of excise tax according to ATEO 5's calculation only. Thus, CORP 2's excise tax liability with respect to Employee B is $182,000 for its 2023 taxable year.

(d) *Calculation of liability for excess parachute payments*—(1) *In general.* Except as provided in paragraph (d)(3) of this section, only excess parachute payments made by or on behalf of an ATEO are subject to tax under this section. However, parachute payments made by related organizations that are not made by or on behalf of an ATEO are taken into account for purposes of determining the total amount of excess parachute payments.

(2) *Computation of excess parachute payments*—(i) *Calculation.* The amount of an excess parachute payment is the excess of the amount of any parachute payment made by an ATEO, a predecessor of the ATEO, or a related organization, or on behalf of any such person, over the portion of the covered employee's base amount that is allocated to the payment. The portion of the base amount allocated to any parachute payment is the amount that bears the same ratio to the base amount as the present value of the parachute payment bears to the aggregate present value of all parachute payments made or to be made to (or for the benefit of) the same covered employee. Thus, the portion of the base amount allocated to any parachute payment is determined by multiplying the base amount by a fraction, the numerator of which is the present value of the parachute payment and the denominator of which is the aggregate present value of all parachute payments.

(ii) *Examples.* The following examples illustrate the rules of this

paragraph (d)(2). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO and all employees are HCEs of their respective employers.

(A) *Example 1 (Compensation from related organizations)*—(*1*) *Facts.* ATEO 1 and ATEO 2 are related organizations. Employee A is a covered employee of ATEO 1 and an employee of ATEO 2 who has an involuntary separation from employment with ATEO 1 and ATEO 2. Employee A's base amount is $200,000 with respect to ATEO 1 and $400,000 with respect to ATEO 2. A receives $1 million from ATEO 1 contingent upon Employee A's involuntary separation from employment from ATEO 1 and $1 million from ATEO 2 contingent upon Employee A's involuntary separation from employment from ATEO 2.

(*2*) *Conclusion.* Employee A has a base amount of $600,000 ($200,000 + $400,000). The two $1 million payments are parachute payments because their aggregate present value is at least 3-times Employee A's base amount (3 × $600,000 = $1.8 million). The portion of the base amount allocated to each parachute payment is $300,000 (($1 million/$2 million) × $600,000). Thus, the amount of each excess parachute payment is $700,000 ($1 million − $300,000).

(B) *Example 2 (Multiple parachute payments)*—(*1*) *Facts.* Employee B is a covered employee of ATEO 3 with a base amount of $200,000 who is entitled to receive two parachute payments: One of $200,000 and the other of $900,000. The $200,000 payment is made upon separation from employment, and the $900,000 payment is to be made on a date in a future taxable year. The present value of the $900,000 payment is $800,000 as of the date of the separation from employment.

(*2*) *Conclusion.* The portion of the base amount allocated to the first payment is $40,000 (($200,000 present value of the parachute payment/$1 million present value of all parachute payments) × $200,000 total base amount) and the portion of the base amount allocated to the second payment is $160,000 (($800,000 present value of the parachute payment/$1 million present value of all parachute payments) × $200,000 total base amount). Thus, the amount of the first excess parachute payment is $160,000 ($200,000 − $40,000) and that the amount of the second excess parachute payment is $740,000 ($900,000 − $160,000).

(3) *Reallocation when the payment is disproportionate to base amount.* In accordance with section 4960(d), the Commissioner may treat a parachute payment as paid by an ATEO if the facts and circumstances indicate that the ATEO and other payors of parachute payments structured the payments in a manner primarily to avoid liability under section 4960. For example, if an ATEO would otherwise be treated as paying a portion of an excess parachute payment in an amount that is materially lower in proportion to the total excess parachute payment than the proportion that the amount of average annual compensation paid by the ATEO (or any predecessor) during the base period bears to the total average annual compensation paid by the ATEO (or any predecessor) and any related organization (or organizations), and the lower amount is offset by payments from a non-ATEO or an unrelated ATEO, this may indicate that that the parachute payments were structured in a manner primarily to avoid liability under section 4960.

(4) *Election to prepay tax.* An ATEO may prepay the excise tax under paragraph (a)(1) of this section on any excess parachute payment for the taxable year of the separation from employment or any later taxable year before the taxable year in which the parachute payment is actually or constructively paid. However, an employer may not prepay the excise tax on a payment to be made in cash if the present value of the payment is not reasonably ascertainable under § 31.3121(v)(2)–1(e)(4) or on a payment related to health coverage. Any prepayment must be based on the present value of the excise tax that would be due for the taxable year in which the employer will pay the excess parachute payment, and be calculated using the discount rate equal to 120 percent of the applicable Federal rate (determined under section 1274(d) and the regulations in part 1 under section 1274) and the tax rate in effect under section 11 for the year in which the excise tax is paid. For purposes of projecting the future value of a payment that provides for interest to be credited at a variable interest rate, the employer may make a reasonable assumption regarding the variable rate. An employer is not required to adjust the excise tax paid merely because the actual future interest rates are not the same as the rate used for purposes of projecting the future value of the payment.

(5) *Liability after a redetermination of total parachute payments.* If an ATEO determines that an estimate made under § 53.4960–3(j)(1) was incorrect, it must reapply the 3-times-base-amount test to reflect the actual time and amount of the payment. In reapplying the 3-times-base-amount test (and, if necessary, reallocating the base amount), the ATEO must determine the correct base amount allocable to any parachute payment paid in the taxable year. See § 1.280G–1, Q/A–33(d) for examples that may be applied by analogy to illustrate the rules of this paragraph (d)(5).

(6) *Examples.* The following examples illustrate the rules of this paragraph (d). For purposes of these examples, assume any entity referred to as ''ATEO'' is an ATEO, any entity referred to as ''CORP'' is not an ATEO, and all employees are HCEs of their respective employers.

(i) *Example 1 (Excess parachute payment paid by a non-ATEO)*—(A) *Facts.* ATEO 1 and CORP 1 are related organizations that are treated as the same employer for purposes of § 53.4960–3(e)(3) (defining separation from employment) and are both calendar year taxpayers. For 2022 through 2026, ATEO 1 and CORP 1 each pay Employee A $250,000 of compensation per year for services performed as an employee of each organization ($500,000 total per year). In 2027, ATEO 1 and CORP 1 each pay Employee A $1 million payment ($2 million total) that is contingent on Employee A's separation from employment with both ATEO 1 and CORP 1, all of which is remuneration, and no other compensation. Employee A is a covered employee of ATEO 1 in 2027.

(B) *Conclusion.* Employee A's base amount in 2027 is $500,000 (Employee A's average annual compensation from both ATEO 1 and CORP 1 for the previous 5 years). ATEO 1 makes a parachute payment of $2 million in 2027, the amount paid by both ATEO 1 and CORP 1 that is contingent on Employee A's separation from employment with ATEO 1 and all organizations that are treated as the same employer under § 53.4960–3(e)(3). Employee A's $2 million payment exceeds 3-times the base amount ($1.5 million). ATEO 1 makes a $1.5 million excess parachute payment (the amount by which $2 million exceeds the $500,000 base amount). However, ATEO 1 is liable for tax only on the excess parachute payment paid by ATEO 1 ($1 million parachute payment − $250,000 base amount = $750,000) that is subject to tax under § 53.4960–4(a). CORP 1 is not liable for tax under § 53.4960–4(a) in 2027.

(ii) *Example 2 (Election to prepay tax on excess parachute payments and effect on excess remuneration)*—(A) *Facts.* Employee B is a covered employee of ATEO 2 with a base amount of $200,000 who is entitled to receive two parachute payments from ATEO 2, one of $200,000 and the other

of $900,000. The $200,000 payment is made upon separation from employment, and the $900,000 payment is to be made on a date in a future taxable year. The present value of the $900,000 payment is $800,000 as of the date of the separation from employment. ATEO 2 elects to prepay the excise tax on the $900,000 future parachute payment (of which $740,000 is an excess parachute payment). The tax rate under section 11 is 21 percent for the taxable year the excise tax is paid and, using a discount rate determined under § 53.4960–3(i), the present value of the $155,400 ($740,000 × 21 percent) excise tax on the $740,000 future excess parachute payment is $140,000.

(B) *Conclusion.* The excess parachute payment is thus $800,000 ($200,000 plus $800,000 present value of the $900,000 future payment, less $200,000 base amount), with $40,000 of the base amount allocable to the $200,000 payment and $160,000 of the base amount allocable to the $900,000 payment. To prepay the excise tax on the $740,000 future excess parachute payment, the employer must satisfy its $140,000 obligation under section 4960 with respect to the future payment, in addition to the $33,600 excise tax ($160,000 × 21 percent) on the $160,000 excess parachute payment made upon separation from employment. For purposes of determining the amount of excess remuneration (if any) under section 4960(a)(1), the amount of remuneration paid by the employer to the covered employee for the taxable year of the separation from employment is reduced by the $900,000 of total excess parachute payments ($160,000 + $740,000).

§ 53.4960–5 [Reserved]

§ 53.4960–6 Applicability date.

(a) *General applicability date.* Sections 53.4960–0 through 53.4960–4 apply to taxable years beginning after December 31, 2021. Taxpayers may choose to apply §§ 53.4960–0 through 53.4960–4 to taxable years beginning after December 31, 2017, and on or before December 31, 2021, provided the taxpayer applies §§ 53.4960–0 through 53.4960–4 in their entirety and in a consistent manner.

(b) [Reserved]

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: January 9, 2021.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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LIST OF PUBLIC LAWS

This is the final list of public bills from the 2d session of the 116th Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

S. 4996/P.L. 116–325
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H.R. 1925/P.L. 116–331
To designate the Manhattan Campus of the New York Harbor Health Care System of the Department of Veterans Affairs as the ''Margaret Cochran Corbin Campus of the New York Harbor Health Care System.'' (Jan. 13, 2021; 134 Stat. 5109)

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H.R. 3250/P.L. 116–336
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S. 371/P.L. 116–342
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